

PTHB Board Meeting

27 May 2020, 09:30 to 12:30
Skype

Agenda

1

PRELIMINARY MATTERS

 Board_Agenda_27May20_Final.pdf (2 pages)

1.1


Welcome and apologies for absence

1.2

Declarations of interest

1.3

Minutes of previous meeting: 25 March 2020 (for approval)

 Board_Item_1.3_2020-03-25 PTHB Board Minutes unconfirmed.pdf (11 pages)

1.4

Matters arising from the minutes of the previous meeting

1.5

Board Action Log

 Board_Item_1.5_PTHB_Action_Log_May20v1.pdf (1 pages)

1.6

Update reports

1.6.1

Chair

1.6.2

Vice-Chair

1.6.3

Chief Executive

2

ITEMS FOR APPROVAL/RATIFICATION/DECISION

2.1

COVID-19 Response: Review of Phase 1 including: Decisions, Learning and Reflections


 Board_Item_2.1_Phase 1 Review.pdf (2 pages)

 Board_Item_2.1a_COVID-19_Phase1 Review.pdf (14 pages)

2.2

COVID-19 Response: Phase 2, Response Plan


 Board_Item_2.2_Phase 2 Response Plan.pdf (6 pages)

 Board_Item_2.2a_Powys Response Plan Phase 2 incorporating Operating Framework Q1 18 May 2020.pdf (21 pages)

2.3

Re-prioritised Annual Plan 2020/21

 Board_Item_2.3_Revised Annual Plan_May 2020.pdf (6 pages)

 Board_Item_2.3a Revised annual plan_May 2020.pdf (18 pages)

2.4

COVID-19: Maintaining Good Governance Arrangements

 Board_Item_2.4_Maintaining Good Governance.pdf (15 pages)


2.5

Policies reserved for the Board

2.5.1

Serious Incidents

 Board_Item_2.5a_Serious Incidents Policy.pdf (6 pages)

 Board_Item_2.5ai_Appendix 1 Serious Incidents Policy.pdf (63 pages)

2.5.2


Claims


 Board_Item_2.5b_Claims Policy.pdf (4 pages)

 Board_Item_2.5bi_Appendix 1 Claims Policy.pdf (19 pages)

2.6

Welsh Language Standards Compliance

 Board_Item_2.6_Welsh Language Standards Appeals Update for Board FINAL.pdf (5 pages)

 Board_Item_2.6a_Appendix 1.pdf (32 pages)

2.7


Strategic Equality Plan


 Board_Item_2.7_SEP May 2020.pdf (6 pages)


 Board_Item_2.7a_Appendix 1 SEP.pdf (25 pages)

2.8

Pharmaceutical Applications Committee Terms of Reference


 Board_Item_2.8_Pharmaceutical Applications Committee.pdf (3 pages)

 Board_Item_2.8a_Pharmaceutical Applications Committee ToR_May20_DRAFT.pdf (7 pages)

 Board_Item_2.8b_Appendix 2_National Health Service (Pharmaceutical Services) (Wales) Regulations 2013.pdf (184 pages)

2.9


Financial Resource Plan 2020/21

 Board_Item_2.9_Resource Plan & Financial Mangement 202021 Board.pdf (9 pages)

2.10

Corporate Risk Register - May 2020

 Board_Item_2.10_CRR_May 2020.pdf (6 pages)

 Board_Item_2.10a_2020-05-19 Corporate Risk Register.pdf (30 pages)

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ITEMS FOR DISCUSSION

3.1

Financial Performance Reports Month 12, 2019-20

3.1.1


Month 12, 2019-20

 Board_Item_3.1a_Financial Performance Report Mth 12.pdf (7 pages)

3.1.2

Month 1, 2020-21

Patricia Jones
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 Board_Item_3.1b_Financial Performance Report Mth 1.pdf (10 pages)


3.2


Assurance Reports of the Board's Committees

3.2.1

a) PTHB Committees

 Board_Item_3.2a_Chair's Assurance Reports.pdf (2 pages)


 Board_Item_3.2ai_Experience, Quality & Safety Chairs Assurance Report 16 April 2020.pdf (22 pages)

 Board_Item_3.2aii_Audit Risk and Assurance Committee Chairs Report 18 May 2020.pdf (18 pages)


 Board_Item_3.2aiii_Charitable Funds Chair's Assurance Report Feb 2020.pdf (17 pages)


3.2.2

b) Joint Committees

 Board_Item_3.2b_Joint Committee Reports_May 20.pdf (3 pages)

 Board_Item_3.2bi_2020-03.10 JC Briefing v1.0.pdf (3 pages)

 Board_Item_3.2bii_2020.05.12 JC Briefing v1.0.pdf (2 pages)

 Board_Item_3.2biii_Chair's EASC Summary from 12 May 2020.pdf (4 pages)


3.3

Assurance Report of the Board's Partnership Arrangements

 Board_Item_3.3_Partnership Board Reports_May_20.pdf (3 pages)

3.4

Update Reports of the Board's Advisory Fora

 Board_Item_3.4_Advisory Groups_May_20.pdf (4 pages)

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OTHER MATTERS

4.1

Any other urgent business

4.2

Date of next meeting: 29 July 2020 9.30am venue TBC

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**POWYS TEACHING HEALTH BOARD
BOARD MEETING
WEDNESDAY 27 MAY 2020
9.30 AM – 12.30 AM
TO BE HELD VIA SKYPE**



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

AGENDA

Time	Item	Title	Attached / Oral	Presenter
1: PRELIMINARY MATTERS				
09.30am	1.1	Welcome and Apologies for Absence	Oral	Chair
	1.2	Declarations of Interest	Oral	All
	1.3	Minutes of Previous Meeting: 25 March 2020 (for approval)	Attached	Chair
	1.4	Matters Arising from the Minutes of the Previous Meeting	Oral	Chair
	1.5	Board Action Log	Attached	Chair
	1.6	Update from the: a) Chair b) Vice Chair c) Chief Executive	Oral	Chair Vice Chair Chief Executive
2: ITEMS FOR APPROVAL/RATIFICATION/DECISION				
9.45am	2.1	COVID-19 Response: Review of Phase 1, including: Decisions; Learning & Reflections	Attached	Chief Executive
10.00am	2.2	COVID-19 Response: Phase 2 Response Plan	Attached	Chief Executive
10.15am	2.3	Re-prioritised Annual Plan 2020/21	Attached	Chief Executive
10.30am	2.4	COVID-19: Maintaining Good Governance Arrangements	Attached	Board Secretary
10.40am	2.5	Policies reserved for Board: a) Serious Incidents b) Claims	Attached	Director of Nursing & Midwifery
11.00am	2.6	Welsh Language Standards Compliance	Attached	Director of Therapies & Health Sciences
11.10am	2.7	Strategic Equality Plan	Attached	Director of Therapies & Health Sciences
11.25am	2.8	Pharmaceutical Applications Committee: Terms of Reference	Attached	Board Secretary & Director of PCCMH
11.35am	2.9	Financial Resource Plan 2020/21	Attached	Director of Finance & IT
11.50am	2.10	Corporate Risk Register – May 2020	Attached	Board Secretary

3: ITEMS FOR DISCUSSION				
12.00pm	3.1	a)Financial Performance Report Month 12, 2019-20 b)Financial Performance Report Month 1, 2020-21	Attached	Director of Finance & IT
	3.2	Assurance Reports of the Board's Committees: a) PTHB Committees b) Joint Committees	Attached	Committee Chairs Chief Executive
	3.3	Assurance Reports of the Board's Partnership Arrangements	Attached	Chief Executive
	3.4	Update Reports from the Board's Advisory Fora	Attached	Chief Executive
4: OTHER MATTERS				
12.25pm	4.1	Any Other Urgent Business	Oral	Chair
12.30pm	4.2	Close		
	4.3	Date of the Next Meeting: ▪ 29 June 2020, 9.30am, Venue TBC		

Key:

Well-being Objective 1: Focus on Well-being	
Well-being Objective 2: Early Help and Support	
Well-being Objective 3: Tackle the Big Four	
Well-being Objective 4: Joined Up Care	
Well-being Objective 5: Workforce Futures	
Well-being Objective 6: Innovative Environments	
Well-being Objective 7: Digital First	
Well-being Objective 8: Transforming in Partnership	
All Well-being Objectives	

MESSAGE TO THE PUBLIC:

Powys Teaching Health Board is committed to openness and transparency, and conducts as much of its business as possible in a session that members of the public are normally welcome to attend and observe. However, in light of the current advice and guidance in relation to Coronavirus (COVID-19), the Board has agreed to run meetings by electronic / telephony means as opposed to in a physical location, for the foreseeable future. This will mean that members of the public will not be able attend in person or observe on-line.

The Board has taken this decision in the best interests of protecting the public, our staff and Board members. The Board will publish a summary of meetings held on our website within a week of the meeting to promote openness and transparency.

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POWYS TEACHING HEALTH BOARD

UNCONFIRMED

MINUTES OF THE MEETING OF THE BOARD

HELD ON WEDNESDAY 25th MARCH 2020, AT 9.30AM

IN THE BOARD ROOM, BRONLLYS HOSPITAL

Present

Vivienne Harpwood	Chair (remote attendee)
Carol Shillabeer	Chief Executive
Melanie Davies	Vice Chair (remote attendee)
Trish Buchan	Independent Member (Third Sector Voluntary) (remote attendee)
Matthew Dorrance	Independent Member (Local Authority) (remote attendee)
Owen James	Independent Member (Community) (remote attendee)
Susan Newport	Independent Member (TUC) (remote attendee)
Ian Phillips	Independent Member (ICT)(remote attendee)
Mark Taylor	Independent Member (Capital & Estates) (remote attendee)
Pete Hopgood	Interim Director of Finance & IT
Julie Rowles	Director of Workforce, OD & Support Services
Stuart Bourne	Director of Public Health
Hayley Thomas	Director of Planning & Performance
Wyn Parry	Medical Director
Claire Madsen	Director of Therapies & Health Sciences
Alison Davies	Director of Nursing & Midwifery

In Attendance

Rani Mallison	Board Secretary
Adrian Osbourne	Assistant Director Communications (remote attendee)
Liz Patterson	Corporate Governance Manager (remote attendee)

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Apologies for absence

Frances Gerard	Independent Member (University)
Frances Hunt	CHC Chair
Tony Thomas	Independent Member (Finance)
Jamie Marchant	Director of Primary, Community & Mental Health Service
Alison Bulman	Corporate Director Children & Adults (PCC)
Katie Blackburn	CHC Chief Officer

PRELIMINARY MATTERS	
RESOLVED THAT due to the unprecedented health emergency of COVID-19, and the clear Public Health instruction to practice social distancing, meetings will run by electronic / telephony means as opposed to in a physical location. Members of the public will not be able to attend in person or observe on-line. This decision has been taken in the best interests of protecting the public, our staff and Board members. A summary of this Board Meeting will be published on our website within a week of the meeting.	
PTHB/19/163	WELCOME AND APOLOGIES FOR ABSENCE The Chair confirmed that there was a quorum present. Apologies for absence were noted as recorded above. The Chair advised that she had written to Frances Hunt who had finished her term of office as CHC representative thanking her for her contribution during the 3 years she had held this role.
PTHB/19/164	DECLARATIONS OF INTEREST No declarations of interest were declared.
PTHB/19/165	MINUTES OF MEETING HELD ON 29 JANUARY 2020 The minutes of the meeting held on 29 January 2020 were received and AGREED as being a true and accurate record.
PTHB/19/166	MATTERS ARISING No matters arising were noted.
PTHB/19/167	BOARD ACTION LOG The Board Secretary advised that two outstanding issues remained namely: <ul style="list-style-type: none">• A Board Briefing will be arranged on CHKS/Data Intelligence when possible

	<ul style="list-style-type: none"> The Serious Incidents Policy will be presented to the Board in May 2020 <p>Both items were deferred and would be brought back to Board when the organisation has reached post-COVID-19 Recovery phase.</p>
PTHB/19/168	<p>UPDATE FROM CHAIR</p> <p>The Chair gave a brief oral report thanking the Executive Team, PAs, support staff, front line staff, staff in the local authority other health board partners and volunteers for the tremendous contribution that is being made during the COVID-19 public health emergency.</p> <p>Independent Members were specifically invited to stay in communication with the Chair during this period where business as usual had been suspended.</p> <p>The Chair indicated that she intended to complete the annual Independent Member appraisal system electronically over the coming weeks.</p> <p>The Chair also noted that urgent improvements in the accessibility to IT were needed.</p> <p>Members expressed a view that the decision to hold Board Meetings in closed session, whilst understandable during the current situation, did not offer the public an opportunity to get involved.</p> <p>The Board Secretary confirmed that Board meetings were not Public Meetings but were Meetings held in Public. Arrangements were being put in place to enable the Experience, Quality and Safety Committee and the Audit, Risk and Assurance Committee to continue to meet remotely. All other Committee meetings had been cancelled under the cessation of business as usual arrangements.</p> <p>The Board NOTED the report of the Chair.</p> <p>UPDATE FROM VICE-CHAIR</p> <p>The Vice-Chair confirmed that she had undertaken digital meetings in respect of Community Mental Health Orders during the past week.</p> <p>UPDATE FROM CHIEF EXECUTIVE</p> <p>The Chief Executive confirmed that business as usual had been suspended since 17th March 2020 in light of the public health emergency.</p>

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	<p>Prior to this PTHB had been implementing the end of the Winter Plan and had been in a good position working on planned care. An HIW Inspection had been expected for Maternity Service and Governance arrangements. The Minister's announcement 10 days prior had allowed the organisation to enter an intensive period of preparation and planning by permitting the suspension of business as usual arrangements.</p> <p><i>Following on from Winter Pressures is the organisation having to make substantial readjustments in light of COVID-19?</i></p> <p>The Chief Executive advised that arrangements for dealing with the winter surge had been successfully deployed and will be used for managing the COVID-19 surge. For example Discharge – Recover – Assess arrangements will be an essential part of the COVID-19 response. Some of the ongoing work under the Integrated Care Fund would be paused but some would relate to COVID-19 requirements and this would continue.</p> <p><i>Has business as usual for the Audit team ceased and would it be possible for them to be redeployed in capturing learning and innovation?</i></p> <p>The Chief Executive confirmed a Recovery, Reflection and Learning workstream would be included in the COVID-19 Master Plan. The Chief Executive and Director of Public Health would take the opportunity to capture learning at a Stocktake item in Gold Group meetings.</p> <p>The Director of Public Health confirmed that this information would be captured by the Civic Contingencies Manager under the COVID-19 Master Plan.</p>
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ITEM FOR BRIEFING

PTHB/19/169	<p>BRIEFING ON CORONAVIRUS (COVID-19)</p> <p>The Director of Public Health presented the Board briefing (copy filed with minutes) advising the situation was fast moving and the written briefing was prepared some time ago.</p> <p>As of 24 March 2020 there were 8,077 confirmed cases in the UK of which 1,427 were new cases (an increase of approximately 1,000 new cases/day from one week ago). There have been 422 deaths in the UK.</p>
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	<p>As of 24 March 2020 there were 478 confirmed cases in Wales of which 60 were new cases. In Wales there had been 17 deaths. In Powys there had been 11 confirmed cases.</p> <p>The level of risk in the UK had been assessed as HIGH. The UK is still in the Delay phase having moved from the Contain phase but not yet reached the Mitigation phase. Research is ongoing. During the Delay phase behavioural interventions have been introduced namely:</p> <ul style="list-style-type: none"> • Stay at Home • Social Distancing • Shielding of people vulnerable to COVID-19 <p>Gold Group was now meeting daily, with an Action Plan under which are a series of work streams. The organisation was feeding into a series of regional and national co-ordination groups such as the Local Resilience Forum for Dyfed/Powys. Nationally there are a series of groups led by Welsh Government and Public Health Wales. A Governance Diagram has been produced which outlines the links between the various groups.</p> <p>It was AGREED that the Governance Diagram outlining the national and regional arrangements, together with the local Governance arrangements would be made available to Independent Members.</p> <p><i>Members requested an outline of their role under the current arrangements.</i></p> <p>The Chief Executive advised the Board of the following main risks which would be included in the COVID-19 Risk Register:</p> <ul style="list-style-type: none"> • Planning and preparation – does the organisation have the information necessary to plan • Is there sufficient capacity in the system to respond • Are there sufficient staff (both in terms of numbers and skills) • Can the organisation supply direct patient care and critical support services • Leadership and Management – is there capacity to manage in the long term
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	<ul style="list-style-type: none"> • What are the arrangements for clinical outcomes and decision-making • What are the arrangements for the care of the deceased • What are the plans for Communications • What arrangements are in place for the Health and Safety of staff • What Governance arrangements are in place and is the organisation in legislative compliance • What are the Recovery plans <p>The Chief Executive confirmed all these risks were contained within the Master Plan with the risks being picked up within a number of work streams. Within the next week the planning and preparation will be complete and it will be possible to risk assess the arrangements.</p> <p>It was AGREED that this information needed to be provided in a brief paper to Independent Members and Executive Members.</p> <p>The Chair confirmed that the oral update provided assurance which would be followed up in the next few days with a short paper to confirm the position.</p> <p>The Vice-Chair suggested that the Experience, Quality and Safety Committee would have a continuing role to play in providing assurance and that other Independent Members were welcome to attend remotely as Observers at the next meeting.</p>
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ITEMS FOR APPROVAL, DECISION OR RATIFICATION

PTHB/19/170	<p>NORTH POWYS WELLBEING PROGRAMME: MODEL OF CARE</p> <p>The Director of Planning and Performance presented the report (copy filed with minutes).</p> <p>Approval was sought to move to the next stage of development of this project although work on the project would be paused until post COVID-19.</p> <p>The North Powys Wellbeing Programme was a joint programme with Powys County Council (PCC) and it would be necessary for both the Board and PCC Cabinet to approve to proceed. This had been an item on their</p>
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	<p>Cabinet agenda for a meeting on 24 March 2020. However, this meeting was cancelled due to COVID-19 restrictions. It was not known when PCC Cabinet intend to convene a meeting where this matter can be considered.</p> <p>This programme aligns with the PTHBs 10 year strategy and has been co-produced with colleagues, partners and wider stakeholders. The delivery model focussed on four areas:</p> <ul style="list-style-type: none"> • Wellbeing • Early help and support • Joined up care • Tackling the big four – mental health, respiratory, cancer and circulatory <p>To support this it would be necessary to ensure that the right workforce is available, digital solutions can be implemented, partnership working was effective and the right physical estate was available to support the model of care.</p> <p><i>Will there be any inpatient beds in North Powys?</i></p> <p>There will be inpatient beds but the work to ascertain the level of beds needed would be undertaken in the next phase of this programme where a schedule of accommodation will be outlined.</p> <p><i>The governance arrangements between the Regional Partnership Board, Public Service Board and PTHB remain unclear. Can assurance be given that this will be considered post COVID-19?</i></p> <p>The Chief Executive confirmed that the Strategy and Planning Committee had identified this issue and confirmed that this work would be undertaken when the current COVID-19 related pressures eased.</p> <p><i>Concern had been expressed that the model of care was too medically orientated. Can assurance be given that the response to such concerns is appropriate?</i></p> <p>The Director of Planning and Performance confirmed that the document would be checked to ensure that the language used in addressing concerns was appropriate.</p>
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	<p><i>The current situation arising from the COVID-19 restrictions is forcing an increased pace in the use of digital technology. Can assurance be given that the experience of the current situation is used to best advantage when considering the Digital First element of the programme?</i></p> <p>The Director of Planning and Performance confirmed that this would form part of the next stage and that the experience of the current situation would help inform the development of this workstream.</p> <p>The Board APPROVED the Model of Care to enable the team to undertake further detailed design.</p>
ITEMS FOR DISCUSSION	
PTHB/19/171	<p>ANNUAL REPORT OF THE DIRECTOR OF PUBLIC HEALTH</p> <p>The Director of Public Health presented the draft Annual Report, his first in his substantive role (copy filed with minutes). The report would be finalised and brought back to a future meeting of the Board.</p> <p>Independent Members observed that the document was excellent and had been prepared to be easily read.</p>
PTHB/19/172	<p>FINANCIAL PERFORMANCE REPORT MONTH 11, 2019-20</p> <p>The Director of Finance and IT presented the Finance Report (copy filed with minutes).</p> <p>The Month 11 reported position is an in-month underspend of £318k and a cumulative overspend of £374k with a breakeven forecast for year end. The improved position is due to a reduction in contributions required to be made to the All Wales Risk Pool from £0.474m in Month 10 to £0.213m in Month 11.</p> <p>It is expected that the organisation will stay within the capital resource limit but there is a degree of flexibility in this regard.</p> <p>Trends in spend on Commissioning, Continuing Health Care and Prescribing are all above 2018/19 levels and these will all be subject to COVID-19 related spend.</p>

	<p>The Chair observed that scrutiny of the financial position at this stage in dealing with the COVID-19 outbreak appeared academic.</p> <p>The Chief Executive advised that it was intended to ascertain a method whereby the Independent Member (Finance) could have some oversight of the financial position during the COVID-19 outbreak. The Board Secretary would make the necessary arrangements.</p> <p>The Board NOTED the report.</p>
PTHB/19/173	<p>CORPORATE RISK REGISTER</p> <p>The Board Secretary presented the Corporate Risk Register (copy filed with minutes) advising that the document would require updating in light of the COVID-19 risks which were currently being collated.</p> <p>The Board NOTED the Corporate Risk Register subject to the inclusion of COVID-19 related risks.</p>
PTHB/19/174	<p>ASSURANCE REPORTS OF THE BOARD'S COMMITTEES:</p> <p>The Board RECEIVED the reports from the Chairs of Committees of the Board (copy filed with minutes):</p> <p>a) PTHB Committees</p> <ul style="list-style-type: none"> • Experience, Quality and Safety Committee 4 January 2020 • Performance and Resources Committee 24 February 2020 • Audit, Risk and Assurance Committee 9 March 2020 <p>The Board Secretary advised that in light of the COVID-19 outbreak all Committees of the Board had been stood down in the immediate future except for the Board, the Experience, Quality and Safety Committee and the Audit, Risk and Assurance Committee. These Committees would be run as virtual meetings to comply with the new COVID-19 regulations around social distancing and lock-down.</p> <p>Independent Members observed that an update from the Charitable Funds Committee held on the 3rd February was missing from the update and requested that this be included at the next meeting of the Board.</p> <p>b) Updates for the following Joint Committees:</p>

	<ul style="list-style-type: none"> • Welsh Health Specialised Services Committee (WHSSC); • Emergency Ambulance Service Committee (EASC); • NHS Wales Shared Services Partnership Committee (NWSSPC). <p>The Chief Executive advised that all Executive level work had been suspended at present unless it was COVID-19 related.</p>
PTHB/19/175	<p>ASSURANCE REPORT OF THE BOARD'S PARTNERSHIP ARRANGEMENTS</p> <p>The Board NOTED the Partnership Board Activity Report. (copy filed with minutes) including updates on the following partnerships:</p> <ul style="list-style-type: none"> • Powys Public Services Board (PSB); • Regional Partnership Board (RPB); • Joint Partnership Board (JPB). <p>It was confirmed that the Joint Partnership Board was continuing with its work but was not meeting as a Committee.</p> <p>The Board NOTED the Joint Committee Activity Report.</p>
PTHB/19/176	<p>UPDATE REPORTS FROM THE BOARD'S ADVISORY FORA</p> <p>The Board NOTED the Advisory Group Activity Report.</p>
OTHER MATTERS	
PTHB/19/177	<p>ANY OTHER URGENT BUSINESS:</p> <p>No other urgent business was considered.</p> <p>Independent Members wished to record their gratitude to the Senior Leadership Team for the detailed work undertaken to date which has provided a great deal of reassurance as to the level of planning and preparation during this unprecedented time.</p>
PTHB/19/162	<p>DATE OF THE NEXT MEETING:</p> <p>20 May 2020: Bronllys Hospital (under review)</p>

The public meeting closed at 12:45.

It was RESOLVED that representatives of the press and other members of the public shall be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest".

Motion under Section 1(2) Public Bodies (Admission to Meetings) Act 1960

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Key:

Action Complete
Not yet due
Due
Overdue

BOARD ACTION LOG (Updated May 2020)

Board Minute	Board Date	Action	Responsible	Progress at 27/05/2020	Status
EQS/19/72	3 December 2020	A Board Briefing will be arranged on CHKS/Data Intelligence	Board Secretary	To be delayed in-light of COVID-19. To be considered when re-prioritising the Board's Development and Briefing Plan for 2020/21.	
EQS/19/68	3 December 2019	The Serious Incidents Policy will be presented to the Board	Board Secretary	Included on the agenda for 27 th May 2020 Board meeting.	
PTHB/19/171	25 March 2020	Annual Report of Director of Public Health	Director of Public Health	To be delayed in light of COVID-19. Draft report received at March 2020 Board meeting, Final report to be brought back to a future meeting of the Board.	

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Agenda item: 2.1

BOARD MEETING		Date of Meeting: 27 May 2020	
Subject :	COVID-19: Phase 1 Response		
Approved and Presented by:	Carol Shillabeer Chief Executive Officer		
Prepared by:	Carol Shillabeer Chief Executive Officer		
Other Committees and meetings considered at:	None at the time of reporting		
PURPOSE:			
The purpose of this report is to provide an overview of the organisations response to the COVID-19 pandemic during its first phase (end May 2020). The report seeks to describe the measures the health board took to plan and prepare, and where necessary to activate those plans. It also seeks to outline decisions, reflections and learning that provide a useful analysis to support planning and preparation for Phase 2 of the management of the pandemic and its consequences.			
RECOMMENDATION(S):			
The Board is asked to DISCUSS and APPROVE the Review of Powys Teaching Health Board’s Response to COVID-19 (Phase 1), including Decisions, Reflections and Learning.			
Approval/Ratification/Decision		Discussion	Information
✓		✓	

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THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	✓
	2. Provide Early Help and Support	✓
	3. Tackle the Big Four	✓
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	✓
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	✓
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

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COVID-19 Response Plan: Review of Phase 1 Response: Decisions, Reflections and Learning

PURPOSE OF THE REPORT

The purpose of this report is to provide an overview of the organisations response to the COVID-19 pandemic during its first phase (end May 2020). The report seeks to describe the measures the health board took to plan and prepare, and where necessary to activate those plans. It also seeks to outline decisions, reflections and learning that provide a useful analysis to support planning and preparation for Phase 2 of the management of the pandemic and its consequences.

BACKGROUND TO COVID-19 PANDEMIC

The coronavirus, known as COVID-19, emerged early in 2020 from reports in China. It became clearer through January and February 2020 that the virus was having a significant public health impact in China and through the latter part of that period in Italy. The potential for global impact became significant as increasing numbers of cases emerged across Europe and the United States in early March 2020. By 13th March 2020, Welsh Ministers took the decision to direct the NHS in Wales to formally prepare for a significant surge in cases of COVID-19. This preparation included the reduction of planned care services, the maximisation of hospital bed capacity and a change in the way services are accessed in order to protect staff and patients through reduced face to face interaction.

ACTIVATION OF BUSINESS CONTINUITY ARRANGEMENTS

Powys Teaching Health Board (THB) is a Category 1 responder under the Civil Contingencies Act 2014 and is therefore required to comply with all the legislative duties set out in the Act.

The Act places five statutory duties upon Category 1 responders, these being:-

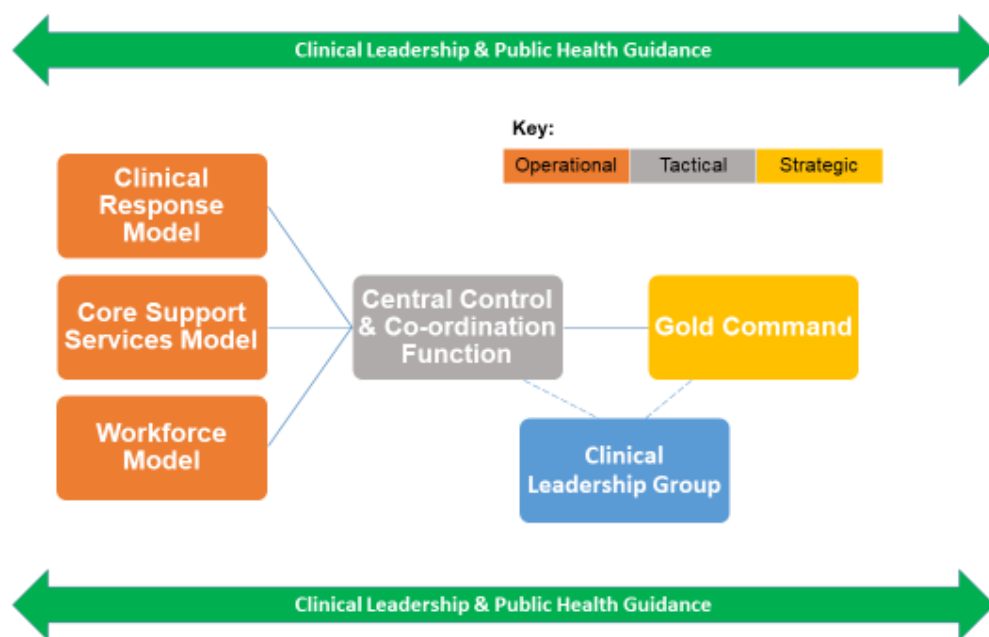
- Assess the risks of emergencies and use this to inform contingency planning;
- Have in place emergency plans;
- Establish business continuity management arrangements;
- Have in place arrangements to warn, inform and advise the public in the event of an emergency; and
- Share information with other local responders to enhance coordination and efficiency

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In December 2014, the Board approved the Powys Pandemic Framework which provides an overarching framework that details the Powys THB response to an influenza pandemic. The Pandemic Framework was developed in considering Welsh Government Guidance and other Multi-Agency Response Plans.

The Board also approved (January 2020) its Civil Contingency Plan. The purpose of which is to enable PTHB to respond effectively to a major incident or an emergency situation.

In respect of COVID-19, the Chief Executive established the following internal hierarchical structure known as "Command and Control":



Strategic (Gold) Group

The Strategic (Gold) Group, chaired by the Chief Executive, was responsible for determining the coordinated strategy and policy for the overall management of the health board's response to COVID-19, to protect the reputation of the organisation and ensure the delivery of effective, efficient and safe care for the population of Powys.

The Strategic (Gold) Group was specifically responsible for:

- Coordinating strategic decision making and effective use of resources throughout the assessment, treatment and recovery phases; ensuring key supporting roles are covered;
- Ensuring strategic oversight of the response to COVID-19 for the health board as a whole;
- Delegating actions to the Central Control & Coordination Function to ensure implementation of a tactical plan to deliver the strategic aim and objectives;

- Formulating media handling and public communications strategies, as required and necessary;
- Protecting the wellbeing of staff and patients within the health board;
- Deciding when the pandemic response arrangements should be stood-down and recovery phase implemented.

The Strategic (Gold) Group was constituted by Executive Directors and will include a Military Liaison Officer and the Director of Adult's & Children's, Powys County Council.

Meetings of the Strategic (Gold) Group were formally recorded and all decisions approved, in-line with the Civil Contingency Plan's approach on logging.

Central Control & Coordination Function

The Central Control & Coordination Function, led by the Director of Planning & Performance, was responsible for coordinating actions taken by the organisation to limit the impact on any business continuity disruption and manage the key stages of response (incident management response, recovery and resumption of 'business as usual') to the COVID-19 pandemic.

Programme Workstreams

The Strategic (Gold) Group established three programme Workstreams, led by nominated Executive Directors, to provide planning and operational management support in response to implementing the tactical plan, set by the Strategic (Gold) Group, to deliver the strategic aim and objectives in response to COVID-19. Specifically, Programme Workstreams:

- co-ordinated implementation of the respective workstream actions contained within the COVID-19 detailed action plan;
- updated and reported respective actions contained within the COVID-19 detailed action plan; and
- identified, manage and escalate key risks associated with implementation.

	Areas of work delegated to Programme Workstreams	Chair of Workstream
Clinical Response Model	<ul style="list-style-type: none"> • Operational Oversight of Delivery of Clinical Response Model • Testing • Self-care • Primary Care • Home / Community • Excess Death Plan 	Director of Primary, Community Care & Mental Health
Core Support Services Model	<ul style="list-style-type: none"> • Operational Oversight of Delivery of Core Support Services Model • Transport • Estates 	Director of Finance & IT

	<ul style="list-style-type: none"> • IT & Information • Support Services • Equipment & Procurement 	
Workforce Model	<ul style="list-style-type: none"> • Operational Oversight of Delivery of Workforce Model • Planning • Recruitment • Staff Testing • Redeployment • Policies / Guidance • Staff wellbeing • Staff Side Partnership link 	Director of Workforce & OD

Clinical Leadership Group (Advisory)

The Clinical Leadership Group, chaired by the Director of Public Health, was established to provide direction, leadership and guidance to Strategic (Gold) Group, the Central Control and Co-ordination Function and clinical staff responding to COVID-19 in Powys Teaching Health Board. This included all aspects of public health and individual patient care, across all settings, including inpatient, community and primary care services. Specifically, the Group:

- Provided a central route for clinical issues to be raised, considered and responded to within the health board.
- Ensured consistency and accuracy in the clinical advice given to staff.
- Supported the local interpretation and implementation of national guidance.
- Provided direction on clinical issues where national guidance is lacking.
- Established a process for ethical decision making in response to COVID-19.
- Established mechanisms for signposting and directing staff to the most up to date guidance as and when it is published.

Clinical Leadership & Public Health Guidance

The Director of Public Health and Clinical Directors (Medical Director, Director of Nursing & Midwifery and Director of Therapies & Health Sciences) led the delivery of professional leadership and guidance at all levels of the Command and Control Structure. Specifically, the Director of Public Health and Clinical Directors, will:

- Provide Public Health Liaison and Guidance
- Provide Clinical Professional Leadership and Guidance
- Support Clinical Decision Making at Strategic, Tactical and Operational levels
- Oversee the COVID-19 detailed action plan and Clinical Response Model in line with National, Regional and Surge Planning.

BOARD LEADERSHIP AND OVERSIGHT AND GOVERNANCE ARRANGEMENTS

The following governance principles were adopted during Phase 1:

- **Public interest and patient safety** – We will always act in the best interests of the population of Wales and will ensure every decision we take sits in this context, taking in to account the national public health emergency that (COVID-19) presents.
- **Staff wellbeing and deployment** – we will protect and support our staff in the best ways we can. We will deploy our knowledge and assets where there are identified greatest needs.
- **Good governance and risk management** – we will maintain the principles of good governance and risk management ensuring decisions and actions are taken in the best interest of the public, our staff and stakeholders ensuring risk and impact is appropriately considered.
- **Delegation and Escalation** – any changes to our delegation and escalation frameworks will be made using these principles, will be documented for future record and will be continually reviewed as the situation unfolds. Boards and other governing for a will retain appropriate oversight, acknowledging different arrangements may need to be in place for designated officers, deputies and decisions.
- **Departures** – where it is necessary to depart from existing standards, policies or practices to make rapid but effective decisions – these decisions will be documented appropriately. Departures are likely, but not exclusively, to occur in areas such as standing orders (for example in how the Board operates), Board and executive scheme of delegation, consultations, recruitment, training and procurement, audit and revalidation.
- **One Wales** – we will act in the best interest of all of Wales ensuring where possible resources and partnerships are maximised and consistency is achieved where it is appropriate to do so. We will support our own organisation and the wider NHS to recover as quickly as possible from the national public health emergency that COVID-19 presents returning to business as usual as early as is safe to do so.
- **Communication and transparency** – we will communicate openly and transparently always with the public interest in mind accepting our normal arrangements may need to be adapted, for example Board and Board Committee meetings being held in public.

In light of the COVID-19 pandemic and associated guidance and restrictions, at its meeting on 25th March 2020, the Board took a decision to run future meetings of the Board and its committees via electronic/telephony means as opposed to in a physical location. This would mean that for a period of time members of the public would not

be able to attend meetings in person, or observe on-line. The Board took this decision in the best interests of protecting the public, our staff and board members. The Board committed to publish a summary of board and committee meetings held on the health board's website within a week of the meeting to promote openness and transparency.

In addition, a decision was taken in consultation with the Chair and Chief Executive to revise planned meetings as follows:

- **Board Development and Briefing Sessions** – development sessions would be stood down with briefing sessions stood up every two weeks to enable briefings on the health board's response to COVID-19;
- The **Experience, Quality and Safety Committee** would continue to meet as planned with a focus on essential matters only, which would include COVID-19;
- The **Audit, Risk & Assurance Committee** would continue to meet as planned, with a particular focus on reviewing annual accounts, public disclosure statements and assurance for the audit opinion;
- The **Remuneration & Terms of Service Committee** would continue to meet as planned;
- The **Local Partnership Forum** meeting scheduled to be held in May would be cancelled, with briefing sessions stood up every two weeks to enable briefings on the health board's response to COVID-19;
- The **Performance and Resources Committee** meeting scheduled for 29th April would be cancelled with finance and performance reporting being routed through to the full Board (the usual Finance Monthly Report will be issued and Integrated Performance Report) along with any other critical areas and material issues;
- The **Strategy and Planning Committee** meeting scheduled to take place on 23 April would be cancelled;
- The **Charitable Funds Committee** meeting scheduled to take place on 2 June would be cancelled with Charitable Funds bids being considered by the Committee virtually;
- The **Executive Committee** would stand down meetings, as the Strategic (Gold) Group established through the Command and Control Structure would meet at least three times a week.

It was agreed that these arrangements would remain under review by the Chair, Chief Executive and Board Secretary. A further paper on governance arrangements will be considered by the Board at its meeting on 27th May 2020.

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KEY WG/MINISTERIAL DIRECTIONS

On 13th March, in a written statement, the Minister for Health and Social Services issued a framework of actions for the health and social care system to assist in preparing for a significant surge in COVID-19 cases.

1. Suspend non-urgent outpatient appointments and ensure urgent appointments are prioritised.
2. Suspend non-urgent surgical admissions and procedures (whilst ensuring access for emergency and urgent surgery).
3. Prioritise use of Non-Emergency Patient Transport Services to focus on hospital discharge and ambulance emergency response.
4. Expedite discharge of vulnerable patients from acute and community hospitals.
5. Relax targets and monitoring arrangements across the health and care system.
6. Minimise regulation requirements for health and care settings.
7. Fast track placements to care homes by suspending the current protocol which gives the right to a choice of home.
8. Permission to cancel internal and professional events, including study leave, to free up staff for preparations.
9. Relaxation of contract and monitoring arrangements for GPs and primary care practitioners.
10. Suspend NHS emergency service and health volunteer support to mass gatherings and events.

This framework for actions has remained in place until recently when the publication to the service of the Operating Framework Q1 outlined the key considerations for planning the next phase of managing the pandemic and its impacts. This includes some modification of some of the actions described above.

Another key feature of the Welsh and UK Government direction of travel centred on the scientific modelling of the disease progression. Recognising the novel nature of the virus, the modelling of scenarios indicated to the service the potential scenarios of demand for services. The core scenario indicated a significant risk of an overwhelmed health and social care system. The UK wide actions to introduce 'lockdown' were implemented on 23rd March 2020. The core aim of this strategy was to suppress the transmission of the virus in order to 'flatten the curve' of demand.

KEY STRATEGIC DECISIONS

The Chief Executive, as Accountable Officer, is delegated authority by the Board to make decisions with regard to the management of the health board. Executive Directors have been delegated certain responsibilities and decision making powers through the Board's Scheme of Reservation and Delegation of Powers. These arrangements

remained in place with regard to the ongoing functioning of the organisation during Phase 1.

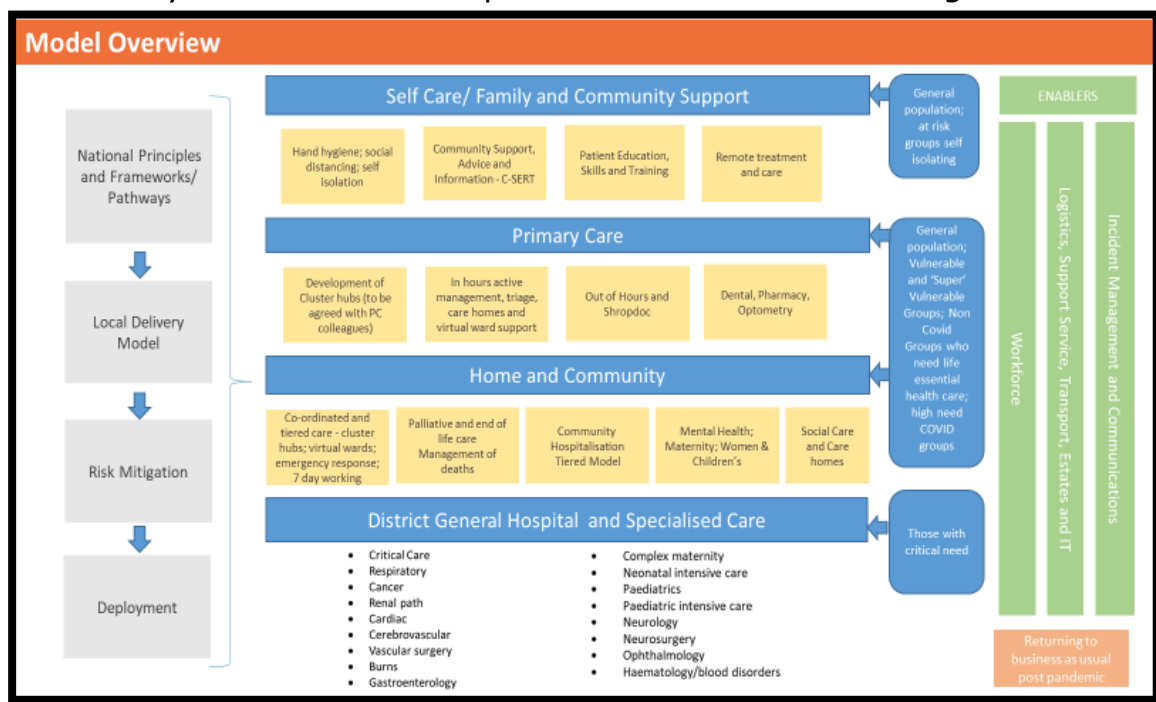
In respect of COVID-19, the Chief Executive deployed decision making through the established command and control structure with strategic decision making reserved for the Strategic (Gold) Group, other than where specific decisions were reserved for the Board, in-line with the Scheme of Delegation and Reservation of Powers.

Clinical Response Model, including Capacity Planning

At its meeting on 25th March 2020, the Board approved the Clinical Response for Covid-19, Phase 1, as per schedule 1a of the Scheme of Reservation and Delegation of Powers (November 2019):

"The full Board must approve the introduction or discontinuance of any significant activity or operation. Any activity or operation shall be regarded as significant if the Board determines it so based upon its contribution/impact on the achievement of the health board's aims, objectives and priorities."

A summary of the Clinical Response Model is outlined at Figure 1:



The Strategic (Gold) Group approved the following key plans during Phase 1:

- COVID-19 Action Plan

An overarching action plan was developed to guide the strategic and operational actions required to respond to the pandemic. There were a number of key components identified which formed the action plan including:

- 1: Leadership and management

2. Public health advice and guidance
3. Clinical Response model
4. Support service model
5. Workforce model
6. Communication and engagement
 - COVID-19 Support Plan
 - Workforce Deployment Plan
 - Communication and Engagement Plan
 - Excess Deaths Plan

RISK IDENTIFICATION AND MANAGEMENT

During COVID-19, Phase 1, the Board's approach to risk management was required to be balanced and proportionate to ensure effective risk management arrangements, whilst ensuring capacity is made available to plan and respond to COVID-19. Additionally, the approach to releasing capacity and determining priorities (COVID and 'business as usual' related) during this period were determined by an assessment of risk.

Strategic Risks

Strategic risks are those risks that represent a threat to achieving the health board's strategic objectives or its continued existence.

Strategic risks are recorded in the Board's Corporate Risk Register (CRR), which provides an organisational-wide summary of significant risks facing the Board.

The Corporate Risk Register (CRR) is reviewed by the Executive Committee in advance of consideration by the Board at each of its meetings. This arrangement continued during COVID-19, Phase 1.

The Executive Committee reviewed the existing CRR in light of the emerging COVID-19 pandemic to:

- Consider whether any existing risks needed to be updated to reflect the impact of COVID-19 on them which may reduce/increase the risk score in terms of likelihood and/or impact;
- Consider whether there were new risks emerging from the impact of COVID-19 on the achievement of the board's strategic objectives;
- Assess and make recommendations to the Board regarding those risks where appetite and tolerance may need adjusting to recognise the impact of COVID-19 on the organisation.

In March 2020, the Board received its Corporate Risk Register which outlined its key strategic risks:

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There is a risk that...						
Impact	Catastrophic	5				
	Major	4		<ul style="list-style-type: none"> The health board does not meet its statutory duty to achieve a breakeven position ICT systems are not robust or stable enough to support safe, effective and up to date care The health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctors Effective governance arrangements are not embedded across all parts of the health board Resources (financial and other) are not fully aligned to the health board's priorities 	<ul style="list-style-type: none"> The care provided in some areas is compromised due to the health board's estate being non-compliant and not fit for purpose Fragmented and unsustainable service models as a result of population changing need and service reconfiguration of neighbouring NHS bodies Potential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19) 	<ul style="list-style-type: none"> Some commissioned services are not sustainable or safe, and do not meet national targets
	Moderate	3			<ul style="list-style-type: none"> The health board does not comply to the Welsh Language standards, as outlined in the compliance notice Services provided are fragile, not sustainable, and impact on PTHB ability to achieve National Outcome Framework measures 	
	Minor	2				
	Negligible	1				
			1	2	3	4
Likelihood		Rare	Unlikely	Possible	Likely	Almost Certain

Figure 2: Corporate Risk Register (as at March 2020)

Management of COVID-19 Specific Risks

As mentioned previously, the Strategic (Gold) Group, established under business continuity arrangements, has responsibility for determining the coordinated strategy and policy for the overall management of the health board's response to COVID-19, to protect the reputation of the organisation and ensure the delivery of effective, efficient and safe care for the population of Powys.

In assessing the health board's ability to respond to COVID-19 Phase 1, the Strategic (Gold) Group identified the key risks which required mitigation and monitoring and a COVID-19 Risk Register was developed. Risks contained within the COVID-19 Risk Register related solely to the health board's arrangements for responding to COVID-19 and did not include COVID-19 related risks relevant to the achievement of the Board's strategic objectives (recorded through the Corporate Risk Register).

The COVID-19, Phase 1, Risk Register provides detail of mitigating actions taken to minimise the identified risks materialising during phase 1. In summary, the following assessment is made as Phase 1 ends:

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COVID-19 RISK HEAT MAP: May 2020					
There is a risk that...					
Impact	Catastrophic	5	<ul style="list-style-type: none"> We do not have the required level of equipment and supplies to achieve implementation of the Clinical Response Model – Including Beds, General Equipment, PPE Supplies and Oxygen 		
	Major	4	<ul style="list-style-type: none"> Arrangements for the deceased are insufficient and compromised The need to monitor oxygen supply arrangements and how we identify whether we are reaching capacity 	<ul style="list-style-type: none"> Modelling assumptions to inform planning and response arrangements are not robust Infection, Prevention and Control arrangements are not robust and effective Clinical outcomes for patients are compromised COVID-19 may be transmitted in the workplace The total quantum for funding for addressing COVID-19 across Wales remains fluid and uncertain 	
	Moderate	3	<ul style="list-style-type: none"> Governance arrangements required to effectively respond to COVID-19 are not robust and embedded We do not have sufficient leadership and management capacity to design, lead and support the response to COVID-19 Procedures in place for essential worker testing are not robust or sufficient 	<ul style="list-style-type: none"> Insufficient strategic delivery and benefits realization and/or loss of reputation due to ineffective communications and engagement arrangements We do not have sufficient workforce capacity to achieve implementation of the Clinical Response Model Our workforce does not have the required skills and expertise required to achieve implementation of the Clinical Response Model 	
	Minor	2	<ul style="list-style-type: none"> The organisation does not have effective planning in place to recover from COVID-19 response 		
	Negligible	1			
Likelihood		1	2	3	4
		Rare	Unlikely	Possible	Likely
					Almost Certain

Figure 3: Covid-19 Risk Register (as at end May 2020)

It is important to draw attention to a small number of significant system issues, reflected nationally as well as locally.

1. Personal Protective Equipment: national challenges have existed relating primarily to the supply of equipment in sufficient volumes to meet the standard outlined in national guidance. Changes in guidance and at times conflicting guidance created a need to be sufficiently sighted, determine a health board position and be able to communicate changes across the organisation. Importantly the health board did not exhaust its supplies of PPE at any point, although stock level became significantly challenges in some areas. Improving the distribution featured highly as a risk control measure and military input had been particularly helpful in this regard.
2. Testing: considerable focus continues in relation to the national and local approach to testing. The changing strategy and guidance through the course of the pandemic has required flexibility and approach and careful communication. The focus on staff testing (symptomatic) has been key and a high level of flexibility adopted in this regard. Inpatient testing and testing in other closed settings (care homes) has been important and the guidance has increased the intensity of testing over recent weeks. Understanding the data (people tested including results) has further complexities given the differences of in data routes in England.

3. Closed settings: a focus on closed settings, particularly care homes, has been needed to manage the protection of patients/residents and staff and reduce the risks of transmission of the virus. A rapid review of the management of care homes as a closed setting was undertaken in order to identify further supportive measures that could be implemented. Further detailed work in this area, across multiple closed settings, is likely as Phase 2 develops.

IMPACT ON HEALTH BOARD AGREED OBJECTIVES AND PRIORITIES

As a result of the COVID-19 pandemic and the activation of Business Continuity Arrangements, there has been and is likely to continue to be an impact on the timescales for delivery of some of the objectives in the previously agreed Annual Plan (approved by the Board, January 2020).

As the health board moves into Phase 2 of the Response to the pandemic, the Annual Plan has been reviewed to assess relative priority and deliverability. There are some actions that will assist in the management of Phase 2 of the pandemic response.

The review and revision of the previously approved Annual Plan has been undertaken by Executive Directors, aligned to the planning for the Phase 2 Response to the managing the pandemic. It is essential that the plan is kept under regular review as the impact of the next phase of the pandemic emerges.

REFLECTION & LEARNING

There will be further opportunity to discuss and review reflections and learning regarding the response to COVID-19 pandemic. This will be important to do at regular intervals through the rest of the course of the pandemic and beyond; however, the need to take initial reflections is key to help inform leadership and management actions and the Response Plan for Phase 2. The learning will also help to inform any revision to the health board's Organisational Development Framework which was due for review by the Board in May 2020.

The reflections presented below are collated through individual Directors; Directorates and through Trade Union partners. Collated in themes, the key aspects include:

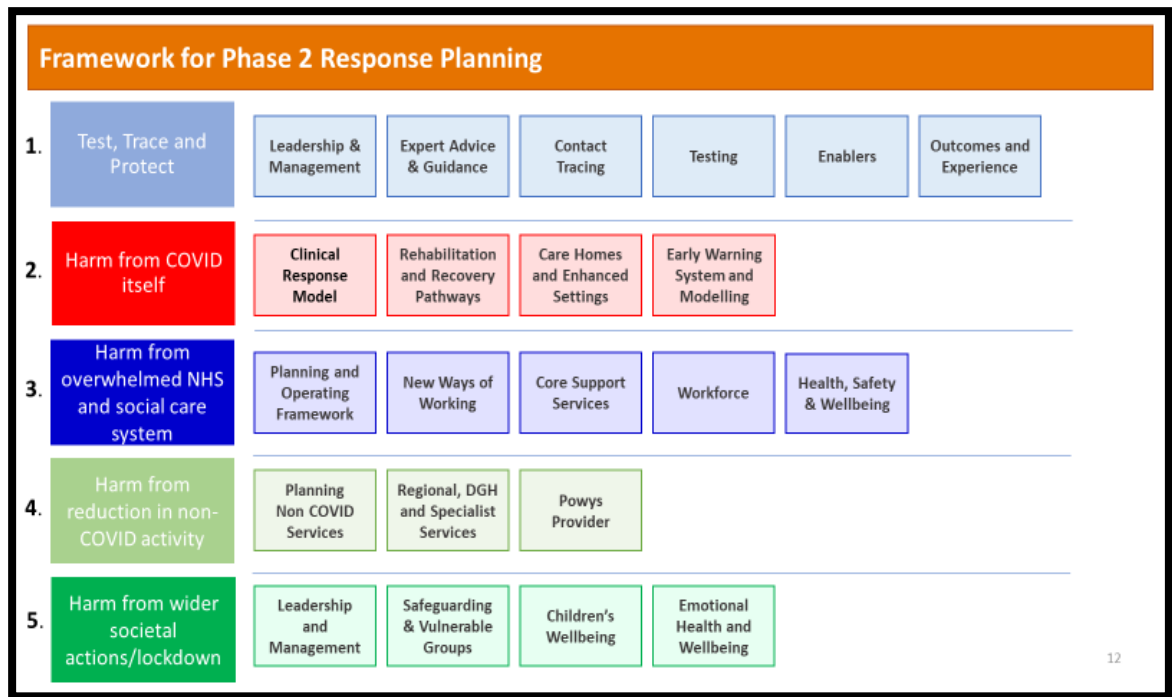
- The organisation has had to work in a context and environment of significant uncertainty. There has been a need to plan for scenarios that were untested, with only emerging information coming from other countries experience of the pandemic. Nonetheless, the organisation needed to make decisions, recognising the need for flexibility and adaptability.

- The pace of change has required more flexible working. Greater productivity has resulted although this needs to be weighted up around the intensity of the work that has needed to take place. In conjunction with this, challenges have been expressed in relation to keeping on top of the issuing of guidance, with new evidence emerging at regular intervals.
- The acceleration of digital solutions for a broad range of uses has been significant. From changing meetings and general communication to making important changes to the way in which interactions with patients take place, this is considered by many to be a positive, accelerated development that should be built upon.
- Staff and patients have needed to be flexible in response to the pandemic. For staff, many have been prepared to redeploy into areas outside of their usual role, and although there have been expressed apprehensions, the majority of staff supported the action. This presents opportunity for developing more flexible learning and roles moving forward. For patients, although further work is needed in relation to evaluate their experience, there has been flexibility with the use of much more self-care, phone first or technology-based care.
- Partnership working has been positive, including with Powys County Council, the Third Sector and organisations that provide services to the population of Powys. There is also awareness of pressure points.
- There has been important emphasis on clinical leadership to guide the organisations response. Over the last few months, new emergent clinical leaders have emerged and as part of ongoing clinical leadership development will play an important role moving forward. Areas of weakness have also been highlighted, potentially informing future development programmes at individual and collective level.
- Managing communication has been important and has generally been very successful. Regular, targeted and focused communication with external stakeholders including elected representatives have been managed with positive feedback. Internally, daily communication has taken place using various mechanisms including a dedicated email address for queries from staff.

APPROACH TO PHASE 2 RESPONSE PLAN

The Response Plan Phase 2 has been developed using the reflections and learning from Phase 1, with additional guidance from Welsh Government. The Plan seeks to implement at a local level the Test, Trace, Protect strategy of Welsh Government as well as steer a course

of flexibility and adaptability to address the four categories of harm. A summary of the Phase 2 plan is presented below:



CONCLUSION

This paper sought to outline the key elements of the Phase 1 Response to the COVID-19 pandemic. It included the activation of business continuity planning; the Board leadership and oversight arrangements; Ministerial directions and the organisations response. Further the paper outlined the strategic decisions taken in developing a clinical response, an overarching action plan, a support plan, a workforce deployment plan, communication and engagement plan, and excess deaths plan.

There were significant levels of risk that required active management in order to mitigate their likelihood and impact and the outcomes of these risk management efforts have been presented. The management of phase 1 of the pandemic has however impacted on the ability of the organisation to implement that objectives of the Board as outlined in the IMTP and Annual Plan, approved by Board in January 2020. These have now been reset and are presented in a revised Annual Plan.

Finally, a high-level overview of the reflections and learning sourced so far has been presented as key themes. This has helped to inform the development of the Phase 2 plan.

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AGENDA ITEM: 2.2

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	COVID-19: PTHB PHASE 2 RESPONSE PLAN	
Approved and Presented by:	Chief Executive	
Prepared by:	Director of Planning and Performance and team	
Considered by Executive Committee on:	Not considered at time of reporting	
Other Committees and meetings considered at:	<ul style="list-style-type: none"> Central Co-ordination Function Strategic (Gold) Group 	

PURPOSE:

To discuss and approve Powys Teaching Health Board Response Plan for Phase 2 which incorporates the response to the Welsh Government Operating Framework Q1

RECOMMENDATION(S):

It is recommended that the Board agree the content of the plan.

Approval/Ratification/Decision	Discussion	Information
✓		

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:		
	1. Provide Early Help and Support	✓
	2. Tackle the Big Four	✓
	3. Enable Joined up Care	✓
	4. Develop Workforce Futures	✓
	5. Promote Innovative Environments	✓
	6. Put Digital First	✓
	7. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	

EXECUTIVE SUMMARY:

This paper sets out the Health Board's response for managing phase 2 of the coronavirus pandemic in line with the Welsh Government Operating Framework for Quarter 1. The high-level approach includes:

- Phase 1
 - Progress, reflections, decisions and learning
- Response Plan for Phase 2
 - Current Modelling Assumptions
 - Framework for Phase 2 Response
 - Engagement & Communications
 - Governance
 - Finance summary
 - Risks

The Response Plan for Phase 2 provides a framework for delivery based on the Welsh Government 4 Harm Framework and includes test, track and protect. The next phase will require an agile approach to planning which enables a stepped approach based on robust modelling of the R value and early warnings. It will be underpinned with a 60-day planning cycle and continuous review and assessment of the system to manage COVID and Non COVID activity.

The outline plan has been prepared via the existing COVID workstream arrangements which are chaired by the Executive Leads, the planning process included a review of the phase 1 Implementation Plan, Clinical Response Model and Core Support model in line with WG guidance and best practice.

Alongside this, an initial high-level decisions reflection and learning evaluation has taken place, allowing for new ways of working to be considered as part of phase 2. A financial assessment and review of the risk register has also been undertaken and incorporated into the plan.

Further work is underway to assess the approach/availability of essential services provided by each of our commissioned partners in both Wales and England and will enable the Health Board to take a more comprehensive population view. Following this assessment, a further detailed plan will be developed.

DETAILED BACKGROUND AND ASSESSMENT:

The Welsh Government Operating Framework provides a framework for Q1. In summary it outlined the following high-level actions that NHS organisations need to consider in their local operational plans:

- A specific focus on Essential Services, any risks and regional solutions
- A summary of new ways of working and plans for evaluation
- Clear roles and activity plans for independent sector facilities and field hospitals
- Progressive implementation of routine activity
- A reflection of local discussions with partners about social care resilience
- Workforce plans including use of additional temporary workforce.
- Financial implications
- Risks to delivery.

The Health Board has developed an outline Response Plan for Phase 2 which responds to WG requirements and also provides a framework and high-level plan for delivery of Phase 2 (until March 21). Due to the developmental timescales, further discussions are required to strengthen the engagement which underpins Phase 2 and ensure alignment with partners and plans of the Regional Partnership Board and Public Service Board, particularly in respect of the populations wellbeing and reducing harm from lockdown.

The Phase 2 Response period needs to be based on robust evidence and modelling to support strategic planning decisions and to understand the potential impact on both the health and social care systems across Powys.

To support this modelling, work has been expanded to look at a whole system approach. This is linked closely with our key partner, Powys County Council. To date, the demand & capacity has been reviewed; resulting in processes including; flow mapping for the resident population, understanding the interface with health and social care e.g. primary care, home support, care homes, Powys hospital sites and acute flows to secondary and specialised services.

All of this work enables Powys, to understand the current and potential impacts to the system including future demand and capacity flow analysis which in turn will support robust working arrangements between health and social care.

During phase 1 decisions, reflections and learning has highlighted a good level of compliance with 'lockdown' which has helped to keep the r value low. During this time there has been a robust 5-point COVID Response plan and strong partnership working to support vulnerable people at home. The GP's have established COVID hot assessment facilities and there has been an expansion of community hospital and social care beds to support the potential increase in activity. The community response has been underpinned with excellent relationships/pathways for Powys residents in DGHs (Wales and England) and equips Powys with a wealth of new ways of working to embed in our phase 2 plan – with particular strong emphasis on digital technology. However, during this time, there have also been some system challenges around PPE availability, scaling up of testing and management of the pandemic within Closed Settings – particularly care homes. The Response Plan for Phase 2 will need to continue to address and strengthen its management in these areas.

The framework below has been developed to ensure appropriate emphasis on key priorities during the next phase.



The framework is based on the Welsh Government 4 Harm Framework and includes test, track and protect. Operational and planning teams have worked together to develop a high-level plan to underpin this framework.

This work has included a review of the phase 1 Implementation Plan, review of risks and identification of further areas of work required to support delivery of phase 2; the high-level plan is included in appendix A.

The key focus includes:

1. Scaling up the test, track and protect services across Powys in line with the national strategy
2. Ongoing management of COVID patients to include particular focus on rehabilitation and recovery pathways, care homes/closed settings and development of early warning systems.
3. Management of the health and care system to ensure a robust operating and planning framework is in place, new ways of working are adopted and sustained and that there are appropriate workforce, health and safety arrangements in place.
4. Careful ongoing management of essential services and a phased re-instatement of some routine services.
5. Management of the broader implications of lockdown to include ongoing leadership and management, safeguarding and support to vulnerable groups, and focus on wellbeing for adults and children.

An initial assessment of essential services has been undertaken in Powys and a number of SBARS have been completed. This has identified that whilst a broad range of services have been stopped or modified, that there has also been a number that have continued to be provided. New referrals are still being received and many services have established arrangements for the review of 'urgent' cases remotely.

In addition, new ways of working have been identified and further potential benefits could be delivered during Phase 2 to support the delivery of essential services. A more detailed phasing plan will be developed following a review of external provider commissioning plans and intentions, this will include identification and management of gaps in essential services and support with development of regional solutions (where required).

To support delivery of Phase 2, it is proposed revised governance arrangements are put in place. This will include the continuation of the existing Strategic GOLD Command arrangements, that will be supported by a Clinical Leadership Group and three Strategic Oversight Groups – 1) Test, Trace and Protect, 2) Care Homes and 3) Operational.

An initial risk assessment has been undertaken and the following risks are highlighted to the Board in relation to Phase 2 delivery:

- Ability to provide robust modelling assumptions to inform planning and response arrangements;

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- Ongoing management of the medical model and impact on surge capacity and delivery of essential and routine services;
- Workforce capacity and skills gap;
- Ongoing management of effective infection, prevention and control arrangements to support COVID and non COVID activity.
- Health and social care capacity; potentially impacting on care, adherence to discharge arrangements and ability of patients to return home.
- Risk that clinical outcomes for patients are compromised.
- Potential financial impact of COVID and cost of backlog.

NEXT STEPS:

- The Board is asked to approve the Response Plan for Phase 2.
- Following approval, a final version will be issued to Welsh Government and will form the formal response to the Q1 operating framework, and the Health Board will start the transition into Phase 2.
- Relevant communication materials will be prepared to support the transition into phase 2.

Patterson, Liz
05/26/2020 17:09:13

Phase 2 Response Plan

Version Draft: Subject to Board Approval on 27th May 2020.

Board Agenda Item 2.2

Patterson, Liz
05/26/2020 17:09:13

Purpose & High Level Approach

Purpose

To outline Powys Teaching Health Board's draft Phase 2 Response Plan in line with the WG Operating Framework for Q1.

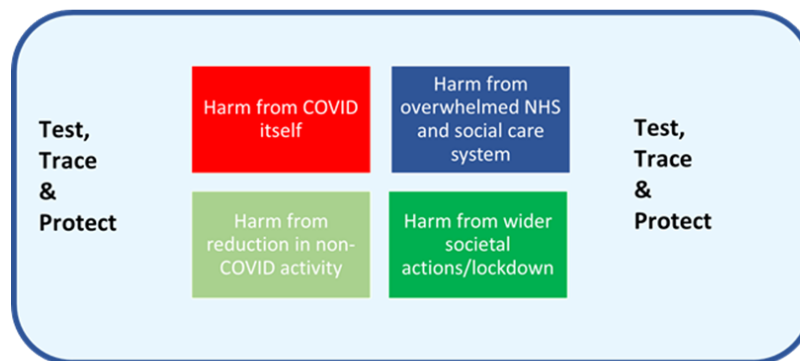
High Level Approach

Section 1 - Phase 1 (slides 1 to 11)

- Progress
- Reflections, decisions and learning

Section 2 - Phase 2 Response Plan (slides 12 to 22)

- Current Modelling Assumptions
- Framework for Phase 2 Response
- Engagement & Communications
- Governance
- Finance summary
- Risks



Underpinned by Planning Framework:

- Agile planning 60 day cycle
- Stepped approach based on robust modelling, R value, early warnings.
- Early warning system, continuous review and assessment to ensure balance COVID and Non COVID system
- Partnership approach RPB/PSB alignment
- Evidence base, national and international learning, policy and practice.

Phase 1 Progress

Programme Approach

Leadership and Management

Communication & Engagement

Testing

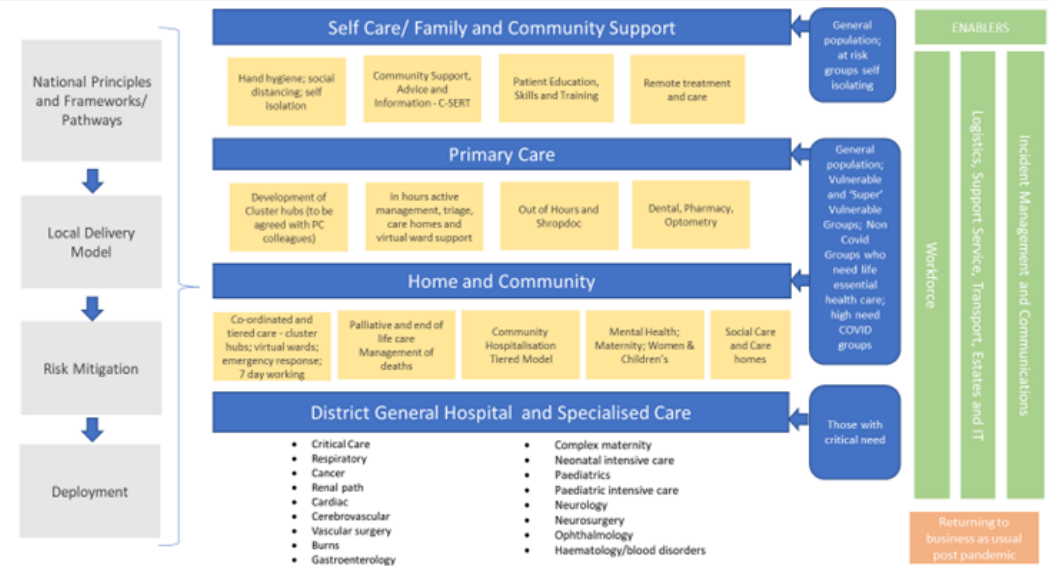
Clinical Response Model

Core Support Model

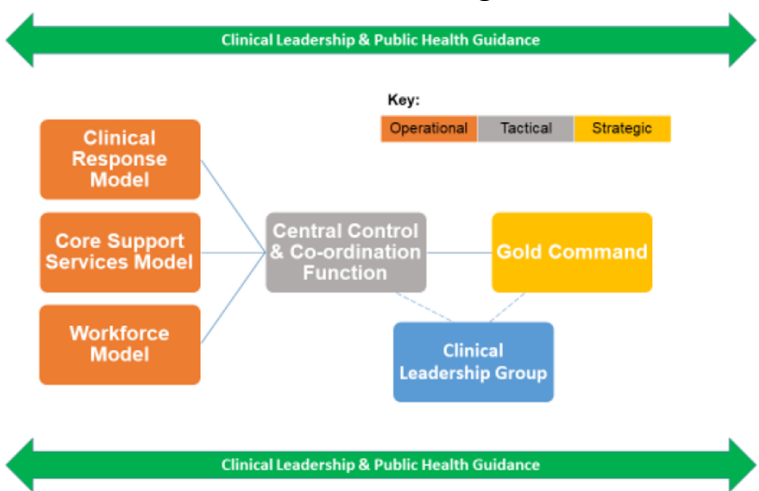
Workforce

5 step clinical response model

Model Overview



Robust Governance Arrangements








Robust detailed implementation plan

2. COMMUNICATION & ENGAGEMENT - Director of Planning & Performance					
2.1	Internal communications plan agreed and monitored	DPP	20/03/20	B	
2.2	New internal communication mechanisms in place	DPP	20/03/20	B	
SUB TASK 2.2a	Establish a standard operating procedure for how a positive result will be handled.	DPP	11/03/20	B	
SUB TASK 2.2b	Create a COVID-19 email account for the central receipt of external comms and internal queries.	DoF	13/03/20	B	
SUB TASK 2.2c	Establish cross border protocol for communication of deaths/positive results	DPP	13/03/20	B	
2.3	Implement SOP for internal communications	DPP	20/03/20	B	
2.4	Implement SOP for external communications	DPP	20/03/20	B	
2.5	Implement SOP for stakeholder communications	DPP	20/03/20	B	
2.6	Review of communication in line with national guidance	DPP	30/03/20	B	
2.7	Communication plan and arrangements reviewed in line with Central Control and Co-ordination Function and Clinical Response Model	DPP	06/04/20	B	
2.8	CHC Communication and engagement discussions (in line with guidance)	DPP	ongoing	G	
2.9	Fortnightly review of communication and engagement by GOLD	DPP	ongoing	G	

Phase 1 Communication and Engagement


A clear narrative to build and maintain confidence in the NHS response

<p>Aros Adref Achub Bywydau</p> <p><i>Nae pob un ohonon yn rhwng cyfrifoldeb i llohuo'r deddfem yn haint</i></p>		<p>Stay Home Save Lives</p> <p><i>We all share a responsibility to reduce the spread of infection</i></p>
<p>Hunanofal, Teuluodd a Chefnogaeth</p> <p><i>Rydym yn cefnogi pobl i gynnal eu hiesych a'u fies</i></p>		<p>Self Care, Families and Support</p> <p><i>We are working in partnership to support people to maintain their health and wellbeing</i></p>
<p>Gofal Sylfaenol Ym Mhows</p> <p><i>Rydym yn galluogi mynediad lleol i iesych a gofal i'w eidd cymunedau lleol</i></p>		<p>Powys Primary Care</p> <p><i>We are enabling local access to primary care within your local communities</i></p>
<p>Gofal Cymunedol Ym Mhows</p> <p><i>Rydym yn cynyddu'r gweledau a'r sgiliau yn Mhows i ddatparu gofal lleol</i></p>		<p>Powys Community Care</p> <p><i>We are increasing beds and skills in Powys to provide local care</i></p>
<p>Partneriaethau gofal acwït ac arbenigol</p> <p><i>Nae genym y berthnasolaeth cryf ag ysgolau cydlynus ac gyfyr mynediad at siâl acwït ac arbenigol i llohuo'r fies</i></p>		<p>Acute and Specialist Care Partnerships</p> <p><i>We have strong relationships with neighbouring hospitals for acute & specialist care for the people</i></p>

Patterson, Liz
05/26/2020 17:09:13


Multi-channel internal communications to inform, engage, and deliver benefits

Coronavirus COVID-19



Bardachyd
Addysgu Pwyws
Iechyd
Health Board

COVID-19 Daily Bulletin



**TELEDU
BIAP
PTHB TV**



PTHB-TV launches

We are pleased to announce that PTHB-TV or Teledu BIAP has regular access in every hospital in Pwys. Initially a staff resource, there is now a large screen in each hospital, generally in staff canteens or dining rooms, delivering a range of news items and alerts for staff.

Especially valuable for those staff who do not have regular access to staff email or the intranet, these screens show a regularly updated suite of information including animations, all staff bulletins as well as local news, BBC Wales News feed, Twitter and local weather. In time we also hope to be able to show hospital/town specific content.

These screens were installed with the generous support of the health board's own charity, which now has its own Just Giving page for donations – www.justgiving.com/PTHBCharity

Moving forward we hope to extend PTHB-TV to include hospital entrances and patient waiting areas where it will display different content to the public, highlighting public health messages and giving valuable guidance and information to visitors.

In this bulletin:

- **PTHB-TV**
- **PPE training sessions**
- **Wellbeing Hubs**
- **Just giving**

Just Giving

For those wishing to donate to the health board, we have made it easier by creating a Just Giving page – www.justgiving.com/PTHBCharity

Donations go to the health board charity which supports initiatives to benefit NHS staff and patients in Pwys.

Now anyone who wants to raise money can do so via this page or by connecting their fundraising activity to the page so that donations go straight to the charity.

The image is a composite of two parts. The top part is a colorful infographic titled "5 Ways to CATCH" (Catch, Avoid, Track, Help, and Notify) for COVID-19. It features a rainbow and the text "STAY HOME IF YOU CAN". Below the title, it lists five ways to catch the virus, each with a numbered box and a list of symptoms or actions. The bottom part is a screenshot of the TVBH YouTube channel page, showing the channel name "TELEVISION BIAP PTBH TV", a subscriber count of 41,000, and a video titled "Knighton" with 118 views.

5 Ways to CATCH

1. A Catch Room
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.

2. A Catch Outside
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.

3. A Virtual Catch
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.

4. A Mutual Catch
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.

5. A Reported Catch
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.
 • Catching the virus in a room where you are not supposed to be.

Take time out and give yourself a Catch!

TELEVISION BIAP PTBH TV
 41,000 subscribers
 Knighton
 118 views

Social, digital, media, and public communication with call-to-action

Only Leave Home For Essentials **Be Smart, Stay 2 Metres Apart** **Wash Your Hands Frequently**

Only Leave Home For Essentials

- For essential travel, such as to travel or medicine.
- To travel to work where no contact work is possible.
- For medical needs, for to help a vulnerable person.
- To exercise, alone or with people you live with.

Be Smart, Stay 2 Metres Apart

For more information about social distancing, and reducing the spread of Coronavirus, visit gov.uk/coronavirus or phh.nhs.uk/covid19

Wash Your Hands Frequently

Wash your hands often for at least 20 seconds using soap and water on hard surfaces repeatedly after touching a surface that may have been touched by someone else. Avoid touching your face.

For more information about social distancing, and reducing the spread of Coronavirus, visit gov.uk/coronavirus or phh.nhs.uk/covid19

[illegible]

Prawf COVID-19 ar gyfer gweithwyr allweddlod ym Mhowy

Ydych chi'n weichiwr allweddlod ym Mhowys?
A oes gennych chi neu rywun yn eich cartref symptomau COVID-19?

Efallai y bydddech yn gymwys i gael prawf COVID-19 ar yr unedau profi symudol newydd yn y sir.

Darganfon mwyr at
www.powyshst.wales.nhs.uk/coronavirus-testing

NHS	NHS	Cwmni Gŵyl Dyffordd

Critical stakeholders identified with engagement activity in place

Coronavirus COVID-19

GIG
CYMRU
NHS
WALES

Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

6 Ebrill 2020

Diweddariad ar gyfer Rhanddeiliaid wrth Fwrdd Iechyd Addysgu Powys

Neges oddi wrth Carol Shillabeer

Yma ym Mhowsy rŵ'n hyndod falch o'r ffordd y mae staff iechyd a gofal, gwirfoddolwyr, gweithwyr hanfodol a'n cymunedau wedi ymateb i heriau Coronafeirws (COVID-19).

Mae'r rhain yn amserodd heriol a digynsall, na fy'r GIG erioed wedi profi o'r blaen.

Gwn hefyd y bydd y rhain yn amserodd prydysau gan y byddwn i gyd yn poeni am sut mae Coronafeirws (COVID-19) wedi effeithio ac yn parhau i effeithio arnau ni, ein teulu, ein ffrindiau, ein cymdogaion.

Y neges byswicaf i bawb yw Aros Adref ac Achub Byddiadau.

Rhaid i ni i gyd chwarae ein rhani i llesu llesdianau ym haint.

- Ewch allan am feyd, rhesymau iechyd neu walrh yn unig (ond dim ond os na allwch weithio gartref)
- Arhoswch 2 fetr (6 troedfedd) i ffwrdd oddi wrth bob eraill
- Golwch eich dwylo cyn gynted ag y byddwch chi'n cyrraedd adref

Bydd y camau hyn i lesu llesdianau Coronafeirws (COVID-19). Byddant yn llesu nifer y bobi sydd yn dod yn sicr. Byddant rhw'n achub bywydau. Byddant yn helpu gwasanaethau iechyd a gofal i gydymhellhau i bobol sydd y rhai sydd iechyd fwyaf mewn angen.

Mae'r camau hyn yn arbennig a byswis i bobol sy'n fwy agored i haint. Mae Bythruan yn cael eu hanfon at bobol sydd i'r sig uchel o safon dalwedd i'w cynhygri. I'w aros gartref am 12 wythnos i amddiffyn eu hunain. Mae ein gwasanaethau iechyd a gofal yn gweithio'n galed i estyn allan i ddarparu cefnogaeth i bobol sy'n agored i niweid ac yn ynnig. ac i'w cysylltu i chefnogaeth gymunedol trwy Gysylltwyr Cymunedol lleol.

Gwn y bydd pobl yn awyddus i ddeall sut y ydym ni ym Mwrded Iechyd Addysgu Powys yn ymateb. Yn y bwletin sydd ynghlwm, nodais ein model ymateb cningol ar gyfer achub bywydau. Mae hyn yn amlinellu sut rydym yn cryfhau ein gwasanaethau gofal syffwrdd a chymunedol i allwngi mwy o bobol i lesu nifer y bobol sy'n agored at adref, a sut rydym yn gweithio galed gyfnewid cyfagos i sicrhau eich bod yn parhau i gael mynediad cyffwrdd i'r gofal aciwit ac arbennig hynny sydd angen annoch chi. Mae angen offer a sgiliau arbennigol ar ofal achub bywyd ar gyfer Coronafeirws (COVID-19) a ddarperir mewn ystybiat aciwit, yn hytrach nag mewn ardaloedd ynghyngell a gwledf fel Powys. Dyna pam rydym yn gweithio'n galed i ddarparu llesu uwch o'f al yn y sir nag ydym fel Powys yn gallu ei ddarparu, ond hefyd i sicrhau bod ein holl ystybiat cyfagos yn gallu diwallu angenion pobl Powys.

Gwn hefyd, fod materion fel Offer Amddiffyn Personol (PPE) a phrifri wedi hyn bysiau trafed mawr, felly yn y bwletin hwn rydym i'w siarad am y cyfnewidau cenedlaethol ar y materion hyn, a sut rydym yn canfod hyn yn leol.

Mae genym heriau mawr o'r blaenau. Diodli i bawb am eu hamynwedd, eu cefnogaeth a'u tosturi wrth i ni i gyd dodd o hyd i'n ffordd trwy hyn.

Yr eiddodd yn gywir,

Carol Shillabeer, Prif Weithredwr, Bwrdd Iechyd Addysgu Powys

Page 1

Phase 1: Decisions, reflections & learning

Public Health Wales Rapid COVID-19 surveillance Confirmed case data



GIG
CYMRU
NHS
WALES

Iechyd Cyhoeddus
Cymru
Public Health
Wales

Data correct as of:

17 May 2020 13:00

Cases and tests, by Local Authority of residence

		New cases	Cumulative cases	Cases per 100,000 population	Testing episodes	Testing per 100,000 population	Positive proportion
Aneurin Bevan University Health Board	Blaenau Gwent	1	316	453.3	1,087	1,559.3	29.1%
	Caerphilly	3	644	355.8	2,416	1,334.7	26.7%
	Monmouthshire	1	305	324.0	1,116	1,185.4	27.3%
	Newport	2	803	523.8	2,593	1,691.4	31.0%
	Torfaen	0	320	343.9	1,260	1,354.1	25.4%
Betsi Cadwaldr University Health Board	Anglesey	13	170	243.0	820	1,172.1	20.7%
	Conwy	6	408	348.2	1,674	1,428.6	24.4%
	Denbighshire	9	414	434.3	1,675	1,757.1	24.7%
	Flintshire	2	384	246.8	1,456	935.8	26.4%
	Gwynedd	8	341	274.6	1,528	1,230.5	22.3%
Cardiff and Vale University Health Board	Cardiff	13	1,915	525.7	6,594	1,810.3	29.0%
	Vale of Glamorgan	4	596	451.0	2,508	1,897.6	23.8%
Cwm Taf Morgannwg University Health Board	Bridgend	2	482	332.7	2,577	1,778.8	18.7%
	Merthyr Tydfil	1	327	543.3	1,157	1,922.5	28.3%
	Rhondda Cynon Taf	11	1,401	583.4	4,554	1,896.5	30.8%
Hywel Dda University Health Board	Cardiff	12	642	342.3	3,155	1,682.1	20.3%
	Ceredigion	0	39	53.4	609	834.3	6.4%
	Pembrokeshire	0	271	216.7	1,681	1,344.2	16.1%
Powys Teaching Health Board	Powys	3	244	184.2	1,106	835.1	22.1%
Swansea Bay University Health Board	Neath Port Talbot	3	558	390.5	2,323	1,625.5	24.0%
	Swansea	4	1,216	493.4	4,792	1,944.3	25.4%
	Unknown location	0	92		1,988		4.6%
	Wales total*	101	12,294	391.7	50,337	1,603.8	24.4%
	Resident outside Wales	0	110		436		25.2%

Headlines on cases:

NB – Wales data only; further cases of Powys patients in English Hospitals (hence cases and testing will be higher)

2nd lowest county cases/100,000 population

2nd lowest county testing

5th lowest county on positive cases/proportion to testing

Individuals may be tested more than once for COVID-19. Information presented here is based on 6-week episode periods. If an individual is tested more than once within a 6-week period they are only counted once and if any of their test results are positive, that is the result which is presented.

*Wales total includes cases where a location could not be determined, and excludes those resident outside Wales.

Phase 1: Decisions, reflections & learning

<p>Aros Adref Achub Bywydau</p> <p><i>Mae pob un ohonom yn rhannu cyfrifoldeb i leihau lledaeniad yr haint</i></p>		<p>Stay Home Save Lives</p> <p><i>We all share a responsibility to reduce the spread of infection</i></p>
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5 point COVID-19 Response Plan (phase 1) – headline summary:

1. Good compliance with 'lockdown' (helped push down r value)

2. Excellent partnership working to support vulnerable people at home

3. COVID assessment facilities established by GPs

4. Expansion of community hospital and social care beds established/tested (Field Hospital plans drawn up – not activated)

5. Excellent relationships/pathways for Powys residents in DGHs (Wales and England)

Phase 1: Decisions, reflections & learning

Aros Adref Achub Bywydau <i>Mae pob un ohonom yn rhannu cyfrifoldeb i leihau lledaeniad yr haint</i>		Stay Home Save Lives <i>We all share a responsibility to reduce the spread of infection</i>
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System challenges:

- **PPE** (Personal Protective Equipment): much improved position in health board; Military expertise; new system of distribution via national supply; queries regarding donated items and process for British Standards etc
- **Testing**: scaling up testing key; good access for key workers; local Testing Units x 2 in Powys running throughout; some patients tested in England – cross border data issues.
- **Closed Settings** - particularly care homes: significant loss of life (excess deaths); rapid review exercise - integrated working approach enhanced; testing policy changed; significant support required.

Phase 1: Decisions, reflections & learning

Decisions taken:

- COVID-19 Action Plan
- Clinical Response Plan, including capacity planning
- Support Plan (Logistics, IT, Support services, Estates etc)
- Workforce Deployment Plan
- Communication & Engagement Plan
- Excess Deaths Plan

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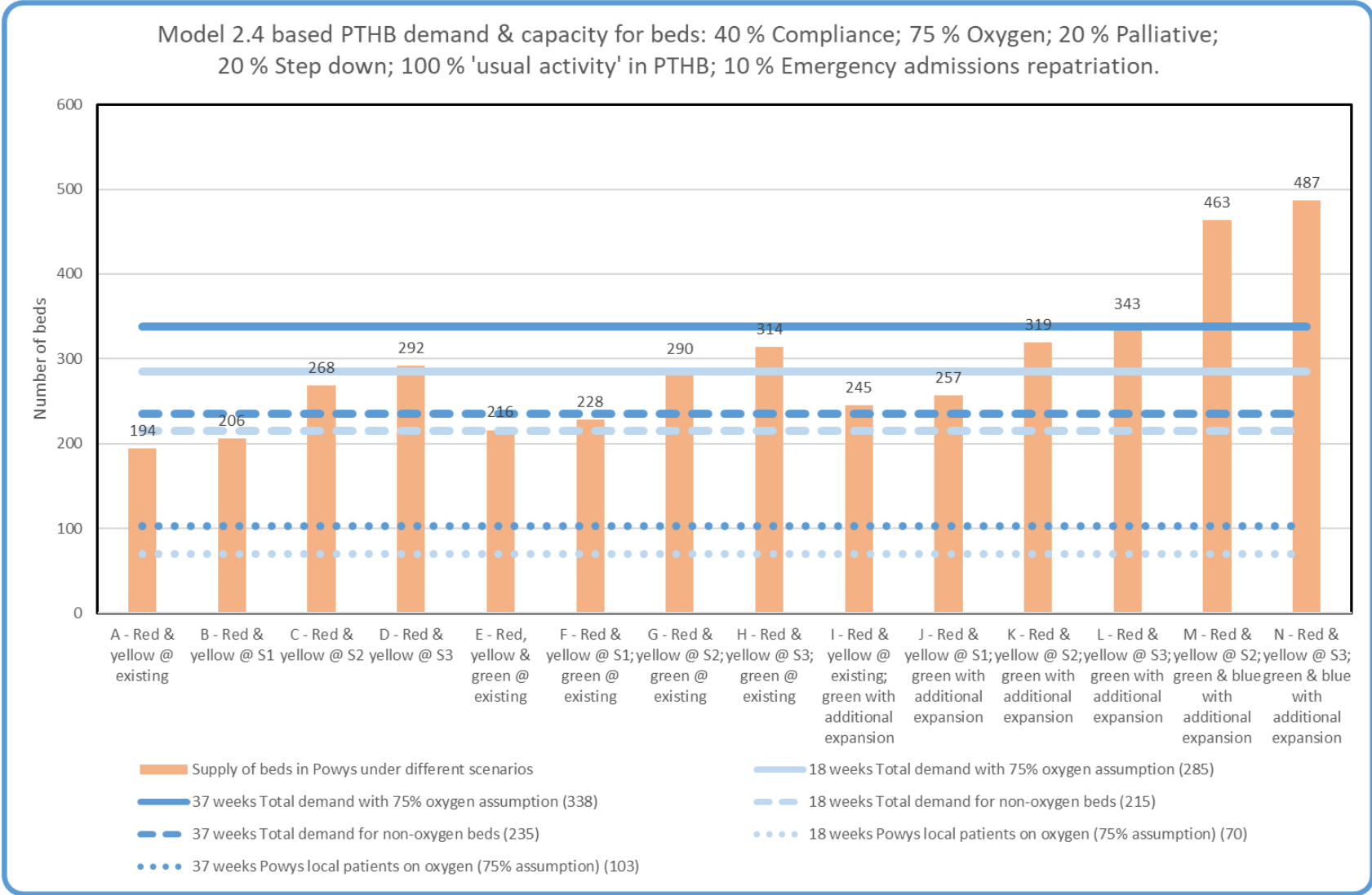
Reflections/learning (high level):

- Working with uncertainty (planning assumptions/modelling) – decisions made nonetheless;
- Pace and agility – more flexible working, increased productivity
- Keeping on top of ‘everything’ a challenge, securing enough ‘headspace’
- Acceleration of digital – not seeking perfection but good enough to build on (and not go ‘back’): patient consultations, staff remote working
- Creative and flexible solutions (staff & patients) achieved
- Strength of partnerships key – overall excellent, awareness of pressure points
- New leaders emerging and greater awareness of weaker areas
- Comms – daily rhythm otherwise hard to keep up, generally positive feedback (some learning)

NB: a separate, more detailed reflections and feedback report is available, sources drawn through organisation. Partnership working reflections due w/c 18 May.

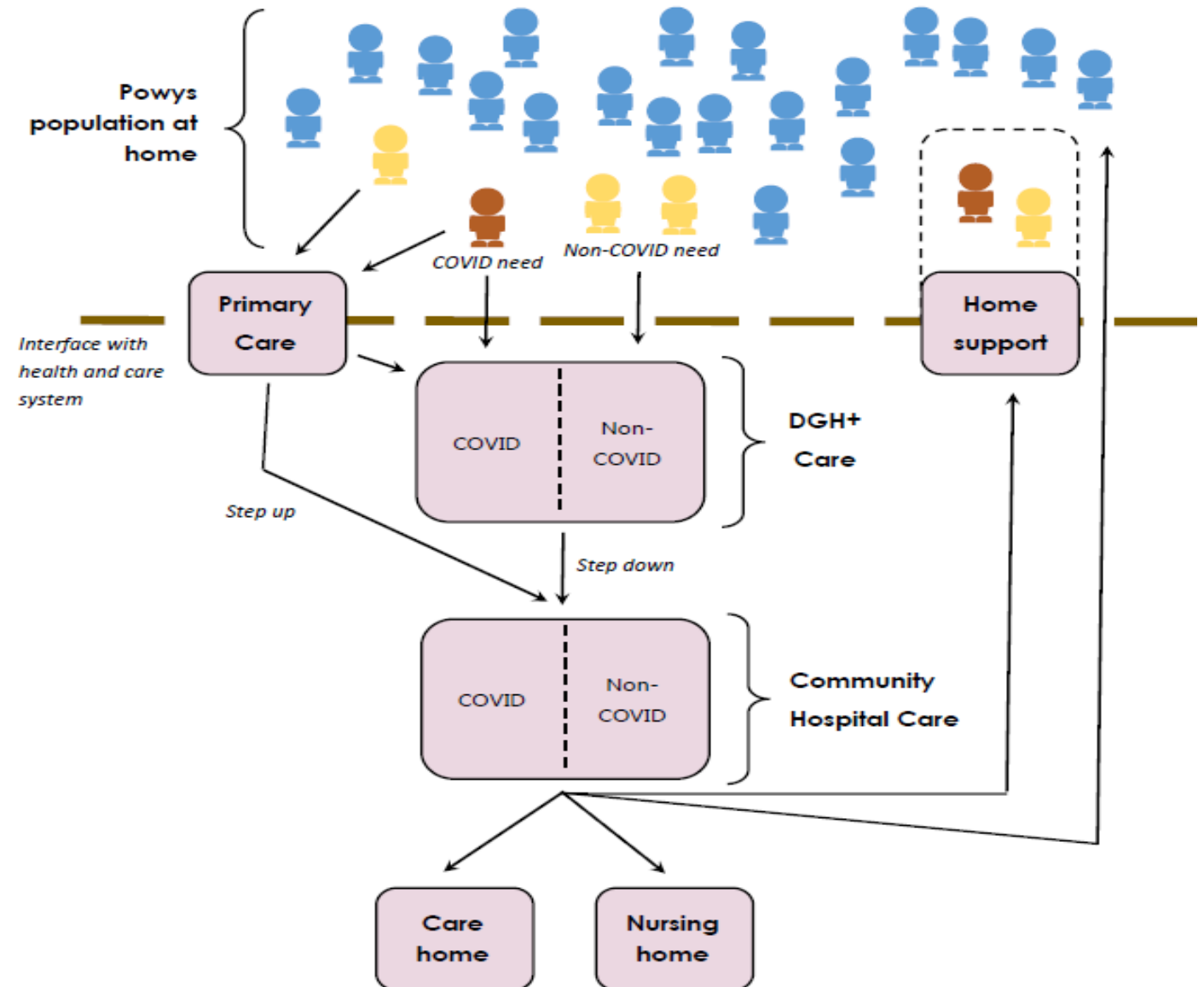
Surge Capacity Modelling & Recommendations

- Model 2.4 had been used to assess the requirement of surge facilities.
- Demand was determined from cases at 37 weeks and utilising the RWC scenarios that included:
 - 40% compliance.
 - 100% of normal patient activity within admitted care setting.
 - 75% oxygen support required (requirement modelled worst case).
 - Additional surge bed capacity will be opened in community hospital sites (up to total 199 beds)
- PTHB used a tiered site model, inline with capacity projections. This resulted in the creation of 14 different capacity scenarios (horizontal axis). These models include breakdowns of current PTHB capacity and potential surge capacity including the potential utilisation of a field hospital in Powys..
- The graph (right) supported the assessment, and current outcome that the health board does not require a field hospital in Powys & other additional non health surge capacity.
- Critical care for Powys residents follows Commissioned care flows to acute providers e.g. Ventilated and Non invasive ventilation including CPAP.

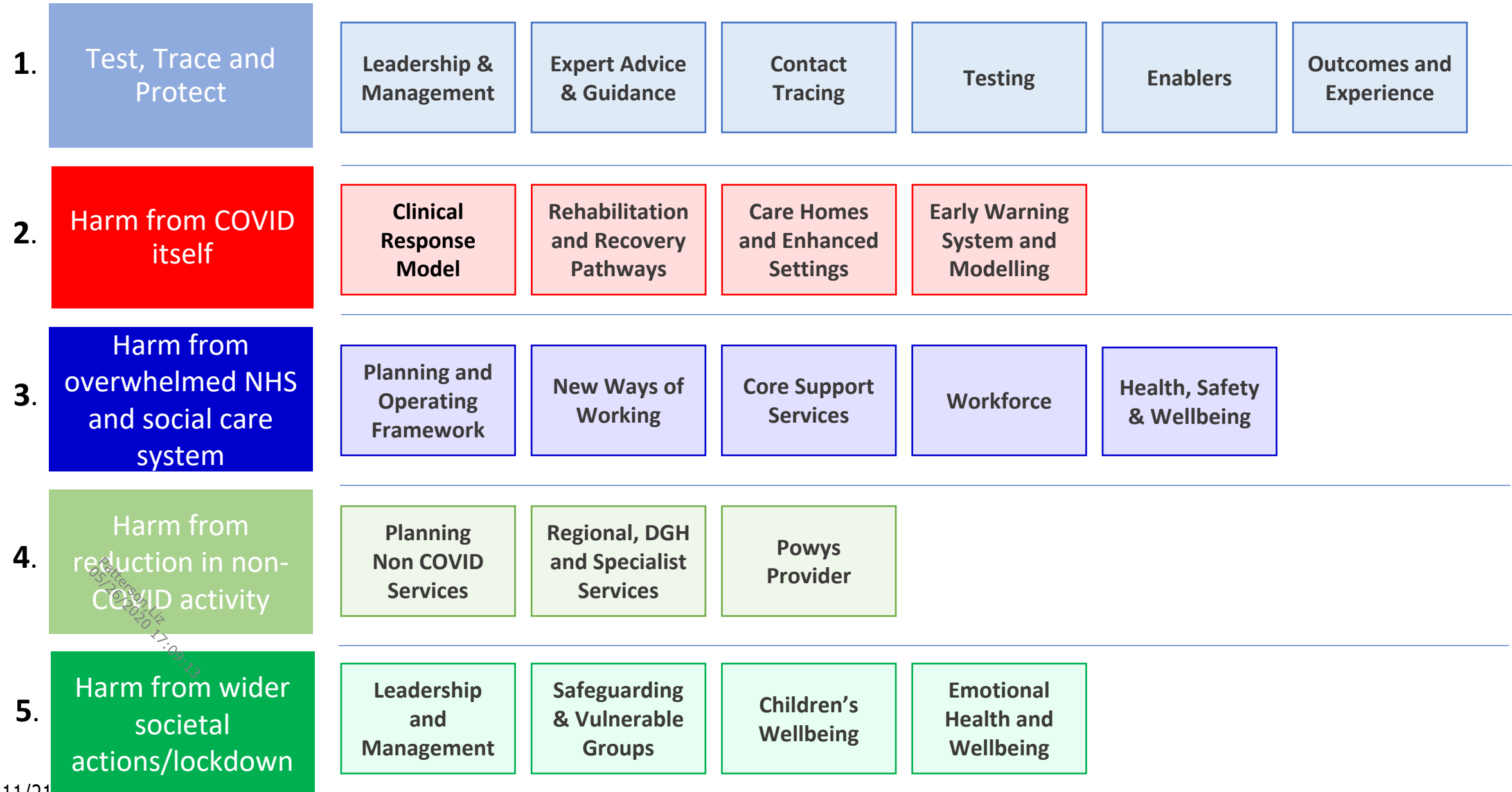


Modelling – Phase 2 Whole System Approach

- To ensure that Powys is ready for future demand as a result of the pandemic, and its potential impact on both the health and social care systems, work is underway to extend the whole system approach.
- Linking closely with Powys County Council a modelling collaborative has been created to carry out the work required in demand & capacity.
- The process includes flow mapping for the resident population, understanding the interface with health and social care e.g. primary care, home support, care homes, Powys hospital sites and acute flows to secondary and specialised services.
- This work will enable Powys to understand the current and potential impacts to the system including future demand and capacity flow analysis which in turn will support robust working arrangements between health and social care.

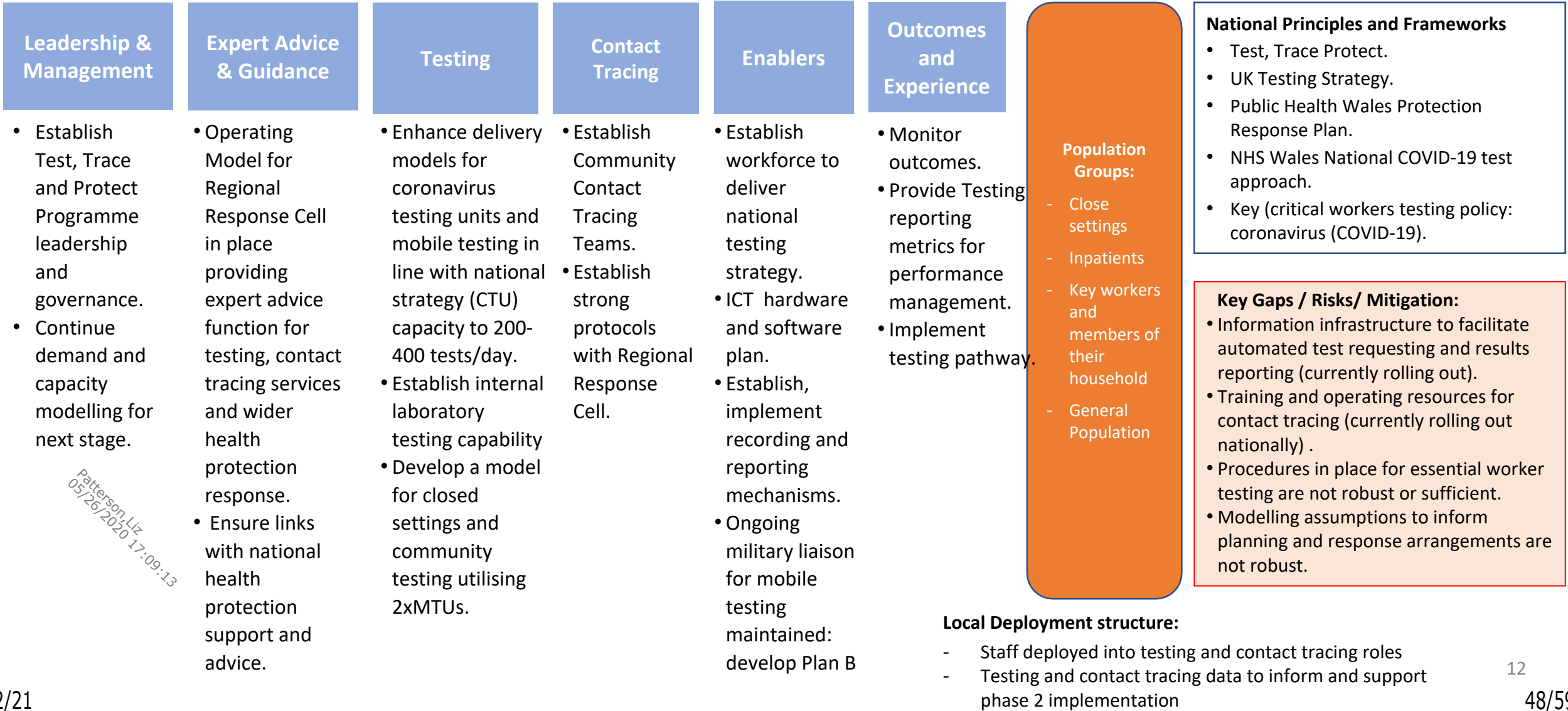


Framework for Phase 2 Response Planning



Test, Track and Protect

1. Objective: Test and Trace function to quickly identify, test and isolate COVID-19 cases in settings and communities



Patterson, Liz
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2. Objective: To ensure effective management of COVID-19 in health and care settings and communities

Clinical Response Model	Rehabilitation and Recovery Pathways	Care Homes and Enhanced Settings	Early Warning System and Modelling	Population Groups:	National Principles and Frameworks
<p>Continue to deliver clinical response model with focus on:</p> <ul style="list-style-type: none">• Self care and support.• Sustainable primary care across all contractors, COVID & non-COVID.• Access to home and community care based on need and proportionality.• Ensure access to essential DGH and specialised services including critical care.	<ul style="list-style-type: none">• Implement rehabilitation pathways to support Acute COVID19 pathways.• Implement rehabilitation pathways for the new normal.	<ul style="list-style-type: none">• Capacity in place to support hospital discharge process in relation to step up / step down.• Support providers with training and workforce requirements as per agreed escalation matrix framework.• Ensure primary care and MDT support inc respiratory.• Implement Commissioning Assurance Framework for Care Homes.• Complete COVID19 Self-Assessment of Children’s Homes.• Complete COVID19 Self-Assessment of Mental Health & LD Homes. Practice.	<ul style="list-style-type: none">• Develop Early Warning system - 'triggers' / escalation plan linked with R value, surveillance data and other intelligence.• Implement Early Warning system linked to Test, Trace and Protect.	<ul style="list-style-type: none">- Care Home and Close settings- Inpatients- General Population- At risk groups those self isolating / super vulnerable- High need COVID Groups at peak periods	<p>National Principles and Frameworks</p> <ul style="list-style-type: none">• National ethical framework.• NHS Wales National COVID 19 Framework.• WG Essential Health services during COVID-19.• National Acute Secondary Care Group Guidance.• Guidance to Prevent COVID-19 Among Care Home Residents.• Manage Cases & Outbreaks in Residential Care Settings in Wales’. <p>Key Gaps / Risks/ Mitigation:</p> <ul style="list-style-type: none">• Modelling assumptions are not robust enough.• Medical model requires scaling down of surge capacity.• Ongoing cross border information gaps (positive cases and deaths).• Workforce capacity and skills gap.• Effective infection, prevention and control arrangements.

Harm from an Overwhelmed System

3. Objective: To effectively manage the system priorities through flexibility and agility.

Planning and Operating Framework	New Ways of Working	Core Support Services	Workforce	Health, Safety & Wellbeing	Population Groups:	National Principles and Frameworks
<ul style="list-style-type: none">• Agree Strategic planning framework and whole system modelling• Set 80% bed occupancy levels, with escalation and trigger points• Agree protocols for Streaming of Pathways /flows for COVID and Non COVID - designated red and green areas.• Provide primary care hot sites when triggered by practice demand.	<ul style="list-style-type: none">• Establish a specific focus on ;new ways of working' under the Innovation and Improvement mechanisms.• Capture learning• Evaluate new practice• Sustain new ways of working and best practice• Promote success for spread and scale; learn from failure	<ul style="list-style-type: none">• Support Clinical Response Model• Resource Digital Acceleration<ul style="list-style-type: none">-Remote working-Attend Anywhere-Consultant Connect- Remote Video Consultations- Self care apps	<ul style="list-style-type: none">• Assessment of workforce supply for the next 3, 6, and 9 months.• Ensure staff protection, wellbeing and social distancing in the workplace.• Provide staff Psychological Wellbeing support services via the Wellbeing Hub.• Review local mechanisms to capture lessons learnt and raising of concerns.• Start to re-instate broader professional training etc.	<ul style="list-style-type: none">• Update comprehensive risk assessment following evaluation• Implement Social distancing measures including shielding where appropriate.• Continue to provide advice and guidance relating to Infection Prevention Control (IPC) along with training in personal protective equipment (PPE)• Continue to support staff with home working arrangements	<ul style="list-style-type: none">- Staff- General Population- At risk Groups – Long term conditions- Non Covid Groups with life-essential and routine health care needs- COVID groups	<p>National Principles and Frameworks</p> <ul style="list-style-type: none">• Manage Cases & Outbreaks in Residential Care Settings in Wales’.• Guidance to Prevent COVID-19 Among Care Home Residents.• Maintaining Essential Health Services during the COVID 19 Pandemic.• National Ethical Framework.• NHS Wales National COVID 19. <p>Key Gaps / Risks/ Mitigation:</p> <ul style="list-style-type: none">• Ability to create agility in system to respond to triggers.• Ability to quickly re-deploy staff.• Health and social care capacity, potentially impacting on care and adherence to discharge arrangements and ability of patients to return home.• Risk that equipment and supplies not available to support delivery.• Transmission and management of COVID19 in the workplace.• Risk that clinical outcomes for patients are compromised.

4. Objective: Support delivery of essential services in health and care settings and communities to minimise harm

Planning Non COVID Services	Regional, DGH and Specialist Services	Powys Provider		National Principles and Frameworks
<ul style="list-style-type: none">Assess backlog and continue with tracking system for deferred procedures.Continue to apply national definitions of service prioritisation to local provision and agree local decision making approach.Phasing plan to be agreed and implemented.	<ul style="list-style-type: none">Implement a whole system approach, modelling and phasing of routine services.Identify and manage gaps in essential services.Support development of regional solutions.Continue to provide access to specialised mental health services.Continue with joint planning with WAST.Continue to participate in WG Essential Services Group.Manage Independent Sector e.g. reinstatement of services.Powys population will access independent hospital capacity via commissioned acute flows.Responsible commissioner regulations for Vulnerable children out of county.Sustainability arrangements for at risk independent providers.	<ul style="list-style-type: none">Agree essential services to be reinstated – critical dependency of SLAs with other HBs/Trusts.Work within services to confirm implementation dates of service level increases.Continue to respond to WG re what parts of the GP, Dental, Ophthalmology and Pharmacy contracts to be reinstated.	<p>Population Groups:</p> <ul style="list-style-type: none">General PopulationAt risk Groups – Long term conditions/shieldingNon Covid Groups with life-essential and routine health care needs	<p>National Principles and Frameworks</p> <ul style="list-style-type: none">NHS Wales National COVID 19 Framework.National ethical framework.NHS Wales COVID-19 Operating Framework: quarter 1 2020 to 2021.WG Essential health services during COVID-19. <p>Key Gaps / Risks/ Mitigation:</p> <ul style="list-style-type: none">Clinical assessment of backlog and prioritisation process.Capacity to manage backlog and financial implications.Ability to understand whole system approach in a timely manner and impact on provider services and resultant inequity of service offer across external providers.Potential fragility of provider services due to inability to maintain support from external commissioned services in relation to Consultant workforce.

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Essential Services – Initial Assessment of Powys Provider Services

General

- Broad range of services have been modified or stopped; however a broad range of services remain in place
- New referrals are still being received.
- Variety of clinical review and other “safety netting” arrangements are in place.
- Many services have established arrangements for the review of “urgent” cases (including within new/existing caseloads) following triage. While most of this activity is being handled remotely, some face to face contact is still continuing
- Potential benefits, going forward, from being able to maintain the new ways of working established during the first phase of the COVID response
- Need for COVID infection control and PPE arrangements in re-establishing services
- Detailed risk assessment to be undertaken for phase 2 essential services (due to complete by 26th May 2020).

Specific Services

- All PTHB surgical planned care is currently suspended, “urgent” clinics operating, new referrals being forwarded to outside consultants for clinical “prioritisation”; in-reach consultants have been re-deployed within their own HBs. Any plan for local re-provision will require joint working/planning with relevant neighbouring Trusts/HBs.
- Healthy Child Wales Programme - to reintroduce elements of HCW programme which had previously been stood down by WG.
- Antenatal care being delivered in line with RCOG guidance.
- All routine PTHB X-ray and USS stood down; “urgent” is continuing.
- Detailed prioritisation of therapy services undertaken in line with WG “essential services” list.

SBAR assessment completed:

- Women and children’s service (including a “stand-alone” SBAR for the Healthy Child Wales (HCW) Programme)
- Mental health and learning disability services
- Respiratory nurse-led service
- Cardiac rehabilitation nurse-led service
- Diabetes nurse-led service
- Pain and fatigue service
- Ear care service
- Lymphoedema service
- Tissue viability service
- Therapy and health sciences service
- Out-patients and surgery
- Endoscopy

5. Objective: To enable effective support to people at home and in the community as a result of the lockdown arrangements

Leadership and Management	Safeguarding & Vulnerable Groups	Children Wellbeing	Emotional Health and Wellbeing	Population Groups:	National Principles and Frameworks
<ul style="list-style-type: none">• Review and revise governance, management and communication arrangements for next phase.• Review and update local planning based on SAGE planning assumptions in line with national, regional and local context.• Re-establish RPB/PSB arrangements.• Continue with regular review of communication & engagement.	<ul style="list-style-type: none">• Review and revise Third sector support to vulnerable groups i.e. self isolating, domestic violence.• Maintain focus on sharing publicity regarding "Home is not always a safe space" to staff and wider population.• Provide respite support for vulnerable groups.• Enhance profile of Safeguarding- continue arrangements for staff.	<ul style="list-style-type: none">• Implement Child Health Programme.• Promote uptake of childhood immunisation programme.• Looked After Children Nurses increasing support to Children's Homes in Powys.	<ul style="list-style-type: none">• Provide remote treatment and care for people with mental health conditions and learning disabilities.• Increase Digital therapies and online support.• Enhance further Bereavement support where required.	<ul style="list-style-type: none">- General Population- Close settings- COVID and Non COVID groups.- Children- Vulnerable groups	<div><p>National Principles and Frameworks</p><ul style="list-style-type: none">• NHS Wales National COVID 19 Framework.• National Ethical framework.• Healthy Child Wales Programme.• Wales Safeguarding Procedure 2019.• VAWDASV – Ask and Act.• UN COVID 19 & the need for action on Mental Health.</div> <div><p>Key Gaps / Risks/ Mitigation:</p><ul style="list-style-type: none">• Ensure effective whole system planning is in place to respond to phase 2.• Partnership governance arrangements need to be reinstated to support phase 2.• Potential financial impact of COVID19 and cost of backlog.</div>

Finance - Summary Covid-19 Revenue Spend 2020/21 @ 18th May 2020

Summary Forecast Covid-19 Revenue Expenditure 2020/21

Areas	£ m	£m
Pay		3.8
Non Pay		
- PC	0.9	
- PPE	1.4	
- Provider	2.1	
- Block LTA	2.3	
		6.7
Non Delivery Savings		2.2
Total Spend		12.7

Note – above table excludes any capital costs

Key Assumptions Support Forecast Covid-19 Revenue Expenditure 2020/21

Timeframe

- Costs for 12 month period from April 2020– March 2021

General Assumptions

- Cost April as per Ledger and May assumed in line April
- Forecast June 2020 – March 2021 based on flexibility to increase beds up to 199

Pay

- Based on Workforce model required to support 199 beds
- Additional costs included for facilities
- Variable pay costs based on Covid-19 FCP process

Non Pay

- Equipment excludes any costs in relation to the all Wales procurement process based on the assumption this will be centrally funded
- PPE costed based on current modelling
- LTA pressures are based on current block arrangements compared to IMTP plan
- Other costs identified via Covid-19 Cost Centre (B259)



There is a risk that...

Impact	Catastrophic	5		<ul style="list-style-type: none"> We do not have the required level of equipment to achieve implementation of the Clinical Response Model, E.g. Beds 	<ul style="list-style-type: none"> Modelling assumptions to inform planning and response arrangements are not robust The total quantum for funding for addressing COVID-19 across Wales remains fluid and uncertain 		
	Major	4	<ul style="list-style-type: none"> Arrangements for the deceased are insufficient and compromised 	<ul style="list-style-type: none"> Procedures in place for essential worker testing are not robust or sufficient The need to monitor oxygen supply arrangements and how we identify whether we are reaching capacity 	<ul style="list-style-type: none"> Insufficient strategic delivery and benefits realization and/or loss of reputation due to ineffective communications and engagement arrangements Infection, Prevention and Control arrangements are not robust and effective Clinical outcomes for patients are compromised We do not have sufficient workforce capacity to achieve implementation of the Clinical Response Model Our workforce does not have the required skills and expertise required to achieve implementation of the Clinical Response Model 	<ul style="list-style-type: none"> COVID-19 may be transmitted in the workplace We are unable to procure sufficient levels of supplies to achieve the implementation of the Clinical Response Model e.g. Oxygen 	
	Moderate	3		<ul style="list-style-type: none"> Governance arrangements required to effectively respond to COVID-19 are not robust and embedded We do not have sufficient leadership and management capacity to design, lead and support the response to COVID-19 The organisation does not have effective planning in place to recover from COVID-19 response 			
	Minor	2					
	Negligible	1					
			1	2	3	4	5
Likelihood			Rare	Unlikely	Possible	Likely	Almost Certain

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Agenda item: 2.3

BOARD MEETING		Date of Meeting: 27 May 2020	
Subject :	Revised Annual Plan 2020/21		
Approved and Presented by:	Carol Shillabeer Chief Executive Officer		
Prepared by:	Carol Shillabeer Chief Executive Officer		
Other Committees and meetings considered at:	Considered by Executive Directors via email		
PURPOSE:			
The purpose of this paper is to present a revised annual plan for 2020/21. As a result of the COVID-19 pandemic and the activation of Business Continuity Arrangements, there has been and is likely to continue to be an impact on the timescales for delivery of some of the objectives in the previously agreed Annual Plan (approved at Board end of January 2020). Given the uncertain nature of the pandemic, the annual plan milestones will need to be kept under close review, formally reviewed every 90 days.			
RECOMMENDATION(S):			
The Board is asked to DISCUSS and APPROVE the revised annual plan milestones, recognising the need for regular review and potential further revision.			
Approval/Ratification/Decision ¹		Discussion	Information
✓		✓	

¹ Equality Impact Assessment (EiA) must be undertaken to support all organisational decision-making at a strategic level

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	✓
	2. Provide Early Help and Support	✓
	3. Tackle the Big Four	✓
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	✓
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	✓
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

This paper outlines a proposed revision to the Annual Plan 2020/21 milestones for implementation (see Appendix). As a result of the COVID-19 pandemic and the activation of Business Continuity Arrangements, there has been and is likely to continue to be an impact on the timescales for delivery of some of the objectives in the previously agreed Annual Plan (approved at Board end of January 2020). As the health board moves into Phase 2 of the Response to the pandemic, the annual plan has been reviewed to assess relative priority and deliverability. There are some actions that will assist in the management of Phase 2 of the pandemic response and these are indicated below.

The revised Annual Plan is split into quarters for delivery:

Red rated actions are considered to be deliverable or can be started in the remainder of Quarter 1;

Amber rated actions are considered to be deliverable or can be started in Quarter 2; and

Green rated actions are considered to be deliverable or can be started in Quarters 3 and 4.

Given the uncertain nature of the pandemic, the annual plan milestones will need to be kept under close review, formally reviewed every 90 days.

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DETAILED BACKGROUND AND ASSESSMENT:

The review and revision of the previously approved Annual Plan has been undertaken by Executive Directors, aligned to the planning for the Phase 2 Response to the managing the pandemic. The two documents, presented to Board are companions and outline the actions planned for the remainder of Quarter 1 and quarter 2 specifically. Quarters 3 and 4 are outlined in the revised Annual Plan, however will be subject to further review as the next phase of the pandemic is managed. It is important to note that the Phase 2 Response Plan presented further on the agenda, aligns to the requirement of Welsh Government to submit Quarter 1 Operational Plans. There is no requirement at this stage to submit to Welsh government a revised Annual Plan.

The areas of the Annual Plan considered to be deliverable or can be started during the remainder of Quarter 1 are:

- Develop 2020/12 flu immunisation plans
- Substance Misuse Partnership strategy – (aspects of)
- Providing leadership to facilitate multi agency working through the Carers Steering Group; Engagement in Carers Trust Wales national work
- Implement Medical Gas Policy provider units
- Volunteering Development – Framework to be developed with WOD
- Continue with the delivery of the HCWP (annual programme)
- Deliver the T4MH strategy and achieve the milestones set out in the strategy (re-prioritise key COVID supporting actions)
- Implementation of the Powys Maternal and Infant MH Plan, and achievement of milestones. (re-prioritise key COVID supporting actions)
- Deliver the CAMHS improvement plan and achieve agreed milestones. (re-prioritise key COVID supporting actions)
- Monitor robust management of Single Cancer Pathway, adoption of optimal pathways (re-prioritise key COVID supporting actions)
- As per Unscheduled Care Programme (Review in relation to COVID Response Plan Phase 2)
- As per Planned Care Programme (Review in relation to COVID Response Plan Phase 2)
- As per WHSSC ICP (Review in relation to COVID Response Plan Phase 2)
- Clinical Quality Framework Work Programme Q1-Q4
- Implement a targeted internal staff survey; Submit application for funding of 2 Workforce Health Intervention Co-coordinators focused on Healthy weights and stress management; Stress Management Toolkit and Policy Review; Chat2Change in house PULSE survey on stress and well-being
- Strengthen assurance and compliance for Health and Safety
- Develop the approach to volunteering and work experience

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- Implement as per agreed Capital programme and project plans (Review in relation to COVID Response Plan Phase 2)
- Delivery of agreed Telehealth and Telecare work programme
- Rollout Microsoft 365: Agree Programme at Local Level
- Commissioning Assurance Framework and CQPRMs; Quarterly CAF; Service Fragility Log

The areas of the Annual Plan considered to be deliverable or can be started during Quarter 2 (July – Sept) include:

- Finalise costed business case for Level 2 and 3 obesity services/pathway
- Review Healthy Weight Action Plan to ensure alignment with Healthy Weight: Healthy Wales and 2020-2022 HW:HW Delivery Plan
- Development and implementation of local measles and mumps elimination plan
- Implement 2021/22 flu immunisation plans
- Extended role Gap Analysis and workforce development/ transformation plan completed;
- Extended GDS access arrangements for mid Powys; Deployment of mobile dental unit in relevant location; Decontamination improvements required costed
- At least 1 additional High Street Pharmacist Prescriber
- Proactive care for those with complex needs: Top 3% at risk identified by Practice; Plans in place; Complex needs Specialist Advisors in Clusters
- Define Powys Medicines Safety Officer Role; Implement revised Medicines Policy and procedures; Initiate Community Pharmacy IP service for respiratory care in Hay area; Implement digital technology supporting access to medicines and to lifestyle advice
- Dementia Action Plan
- DoLS Plan
- Maternity & Neonatal Network Plan (annual programme)
- Delivery of the Community Paediatric remodelling Project (annual programme)
- Work with Medical Director and GPs to develop model for Physical health input into Inpatient mental health settings
- Complete engagement with stakeholders on potential change of s136 pathway to Felindre Ward (Pan Powys).
- Develop options for the development of an age appropriate bed at Felindre for 16-17 year olds and gain capital funding.
- Cancer: Transformation Programme Plan agreed; Needs assessment & review of existing services and pathways
- Respiratory: Implement Phase 2; Service specification approved; WAST pilot project implemented; Workforce model
- Circulatory: Finalise scope for Phase 1; establish Programme mechanisms; agree and commence Comms / Engagement
- North Powys Well-being Programme Plan review/revision

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- Implementation of Phase 2 of the Organisational Change Process; begin roll out of the e-community rostering system; implementation of the Workforce Futures Strategic Framework
- Implement a cultural development programme based upon the Compassionate Leadership Model; evaluate PTHB Manager's Programme
- Implement an engagement framework through Chat2Change
- Implement a talent management approach for HCSW to access Nursing/Therapies.
- Develop the business case to deliver the Health and Care Academy
- Long Term Estates Strategy
- Further rollout of WCCIS
- Delivery of Annual Governance Framework
- Detailed financial monitoring and reporting (Q1-4)
- Individual Programme / Project Plans for key live programmes (Eg. NHS Future Fit/ ABUHB Clinical Futures)

It is important to stress that these milestones are subject to change depending on the implementation of the organisation's response (Phase 2). Reporting on progress will be through specific Committee and Board reporting in line with Governance arrangements proposal, presented separately on the Board agenda.

NEXT STEPS:

Implementation of the agreed Annual Plan action in line with the revised timeframes, subject to adaption in line with Phase 2 pandemic response.

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The following Impact Assessment must be completed for all reports requesting Approval, Ratification or Decision, in-line with the Health Board's Equality Impact Assessment Policy (HR075):

IMPACT ASSESSMENT					
Equality Act 2010, Protected Characteristics:					
	No impact	Adverse	Differential	Positive	Statement
Age				✓	<p>Please provide supporting narrative for any adverse, differential or positive impact that may arise from a decision being taken</p> <p>The actions proposed in the paper outline a positive impact on protected characteristics, given the core objectives that the Board has already approved.</p>
Disability				✓	
Gender reassignment				✓	
Pregnancy and maternity				✓	
Race				✓	
Religion/ Belief				✓	
Sex				✓	
Sexual Orientation				✓	
Marriage and civil partnership				✓	
Welsh Language				✓	
Risk Assessment:					Statement
	Level of risk identified				<p>Please provide supporting narrative for any risks identified that may occur if a decision is taken</p> <p>There is some risk that the milestones may not be achieved. This would be as a priorities being amended in response to the pandemic.</p>
	None	Low	Moderate	High	
Clinical		✓			
Financial		✓			
Corporate		✓			
Operational		✓			
Reputational		✓			

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Summary Guide to Key Deliverables in IMTP 2020/21 – 2022/23 and Annual Plan 2020/21

Revised milestones May 2020

THE HEALTH AND CARE STRATEGY FOR POWYS 'AT A GLANCE'



WE ARE DEVELOPING
A VISION OF THE
FUTURE OF HEALTH
AND CARE IN POWYS...



TO
2027
AND
BEYOND...



WE AIM TO DELIVER
THIS VISION THROUGH-OUT
THE LIVES OF THE PEOPLE OF
POWYS...



WE WILL SUPPORT
PEOPLE TO IMPROVE
THEIR HEALTH AND
WELLBEING THROUGH...



OUR PRIORITIES AND
ACTION WILL BE
DRIVEN BY CLEAR
PRINCIPLES...



THE FUTURE OF
HEALTH AND CARE
WILL IMPROVE
THROUGH...



WORKFORCE FUTURES

INNOVATIVE ENVIRONMENTS

DIGITAL FIRST

TRANSFORMING IN PARTNERSHIP

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Well-being Objectives and Organisational Priorities

<p>Core Well-being Objective 1</p> <p>FOCUS ON WELLBEING</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Wider Determinants of Health • Health improvement & Disease Prevention • Supporting Communities and Carers 	<p>Core Well-being Objective 2</p> <p>EARLY HELP AND SUPPORT</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Primary and Community Care • Cluster Working • Connecting Communities
<p>Core Well-being Objective 3</p> <p>TACKLING THE BIG FOUR</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Mental Health • Cancer • Respiratory Conditions • Circulatory Disease 	<p>Core Well-being Objective 4</p> <p>ENABLE JOINED UP CARE</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • North Powys Well-being Programme • Unscheduled Care and Out of Hours • Planned Care • Specialised Care • Quality and Citizen Experience
<p>Enabling Well-being Objective 1</p> <p>DEVELOP WORKFORCE FUTURES</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Designing, Planning and Attracting Workforce • Leading the Workforce • Engagement and Well-being • Education, Training and Development • Partnership and Citizenship 	<p>Enabling Well-being Objective 2</p> <p>PROMOTE INNOVATIVE ENVIRONMENTS</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Research Development and Innovation • Capital Programme and Estates • Facilities
<p>Enabling Well-being Objective 3</p> <p>PUT DIGITAL FIRST</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Digital Care • Digital Access • Digital Infrastructure & Intelligence 	<p>Enabling Well-being Objective 4</p> <p>TRANSFORMING IN PARTNERSHIP</p>  <p>PRIORITIES</p> <ul style="list-style-type: none"> • Good Governance • Financial Management • Partnership, Planning, Performance and Commissioning

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FOCUS ON WELLBEING

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Wider Determinants of Health			
1.1 Implement the Powys Wellbeing Plan as a partner of the Public Service Board			
<ul style="list-style-type: none"> Implement the Powys Wellbeing Plan (Public Service Board) 	Director of Public Health	This is a long term partnership plan, tracked by the Public Service Board	<ul style="list-style-type: none"> Refer to the Powys (PSB) Wellbeing Plan
Health Improvement and Disease Prevention			
1.2 Implement the health improvement and disease prevention programme			
<ul style="list-style-type: none"> Implement the health improvement and disease prevention programme Implement Sexual Health Improvement Plan Implement Substance Misuse Strategy as a partner in the Substance Misuse Partnership 	Director of Public Health	<p>Key milestones to be agreed in Q4 2019/20 as part of 2020/21 annual delivery plan and will include:</p> <ul style="list-style-type: none"> Review current specialist stop smoking service (Q4 2019/20 and Q1 2020/21) Develop plans (Q1 and Q2 2020/21) and start implementation of plans (Q3 2020/21 and beyond) for future sustainable model for stop smoking service Review Tobacco Control Action Plan to include specific actions for 2020/21 and beyond regarding smoke free hospital sites and no-smoking mental health units Continue to progress work developed with 2 GP practices (Haygarth and Presteigne) Finalise costed business case for Level 2 and 3 obesity services/pathway (Q4 2019/20 and Q1 2020/21) Subject to funding, develop action plans to establish new obesity services at Level 1, 2 and 3 (Q2 2020/21) and commence delivery (Q3/4 2020/21). Further roll-out of Level 1, 2 and 3 services in 2021/22-2022/23 subject to funding. Develop an action plan (Q4 2019/20) and commence delivery (Q1 2020/21) of Foundation Phase Bach a lach in North Powys (project runs until Q4 2020/21) Review Healthy Weight Action Plan to ensure alignment with Healthy Weight: Healthy Wales and 2020-2022 HW:HW Delivery Plan (Q4 2019/20 and Q1 2020/21) Continue to promote physical activity for children and young people through the Healthy Schools and Healthy Pre-schools Scheme and through Bach a lach Review physical activity-related actions as part of review of Healthy Weight Action Plan ((Q4 2019/20 and Q1 2020/21) – see “Healthy Body Weight” above 	<ul style="list-style-type: none"> % adults who smoke (PHOF25) % adult smokers who make a quit attempt via smoking cessation services (cumulative data) (NOF) Adolescents who smoke (PHOF20) Children age 5 of healthy weight (PHOF32) Adolescents of healthy weight (PHOF33) Working age adults of healthy weight (PHOF38a) Physical activity in adolescents (PHOF_19) Adults meeting physical activity guidelines (PHOF24) Uptake of the influenza vaccination (NOF05) Uptake of Childhood Vaccinations (NOF02/03) Attainment of influenza vaccination targets (NOF) % of children who have had 3 doses of 6in1 vaccination by age 1 year (NOF2) % of children x 2 doses of MMR by age 5 years (NOF3) Vaccination rates at age 4 (PHOF30) % adults who smoke (PHOF25) Adults meeting physical activity guidelines (PHOF24) The gap in life expectancy at birth between the most and least deprived (PHOF04) and the gap in healthy life

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PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Health Improvement and Disease Prevention (Continued)			
1.2 Implement the health improvement and disease prevention programme (Continued)			
		<ul style="list-style-type: none"> Development (Q4 2019/20 and Q1 2020/21) and implementation (Q1 2021/22) of local measles and mumps elimination plan Evaluation of "MECC for Flu" programme introduced in 2019/20 (Q4 2020/21) Develop 2021/22 flu immunisation plans (Q2/Q3 2020/21) Implement 2021/22 flu immunisation plans (Q3/Q4 2020/21) Continue to promote level 1 and 2 Making Every Contact Count training and embed MECC approach in practice (Q1-Q4 2020/21 and 2021/22 onwards) Continue to promote Invest in Your Health (Q1-Q4 2020/21 and 2021/22 onwards) Substance Misuse Partnership strategy - refer to full plan for detailed delivery (hyperlink in IMTP Appendix) Implementation of Sexual Health Improvement Plan – refer to full plan for detailed delivery (hyperlink in IMTP Appendix) 	<ul style="list-style-type: none"> expectancy between the most and least deprived (PHOF05) Adolescents using alcohol (PHOF21) Teenage pregnancies (PHOF27)
Supporting Communities and Carers			
1.3 Deliver Community and Carers Support as per RPB Plan			
<ul style="list-style-type: none"> Delivery of Carers Support as per plan agreed with RPB partners 	Director of Nursing	<ul style="list-style-type: none"> Providing leadership to facilitate multi agency working through the Carers Steering Group Engagement in Carers Trust Wales national work 	<ul style="list-style-type: none"> Census data in relation to Carers in Powys – estimates of numbers of unpaid carer roles Measures of Carers Support uptake / participation in schemes and initiatives

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EARLY HELP AND SUPPORT

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Primary and Community Care			
2.1 Implement the transformation programme for primary and community care			
<ul style="list-style-type: none"> Scope and implement delivery of anticipated Transformation funding to support extended roles and models of care Implement support to manage an extended Managed Practice portfolio including temporary support to independent practices to support sustainability Support practices to achieve national access standards. Identify solutions, utilising digital support Review governance arrangements and wider strategic context of Enhanced Service delivery across Powys Support Clusters to achieve the QAIF targets, in particular the Quality Improvement (QI) element Review resources into mental health e.g. HCSWs Continue to work collaboratively with Community Resource Teams (CRT) to ensure safe and effective care in line with national work and policy refine OOH model through wider MDT working 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> Extended role Gap Analysis and workforce development/ transformation plan completed (Q1); Commence implementation of transformation plan Q2 – 4) Implement PTHB Access Forum (Q1) Quarterly review of GP access standards achievement (Q1- 4) QAIF, Quality Improvement Project Cluster Peer Review Q1 QAIF achievement (Q3) 	<ul style="list-style-type: none"> Primary Care measures Delivery milestones 2020-21 GP contract National Access standards – Group 1 & 2 GP Contract - QAIF achievement
<ul style="list-style-type: none"> Expand managed dental service at Builth Wells to improve patient access Maintain and expand the development of specialist dental services based within the community dental service. Identify areas of need across Powys that could be supported by the mobile dental unit. Scope and cost the implementation implications following the WHTM01-05 decontamination review Develop workforce plan to implement Gwen am Byth care home programme 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> Extended GDS access arrangements for mid Powys (Q1) Deployment of mobile dental unit in relevant location (Q1) Decontamination improvements required costed (Q1) Expansion of Specialist dental services scoped 	<ul style="list-style-type: none"> Dental Access rates/ UDA achievement Delivery milestones 2020-21 WHTM01-05 decontamination requirements Gwen am Byth Care home programme
<ul style="list-style-type: none"> Focus on patient safety, use of medicines, promoting prevention and self care, ensuring legal compliance Further develop the Non-Medical Prescriber workforce to improve safe access. Multi professional Medical Gases Group will ensure robust policy and standard operating procedures Continue improvement against the National Prescribing Indicators, focus on antimicrobial stewardship 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> At least 1 additional High Street Pharmacist Prescriber (Q4) Action plan with PCC for domiciliary care Medicines awareness support (Q1) Your medicines Your Health campaign (by Q2) Implement plan for integrated medicines support between community pharmacy and hospital pharmacies, in Powys, to align to Pharmacy: Delivering a Healthier Wales (by Q2) 	<ul style="list-style-type: none"> Delivery milestones 2020-21 GP Contract - QAIF achievement National prescribing indicator targets Care Home DES
<ul style="list-style-type: none"> Improved proactive care for those with complex needs Care Plans in place for individuals deemed high risk Extended roles deployed within and between Practices Take up of enhanced services contracts across Clusters Evaluate and extend Community Resource Teams 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> Top 3% at risk identified by Practice (Q1); Plans (Q2) Complex needs Specialist Advisors in Clusters (Q3) Evaluate Neighbourhood Nursing Pilot (Q2) Plan for extended Teams complete (Q3) 	<ul style="list-style-type: none"> % of people with learning disabilities who have an annual health check (NOF_08) Planned care access measures

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Primary and Community Care (Continued)			
2.1 Implement the transformation programme for primary and community care (continued)			
<ul style="list-style-type: none"> Support Community Pharmacy developments, including uptake of services and integration within clusters Enable Community pharmacies to deliver the Common Ailments Scheme to maximise access across Powys Develop medicines management support to care homes Implement digital technology, such as the Medicines Transcribing electronic Discharge system, Work with Social Services to improve the safety of medicines support for cared for patients Build on the 4 independent prescriber community pharmacists active in Powys. Develop further use of pharmacy skills such as the IP Pharmacist undertaking clinics for osteoporosis 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> 'Grow our own' pharmacy professionals (1 pharmacy technician (Q1), 2 Pharmacists (Q3)) Define Powys Medicines Safety Officer Role (Q1) Implement Medical Gas Policy provider units (Q1) Implement revised Medicines Policy and procedures (by Q2) Initiate Community Pharmacy IP service for respiratory care in Hay area.(byQ2) Report on Common Ailments service, and data capture for patients converted to self care. (Q1) Map the Care Homes Medicines management support, and produce an issues document (by Q2) Implement digital technology supporting access to medicines and to lifestyle advice (by Q2) 	<ul style="list-style-type: none"> As above
Cluster Working			
2.2 Deliver Cluster IMTPs (Integrated Medium Term Plans)			
Delivery of Cluster IMTPs (full documents in IMTP Appendix)	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> As per Cluster IMTPs (full documents in IMTP Appendix) <p>(NOTE - NEED TO REVIEW)</p>	<ul style="list-style-type: none"> GP Contract - QAIF achievement' National Access standards National prescribing indicators
Connecting Communities			
2.3 Delivery of Start Well, Live Well and Age Well Programmes			
<ul style="list-style-type: none"> Delivery of Nursing Directorate Actions including: <ul style="list-style-type: none"> Neighbourhood Nursing model Volunteering development Adverse Childhood Experiences (RPB Plan) Dementia Plan DOLS Plan 	Director of Nursing	<ul style="list-style-type: none"> Neighbourhood Nursing project is due to be complete April 2020 to be evaluated Q2 Volunteering Development – Framework to be developed with WOD Q2 Dementia Action Plan – reporting timeframes Q1 and Q3 DoLS Plan – 1 outstanding action to be completed Q1 	<ul style="list-style-type: none"> A sense of community (PHOF_14) People reporting that they feel a part of their community (SSWB_08) % registrations of children on Child Protection Registers (SSWB_27) Specific Project Plan based measures 10 day Primary Birth Visit (NOFF Framework)
<ul style="list-style-type: none"> Delivery of Women and Children's Actions including: <ul style="list-style-type: none"> Maternity Vision Healthy child Wales and First 1000 Days Bach A lach Infant Feeding Action Plan 	Director of Primary, Community & Mental Health (?ND)	<ul style="list-style-type: none"> As per the Maternity & Neonatal Network Plan (annual programme) All Wales Infant Feeding Strategic Action Plan (annual programme) Continue with the delivery of the HCWP (annual programme) Delivery of the Community Paediatric remodelling Project (annual programme) 	
Connecting Communities			
2.3 Delivery of Start Well, Live Well and Age Well Programmes			
<ul style="list-style-type: none"> Implementation of ACC Pathway (paediatric therapy) Community paediatrics 	Director of Nursing (see above – need to sort acct)	<ul style="list-style-type: none"> Development of the local ACC Pathway in line with the Welsh Health Circular (annual programme) 	

THE BIG FOUR

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Mental Health			
3.1 Deliver Mental Health Services Programme			
Organic Mental Health and Older Adult Mental Health: <ul style="list-style-type: none"> Evaluate the newly introduced Dementia Home treatment Team model in South Powys (refer to Early Help and Support Section for detail) Develop and implement options for improvement of physical health care to Mental Health inpatients living with organic conditions. 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> Q4 Evaluation of first 18 Months of full operation of the South Powys DHTT. Q1: work with Medical Director and GPs to develop model for Physical health input into Inpatient settings. Q1-4 Deliver the T4MH strategy and achieve the milestones set out in the strategy. (re-prioritise key COVID supporting actions) Q1-2 Complete recruitment of staff to the ED service. Q1-3 Develop options for a Crisis House/Sanctuary provision in North Powys. Q1-4 Complete recruitment of staff and develop the rural model of EIP for Powys. Q1-2 Complete engagement with stakeholders on change of s136 pathway to Felindre Ward (Pan Powys). Q1-2 complete introduction of new Personality disorder pathway and design of SPA. Q1-4 Implementation of the Powys Maternal and Infant MH Plan, and achievement of milestones. (re-prioritise key COVID supporting actions) 	<ul style="list-style-type: none"> Mental well-being among adults (PHOF_03b) Mental health access measures (NOF_11/30/46/72/73) Treatment Plans in place (NOF_83) Timely receipt of outcome assessment reports (NOF_84) Mental well-being among adults (PHOF_03b) Mental health access measures (NOF_11/30/46/72/73)
Adult and Functional Mental Health: <ul style="list-style-type: none"> Continue to deliver the Together for Mental Health Strategy. Continue to implement the improvement trajectory to secure compliance with all parts of the Mental Health Measure Implement the agreed developments to the Eating Disorder Service- including recruitment & training of specialist staff. In partnership with the third Sector, explore the development of a Crisis House/Sanctuary Provision for North Powys. Implement the new service model for Early Intervention in Psychosis. Complete consultation with stakeholders on centralisation of the s136 suite to Felindre Ward for all Powys patients. Extend the South Powys Crisis and Home Treatment Team operational geographical area to include Ystradgynlais. Develop and implement options for improvement of physical health care to Adult Functional inpatients. Complete the implementation of the Personality Disorder/ Complex Trauma pathway in North Powys. Design and implement the Single Point of Access for Psychology 	Director of Primary, Community & Mental Health		
Perinatal Mental Health: <ul style="list-style-type: none"> Implement the Powys Maternal and Infant Mental Health plan, as part of the Start Well Programme to include recommendations for the First 1000 Days work stream. 	Director of Primary, Community & Mental Health		
CAMHS <ul style="list-style-type: none"> Deliver the CAMHS improvement plan (arising from the CAMHS review). Implement the Early intervention in Psychosis (all age model). Implement the development of an age appropriate bed for 16-17 years olds at Felindre Ward. Deliver the national Together for Children and Young People programme. 	Director of Primary, Community & Mental Health	<ul style="list-style-type: none"> Q1-4 Deliver the CAMHS improvement plan and achieve agreed milestones. (re-prioritise key COVID supporting actions) Q1 develop options for the development of an age appropriate bed at Felindre for 16-17 year olds and gain capital funding. 	<ul style="list-style-type: none"> Mental well-being among children and young people (PHOF_37b)

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Cancer			
3.2 Implement the Powys Cancer Transformation Programme			
<ul style="list-style-type: none"> Implementation of Cancer Transformation Programme: Analysis of population need, evidence and opportunities; Programme Plan Implementation of the Improving Cancer Journey (ICJ) including governance framework, pathway development and engagement, focusing on the experience of the cancer pathway and treatment Full implementation of the Single Cancer Pathway building on successful tracking development in 2019/20 and rapid diagnosis via JAG accredited theatre in Brecon for endoscopy procedures; further strengthening of early diagnosis with SCP bid for Joint consultants; ensuring appropriate access to MRI and CT scanning with timely receipt of reports and onward referral including pathways for urgent assessment working with acute providers Ensure appropriate access to MRI & CT scanning with timely receipt of reports to ensure timely onward referral Training and development including Macmillan Framework to support clinical leadership development; GP Practice cancer champions; GP oncology and palliative care education programme Upscale information provision, accessibility and awareness including work with third sector partners, neighbourhood schemes and community connectors and workplace communication mechanisms Commissioning Assurance Framework in place to robustly manage performance of directly provided and commissioned services and use of commissioning intelligence to inform Cancer Transformation Programme See End of Life Plan in Appendix for palliative care programme My life , My Wishes launched, Adopt and Spread supported by Bevan Commission Cross reference to Focus on Well-being section for health improvement programmes and campaigns including smoking cessation, substance and alcohol misuse, healthy weights, physical activity and immunisation, promotion of healthy lifestyles; targeted screening campaigns Refer to the End of Life Delivery Plan in the Appendix for palliative care 	Medical Director	<p>Q1 20/21</p> <ul style="list-style-type: none"> Transformation Programme Plan agreed ICJ Launch & Programme Plan sign off Good Practice / Evidence Review Monitor robust management of SCP, adoption of optimal pathways Monitor theatre nurse scheme <p>Q2 20/21</p> <ul style="list-style-type: none"> Needs assessment & review of existing services and pathways Engagement on pathway experience Robust management of SCP, adoption of optimal pathways Monitor SCP theatre nurse scheme <p>Q3 20/21</p> <ul style="list-style-type: none"> ICJ engagement phase management of SCP, adoption of optimal pathways where appropriate Monitor SCP scheme for theatre nurses funded by WG Further milestones to be defined in Q1 and Q2 following plan sign off <p>Q4 20/21</p> <ul style="list-style-type: none"> Final Powys Model of Care for cancer; feasibility of options – further milestones to be determined Robust management of SCP measure in PTHB, adoption of optimal pathways where appropriate Monitor SCP scheme for theatre nurses funded by WG <p>2021/22 – 2022/2023</p> <ul style="list-style-type: none"> Implement further phases of Cancer Transformation Plan (detailed work to be conducted in Phase 1 to identify longer term programme actions and milestones) 	<ul style="list-style-type: none"> Cancer access targets Hospital activity data Population needs Screening uptake Training activity Measures relating to health inequalities (Powys Well-being Assessment)

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Respiratory			
3.3 Deliver the Breathe Well Programme			
<ul style="list-style-type: none"> Implement phase 2 of the Breathe Well Programme: <ul style="list-style-type: none"> Complete the programme impact assessment Complete the risk mitigation of the proposals Respiratory model for Powys will be completed by March 2020 and the Phase 2 plan finalised for implementation in 2020-23 Service specification developed and approved, with preferred option(s) identified and agreed Develop workforce model with the model of care and service specification <ul style="list-style-type: none"> Implications for LTAs and SLAs identified Deliver and evaluate Respiratory Response Team pilot project with WAST Work with RHIG (Respiratory Health Implementation Group) to strengthen asthma plans for children & young people; physiology and sleep services. 	Medical Director	<p>Q1 20/21</p> <ul style="list-style-type: none"> Implement Phase 2 Service specification approved WAST pilot project implemented Workforce model <p>Q2 20/21</p> <ul style="list-style-type: none"> Phase 2 Centenary Workforce model including joint appointments Transition of LTAs & SLAs WAST pilot evaluated Winter plan <p>Q3 20/21</p> <ul style="list-style-type: none"> Phase 2 Children & young people's asthma plans strengthened Winter plan implementation Review workshop Patient Forums Phase 3 development & embed in next IMTP <p>Q4 20/21</p> <ul style="list-style-type: none"> Phase 2 completion Children & young people's asthma plans strengthened Winter plan implementation Strengthened intelligence and performance reporting <p>2021/22 – 2022/23</p> <ul style="list-style-type: none"> Implementation of Phase 3 of Breathe Well Programme (detailed programme actions and milestones to be determined by work carried out in Phase 2) 	<ul style="list-style-type: none"> Hospital / primary care / clinic activity Referrals for pulmonary rehab Smoking cessation COPD related measures Oxygen variation
Circulatory			
3.4 Implement the Powys Circulatory Conditions Programme			
<ul style="list-style-type: none"> Fully scope and finalise plan for Circulatory Clinical Change Programme, to include value based analysis of opportunities and evidence and establishment of Programme mechanisms Implement Phase 1 of the Circulatory Programme Detailed actions to be agreed as part of Phase 1; to include model of care and development of specification(s)/ workforce models Programme encompasses the Powys implementation of the National Delivery Plans for Stroke, Diabetes and Heart/ Cardiac and the development of the relevant action plans as detailed in the IMTP 	Director of Public Health	<p>2020/21 Q1</p> <ul style="list-style-type: none"> Finalise scope for Phase 1 Establish Programme mechanisms Agree and commence Comms / Engagement <p>2020/21 Q2</p> <ul style="list-style-type: none"> Baseline and needs assessment Engagement with users, stakeholders, professionals <p>Further milestones to be defined in Q1 and Q2 following analysis</p>	<ul style="list-style-type: none"> Population health outcomes Powys Outcomes Patient experience / Patient Reported Outcomes Quality measures Service activity and performance

JOINED UP CARE

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
NORTH POWYS WELL_BEING PROGRAMME			
4.1 Deliver the North Powys Well-being Programme (Phase 2) and the Powys Model of Care			
Implementation of North Powys Programme Plan agreed at Regional Partnership Board and delivery against Welsh Government Transformation Fund commitments – refer to IMTP Appendix for hyperlink to further detail.	Director of Planning and Performance	As per North Powys Well-being Programme Plan	<ul style="list-style-type: none"> As per North Powys Well-being Programme Plan
CARE CO-ORDINATION AND URGENT CARE			
4.2 Deliver the Powys Unscheduled Care Programme			
4.3 Deliver the Out of Hours model			
Delivery of Unscheduled Care Programme - as set out in detail on page 54 of this section	Director of Primary, Community & Mental Health	As per Unscheduled Care Programme (Review in relation to COVID Response Plan Phase 2)	<ul style="list-style-type: none"> Delayed Transfers of Care (DTCO) Reablement measures Emergency admissions 111 service measures Ambulance service measures
PLANNED CARE			
4.4 Deliver the Planned Care Programme			
Delivery of Planned Care Programme – as set out in detail on page 56-577 of this section	Director of Primary, Community & Mental Health	As per Planned Care Programme (Review in relation to COVID Response Plan Phase 2)	<ul style="list-style-type: none"> Nos waiting more than 8 weeks for a specified diagnostic (NOF_59) Referral to Treatment Life satisfaction among older people (PHOF_37b) Nos. with anticipatory care plans
SPECIALISED CARE			
4.5 Deliver the WHSSC Integrated Commissioning Plan (PTHB contribution)			
<ul style="list-style-type: none"> Implement WHSSC Integrated Commissioning Plan with annual planning and review of PTHB activity Tracking and responding to NHS England programmes for specialised care and assessing impact for Powys patients 	Director of Planning and Performance	As per WHSSC ICP (Review in relation to COVID Response Plan Phase 2)	<ul style="list-style-type: none"> LTAs signed Other measures as per WHSSC ICP
QUALITY AND CITIZEN EXPERIENCE			
4.6 Deliver the Annual Quality Work Programme			
Implementation of Quality Work Programme, shaped around the Clinical Quality Framework – as set out on pages 60 - 61 of this section – also refer to IMTP Appendix for hyperlink to full Clinical Quality Framework	Director of Nursing	As per Clinical Quality Framework Work Programme Q1-Q4	<ul style="list-style-type: none"> Refer to Clinical Quality Framework

WORKFORCE FUTURES

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Deliver the Workforce Futures Framework			
5.1 Implement the Powys Workforce Futures Strategic Framework (theme 1)			
Designing, Planning and Attracting the Workforce	Director of Workforce and Organisational Development	<p>Q1 - Implementation of Phase 2 of the Organisational Change Process</p> <p>Q1 - Begin roll out of the e-community rostering system.</p> <p>Q1 - Commence implementation of the Workforce Futures Strategic Framework.</p> <p>Q2 - Implement Standard Operating Procedures for internal operational workforce planning.</p> <p>Q3 - Implement an approach to succession planning.</p> <p>Q3 - Develop a brand and approach for resourcing including a website.</p> <p>Yr 2 - 2021-22 - Implementation of new roles; widening access to employment opportunities to those leaving care and those with advanced learning needs</p> <p>Yr3 - 2022-23 - To be developed in line with the National Workforce Futures Programme</p>	<ul style="list-style-type: none"> • % of reduction in the overall vacancy level, • Recruitment timeframes are consistent with national targets • % of OCP completed within agreed timescales, • % of timely responses within the Action Point, • E-Rostering Insight tool reflects rostering compliance with PTHB policies.
5.2 Implement the Powys Workforce Futures Strategic Framework (theme 2)			
Leading the Workforce	Director of Workforce and Organisational Development	<p>Q3 - Implement a cultural development programme based upon the Compassionate Leadership Model.</p> <p>Q4 - Evaluate PTHB Manager's Programme.</p> <p>Q2 - Roll out Assistant Director/Senior Manager Leadership Development.</p> <p>Yr2 - 2021-22 - To be developed in line with the National Workforce Futures Programme</p> <p>Yr3 - 2022-23 - To be developed in line with the National Workforce Futures Programme</p>	<ul style="list-style-type: none"> • % of Managers completing the management development programme • Improved staff survey scores for management section
5.3 Implement the Powys Workforce Futures Strategic Framework (theme 3)			
Engagement and Well-being	Director of Workforce and Organisational Development	<p>Q1 - Implement a targeted internal staff survey</p> <p>Q2 - Submit application for funding of 2 Workforce Health Intervention Co-coordinators focused on Healthy weights and stress management</p> <p>Q2 - Stress Management Toolkit and Policy Review</p> <p>Q3 - Implement an engagement framework through Chat2Change.</p> <p>Q4 - Strengthen assurance and compliance for Health and Safety</p> <p>Q4 - Chat2Change in house PULSE survey on stress and well-being</p> <p>Yr2 and 3 - 2021-22 - To be developed in line with the National Workforce Futures Programme</p>	<ul style="list-style-type: none"> • Improved staff Survey scores, • Workforce Performance measures (NOF 91-95).

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PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
5.4 Implement the Powys Workforce Futures Strategic Framework (theme 4)			
Education and Training	Director of Workforce and Organisational Development	<p>Q2 - Partner with Aberystwyth University to design a new nursing degree, which will meet needs of the rural health board.</p> <p>Q4 - Evaluate the success of the first phase of the Apprentice Academy.</p> <p>Q4 - Implement a talent management approach for HCSW to access Nursing/Therapies.</p> <p>Q4 - Design an Access route to Healthcare Student Academy.</p> <p>Q2 - Develop a training framework that meets all statutory and mandatory training needs.</p> <p>Q2 - Launch the approach to clinical simulated training.</p> <p>Yr2 – 2021-22 - To be developed in line with the National Workforce Futures Programme</p> <p>Yr 3 – 2022-23 - Laying the foundations for a Health and Care faculty in Powys, that offers a wide range of practical, academic and digital learning opportunities for employed staff, volunteers and carers</p>	<ul style="list-style-type: none"> % of training DNA rates % of Statutory and Mandatory Training compliance
5.5 Implement the Powys Workforce Futures Strategic Framework (theme 5)			
Partnership and Citizenship	Director of Workforce and Organisational Development	<p>Q1 - Develop the approach to volunteering and work experience.</p> <p>Q1 - Develop the business case to deliver the Rural Academy of Learning.</p> <p>Q1 – Implement an agreed joint approach to work experience for secondary aged children in conjunction with Powys County Council.</p> <p>Yr 2 - 2021-22 - A shared recruitment platform which automatically matches skill mix opportunities for all employees across health & social care.</p> <p>Yr 3 – 2022-23 - Have a workforce which will include more carers and volunteers working in partnership with paid staff, who all feel valued and engaged in their work.</p>	<ul style="list-style-type: none"> Uptake on the work experience programme Approval of rural academy of learning

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INNOVATIVE ENVIRONMENTS

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Research, Development and Innovation			
6.1 Implement Innovation and Improvement Framework			
<ul style="list-style-type: none">Fully establish the Innovation Research & Improvement Hub & implement 20/21 programme.	Medical Director	<ul style="list-style-type: none">Implementation Q1	<ul style="list-style-type: none">To be worked up in detail in Q1
Capital Programme and Estates			
6.2 Deliver the Capital and Estates Programme			
<ul style="list-style-type: none">Deliver agreed Long Term Estates Strategy	Director of Planning and Performance	<ul style="list-style-type: none">As per agreed Estates Strategy (to be produced and agreed at PTHB Board March 2020)	<ul style="list-style-type: none">Condition of Estate SurveyEFPMS dataProject specific measures
<ul style="list-style-type: none">Implement Priority Projects: Llandrindod Wells Community Hospital; Machynlleth Community Hospital; Ystradgynlais Community Hospital; Llanfair Caereinion Medical Practice (third party revenue scheme); North Powys Regional Rural Centre.	Director of Planning and Performance	<ul style="list-style-type: none">As per agreed Project Plans	
<ul style="list-style-type: none">Implement IMTP and Discretionary Capital Programme including management of business cases as appropriate.	Director of Planning and Performance	<ul style="list-style-type: none">As per agreed programme and project plans (Review in relation to COVID Response Plan Phase 2)	
<ul style="list-style-type: none">Improve environmental sustainability; implementation of ISO14001	Director of Planning and Performance		
<ul style="list-style-type: none">Maintenance and compliance in line with standards and in accordance with an agreed risk based approach.	Director of Planning and Performance		
Facilities			
6.3 Deliver Facilities modernisation programme			
<ul style="list-style-type: none">Deliver Facilities modernisation improvements including review of waste and recycling; pool car, lease car and taxi policies and catering.	Director of Workforce and Organisational Development	<ul style="list-style-type: none">As per agreed work programme	<ul style="list-style-type: none">To be worked up in detail in Q1

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DIGITAL FIRST

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Digital Care			
7.1 Develop and implement a Digital Strategic Framework			
Support self-management of citizens who have long term conditions to remain active.	Director of Finance	Delivery of agreed Telehealth and Telecare work programme – this work is detailed in multiple Directorate plans and leads and timescales will be confirmed in the Directorate Planning February – March 2020	Access/ availability / Utilisation and take up
Digital Access			
7.2 Implement the systems to improve digital access			
Fully implement the WCCIS system across Powys to support care coordination. Lead: Powys ICT	Director of Finance	Services/ processes live on WCCIS according to phasing detail to be agreed / Project Plan	WCCIS utilisation and access
Fully implement the WCP system across Powys to provide the national Electronic Patient Record.	Director of Finance	Implement MTED- MTED rollout completed	The completion of these milestones will result in increased electronic access to Patient information via WCP and less reliance on paper Case Notes. WCP utilisation figures
		Q2 - Implement WGPR- To provide Cross Border Access to WGPR for RHAJ, SaTH, WVT	
		Implement WRRS To have implementation completed (including Cross Border Test Results feeding in to the WRRS)	
		Q3 - Implement WCRS- To have "Nursing eDocs" and "WPAS Clinic Letters" projects complete.	
		Q3 - Implement WPRS- To implement Welsh Admin Portal (all Providers) and Electronic Grading of Referrals (Welsh Providers only). Implement WIAS- National Image Archive will be available in Powys providing easy access to PACS images	
The Cross Border WCP Project	Director of Finance	Q2 - To provide cross border access to WCP for staff at RJA, SaTH and WVT	WCP utilisation figures
The Cross Border WCCG Project	Director of Finance	Further progress is dependent upon the success of the Cross Border Business Case	The number of Discharge Summaries and Clinic Letters sent electronically
		Plan and milestones tbc	
Eye Digitisation Programme	Director of Finance	Yr 3 2022-23 - PTHB working with National Programme Lead & BCUB as Regional partner to develop implementation programme. There has been an implementation delay nationally 6 months+ links to national eye care measure	
Activity- Primary Care: - Implement electronic referral, discharge and diagnostic information across Powys GP practices.	Director of Finance	Project 1 WCCG: • All Powys Practices using WCCG for sending referrals – complete.	Project 1: WCCG Utilisation Figures Project 2: GPTR Utilisation Figures

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Digital Access			
7.2 Implement the systems to improve digital access			
<p>Project 1 WCCG: Encourage GP Practices to use WCCG for clinical communications between Primary and Secondary Care, i.e. referrals, discharge summaries, clinic letters.</p> <p>Project 2 GPTR: Where feasible, implement the national GPTR in Powys (GP Test Requesting and Reporting)</p>		<ul style="list-style-type: none"> All Powys Practices using WCCG for receiving Clinic Letters and Discharge Summaries – complete 2020/21 milestones: Reduce the number of referrals sent on paper to as close to zero as feasible. Increase the number of Discharge Summaries and Clinic letters received electronically to as close to 100% as feasible. <p>Project 2 GPTR: Further progress with GPTR is dependent upon the success of the Cross Border business case to fund NWIS technical resource. Plan/Milestones tbc</p>	
Digital Infrastructure and Intelligence			
7.3 Improve ICT infrastructure and business intelligence			
Improve business intelligence capability to include demand and capacity, Power BI, commissioning reporting with WHSSC and the use of the CHKS intelligence	Director of Finance	Q4 and ongoing into 21/22/23 (dependant on O365 with Power BI) - To be detailed within Directorate work plan –opportunity / resources to be defined in Q1	Project measures to be confirmed post Q1
<p>Improve ICT infrastructure through improving information storage, server hosting, security and disaster recovery, back up and archiving capabilities.</p> <p>Data centre – A programme of work to review the risk associated with our current data centres and assess each risk and the options of mitigation.</p>	Director of Finance	<p>Q2 - Produce a Concept and Business case for each risk to understand viable options.</p> <p>Q3 - On approval Commence design phase - Scoping and specification of requirements.</p> <p>Q4 - Tender, evaluation and Award</p> <p>Implementation</p>	<p>Business Case Approval</p> <p>Specification sign off</p> <p>Tender Award</p> <p>Implementation</p>
<p>Increase flexibility for accessing information and systems (anytime/anywhere/any device) including improved connectivity e.g. mobile coverage, broadband, Wi-Fi and modem, agile ready with integration by design.</p> <p>PTHB Voice – Provide a suitable and modern telephony platform with integrated unified communication tools.</p>	Director of Finance	<p>Q1 - Produce Business Case to confirm scope and understand potential options</p> <p>Q2 - Approval of Business Case</p> <p>Q3 - Agree Project Plan</p> <p>Q4 - Develop specification of requirements</p> <p>Tender, evaluation, contract awarded</p> <p>Implementation</p>	<p>Concept Approval</p> <p>Business Case and Plan approval</p> <p>Contract Award</p> <p>New telephony system adopted by users.</p> <p>Reduced telephony bills.</p>
Microsoft 365 (O365) – Roll out key features of the O365 Suite and provide access to an array of digital tools to enable improved ways of working	Director of Finance	<p>Q1 - Agree Programme at National Level</p> <p>Q1 - Agree Programme at Local Level</p> <p>Q2 - Identify Projects and Prioritise into a High-Level Plan</p> <p>Q4 - Create concept and Business case for each Project</p> <p>Yr 2 2021-22 - Implementation of each Project</p>	<p>National Programme Approved</p> <p>Local Programme Approved</p> <p>High-level Plan Created</p> <p>Business Cases Approved</p> <p>O365 Applications being utilised by PTHB Staff</p>
Windows 10 – Modernisation of fundamental ICT Infrastructure to provide a platform for Digital modernisation and transformation	Director of Finance	<p>Q1 - Approve Project Plan</p> <p>Q2 - Implementation</p>	<p>Approve Plan</p> <p>Complete estate of Windows 10 devices</p>

TRANSFORMING IN PARTNERSHIP

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Good Governance			
8.1 Deliver Annual Governance programme			
<p>Develop and deliver an Annual Governance Programme:</p> <ul style="list-style-type: none"> Finalise and embed a Partnership Governance Framework Implement a Decision Rights Framework, aligned to the Board's Scheme of Delegation and Reservation of Powers Implement an Information Governance Improvement Plan Embed an improved Framework for the development and approval of Policies and Written Control Documents Implement a Legislative Compliance Framework Deliver programme of development for an effective unitary board Conduct Welsh Language self-assessment and implement plan 	Board Secretary	<ul style="list-style-type: none"> Delivery of Annual Governance Framework (see IMTP appendix for hyperlink to full plan with detail of milestones and timescales) 	<ul style="list-style-type: none"> Audit compliance GDPR compliance Findings of welsh language audit & needs assessment to determine further measures / baseline
Financial Management			
8.2 Deliver the Financial Strategy in line with Efficiency Framework			
<ul style="list-style-type: none"> Approval of a balanced IMTP/ financial balance 20/21 – 22/23 Delivery of Financial strategy to include reprioritisation; delivery of savings and cost improvements; management of financial risk Securing investment to accelerate/ upscale transformation 	Director of Finance	<ul style="list-style-type: none"> Approval of IMTP Q1 Detailed financial monitoring and reporting (Q1-4) including JET 	<ul style="list-style-type: none"> Approval of IMTP Financial balance / financial reports
Partnership, Planning, Performance and Commissioning			
8.3 Deliver key partnership plans			
<ul style="list-style-type: none"> Delivery of key Partnership Plans including RPB Area Plan and Health and Care Strategy; MWJC Strategic Intent Management of strategic change including <ul style="list-style-type: none"> NHS Future fit (Shrewsbury and Telford Hospitals) Clinical Futures (Aneurin Bevan UHB) 	Director of Planning and Performance	<ul style="list-style-type: none"> Strategic Planning and Commissioning cycle including Executive Committee Group and Strategic Change Steering Group (Q1-4) Strategic Planning Stocktake produced quarterly Communications/ Engagement Report produced quarterly Communications and Engagement Plans for live programmes Individual Programme / Project Plans for key live programmes will set out detail for each (Eg. NHS Future Fit/ ABUHB Clinical Futures) 	<ul style="list-style-type: none"> Quarterly Stocktake produced Detailed Comms Plans Delivery of CHC Actions

PRIORITY	EXECUTIVE LEAD	KEY MILESTONES	MEASURES
Partnership, Planning, Performance and Commissioning (Continued)			
8.4 Deliver continuous planning, performance and commissioning			
<ul style="list-style-type: none"> • Deliver continuous cycle of planning, performance and Commissioning • Review and strengthen whole system continuous engagement Approval of Trajectories & Integrated Performance Framework • Strengthened approach to Planning & Commissioning aligned to delivery of Health & Care Strategy including; big four; commissioning intelligence; Cross Border Network; Section 33; Third Sector, referral alternatives and cross directorate planning support 	Director of Planning and Performance	<ul style="list-style-type: none"> • IMTP Production and Approval Q1 • IPR Produced quarterly; JET • Q1 – Q4 Commissioning Assurance Framework and CQPRMs • Agreement of commissioning intentions and sign off LTAs • Quarterly CAF; Service Fragility Log 	<ul style="list-style-type: none"> • Approval of IMTP • Delivery of key products • IPR reports • Signed LTAs

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PRIMARY CARE CLUSTERS

<p>North Cluster</p> <p>North Powys Primary Care Cluster is comprised of 7 GP Practices with population of 64,000 people.</p>	<p>Mid Cluster</p> <p>The Mid Powys Cluster comprised of 5 GP Practices with a population of 29,500 people.</p>	<p>South Cluster</p> <p>The South Cluster is comprised of 4 GP practices with a population of 45,580 people.</p>
<p>Priorities 2020-23</p> <ul style="list-style-type: none"> • Further integration of community connectors attached to each practice • Implement local sexual health services / pathway • Increase use of Florence to support self-management of chronic conditions • Clinically led practice triage rollout across practices • Partnership with Wrexham University of Glyndwr to promote nursing placements • Identify factors that make recruiting GPs into some areas of Powys challenging and develop strategies to increase recruitment • Develop telehealth and telecare in partnership with PTHB, the RPB and the Digital First Programme 	<p>Priorities 2020-23</p> <ul style="list-style-type: none"> • Further integration of community connectors attached to each practice • Development of Cluster Health Champion role • Redesign Respiratory pathways and services, in partnership with PTHB and the Breathe Well Programme • Increase use of Florence to support self-management of chronic conditions • Review mental health pathway for young people • Develop Cluster approach to remote GP support • Develop cluster pharmacy team and Cluster Practice Nurse role • Develop telehealth and telecare in partnership with PTHB, the RPB and the Digital First Programme 	<p>Priorities 2020-23</p> <ul style="list-style-type: none"> • Development of GPs with Extended Roles (GPwERs) in Cardiology, Dermatology • Primary care pain management to focus on medication reduction and early intervention • Development of service for Intrauterine contraception (IUCD) to respond to fragility of in reach service • In-house Physiotherapy plus further integration with triage services • Roll out of Primary Care Transformation through Telephone first, Physiotherapy, OT, Pharmacist, Community and third sector services • Integration of services, pathways and patient education to increase service knowledge and access

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BOARD MEETING		Date of Meeting: 27 May 2020
Subject :	COVID-19: Maintaining Good Governance Arrangements	
Approved and Presented by:	Rani Mallison, Board Secretary	
Prepared by:	Rani Mallison, Board Secretary	
Other Committees and meetings considered at:	Executive Quality Governance Group, 21 May 2020.	

PURPOSE:

This paper provides the Board with proposed arrangements for maintaining good governance, ensuring the appropriate level of Board oversight and scrutiny to discharge its responsibilities effectively, whilst recognising the impact of COVID-19 on the organisation and its ability to respond to the business as usual governance approach.

RECOMMENDATION(S):

The Board is asked to APPROVE the proposed arrangements to maintain good governance during the COVID-19 pandemic, as outlined in this paper.

Approval/Ratification/Decision	Discussion	Information
✓	x	x

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

SITUATION:

COVID-19 was declared a pandemic by the World Health Organisation on 11 March 2020, and this has subsequently led to NHS organisations, including Powys Teaching Health Board, needing to focus on preparations and plans for dealing with an expected surge in demand of patients requiring interventions. The nature and scale of the response will depend on the course of the disease. The situation is changing constantly and will require an agile response.

During this time, the Board's fundamental role and purpose does not change. The Board must require and receive ongoing assurance, not only on service preparedness and response but also on clinical leadership, engagement and ownership of developing plans on: the health and wellbeing of staff; on proactive, meaningful and effective communication with staff at all levels; and on health and care system preparedness.

As a result of the pressure placed on NHS bodies in managing the impact of the pandemic it has been necessary to adapt governance arrangements. The Welsh Government has agreed with the All-Wales Board Secretaries Group a set of Governance Principles which are designed to help focus consideration of governance matters over the coming weeks and months. These are:

- **Public interest and patient safety** – We will always act in the best interests of the population of Wales and will ensure every decision we take sits in this context, taking in to account the national public health emergency that (COVID-19) presents.
- **Staff wellbeing and deployment** – we will protect and support our

staff in the best ways we can. We will deploy our knowledge and assets where there are identified greatest needs.

- **Good governance and risk management** – we will maintain the principles of good governance and risk management ensuring decisions and actions are taken in the best interest of the public, our staff and stakeholders ensuring risk and impact is appropriately considered.
- **Delegation and Escalation** – any changes to our delegation and escalation frameworks will be made using these principles, will be documented for future record and will be continually reviewed as the situation unfolds. Boards and other governing for a will retain appropriate oversight, acknowledging different arrangements may need to be in place for designated officers, deputies and decisions.
- **Departures** – where it is necessary to depart from existing standards, policies or practices to make rapid but effective decisions – these decisions will be documented appropriately. Departures are likely, but not exclusively, to occur in areas such as standing orders (for example in how the Board operates), Board and executive scheme of delegation, consultations, recruitment, training and procurement, audit and revalidation.
- **One Wales** – we will act in the best interest of all of Wales ensuring where possible resources and partnerships are maximised and consistency is achieved where it is appropriate to do so. We will support our own organisation and the wider NHS to recover as quickly as possible from the national public health emergency that COVID-19 presents returning to business as usual as early as is safe to do so.
- **Communication and transparency** – we will communicate openly and transparently always with the public interest in mind accepting our normal arrangements may need to be adapted, for example Board and Board Committee meetings being held in public.

BACKGROUND:

In light of the COVID-19 pandemic and associated guidance and restrictions, at its meeting on 25th March 2020, the Board took a decision to run future meetings of the Board and its committees via electronic/telephony means as opposed to in a physical location. This would mean that for a period of time members of the public would not be able to attend meetings in person, or observe on-line. The Board took this decision in the best interests of protecting the public, our staff and board members. The Board committed to publish a summary of board and committee meetings held on the health board's website within a week of the meeting to promote openness and transparency.

In addition, a decision was taken in consultation with the Chair and Chief Executive to revise planned meetings as follows:

- **Board Development and Briefing Sessions** – development sessions would be stood down with briefing sessions stood up every two weeks

to enable briefings on the health board's response to COVID-19;

- The **Experience, Quality and Safety Committee** would continue to meet as planned with a focus on essential matters only, which would include COVID-19;
- The **Audit, Risk & Assurance Committee** would continue to meet as planned, with a particular focus on reviewing annual accounts, public disclosure statements and assurance for the audit opinion;
- The **Remuneration & Terms of Service Committee** would continue to meet as planned;
- The **Local Partnership Forum** meeting scheduled to be held in May would be cancelled, with briefing sessions stood up every two weeks to enable briefings on the health board's response to COVID-19;
- The **Performance and Resources Committee** meeting scheduled for 29th April would be cancelled with finance and performance reporting being routed through to the full Board (the usual Finance Monthly Report will be issued and Integrated Performance Report) along with any other critical areas and material issues;
- The **Strategy and Planning Committee** meeting scheduled to take place on 23 April would be cancelled;
- The **Charitable Funds Committee** meeting scheduled to take place on 2 June would be cancelled with Charitable Funds bids being considered by the Committee virtually;
- The **Executive Committee** would stand down meetings, as the Strategic (Gold) Group established through the Command and Control Structure would meet at least three times a week.

It was agreed that these arrangements would remain under review by the Chair, Chief Executive and Board Secretary.

ASSESSMENT:

At its meeting on 27th May 2020, the Board will consider its Phase 2 Response Plan and a re-prioritised Annual Plan as the organisation moves into the next stage of responding to COVID-19. Having considered the governance arrangements put in place at the start of the pandemic, it is proposed that the Board further adapts its governance arrangements to reflect the organisation's Phase 2 Response Plan and re-prioritised Annual Plan, which cover both COVID-19 and the business as usual identified as essential. It is therefore proposed that:

Decision Making

In principle, the current Board scheme of delegation and specifically the matters the Board reserves for its own decision (Schedule 1 of the Standing Orders) will remain. In the event of a critical or urgent decision(s) needing to be made, use of Chair's Action will be made and subsequently recorded and ratified in the public domain, in-line with the requirements set out in Standing Orders. For the ongoing function of the organisation, current arrangements will remain in place for the Chief Executive, as Accountable Officer, to have delegated authority from the Board to make decisions with

regard to the management of the Health Board, and Executive Directors to have certain responsibilities and decision making powers delegated through the Board's Scheme of Reservation and Delegation of Powers.

In respect of COVID-19, the Chief Executive will continue to deploy decision making through the Strategic (Gold) Group established via a Command and Control Structure within Business Continuity Planning arrangements.

Board Meetings

In accordance with Standing Orders, it is proposed that the Board continues to meet formally every two months, as per its usual schedule. These formal meetings will have a shortened, concise agenda focussing on essential matters and will be held virtually to ensure compliance with social distancing guidance.

Board Briefing Sessions will be held as a minimum monthly and otherwise as deemed necessary by the Chair and Chief Executive. Board Development will be taken forward in-line with a re-prioritised Board Development Plan, focussing on those aspects which can be achieved through the monthly board briefing sessions and individually, recognising that some aspects will need to be taken forward collectively once social distancing measures are lifted.

The Board will continue to conduct as much of its formal business in public as possible. To this end, it is hoped to be able to commence live streaming of the Public Board meeting from July 2020. However, there may be circumstances where it would not be in the public interest to discuss a matter in public, e.g., business that relates to a confidential matter. The Board would therefore operate in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act. In these circumstances, when the Board is not meeting in public session it shall operate in private session, formally reporting any decisions taken to the next meeting of the Board in Public session. These decisions will be kept under review, including the nature and volume of business conducted in private session to ensure such arrangements are adopted only when absolutely necessary.

Given that the Board will not meet in person for some time, electronic meetings and communication will remain key to the Board's functionality. As a result of this, members of the public will be unable to attend public Board meetings, however with the introduction of live streaming from July 2020, the public will be enabled to observe proceedings.

To facilitate as much transparency and openness as possible the Health Board will continue to undertake to: publish agendas and papers as far in advance as possible – ideally 7 days; and publish a summary of meetings held within 7 days on the health board's website.

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Board Level Committee Meetings

Formal meetings of the Board's Committees will have a shortened, concise agenda focussing on essential matters only and will be held virtually to ensure compliance with social distancing guidance. To this end, it is hoped to be able to commence live streaming of those meetings usually held in public from July 2020. As a result of this, members of the public will be unable to attend committee meetings, however with the introduction of live streaming from July 2020, the public will be enabled to observe proceedings.

To facilitate as much transparency and openness as possible the Board will continue to undertake to: publish committee agendas and papers as far in advance as possible; and publish a summary of committee meetings held within 7 days on the health board's website.

It is proposed that the following committees continue to meet as per routine arrangements and agreed Terms of Reference and Operating Arrangements:

- **Experience, Quality & Safety Committee** meeting every 2 months with the next meeting scheduled for 4th June 2020;
- **Audit, Risk & Assurance Committee** meeting every 2 months with the next meeting scheduled for 25th June 2020;
- **Remuneration & Terms of Service Committee** meeting every 3 months (recent meeting held on 20th May 2020);
- **Strategy & Planning Committee** meeting every 3 months with the next meeting scheduled for 9th July 2020 ;
- **Charitable Funds Committee** meeting every 3 months (it is proposed that the meeting previously scheduled for 2nd June 2020 is re-arranged to later in the month).

In addition, it is proposed that the following committees resume meeting as per agreed Terms of Reference and Operating Arrangements, but with a revised frequency:

- **Performance and Resources Committee** meeting every 3 months (amended from meeting every two months as per its Terms of Reference), with the next meeting scheduled for 30th June 2020;
- **Executive Committee** meeting as a minimum monthly but otherwise as deemed necessary by the Chief Executive (amended from meeting every two weeks as per its Terms of Reference).

On 4th May 2020, Welsh Government issued a Guidance Note which was developed to assist in *Discharging the role of board committees during the COVID-19 response phase* (attached at **Appendix A**). Whilst the Guidance Note has some relevance to the Board and all Committees it pays particular attention to the role of the Experience, Quality and Safety Committee and the Audit, Risk and Assurance Committee. Committees will consider this guidance when determining respective priorities and work programmes.

Board Advisory Groups

As mentioned earlier in the paper, arrangements for meetings of the Board's **Local Partnership Forum** (LPF) were amended as a result of the COVID-19 pandemic with formal meetings suspended and replaced by fortnightly informal briefings. It is proposed that formal meetings of the LPF be held two monthly in line with agreed Terms of Reference and Operating Arrangements, with the next scheduled for 16th July 2020. It is also proposed that informal briefings continue, as a minimum monthly, or otherwise deemed necessary by the Chief Executive and Staff Side Chair.

The Board's other advisory groups, the Stakeholder Reference Group and Healthcare Professionals' Forum, are due to be fully established during 2020-21.

NEXT STEPS:

The approach set out in this paper will remain under review by the Chair, Chief Executive and Board Secretary to ensure the Board is able to maintain good governance during the COVID-19 Pandemic.



Guidance Note : Discharging Board Committee Responsibilities during COVID-19 response phase

Introduction

The NHS in Wales is currently facing unprecedented and increasing pressure in planning and providing services to meet the needs of those who are affected by COVID-19. Alongside this is the need for organisations to balance continuing to provide and commission life-saving and life impacting essential services. As a result of the pressure placed on the NHS bodies and the Welsh Government response to managing the impact of the pandemic it has been necessary to adapt governance arrangements. The Welsh Government in its response (dated 26 March 2020) to a letter received on behalf of the Board Secretaries Group, agreed the Governance Principles that are designed to help focus consideration of governance matters over the coming weeks and months (see below).

Governance Principles:

- **Public interest and patient safety** – We will always act in the best interests of the population of Wales and will ensure every decision we take sits in this context taking in to account the national public health emergency that (COVID-19) presents.
- **Staff wellbeing and deployment** – we will protect and support our staff in the best ways we can. We will deploy our knowledge and assets where there are identified greatest needs.
- **Good governance and risk management** – we will maintain the principles of good governance and risk management ensuring decisions and actions are taken in the best interest of the public, our staff and stakeholders ensuring risk and impact is appropriately considered.
- **Delegation and Escalation** – any changes to our delegation and escalation frameworks will be made using these principles, will be documented for future record and will be continually reviewed as the situation unfolds. Boards and other governing for a will retain appropriate oversight, acknowledging different arrangements may need to be in place for designated officers, deputies and decisions.
- **Departures** – where it is necessary to depart from existing standards, policies or practices to make rapid but effective decisions – these decisions will be documented appropriately. Departures are likely, but not exclusively, to occur in areas such as standing orders (for example in ow the Board operates), Board and executive scheme of delegation, consultations, recruitment, training and procurement, audit and revalidation.
- **One Wales** – we will act in the best interest of all of Wales ensuring where possible resources and partnerships are maximised and consistency is achieved where it is appropriate to do so. We will support our own organisation and the wider NHS to recover as quickly as possible

from the national public health emergency that COVID-19 presents returning to business as usual as early as is safe to do so.

- **Communication and transparency** – *we will communicate openly and transparently always with the public interest in mind accepting our normal arrangements may need to be adapted, for example Board and Board Committee meetings being held in public.*

The purpose of this guidance note is to assist the Board in discharging their responsibilities during this time, paying particular attention to the role of the Quality and Safety Committee and Audit Committee.

Background

NHS Boards are required to establish a number of Committees, including a Quality and Safety and an Audit Committee in accordance with the Model Standing Orders for NHS organisations in Wales.¹ In responding to the pandemic, NHS organisations in Wales have revised their arrangements, standing down some board committees and partnership forums, and reviewing the remit of others. Two committees which will continue to meet in all organisations are the Quality and Patient Safety Committee and the Audit Committee, operating where required, through revised arrangements.

Assessment of Board and Committee Roles in Responding to the Pandemic

Whilst the Quality and Patient Safety (Q&PS) and Audit Committees may operate with more focused agendas as the organisation responds to the pandemic a number of areas will still require their attention which are not directly COVID-19 related. Organisations should consider their current governance arrangements including the operation and frequency of the Board and appropriate committees.

It may be sensible for the Board to consider an integrated approach to assurance that limits the amount of management time needed, particularly on those with clinical responsibility where the impact of COVID-19 will be most felt.

As the organisation moves into the recovery and re-activation phase it will be necessary to consider the currency of previous audits and reviews as it is recognised that some services/activities will inevitably change in the long term as a result of the different ways of working that have been established. In the interests of openness and transparency it will be necessary to ensure there is a log of Committee activity pre-Crises to ensure this does not get overlooked and there is a clear audit trail.

Some areas for the Board to consider for the Q&PS Committee and Audit Committee to discharge include:

¹Model Standing Orders, Welsh Government, September 2019, <http://www.wales.nhs.uk/governance-manual/standing-orders>

Quality and Safety Committee

Workforce and volunteers

- Safety and use of temporary staff/staff working in unfamiliar environments (including field hospitals)/with unfamiliar patient mix and use of volunteers
- Sickness absence levels/need for staff to self-isolate and impact on safer staffing
- Capacity of other non-patient areas, e.g. pathology with regard to COVID-19 and non-COVID workloads
- Health and well-being of staff (in the absence of a Workforce Committee this may fall to the Quality and Safety Committee or the Board may decide they wish to maintain oversight of this area).

Equipment, Medicines, Supplies and Facilities Management

- Availability of appropriate PPE, its procurement, deployment, staff training, guidance and communication.
- Availability of equipment and consumables - procurement, deployment, risk assessment and training requirements , monitoring supplies and stocks,
- Medicines management - access to critical medicines, community access etc.
- Cleaning and hygiene – cleaning regimes for all areas, potential impact on other hospital acquired infections, ability of staff to shower and change as appropriate at the end of their shift etc.

Safety, Quality and Clinical Effectiveness

- Maintaining an oversight and monitoring of the organisations ability to provide/ commission essential services and agree action where there are significant risks to delivery.
- Serious incident management – to include any changes to the arrangements for reporting and managing incidents, monitoring and tracking themes as a result of COVID-19
- Responding to patient safety alerts and notices and other improvement actions needed, including any requirements from inspections in line with advice from Healthcare Inspectorate Wales and other regulatory bodies.
- Mortality reviews – maintain oversight of mortality reviews for those deaths where there may be a concern or unusual circumstances. Committees should ensure immediate ‘make safes’ are put in place and learning shared across the organisation in the usual way
- Triggers for clinical harm reviews of those on waiting lists – how will these be identified and will there be any change to the pre-COVID arrangements?
- Understanding position regarding the organisations clinical audit programme (Note – National Programme suspended)
- Arrangements for approving amendments to policies, procedures and protocols – how will this be managed during the phases of the response?
- How is the organisation keeping a track of the published guidance? Are there arrangements for evaluating and ensuring an appropriate response?

- Is the Committee clear regarding the expectations of staff regarding following guidance and maintaining parameters of clinical practice?
- Potential risk to patients if unable to fulfil assessment of specialising needs leading to potential increased Deprivation of Liberty concerns e.g. if clinical areas are locked to maintain patient safety.
- Ensuring that services delivered in surge facilities such as field hospitals have clear operating procedures in place and in line with the organisation's clinical/quality governance arrangements

Patient Experience

- Patient Experience and Concerns Reporting – arrangements for managing and responding during response, recovery and re-activation phases.
- Consideration of issues and concerns which may be raised by the Community Health Council.
- Impact on patients due to their ability to access essential services such as end of life and palliative care, pain control, value based decision making.
- Concerns and mitigation regarding ability to ensure Welsh language, other language and needs as a result of protected characteristics are met.
- DNACPR and ensuring its appropriate use.
- Impact on patients and their families regarding visiting policies, ability to ensure supplies of clothing and basic toiletries, provide for hygiene and nutrition needs, provide comfort towards end of life, pastoral needs etc.

Capacity

- Ability to meet demand of COVID and patients requiring essential services
- Status and utilisation of surge capacity
- Plans for use during response, recovery and re-activation phase.
- Status of life saving and life enhancing services
- Performance split between COVID- and non-COVID patients.

Annual Reporting

- Agree Annual Quality Statement for approval by the Board before 30 September 2020.
- Receive Annual Putting Things Right Report
- Receive information regarding annual reports/programmes which have been suspended (e.g. National Clinical Audit Programme) and arrangements for receiving exception reports if required.

**Decision Making and Delegation of Powers/Risk Management and Assurance*

See below in Audit Committee Section. The Q&PS Committee will need to consider matters which fall within their Terms of Reference and decision making powers.

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Audit Committee

Annual Reporting

Revised timescales were issued in the Welsh Government letter dated 26 March 2020 (see References section below). This will inform the work of the Committee during the annual reporting period.

- Review and recommend the annual accounts for adoption and approval by the Board
- Review the Annual Governance Statement to ensure it is an accurate reflection of the position for 2019/20 and up to the date of approval, prior to signature by the Chief Executive/Accountable Officer – ensure the impact of the need to respond to COVID-19 is clear.
- Review the Remuneration Report and recommend for approval by the Board
- Review the Annual Report and accountability statements in accordance with revised timetable issued by Welsh Government and recommend for approval by the Board

Note: Whilst it is for each organisation to agree the level of assurance required and content of reports consideration should be given to the potential impact of diverting resources to prepare reports which will add limited value to the response, recovery and reactivation of services.

Internal Audit

The Chair may benefit from holding a discussion with the Head of Internal Audit and Board Secretary to help inform the activity of the Committee during the response, recovery and reactivation phase. The Committee will be required to:

- Receive the Annual Audit Opinion of the Head of Internal Audit and Annual Internal Audit Report which will inform the Annual Governance Statement
- Assess the status of the Annual Internal Audit Plan 2019/20 and the potential impact on the 2020/21 Plan
- Review and agree a revised plan for 2020/21 with the Head of Internal Audit. This will need to remain fluid as it is not clear at this stage when the programme will be able to commence or what revisions will be required to cover both supporting recovery and reflecting the revised risk profile of the organisation.
- Agree the arrangements for tracking internal audit actions during the period. The Committee may wish to focus on:
 - Reports which received a Limited Assurance or No Assurance Rating
 - Actions assessed as high priority where the “action by date” has passed
- As the organisation moves into the recovery and reactivation phase consider whether previous reports and resulting actions still remain relevant
- Assess whether any decisions/ways of working which were established during the response phase would benefit from an Internal Audit Review to provide assurance to the organisation.

Audit Wales

As indicated for Internal Audit it is suggested that Chair holds a discussion with the Audit Wales Partner and Board Secretary to inform the activity of the Committee during the response, recovery and reactivation phase. Annual Reports and Structured Assessment reports for 2019 were published before the COVID-19 pandemic was declared. The Auditor General for Wales has advised on the Audit Wales website² that whilst delivering his statutory responsibilities, he wants to ensure that audit work does not have a detrimental impact on audited bodies and their staff at a time when the public service is stretched and focused on more important matters.

Arrangements will be put in place to ensure delivery of the statutory end of year duties in accordance with the revised accounting timetable.

*Risk Management and Assurance**

Although the Committee should not be directly involved in the process of risk management, the organisation's risk management system will underlie the assurance system and the Committee needs to review the risk management processes in exercising its functions in relation to this system of assurance³.

- It is likely that the organisations risk appetite will be higher than in the pre-crises phase to ensure the organisation is able to respond effectively and at pace. This may be evidenced in the speed that decisions have been arrived at for example.
- The Committee should seek assurance that risks have been assessed and evidenced transparently including disproportionate impact on other areas.
- What level of assurance is available from external sources for the risks and what is the level of confidence that can be gained from this as it is likely their programmes have also been impacted? Is there confidence in the sources of internal assurance during this time to help mitigate against the impact on sources of external assurance?
- As the organisation moves into the recovery and reactivation phase it will be necessary to further consider the risk appetite and tolerance of the organisation. Whilst accepting that it unlikely to be appropriate to revert back to the position before the pandemic it is important to ensure that any changes have been considered and agreed by the Board and arrangements are in place to manage appropriately.

*Decision Making and Delegation of Powers**

The Governance Principles recognise there may be changes to the delegation and escalation frameworks, together with departures from existing standards, policies or practice to make rapid but effective decisions. They also recognise the need to document such departures for future record and to ensure their continual review as the situation unfolds.

² <https://www.audit.wales/news/covid-19>

³ Welsh Government Audit Committee Handbook , June 2012,

<http://www.wales.nhs.uk/sitesplus/documents/1064/NHS%20Wales%20Audit%20Committee%20Handbook%20June%202012%29.pdf>

- Committee has a role to consider any variation in Standing Orders, approving these where it considers appropriate and providing a formal report to the Board.
- Assess robustness of the arrangements for recording decisions and arrangements for ensuring business continuity if individuals are not able to discharge their responsibilities.
- Receive information regarding any variation from Schemes of Delegation/Organisational Policies and Procedures/Standard Operating Procedures

* Note –The Audit Committee together with the Quality and Patient Safety Committee will have a role in advising the Board regarding the appropriateness of this risk management arrangements, decision making and the delegation of powers.

Financial Control and Management

The HFMA have published COVID-19 Financial Governance Considerations⁴ which advises of areas which will require consideration such as review of scheme of delegation, authorised signatory arrangements, coding of expenditure etc. The Audit Committee will have a role in:

- Receiving information on the changes to control procedures and delegations which have been necessary to ensure the organisation is able to respond
- Receiving information relating to the arrangements for recording any deviations
- Receiving information regarding these deviations – this may be a list of contracts entered into which have not been subject to the full procurement controls
- Review losses and special payments
- Assurance that there where appropriate legal advice has been sought prior to entering into agreements

Counter Fraud

The Local Counter Fraud Specialist (LCFS) is the main point of contact and will advise regarding reports which should be received by Audit Committees during this time.

The fraud threat posed during emergency situations is higher than at other times and organisations should put in appropriate controls to mitigate where possible.

The UK government are issuing information regarding safeguards which should be put in place⁵ and alerts are also being issued in Wales

⁴ COVID-19 Financial Governance Considerations, Healthcare Financial Management Association (HFMA), <https://www.hfma.org.uk/docs/default-source/publications/covid19-financial-governance-implications.pdf?sfvrsn=0>

⁵ Fraud control in Emergency Management:COVID-19 UK Government response, Government Counter Fraud Function, <https://www.gov.uk/government/publications/fraud-control-in-emergency-management-covid-19-uk-government-guide>

The Audit Committee should consider the arrangements for undertaking post-event assurance to look for fraud and ensure access to fraud investigation resources. This should be undertaken as soon as practicable and the Committee should receive the findings.

Recommendation

NHS organisations should consider the information and guidance provided in this document to inform the arrangements for their Board Committees during the COVID-19 response phase. They will also need to consider the relevance as they move into the recovery/reactivation phase.

Further guidance will be issued if required.

References

COVID-19 Financial Governance Considerations, Healthcare Financial Management Association (HFMA), <https://www.hfma.org.uk/docs/default-source/publications/covid19-financial-governance-implications.pdf?sfvrsn=0>

Fraud control in Emergency Management: COVID-19 UK Government response, Government Counter Fraud Function, <https://www.gov.uk/government/publications/fraud-control-in-emergency-management-covid-19-uk-government-guide>

Strengthening the health system response to COVID-19, Recommendations for the WHO European Region Policy brief, World Health Organisation, 1 April 2020, http://www.euro.who.int/_data/assets/pdf_file/0003/436350/strengthening-health-system-response-COVID-19.pdf

COVID-19: Operational guidance for maintaining essential health services during an outbreak, World Health Organisation, 25 March 2020, <https://www.who.int/publications-detail/covid-19-operational-guidance-for-maintaining-essential-health-services-during-an-outbreak>

Welsh Government Audit Committee Handbook, June 2012, <http://www.wales.nhs.uk/sitesplus/documents/1064/NHS%20Wales%20Audit%20Committee%20Handbook%20%28June%202012%29.pdf>

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Agenda item: 2.5a

BOARD MEETING		Date of Meeting: 27 May 2020
Subject :	Serious Incidents Policy: Serious Incidents Reporting, Investigating and Assurance Processes	
Approved and Presented by:	Alison Davies Executive Director Nursing & Midwifery	
Prepared by:	Wendy Morgan Assistant Director Quality & Safety	
Other Committees and meetings considered at:	Quality Governance Group September 2019; January 2020; May 2020.	

PURPOSE:

This paper provides the Board with the serious incident policy (see **Appendix 1**) for approval.

RECOMMENDATION(S):

The Board is asked to:

- **Approve the Serious Incidents Policy.**

Approval/Ratification/Decision	Discussion	Information
✓	x	x

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Serious Incidents Policy

Board Meeting
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THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	x
	2. Provide Early Help and Support	x
	3. Tackle the Big Four	x
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	x
	6. Promote Innovative Environments	x
	7. Put Digital First	x
	8. Transforming in Partnership	x
Health and Care Standards:	1. Staying Healthy	x
	2. Safe Care	✓
	3. Effective Care	x
	4. Dignified Care	x
	5. Timely Care	x
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

This paper provides the Board with the final version of the serious incident policy for approval.

The policy, during its development, has been presented to the Executive Quality Governance Group on three occasions following which it has been subject to content changes and subsequent review by clinical executives, the outcome a comprehensive policy to promote the effective management of serious incidents across the health board.

DETAILED BACKGROUND AND ASSESSMENT:

The **National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011** (the Regulations), places a statutory duty upon the health board to effectively handle 'concerns'.

The term 'concern' is taken to mean a complaint, a claim or reported patient safety incident (about NHS treatment of services) to be handled under these arrangements; this includes serious incidents.

The Regulations are supported by 'Putting Things Right: Guidance on dealing with concerns about the NHS from April 2011' (Welsh Government V3, 2013),

which is aimed at assisting staff in their interpretation and providing practical advice when handling and investigating a concern.

The **Improving Clinical Quality: Powys Teaching Health Board Framework for Action 2020-2023** (hereafter the 'Framework') purpose is to realise the vision of:

Systematic, clinically-led, continuous and sustained, year-on-year improvement in the quality of clinical care provided by Powys Teaching Health Board.

Goal 1 of the Framework focuses on implementing the Darzi model for clinical quality, encompassing safety, effectiveness and patient experience. The new serious incident policy is one of the five key improvement actions under safe care relating to serious incidents.

Serious Incidents Policy: Serious Incidents: Reporting, Investigating and Assurance Processes

The serious incident policy sets out the arrangements, under Putting Things Right, by which the health board will manage serious incidents.

The policy incorporates the arrangements required for the management of serious incidents in line with the Regulations and applies to all staff, permanent and temporary, employed by or working within the health board, including independent providers who have a responsibility to report, manage and/or be involved in serious incidents.

This policy is supported by a serious incident toolkit which provides staff practical support in managing serious incidents; this will be available via the health board's intranet.

Revision of National Serious Incident Frameworks

The national work underway to refresh the serious incident framework in both Wales and England is at different stages of development. It is recognised the attached serious incident policy will need to consider the outcome of both reviews and reflect required changes to ensure a robust approach to systems and processes within the health board for reporting, investigating and providing assurance on serious incidents that occur in both provider and commissioned services.

Wales

No further activity has taken place with regards to updating the Welsh serious incident framework since the initial meeting 8 November 2019. A second meeting scheduled for the 17 March 2020 has been cancelled reflecting the current public health situation. A new date is awaited.

England

The publication of the revised serious incident framework for England, named 'Patient Safety Response Framework (PSIRF)', is scheduled for Spring 2021. They are acting to work with a small number of early adopters who will work with an introductory version of the framework in their organisations. The introductory framework for implementation by nationally appointed early adopters was published 10 March 2020. Its aim is to guide the NHS on how to develop the cultures, systems and behaviours necessary to respond to patient safety incidents in a way that ensures there is learning and improvement. Organisations in England are not expected to start implementing the requirements in the framework until early 2021, with all NHS-funded organisations likely required to fully deliver the framework by late 2021. This timeline may shift dependent on what is learnt from the early adopters.

Changes to the Serious Incident Policy since January 2020

The main changes to the serious incident policy since a previous draft version in January 2020 have focussed on:

- Format
- Language
- Strengthening explanation on the process for reporting and investigating serious incidents
- Clarity of roles and responsibilities
- Additions relating to Coroner cases and external investigations

The final draft of the policy reviewed by the clinical executives was considered to be comprehensive, with one comment regarding how user friendly the flowchart was and that it was difficult to follow in table format and appeared a bit busy. No changes have been made to the version in the policy but it is currently being explored as to how best this can be extracted into a user-friendly stand-alone flow chart for all areas.

Quality Governance Group

The serious incident policy was discussed at the Executive Quality Governance Group 21 May. It was agreed the policy should be reviewed in 6 months' time to provide the opportunity to review its implementation in the national and local context and provide assurance on the outcome of implementation and related improvement activities. The policy was supported.

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Serious Incident Policy Implementation Plan

It was recognised at the Quality Governance Group there was a need for a robust and strong approach to implementation. The implementation plan will be developed to support its introduction across the health board, supported by investigating officer designation and training and staff training and awareness to ensure staff have the right knowledge and skills.

NEXT STEPS:

- 1) The serious incident policy is made available to all staff.
- 2) The implementation plan is developed.
- 3) The policy and implementation plan scheduled for return to the Quality Governance Group in 6 months' time.

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Serious Incidents Policy

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The following Impact Assessment must be completed for all reports requesting Approval, Ratification or Decision, in-line with the Health Board's Equality Impact Assessment Policy (HR075):

IMPACT ASSESSMENT				
Equality Act 2010, Protected Characteristics:				
	No impact	Adverse	Differential	Positive
Age	✓			
Disability	✓			
Gender reassignment	✓			
Pregnancy and maternity	✓			
Race	✓			
Religion/ Belief	✓			
Sex	✓			
Sexual Orientation	✓			
Marriage and civil partnership	✓			
Welsh Language	✓			
Statement <i>Please provide supporting narrative for any adverse, differential or positive impact that may arise from a decision being taken</i>				
Risk Assessment:				
	Level of risk identified			
	None	Low	Moderate	High
Clinical		✓		
Financial		✓		
Corporate		✓		
Operational		✓		
Reputational		✓		
<p>If the policy is not supported, the health board will not have specific guidance in place for staff on recognising and reporting serious incidents.</p> <p>If action is not taken to report serious incidents and protect patients and staff through corrective actions, improvements and sharing of lessons learnt, there is the potential for harm to be caused and related consequences such as recurring incidents and harm, potential for redress and compensation claims.</p> <p>Following the described framework for acting on serious incidents will assist in mitigating associated risks and harm, and promote shared learning.</p>				

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SERIOUS INCIDENT POLICY: REPORTING, INVESTIGATING AND ASSURANCE PROCESSES

Document Reference No:	PTHB/*** **	
Version No:	1	
Issue Date:	March 2020	
Review Date:	October 2023	
Expiry Date:	March 2023	
Author:	Assistant Director Quality and Safety	
Document Owner:	Assistant Director Quality and Safety	
Accountable Executive:	Chief Executive Officer	
Approved By:		
Approval Date:		
Document Type:	Policy	Non-clinical
Scope:	All PTHB staff	
Links with other policies:	This Policy links to the overarching 'Listening, Acting and Learning: Policy on 'Putting Things Right' and Management of Concerns' within which serious incidents is referenced in the context of concerns. This serious incident policy provides detailed guidance on management of serious incidents from notification through to closure.	

Do not print this document. The latest version will be accessible via the intranet.

If the review date has passed please contact the Author for advice.

Disclaimer

Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

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Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	tbc

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ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Assistant Director Quality & Safety
Clinical Executive Leads
Powys-wide consultation

Circulated to the following for Consultation

Date	Role / Designation
17/09/19	Quality Governance Group
31/10/19	Powys wide
27/11/19	Clinical Executive Leads Observations and Feedback
02/01/20	Feedback amendments undertaken. Key changes include: <ul style="list-style-type: none"> Reordering and formatting of content Links with other policies outlined on front page Purpose of document made more explicit upfront Highlighted risks from policy documented upfront Definitions upfront in document Defined list of never events added to appendices Greater clarity re roles and responsibilities Strengthening of lessons learnt Clarity on focused training
16/01/2020	Quality Governance Group. Key changes included:

	<ul style="list-style-type: none"> • Format • Language • Strengthening explanation on the process for reporting and investigating serious incidents • Clarity of roles and responsibilities • Additions relating to Coroner cases and external investigations
17/03/2020	Quality Governance Group

Evidence Base
<p>This Policy has taken into consideration all national guidance and legislation:</p> <ul style="list-style-type: none"> • National Patient Safety Agency (November 2009) Being Open; Communicating patient safety incidents with patients, their families and carers, London • NHS Wales Informatic Services (June 2018) NHS Wales – Framework for the joint investigation of patient safety Serious Incidents (Sis) related to NWIS delivered or supported services, which affects one or more health body in Wales • Welsh Ambulances Services NHS Trust (July 2019) Framework for the investigation of Patient Safety Serious Incidents (SIs) • Welsh Government (Version 3-November 2013) Putting Things Right: Guidance on dealing with concerns about the NHS from April 2011 • Welsh Government (March 2019) NHS Wales Delivery Framework and Reporting Guidance 2019-2020 • Welsh Government (July 2019) Health and social care (quality and engagement) (wales) bill (preparatory work) • Welsh Statutory Instruments 2011 No. 704 (W.108) NATIONAL HEALTH SERVICE, WALES: The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 • WHC (2018) 015 Welsh Health Circular on revised pressure ulcer reporting including the reporting of serious incidents <p>This Policy takes account of the Health and Care Standards in Wales 2015 and underpins Standard 6.3 Listening and Learning from Feedback http://www.wales.nhs.uk/governance-emanual/standard-6-3-listening-and-learning-from</p> <p>This Policy takes account of local learning/ experience.</p>

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IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	Adverse	Differential	Positive	Statement
					<p>This Policy has undergone an equality impact assessment screening process, using the toolkit designed by the NHS Centre Equality & Human Rights.</p> <p>Details of the screening process for this Policy are available from the Equalities Manager</p>
Age				X	
Disability				X	
Gender				X	
Race				X	
Religion/ Belief				X	
Sexual Orientation				X	
Welsh Language				X	
Human Rights				X	
Risk Assessment Summary					
<p>Have you identified any risks arising from the implementation of this policy / procedure / written control document?</p> <p>Yes. If the policy and procedures are not followed, there are potential risks to patient safety, staff safety, finances, the organisation and its reputation. This could impact on corporate and operational teams.</p> <p>If action is not taken to report serious incidents and protect patients and staff through corrective actions, improvements and sharing of lessons learnt, there is the potential for harm to be caused and related consequences such as recurring incidents and harm, potential for redress and compensation claims.</p> <p>Following the described framework for acting on serious incidents will assist in mitigating associated risks and harm, and promote shared learning.</p>					
<p>Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?</p>					

Sharing of personal identifiable information risks have been mitigated by following PTHB Information Governance policies and procedures and national guidance/legislation regarding confidentiality and data protection.

Have you identified any training and / or resource implications as a result of implementing this?

Training requirements for staff are described in section 19.

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1 Scope

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 define a 'concern' as the notification of an incident concerning patient safety, thus placing a statutory responsibility upon NHS organisations in Wales to manage incidents as set out in the Regulations. Concerns is the NHS Wales collective name for incidents, complaints and claims and reference to 'concerns' includes serious incidents.

This policy and procedure incorporates the arrangements required for the management of serious incidents in line with the Regulations and applies to all staff, permanent and temporary, employed by or working within the Health Board, including independent providers who have a responsibility to report, manage and/or be involved in serious incidents.

2 Purpose

This policy sets out clear guidance on the management of serious incidents from the point of notification to closure of the related investigation, ensuring lessons have been learnt and shared, and assurance provided.

The policy applies to the management of serious incidents that occur in provided services in addition to notifying serious incidents reported through commissioned services that impact on Powys residents. Where a provider organisation reports a serious incident, Powys Teaching Health Board (PTHB) will notify Welsh Government. Serious incidents will be monitored through the PTHB internal commissioning assurance (CAF) framework.

The aim and purpose of this policy is to ensure:

- All staff understand and recognise when a serious incident has occurred and are able to report it in a timely manner;
- Staff are supported and encouraged to engage with the management of Serious Incidents.
- Executive leadership, management and oversight of serious incidents;
- Accurate and full information is gathered quickly from persons involved, facilitating speedy management and analysis of the incident;
- The Health Board is in a position to respond expediently, positively and appropriately to patient(s) and their relatives and to other appropriate bodies;
- That individuals receive a full and honest response, which provides an account of what happened, why it happened and, if appropriate, any actions taken to avoid recurrence;
- Communication methods in place to deal with enquiries from patients, relatives, staff or others following the serious incident as expediently as is reasonable;
- Timely reporting to statutory and external bodies e.g. Medicines and

Healthcare Products Regulatory Agency (MHRA), Health and Safety Executive (HSE) and the Welsh Government (WG);

- All other necessary policies and procedures are evoked as the result of a serious incident;
- Any necessary remedial action is taken and lessons are learned from serious incidents to minimise re-occurrence across the Health Board as appropriate;
- Feedback is given to staff and any appropriate wider audiences so that the information may be used for learning; and
- An integrated approach to the investigation of the serious incident which may identify the potential of a qualifying liability and thereby will trigger consideration of Redress under the Putting Things Right Regulations or which may result in litigation.

All staff are required to report all patient safety incidents, irrespective of seriousness and degree of harm.

Being open involves acknowledging, apologising and explaining when things go wrong. Conducting a thorough investigation into the serious incident reassures patient(s) and their representatives that lessons will be learnt and action taken to prevent a recurrence of the incident. Support will be offered for those involved to cope with the physical and psychological consequences of the Serious Incident.

To say sorry is not an admission of liability and is the right thing to do.

It is important to understand that not all patient safety incidents will require reporting to Welsh Government. Incidents can be classed as serious but they are not necessarily reportable to Welsh Government. If in doubt as to whether it should be reported, advice can be sought from the Concerns Team (concerns.qualityandsafety.pow@wales.nhs.uk).

As an NHS Organisation, Powys Teaching Health Board is required to **report serious incidents as described in section 3** and to provide Welsh Government with an **assurance that a robust investigation has been completed** and **learning identified within 60 working days**.

The table below sets out the timetable for reporting of and action on serious incidents. The flowchart for reporting and investigating Serious Incidents can be accessed at Appendix 1.

Timeframe	Action
Immediate – At point of identifying incident	Staff member completes Datix, draft serious incident notification form and sends to: concerns.qualityandsafety.pow@wales.nhs.uk The Serious Incident Notification and Reporting forms can be accessed at Appendix 2.

24 hours	The Concerns Team confirm a serious incident for reporting. The Concerns Team notify the Welsh Government about the serious incident.
1-2 working days	The Concerns team arrange the internal PTHB serious incident audio meeting. The Executive Lead identifies the terms of reference for the investigation and identifies an Investigation Officer (IO).
3-25 working days	Investigation is led by the assigned IO. On conclusion of the investigation the IO sends a draft investigation report and action plan to concerns.qualityandsafety.pow@wales.nhs.uk
26-30 working days	The Concerns Team send the investigation report and action plan to the Executive Lead. The Executive Lead reviews the investigation report and action plan and makes a recommendation to either (1) request additional work as required, or (2) recommend closure of the serious incident.
31-36 working days	Additional work takes place, as required. Concerns Team request a draft of the serious incident closure form from the service area.
37-42 working days	Following any additional work as requested, the Executive Lead reviews and approves the serious incident investigation report, action plan and closure form and makes recommendation for closure of the serious incident.
42-47 working days	The Concerns Team send the executive the approved serious incident investigation report, action plan and closure form to the CEO for review, approval and sign off for submission to Welsh Government. The Concerns Team provides a written draft response to the patient / families (Regulation 24/ 26 letter) for review by the CEO for review and issue. Where a Regulation 26 letter is issued, the redress process is progressed.
Within 60 working days	The Concerns Team provide assurance to Welsh Government that a robust investigation has been completed and learning identified within 60 working days of the date the incident was reported.

Appendices within this policy provide forms for notification and closure of serious incidents along with direction and guidance with regards their reporting and investigation. The appendices will be referenced at various points throughout the policy, albeit not always in numerical order.

Appendix	Subject	Purpose
1	Flowchart for Reporting and Investigating Serious Incidents	This provides a summary of actions involved in reporting and investigation serious incidents.
2	Serious Incident Notification Forms / Reporting	These forms are used for notification and closure of serious incidents to Welsh Government.
3	Reporting Pressure Ulcers	These are forms specifically for reporting pressure ulcers to Welsh Government.
4	Never Events List 2018-19	This provides the current list of never events.
5	Joint Investigation	This provides information an carrying out joint investigation with other health bodies.
6	Guidance for Investigating Officers	This provides a brief guide for investigating officers.
7	Reporting Serious Incidents that involve other bodies	This provides more detailed information on other bodies who the health board may need to report serious incidents to, for example, HSE.
8	Grading of Concerns	This guide provides guidance on grading serious incidents reflecting the impact or harm experienced by the patient/individual.
9	Levels of Investigation	This guide provides information on the level of investigation required and outlines the recommended, standardised tools which should be used for different grades of concerns/ serious incident and who should investigate.
10	Serious Incident Toolkit	This provides information on a range of useful guides, tools and templates for use when reporting and investigating serious incidents

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3 Definitions

Definitions used in this policy are defined in The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 and further explained in the Putting Things Right: Guidance on dealing with concerns about the NHS from April 2011 (Version 3-November 2013).

A **serious incident**. This is an incident that occurred during NHS funded healthcare (including in the community and serious incidents that affect Powys residents in commissioned services), which resulted in one or more of the following:

- Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public; A never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death (see *Never Events Framework*); A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population; Allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

Examples of serious incidents that must be reported to Welsh Government include but are not limited to:

- Deaths where a healthcare associated infection (including *Clostridium difficile* and methicillin resistant *Staphylococcus aureus*) is mentioned on the death certificate as either the underlying cause of death or
- Contributory factor;
- Outbreak of a healthcare associated infection in a hospital that results in significant disruption;
- Avoidable healthcare associated pressure ulcers graded 3, 4 or unstageable **only notified post completion of the investigation in accordance with WHC (2018) 051; (See Appendix 3 for more detail)
- Suspected suicide/unexpected death of mental health patient (including community and in-patient services);
- Self-Harm incidents categorised as 'severe' under the *Grading Framework for dealing with Concerns*;
- Admission of a child under the age of 18 years to an adult mental health ward;
- Absence without leave of a patient subject to the Mental Health Act;
- Intrauterine Fetal deaths if there is early indication that the death is linked to midwifery/obstetric practice;
- Maternal deaths;
- Patient falls that result in death or severe harm; and

- Radiation incidents resulting in patients receiving a radiation dose that is much greater than intended.

Never Events are defined as serious, largely preventable patient safety incidents that should not occur if the available preventable measures have been implemented. Not all never events necessarily result in severe harm or death. Never events lists change on an annual basis. The current list for 2018/2019 never events can be found at Appendix 4, with full details available online <http://www.patientsafety.wales.nhs.uk/never-events>

All never events must be reported to Welsh Government as per the process described for serious incidents. Please see Appendix 4 for the full list of Never Events.

In some cases, incidents may not result in direct harm to patients but may affect service provision or organisational reputation including adverse media coverage. In such cases, a **No Surprise** notification should be submitted in accordance with the process for reporting serious incidents.

No surprise incidents are automatically closed within 3 working days unless Welsh Government choose to escalate them to serious incident status or the circumstances of the incident change that require the Health Board to report as a serious incident.

The **National Reporting and Learning System (NRLS)** is a central database of patient safety incident reports. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care. Further information can be accessed via <https://report.nrls.nhs.uk/nrlsreporting/>

The language and terminology used to describe serious incidents can also vary and common terms in use are:

- Serious incident (SI)
- Serious untoward incident (SUI)
- Significant incident (SI)
- Significant event (SE)
- Significant event analysis (SEA)

For the purpose of this Health Board, the term 'serious incident' will be used.

4 Policy Statement

Powys Teaching Health Board (PTHB) is committed to ensuring high quality and safe care is provided to Powys residents wherever they access health care services.

The Health Board recognises the requirement to report all incidents concerning patient safety. An unexpected or unintended incident which leads to, or could lead to harm, for a patient has the potential to impact on their health and wellbeing. All patient safety incidents require proportionate investigation that reflects the significance of the reported incident.

Serious incidents in healthcare are adverse events, where the consequences for patients, families and carers, staff or health organisations can be significant and the potential for learning, as a result of these incidents, is so great that a heightened level of response is required. They need to be identified correctly, investigated thoroughly and lessons learnt and shared to prevent the likelihood of similar serious incidents recurring.

The Health Board recognises there are risks associated with the complexities of today's health and care systems. This policy gives an explicit description of the roles and responsibilities of all staff in the management and investigation of serious incident reporting and review. The Health Board aims to ensure that all staff are able to identify serious incidents, take appropriate actions and reduce risks to service users.

Efforts to resolve system failures to support staff in delivering a quality service will be prioritised to improve service delivery. Emphasis on analysis and learning when things go wrong is an important part of patient safety. The Health Board is committed to the development of a learning culture throughout the organisation with the aim that patient safety incidents make a positive contribution to continuous improvement.

5 Learning from Serious Incidents

The Health Board is committed to the development of a learning culture throughout the organisation with the aim that patient safety incidents make a positive contribution to continuous improvement.

Learning from serious incidents and the wider sharing of lessons is necessary to prevent incidents being repeated or occurring elsewhere and to promote patient safety and continuous improvement across the Health Board. **Lessons are shared to minimise the risk of repetition of serious incidents.**

Learning from event reports is required on all serious incidents as part of an investigation, these must be submitted to the Concerns Team on completion.

Themes from serious incidents and lessons learnt will be discussed at the relevant subcommittee of the Quality Governance Group and through local learning groups within service areas. Additionally, learning and lessons for wider sharing and actions taken will be reported through the Quality Governance Group, Executive Team, Experience, Quality and Safety Committee and Board.

The Putting Things Right Annual Report will feature learning from serious incidents.

6 Culture

Integral to managing serious incidents is the development of an organisational culture that allows incidents to be reported in an open and fair environment. In order to promote this philosophy and ensure staff feel they can report incidents they are involved in or are witness to, the Health Board will ensure a fair, equitable and consistent approach by managers when they review incidents.

Where early information highlights potential issues of alleged personal and / or professional misconduct, the disciplinary policy may need to be evoked. Where this is indicated, this will run parallel to the Serious Incident process unless otherwise specified. To support this process, the Health Board will use the National Patient Safety Agency (NPSA) incident decision tree to guide staff.

7 Policy Framework

This is the overarching policy for the identification, notification, investigation, management and organisational learning from serious incidents.

8 Structures

It is recognised that within Directorates across the health board a variety of models/roles have existed that focus on the local management of serious incidents from the time they are identified, notified, investigated, lessons identified and wider learning implemented through to assurance on actions taken and their subsequent closure. Examples such as those within mental health services and women and children's services have shown how these roles have supported robust local management of serious incidents within the broader clinical quality framework and clinical governance activity. The health board expect such roles to exist in all Directorates.

9 Roles and Responsibilities

9.1 Chief Executive Officer (CEO)

The Chief Executive Officer has overall accountability for dealing with incidents concerning patient safety, including serious incidents.

9.2 All Executive Directors

All Executive Directors, clinical and non-clinical, where their services impact on NHS funded care have a responsibility for leading, managing and overseeing serious incidents.

9.3 Clinical Executive Leads

Clinical Executives will be assigned to each serious incident reflecting their key areas of responsibility, overseeing the investigation from notification to closure. This will involve:

- Agreement to report the serious incident;
- To lead the internal meetings for the initial discussion of the serious incident, immediate actions taken, allocation of an IO and oversight of the investigation;
- To review progress of the investigation in line with expected timescales;
- To ensure subsequent remedial actions identified are progressed;
- To review the draft report;
- To agree the final report;
- To ensure learning and lessons learnt are shared and implemented; and,
- To agree closure of the serious incident approving closure to Welsh Government.

As part of their role, the clinical executives will be expected to share knowledge, understanding and actions taken to investigate serious incidents that fall within other executive portfolios and responsibilities, to ensure executive colleagues are sighted on related serious incidents that occur.

Where inaction or concerns arise, the clinical executive lead will escalate to the Chief Executive Officer as required.

9.4 Director of Primary, Community and Mental Health Services

Serious incidents will occur within areas that fall within the responsibility of the Director of Primary, Community and Mental Health Services (DPCMHS). The responsible clinical executive lead will need to ensure communication takes place with the DPCMHS to ensure they are fully aware of actions being taken throughout the investigation.

9.5 Director of Performance & Planning

It is recognised that serious incidents impacting on Powys residents do occur in services provided by NHS organisations outside of Powys.

Every serious incident affecting a Powys resident needs to be notified to an Executive Director. When the Health Board are notified of serious incidents, it acts to notify Welsh Government.

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Through the Commissioning Assurance Framework, the Director of Performance & Planning is made aware of serious incidents, and any themes or never events which are reported via Contract, Quality & Performance Meetings and Provider Quality & Safety Committees.

9.6 Senior Investigations Manager

The Senior Investigations Manager is the Assistant Director Quality and Safety who has delegated responsibility for the handling of incidents concerning patient safety under the Putting Things Right Regulations, including serious incidents.

9.7 The Senior Manager Putting Things Right – Quality & Safety Unit

The Senior Manager Putting Things Right, with support from the Concerns Team, is responsible for:

- Reporting the serious incident to relevant external bodies;
- Providing advice on the management and investigation of serious incidents and joint investigations with other Health Boards and/ or NHS Trusts;
- Offering advice on qualifying liability and its application within the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011;
- Highlighting themes and trends relating to complaints and claims that link to incidents concerning patient safety.

Learning from events reports are required on all serious incidents. A key focus is to share the lessons learned from errors that have caused harm and to reduce the risk of similar occurrences.

The scrutiny of learning and improvement action plans is an important part of all investigations. The scrutiny of learning should be evident throughout the life cycle of the serious incident and clearly identify the actions and interventions taken to reduce the risk of reoccurrence or mitigate the effects of repeat events. The Senior Manager Putting Things Right is responsible for ensuring learning from events reports are completed.

Please see Appendix 5 for information on carrying out joint investigations with other health bodies.

9.8 Directorate Serious Incident Lead Manager

The expected model is for a lead manager in each Directorate to be identified.

A variety of titles may be used to describe this role, for example, quality & safety lead or governance lead. The following activities, the list not exhaustive, will be expected of the appointed individual(s):

- Acts as a point of contact for the Directorate;
- Tracks all serious incidents reported through the Directorate;
- Responsible for file management of serious incident related information/ data and providing copies to the Concerns Team for central corporate files;
- Ensures serious incident reporting takes place timely;
- Supports staff in their understanding and application of the serious incident process;
- Acts as a point of contact with the Executive overseeing reported serious incidents;
- Participates in serious incident audios/ meetings;
- Ensures investigations are carried out timely;
- Ensures action plans are in place and actions are followed through and implemented;
- Provides serious incident reports, highlighting themes and trends;
- Escalates local issues identified in the management of serious incidents;
- Contributes to local serious incident learning groups and wider learning across the health board.

9.9 Investigating Officers (IOs)

Investigating Officers are responsible for completing a comprehensive, open and honest investigation addressing the scope of the serious incident. Investigating officers will be given sufficient time and resources to enable them to complete the investigation in a timely manner.

Staff elected to be IOs must have the necessary skills to be able to carry out an investigation. They will have attended relevant investigation training (*see Section 19 on Education and Training*).

The level of staff deemed appropriate to carry out an investigation will meet the following criteria:

- The IO selected will be determined at the time of the initial Clinical Executive-led serious incident meeting/ discussion;
- The IO is accountable to the Clinical Executive Lead during the time of the investigation;
- The IO selected must be able to deal with the assessed level of complexity and subject matter under investigation;
- The IO will be trained in investigation methodology and its application;

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- The IO's position/ band will be relevant to the assessed level of complexity and subject matter under investigation, for example, a ward sister (Band 7) / deputy ward sister (Band 6) would be suitable to investigate a patient fall or an avoidable pressure ulcer but a more complex mental health/ safeguarding serious incident may require a Band 8a-8c lead;
- Previous experience of carrying out investigations is helpful but where newly trained IOs are identified, shadowing of an experienced IO should be considered for their first investigation to provide support and advice;
- Where it is deemed an external IO is required, their knowledge and experience must reflect the assessed level of complexity and subject matter under review;
- Where an IO determines a breach of duty has occurred or considers this may be likely, the case will be presented to the Redress Panel for consideration, coordinated by the Senior Manager Putting Things Right;
- The IO will be required to complete a Redress proforma - an SBAR (Situation, Background, Assessment, Recommendations) and to attend the Panel to present the case.

If members of staff appointed to investigate serious incidents leave the employment of Powys Teaching Health Board, investigations they are leading must be formally handed over as part of their exit process.

All IOs should follow the guidance as outlined in Appendix 6.

9.10 Responsibility of All Staff

- To abide by the principles outlined in this Policy;
- To report within 24 hours of their occurrence all serious incidents;
- To ensure an open, responsive and transparent approach when serious incidents are raised;
- To cooperate fully and openly in the investigation of serious incidents;
- To comply with the Health Board Values and Behaviours Framework;
- To actively learn from serious incidents; and
- To participate in education and training about serious incidents commensurate with their role and responsibilities.

10 Reporting Serious Incidents to Welsh Government

All staff are required to report all patient safety incidents to the Concerns Team, irrespective of seriousness and degree of harm.

All serious incidents are reported to Welsh Government. Where possible **all serious incidents should be notified to the Concerns Team within 24 hours of the serious incident taking place.**

A flowchart on the process for reporting and managing serious incidents, never events and no surprises can be found at Appendix 1.

11 Reporting Serious Incidents involving Other Bodies

Staff report Serious Incidents involving other bodies to the Concerns Team who then onward report to the relevant body, as reporting of serious incidents is not confined to Welsh Government.

There are occasions where reporting to other bodies is required as appropriate and as required by each individual body, for example:

- Health and Safety Executive (RIDDOR)
- Healthcare Inspectorate Wales (HIW)
- Care Inspectorate Wales (CIW)
- Information Commissioner's Office (ICO)
- Police
- Coroner
- Mothers and Babies - Reducing Risk through Audits and Confidential Enquiries (MBRRACE-UK)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Human Tissue Authority

See Appendix 7 for more detail on each of these bodies. For further information and advice contact the Concerns Team via telephone (01874 712697/2699) or email concerns.qualityandsafety.pow@wales.nhs.uk

12 Reporting Serious Incidents that take place in commissioned services

Where a provider organisation reports a serious incident, Powys Teaching Health Board (PTHB) will report this via Welsh Government. Powys Teaching Health Board will assign an investigating officer to communicate with the provider organisation to monitor the investigation process, seek copies of their root cause analysis investigation and report (Please see Appendix 7 for further information).

The Investigating Officer will be responsible for providing the PTHB serious incident closure form for reporting to Welsh Government.

Serious incidents will be monitored through the commissioning assurance (CAF) framework. The CAF describes a continuous assurance process that aims to provide confidence to internal and external stakeholders and the wider public that PTHB is operating effectively to commission safe, high-quality and sustainable services within the resources available, delivering

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on statutory duties and driving continuous improvement in the quality of services and outcomes achieved for patients.

Further information on the commissioning assurance framework can be found in the PTHB Commissioning Assurance Framework, May 2018.

13 Joint Investigations of serious incidents with other Health Boards/ NHS Trusts

A joint investigation can be triggered by PTHB or by another Health Board / NHS Trust, notified to the other body involved via the Concerns team (different names may be used for these teams in other health bodies, e.g. Putting Things Right Teams).

Where a joint investigation takes place, one Health Board or NHS Trust will be identified as the lead organisation.

When a joint investigation is completed, Welsh Government requires the lead organisation to submit a consolidated incident closure summary form (that is, including the findings from other organisations) in accordance with assurance timeframes.

Joint investigation guidance exists for serious incidents that involve:

- NHS Wales Informatics Services (NWIS)
NHS Wales – Framework for the joint investigation of patient safety Serious Incidents (Sis) related to NWIS delivered or supported services, which affects one or more health body in Wales.
- Welsh Ambulance Services NHS Trust
The Framework has been developed to consider all potential serious incidents reported to WAST via their Serious Case Incident Forum. These incidents may occur as a consequence or during delayed patient handovers at Health Board sites, and as a consequence of patients within the community awaiting a response by WAST, where the primary causative factor was that of notification to handover delays.

Threshold:

It is recognised that Health Boards/ NHS Trusts will have thresholds for reporting serious incidents. Powys Teaching Health Board has a **low** threshold for reporting serious incidents to ensure that no serious incidents are missed. The approach is to report serious incidents and then if necessary following investigation to act to 'stand down' the serious incident.

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All joint investigations must be notified to the Concerns Team at concerns.qualityandsafety.pow@wales.nhs.uk in order that they can be tracked and to support communication between Concerns Teams in each health body.

Guidance on joint investigations can be found in Appendix 5.

14 Section 33 Arrangements

Where a serious incident occurs in services that are commissioned and provided through the Section 33 of the National Health Services (Wales) Act 2006 Overarching Partnership Agreement, reporting of incidents must be through both Powys Teaching Health Board and Powys County Council.

Serious incidents will be reported reflecting each organisation's individual systems and processes and joint discussion will take place with regard to investigation and reporting.

15 Grading of Concerns

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 provided the opportunity to introduce a single and consistent method for grading and investigating concerns, which includes serious incidents.

Through accurately grading serious incidents, choosing the investigator(s) appropriately, agreeing the terms of reference so they are clear and the use of appropriate tools, the investigation can be carried out thoroughly, speedily and efficiently.

The intention to “investigate once, investigate well”.

Information on grading can be accessed at Appendix 8 and guidance on levels of investigation can be accessed at Appendix 9.

16 Communications and the Media

The involvement of the communication team will be dependent on whether the serious incident is known to the media:

- If the serious incident is not known to the media and likely to attract media attention, the communications team will work with the Executive lead to prepare a statement. This will be held by the communication team in readiness to respond to enquiries. Updates will be provided as and when required.

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- If the serious incident is not known to the media but the Health Board considers their involvement will be helpful in managing communication around a serious incident, the Executive lead will work with the communications team to prepare a statement for handling and management, for use in engaging with the media.
- If the serious incident is known to the media, the communication team will work with the Executive lead to prepare a response to questions asked and further statements as necessary.

17 Being Open/ Duty of Candour

Being open involves acknowledging, apologising and explaining when things go wrong. Conducting a thorough investigation into the serious incident and reassuring patient(s) and their representatives that lessons will be learnt and action taken to prevent a recurrence of the incident. Support will be offered for those involved to cope with the physical and psychological consequences of what happened.

To say sorry is not an admission of liability and is the right thing to do.

The principles of being open have been developed to assist healthcare organisations to create and embed a culture of *being open*:

- Acknowledgement;
- Truthfulness, timeliness and clarity of communication;
- Apology;
- Recognising patient(s) and their representatives' expectations;
- Professional support;
- Risk management and systems improvement;
- Multidisciplinary responsibility;
- Clinical governance;
- Confidentiality; and
- Continuity of care.

Powys Teaching Health Board's Board and Senior Managers have a crucial role in ensuring that "*being open*" and its principles are embedded across the Health Board.

Being open from the outset of an incident can often help patients, or their representatives, understand what has happened and avoid any mistrust or suspicions developing.

Where an incident occurs and there has been moderate or severe harm or death, the Health Board is required under Regulation 12(7) of The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, to advise the patient to whom

the incident relates, or his or her representative, of the incident and involve them in the investigation.

The exception to this is if informing the patient or their representative would not be in the best interests of the patient. For example, involving them could cause a deterioration in their physical and/or mental health.

18 Monitoring and Closure of Serious Incidents

NHS Organisations are required to provide Welsh Government with an assurance that a robust investigation has been completed and learning identified within 60 working days of the date that the incident was reported.

Reported serious incidents that involve Coroner Inquests or attract external investigations, such as Health & Safety Executive, can be closed prior to the outcome of an inquest being known or before receipt of a final external report being received. The clinical executive/ executive must be sure the internal health board investigation is robust, immediate 'make safes' are in place, actions have been taken and lessons learnt and shared before making the decision to recommend a serious incident can be closed. When the outcome of an inquest or the final report from an external investigation is received, review of and reflection on the findings and lessons learnt must take place to ensure any additional learning and identified improvements are taken account of. The outcome of review, reflection and action must be reported to Welsh Government once completed. This can be done through reporting the information to the concerns team via concerns.qualityandsafety.pow@wales.nhs.uk who will then notify Welsh Government.

Monitoring of serious incidents will be tracked through Directorate Senior Management teams and via the Senior Manager of the Concerns Team.

Reporting of serious incidents and the implementation of actions in response to lessons learned will be reported to the Quality Governance Group and Executive Committee.

Assurance on serious incidents reported, investigated and actions in response to lessons learned will be reported to the Experience, Quality and Safety Committee.

19 Escalation of Serious Incidents

Where there is apparent lack of progress in responding to a serious incident, regardless of the stage of the incident, action to escalate to the Clinical Executive/ Executive Lead must be taken.

20 Redress

Under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, the Health Board is required to consider when investigating a serious incident, whether there is a qualifying liability in tort i.e. whether there has been a breach of duty of care and whether that breach of duty is causative of any harm or loss to that person.

The legal test for qualifying liability is a two-stage test. Both parts of the test must be established for there to be qualifying liability.

Stage 1 - Breach of duty

The Health Board has a duty of care for all patients accessing its services. This is a duty we take very seriously. The Health Board aims to provide the best possible care to all its patients but there may be occasions when the standard of care falls below what it should be. When assessing qualifying liability, the legal test looks at what would be the minimum standard of care that should have been provided.

The minimum standard of care is assessed against the standard which would have been provided by a responsible body of similar professionals carrying out similar treatment to that complained of. If treatment falls below the minimum standard there has been a breach of duty.

Stage 2 - Causation of harm

To establish the second part of the test it must be established that the breach of duty caused some harm to the patient. This part of the test considers whether the treatment received or omitted made matters worse for that patient. It is a question of whether on the balance of probabilities the outcome would have been different for the patient had the Health Board not breached its duty of care.

Where this is indicated, there is a qualifying liability in tort and a consideration of an offer of redress is necessary.

Redress can take the form of:

- A formal apology.
- Remedial action.
- Investigation and explanation.
- Financial compensation up to £25,000.00.

A Redress Panel has been established to enable the Health Board to manage its responsibilities under the Regulations. The Panel is chaired

by the Director of Nursing. Where an IO determines a breach of duty has occurred or considers this may be likely, the case will be presented to the Redress Panel for consideration, coordinated by the Senior Manager – Putting Things Right.

The IO will complete a Redress proforma (Situation, Background, Assessment, Recommendations - SBAR) and will attend the Panel to present the case.

21 Education and Training

All staff are required to report incidents concerning patient safety. Staff will participate in education and training on serious incidents commensurate with their role and responsibilities.

The Putting Things Right training programme is available two ways:

- A 2-day face-to-face training programme, which includes learning about serious incidents can be booked via Electronic Staff Record (ESR).
- An on-line national course. The level of training required by individual staff is in line with the Key Skills Framework.

Staff at all levels of the Health Board can access the online learning via <C:\Users\we132072\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\LGC2LMQW\tw> the Electronic Staff Record “NHS Wales Putting Things Right”

The training is divided into sections for all staff, at all levels:

- All staff should complete Sections 1, 2 and 5.
- Sections 3 and 4 are applicable to Managers, Specialist Leads, Service Group Leads and Board Members.

Investigating Officers assigned to investigating a serious incident are required to use the toolkit developed by the Quality and Safety Unit to guide their investigation and to ensure a consistent approach to investigating, reporting and managing serious incidents.

Please see Appendix 10 for the Serious Incident Toolkit.

22 Assurance on Reporting Serious Incidents

Monitoring of open and closed serious incidents will be reported bi-monthly through the Quality Governance Group, the Executive Team and assurance via the Experience, Quality and Safety Committee to the Board.

The following key performance indicators comprise an initial suite of indicators for use, recognising that information and data collection is in development for some cited*. Indicators will be subject to change to reflect the NHS Wales Delivery Framework requirements and local performance:

- Number of new serious incidents;
- Overall breakdown of serious incidents, by site, number, subject, staff group and themes;
- Investigating Officer assigned (Yes/ No);
- Proportion of serious incidents reported to Welsh Government;
- Number of serious incidents reported within 24 hours of the event;
- Number of new cases for redress since the last report;
- Overall position on serious incidents since the last report;
- Of the serious incidents due for assurance, the percentage which were assured within the agreed timescales;
- The percentage of serious incidents that remain open after 60 working days;
- Number of new never events;
- The number of avoidable pressure ulcers reported as serious incidents;
- Number of administration, dispensing and prescribing medication errors reported as serious incidents; and,
- Number of patient falls reported as serious incidents.

23 Storage and Management of Serious Incidents Files

All serious incident related information and data, inclusive of the investigation report and action plan will be held by the Concerns Team.

- The Serious Incident file must include the IO's report and any other relevant information concerning the investigation.
- The serious incident file is disclosable.
- The (paper and electronic) serious incident file must be kept for a period of 10 years. Records relating to maternity serious incidents should be retained for 25 years and in the case of children until they attain the age of 25 (with the minimum 10-year provision). ** No medical records can currently be culled due to the IICSA (independent Inquiry into Child Sexual Abuse) and the Infected Blood Inquiry.
- It is the responsibility of the Directorate Management Team to ensure that this file is complete, accurate and holds no contentious remarks.
- If a serious incident becomes a claim then the file will be combined into the Litigation File.

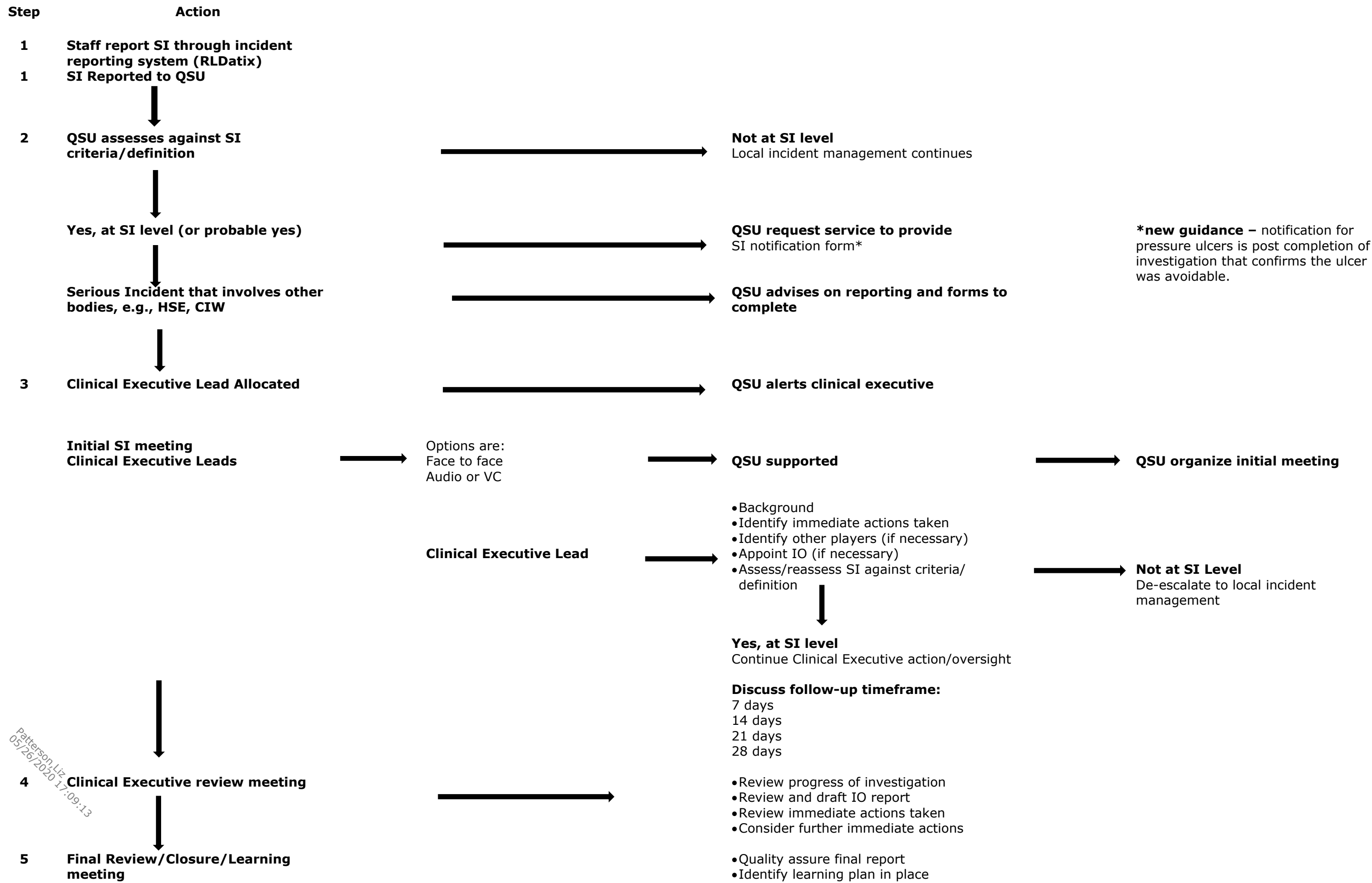
24 Review and Change Control

This Policy will be monitored by the Quality Governance Group and will be subject to review every three years or sooner in light of new guidance, legislation or organisational change.

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Serious Incident Action Flowchart
Key:
Investigation officer: IO
Quality and Safety Unit: QSU
Serious incident : SI



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Closure of Serious Incidents Pre-Coroner Inquests or pre-receipt of external investigation reports, e.g. HSE



- Follow-up actions
- Sign off Welsh Government SI Closure Form
- Clinical Executive/ Executive recommends closure of serious incident on basis of robust internal health board investigation and lessons learnt and shared
- QSU and Directorates track Coroner inquest date and/or date the external report is available to ensure received
- Clinical Executives oversee the review and reflection of Coroner/ external investigation reports, ensuring additional lessons for learning are shared and implemented
- Information on actions taken is reported to the QSU via concerns.qualityandsafety.pow@wales.nhs.uk for onward reporting to Welsh Government

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Appendix 2



Serious Incident Notification Forms / Reporting

The following forms are included in this appendix.

- Notification of serious incident form
- Update on serious incident form
- Closure Summary serious incident form
- No Surprise -Sensitive Issue form
- I(RM)ER – notification of radiation incidents

Please complete the form as much as possible and send to concerns.qualityandsafety.pow@wales.nhs.uk. If you require any assistance with completing a form, please contact the Concerns Team 01874 71267/2699.

When completing the form please ensure:

- All boxes on the form are completed with as much information and detail as possible (**do not include patient or staff identifiable details**);
- An explanation as to why there has been a delay in reporting the incident, if applicable;
- It is clearly noted if another Health Board or NHS Trust is involved and which NHS organisation will lead the investigation;
- Acronyms or abbreviations are not used;
- All forms are password protected; and
- All serious incidents must be reported through the Datix risk management system via the incidents module.

Where **a serious incident is linked to two or more health organisations**, all bodies are required to report the incident. When a joint investigation is completed, Welsh Government requires the lead organisation to submit a consolidated incident closure summary form (that is, including the findings from other organisations) in accordance with assurance timeframes.

Within one working day of receipt of a serious incident form, the Welsh Government will issue an email acknowledgement to the Health Board including a Welsh Government reference number. In addition to the Welsh Government Serious Incident arrangements, the Health Board is required to report all patient safety incidents (irrespective of seriousness and degree of harm) to the National Reporting and Learning System (NRLS). This is to inform the prioritisation and development of safety solutions, including alerts and guidance. This is done via the Datix risk management system administrators.

The arrangements for the reporting of serious incidents to Welsh Government and NRLS do not replace the requirement to report to other bodies.



Notification of Serious Incident form

RESTRICTED WHEN COMPLETED

NOTIFICATION OF SERIOUS INCIDENT (FORM SI 1)

Llywodraeth Cymru
Welsh Government

WG Reference			WG Grading	
Internal Ref or Datix No.			Date reported to Risk Management	
Organisation				
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:			
Date of making this report				
When did the incident occur?	Date:		Time (24 hours):	
Category of Incident (as per NRLS Incident Type Coding List)				
Is this a <i>never event</i> ?				
Where did the incident occur, including site and speciality where relevant?			Local Authority Area	
Who did it affect and how many? (<i>personal details must not be included</i>)			Age of patient(s) if known (<i>Do not provide DOB</i>)	

Brief description of what happened	
Brief description of immediate action taken	
Brief description of action taken if this SI involves another HB/Trust or WHSSC?	
Details of Media interest	
Has this SI been reported to the NRLS?	
What other external agencies have been informed about this incident e.g. HIW/WHSSC?	
Any other relevant information (include No Surprise ref no or Serious Incident ref no if applicable)	
Chief Executive / Executive Sign off (This section must be completed)	Signature: _____ Title: _____ Date: _____
For WG use only:	

Update Summary for Serious Incidents



RESTRICTED WHEN COMPLETED

Llywodraeth Cymru
Welsh Government

WG Ref		NHS Grading	
NHS Ref			
Organisation	Powys Teaching Health Board	Date of incident	
Summary of incident (only complete if there is additional information to the original notification form)			
Cause of death (if applicable)			
Confirmation of actions implemented and arrangements for completing outstanding actions		Timescale (s)	
Please indicate if the incident is associated with non-compliance of a patient safety alert, a never event or a schedule 5?			

Arrangements for dissemination of shared learning / action internally and whether they have been shared with any other NHS Organisation / agency externally			
Is there a recurring Root Cause / Theme / Concern			
Any additional information attached	Yes: [] No: []		
Disclaimer	The information provided on this form summarises the action to date and we request an extension of 0 weeks to complete this investigation.		
Chief Executive / Executive Sign off (This section must be completed)	Signature: _____ Print Name: _____ Title: _____ Date: _____		
FOR WG USE ONLY:			
Incident Closed	Yes: [] No: [] Signature: Date:	Further action required	

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Closure Summary for Serious Incidents



RESTRICTED WHEN COMPLETED

CLOSURE SUMMARY (FORM SI 3)

Llywodraeth Cymru
Welsh Government

WG Ref		NHS Grading	
NHS Ref			
Organisation		Date of incident	
Summary of incident (only complete if there is additional information to the original notification form)			
Please provide the following: Issues/problems identified Contributory factors Root causes			
Cause of death (if applicable)			
Confirmation of actions implemented and arrangements for completing outstanding actions		Timescale (s)	

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Please indicate if the incident is associated with non-compliance of a patient safety alert, a <u>never event</u> or a schedule 5?	
Arrangements for dissemination of shared learning / action internally and whether they have been shared with any other NHS Organisation / agency externally	
Is there a recurring Root Cause / Theme / Concern	
Any additional information attached	Yes: [] No: []
Disclaimer	I confirm that this incident has been thoroughly investigated and the findings and recommendations have been agreed by the appropriate committee and have either been acted upon or plans are in place to implement the actions within an agreed timescale
Chief Executive / Executive Sign off (This section must be completed)	Signature: _____ Print Name: _____ Title: _____ Date: _____
FOR WG USE ONLY:	
Incident Closed	Yes: [] No: [] Signature: Date:
	Further action required

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No Surprise / Sensitive Issue form

RESTRICTED WHEN COMPLETED

Llywodraeth Cymru
Welsh Government

NOTIFICATION OF NO SURPRISE/SENSITIVE ISSUE (FORM SI 2)

WG Reference	
Organisation	
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:
Date of making this report	
Brief description of issue	
Brief description of any action and media handling	
Any other relevant information (include SI ref no if applicable / age of patient(s) if known, rule 43)	
Chief Executive / Executive Sign off (This section must be completed)	Signature: _____ Print Name: _____ Title: _____ Date: _____
For WG use only:	

Notification of IR(ME)R Serious Incident form



DRIVING
IMPROVEMENT
THROUGH
INDEPENDENT AND
OBJECTIVE REVIEW

SICRHAU
GWELLIANT
TRWY
AROLYGU ANNIBYNNOL
A GWRTHRYCHOL

Please complete all fields (* where applicable) - Guidance on completing and submitting IR(ME)R notification form is available on the [HIW Website](#) and the [Welsh Government Putting Things Right Website](#).

Your Reference:		Our Ref:	Our Grading:
Healthcare Organisation:			
*Hospital Name:			
*Department:			
Modality: (Please highlight the appropriate)	Diagnostic Imaging	Radiotherapy	Nuclear Medicine
Speciality:			
Date Incident Occurred:			
Brief Description of Incident:			
Date Incident Reported to Risk Management			
How many 'MGTI' ¹ were affected? (Please anonymise; use Patient A, Patient B)			
Age of 'MGTI' Patient(s)		Gender of 'MGTI' Patient(s)	
*Intended Site of Treatment e.g. Chest, Abdomen etc.		*Actual Site of Treatment	

¹ 'Much Greater Than Intended'

*Intended Dosage		*Actual Dosage	
Brief Description of Immediate Action Taken			
Media Interest (Actual or Potential)			
What other external agencies have been informed about this incident? ²			
Any other relevant information			
Form Completed by: (Name, Designation and e-mail)			
Incident Officer and contact details			
Date:			
Employer: ³ (Name, Designation, e-mail and Authorisation of form)			
Date:			

Please be aware that information collated through these forms will be used to enable HIW to evaluate healthcare organisations in line with the IR(ME)R regulatory requirements. We may also share this data set (anonymised) when we consider the need to do so to ensure patient safety or improve IR(ME)R services.

Please note that the completed form is sent to **both** HIW and the Improving Patient Safety Team.

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² E.g. other Health Boards, WHSSC, NRLS

³ Chief Executive

Appendix 3



Reporting Pressure Ulcers

Pressure ulcers have been the most commonly reported form of harm reported to Welsh Government. **The current method of reporting serious incidents of pressure ulcers to Welsh Government has changed.**

New system of reporting

The new system requires a report to be provided to Welsh Government at the point where the investigation and review is completed. The new report will include details of the incident and the investigation that followed.

Evidence must be provided that the pressure ulcer was avoidable and the actions taken to minimise the risk of recurrence.

The Health Board has **60 days from the time of discovery of the pressure ulcer (the incident) to the time it reports its closure form to Welsh Government.**

A specific form is used to report avoidable pressure ulcers only, as shown on the next page.

This form is **not to be used for other incident types**. You are also required to **attach a copy of the revised All Wales Pressure Damage Review Tool** with the form.

The Health Board's Pressure Ulcer Scrutiny Panel oversees the reporting and investigation process. The panel will agree the avoidable pressure ulcers that require reporting.

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Notification of Serious Incident form

RESTRICTED WHEN COMPLETED
AVOIDABLE PRESSURE ULCER



Llywodraeth Cymru
Welsh Government

Part 1	
NHS Ref	
Organisation	
Reporters name and title	
Date of making this report	
When did the incident occur?	
Pressure Ulcer grade	Grade 3 / Grade 4 / Unstageable
Where did the incident occur? (Hospital & hospital ward / Community setting)	
Age of patient(s) (Do not provide DOB)	
Brief description of what happened	
What immediate action was taken to ensure patient safety	
Have any other organisations been informed?	
Proceed to Part 2	

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Closure Summary for Serious Incidents

RESTRICTED WHEN COMPLETED

CLOSURE SUMMARY

PRESSURE ULCERS



Llywodraeth Cymru
Welsh Government

Part 2	
<p>Summary of the investigation</p> <p><i>Lessons learnt</i></p> <p><i>Issues or problems</i></p> <p><i>Contributory factors</i></p> <p><i>Root causes</i></p> <p>Please attach the All Wales Review Tool for Pressure Damage Investigation.</p>	
<p>Recommendations and actions taken to date</p> <p>Action plan to be attached including timescales of implementation</p>	
<p>Is this incident associated with a non-compliance of a patient safety alert or notice?</p>	
<p>What arrangements have been made to share the investigation report with the patient / family?</p>	
<p>Is this subject to a redress or clinical negligence claim?</p>	

Cause of death (if applicable)			
Has an inquest been scheduled or taken place? (if applicable)		If yes, has a Regulation 28 been issued?	
Is this incident associated with a recurring root cause theme? If so, what wider action is being taken?			
Chief Executive / Executive lead sign off (This section must be completed)			
For WG use only:			

****PLEASE ENSURE THAT THE ALL WALES REVIEW TOOL FOR PRESSURE DAMAGE INVESTIGATION IS ALSO COMPLETED AND SUBMITTED ALONG WITH THIS FORM****

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Appendix 4



Never Events List 2018-2019

The Never Events List is revised annually and the incidents below have been extracted from the 2018-2019 list.

Please go to the website to see the current list with full details
<http://www.patientsafety.wales.nhs.uk/never-events>

Surgical

1. Wrong Site Surgery
2. Wrong Implant / Prosthesis
3. Retained foreign object post procedure

Medication

4. Mis-selection of a strong potassium solution
5. Administration of medication by the wrong route
6. Overdose of insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation

Mental Health

9. Failure to install functional collapsible shower or curtain rails

General

10. Falls from poorly restricted windows
11. Chest or neck entrapment in bed rails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. Scalding of patients
15. Unintentional connection of a patient requiring oxygen to an air flowmeter
16. Undetected oesophageal intubation

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Appendix 5



Joint Investigations

Where a joint investigation takes place, one Health Board or NHS Trust will be identified as the lead organisation.

When a joint investigation is completed, Welsh Government requires the lead organisation to submit a consolidated incident closure summary form (that is, including the findings from other organisations) in accordance with assurance timeframes.

Joint investigation guidance exists for serious incidents that involve:

- NWIS
- Welsh Ambulance Services NHS Trust (WAST)
The Framework has been developed to consider all potential serious incidents reported to WAST via their Serious Case Incident Forum. These incidents may occur as a consequence or during delayed patient handovers at Health Board sites, and as a consequence of patients within the community awaiting a response by WAST, where the primary causative factor was that of notification to handover delays.

All joint investigations must be notified to the Concerns Team at concerns.qualityandsafety.pow@wales.nhs.uk in order that they can be tracked and to support communication between Concerns Teams in each health body.
Steps to take:

- Agree lead organisation
- Agree communication strategy
 - Key staff for communication purposes in each organisation. Representatives need to reflect key areas: executive lead, lead investigator, concerns team and communications team.
 - Being Open - link with patient(s), and/or their representative
 - Link with external bodies
 - Frequency of regular communication
 - Mode of communication (audios, face-to-face, letter)
 - Contact numbers / details
 - Media handling
- Scope of investigation
- Who will investigate
- Timeframes for investigation
- Arrangements for drafting of the investigation report
- Arrangements for sharing of the draft investigation report

- Arrangements for review, approval and sign off of the final investigation report
- Arrangements for putting in place solutions
- Arrangements for learning and sharing of lessons
- Arrangements for communicating the outcome of the investigation with the patient(s) and/ or their representatives
- Arrangements for joint Redress Panel (seek advice from the concerns team)

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Appendix 6



Guidance for Investigating Officers

Brief guide to Investigation

The IO will follow a common template and ascertain relevant factors relating to the actions of the individuals and communications with one another, the influence of the workplace or environment on the incident and the presence or absence of meaningful organisational defences or mitigation against this sort of incident.

Ensure that the staff are aware that they may be expected to complete a full statement to be used as part of the formal investigation. Statements should be completed as soon as possible after the incident (within two weeks). Staff must have support from the Concerns Team and where applicable, NWSSP – Legal and Risk Services or their Staff Side Representative. The IO will be present during these interviews. Signed statements should be agreed by all parties, that is, the IO, Legal & Risk Services, the staff member and the Concerns Team within four weeks. All drafts should be destroyed once final copies are agreed. The statements can then be used to answer any subsequent complaints/claims.

Ensure clinical notes, x-ray films, CTG's, ECG's, pathology and imaging results, observation charts, consent forms, etc., are located and secured by the Investigating Officer whilst the investigation is carried out. Where the notes are still required for patient management the investigation officer should secure copies. In the case of primary care incidents, permission needs to be sought from the Practice Manager and General Practitioner partners for access to their records.

Ensure equipment, medicinal products or other evidence involved in the incident is held in safekeeping by the IO. For primary care related incidents, permission needs to be sought from the Practice Manager and General Practitioner partners to investigate or remove equipment.

Ensure that the patient(s)/staff involved in the incident have been identified and where necessary set up a database of patients involved and their addresses.

Ensure the "Being Open" process has started and that patient(s)/staff directly involved/affected have had an:

- Explanation of what has happened
- Explanation of action to be taken if known
- An Apology

Remedial action for patients may include:

- Offering to provide counselling
- Providing further investigations and/or treatment
- Continued treatment
- Continued counselling and support
- Full explanation of the incident
- Compensation

Identify the staff involved in the incident and take action if required.

- Meet with key staff involved to establish record of events
- Brief them with regard to what is to happen (investigation process)
- If necessary, offer counselling and support
- Warn other staff of a potential increase in workload and time scale of this.
- Contact the Manager as soon as any information suggesting personal or professional misconduct is identified.

Immediate action relating to staff may be:

- Advice and support Suspension
- To consider whether there are any immediate actions necessary to prevent a reoccurrence of incident or to minimise the effects of the incident.

Undertaking the Investigation

- Review all immediate documentation/information, including any information given to patients about any risks involved.
- Obtain and document a chronology of events
- Immediate problems identified
- Arrange formal interviews
- Identify contributory factors

Individual - Sufficient experience/training

Failure to follow Health Board policies/procedures/ guidelines/ protocols

Workload at the time of the incident

Personal problems

Process:

What went wrong?

How did it go wrong?

Where did it go wrong?

Why did it go wrong?

Equipment: Was there a fault?
 Was it maintained properly?
 Was it user error?
 Was the user adequately trained?

Complete a comprehensive report and action plan detailing lead responsibility and time frames for presentation to the Concerns Team.

The initial report should be made available within 28-days of the first review meeting.

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Appendix 7

Reporting Serious Incidents that Involve Other Bodies

There are occasions where reporting to other bodies is required as appropriate and as required by each individual body. **All serious incidents involving other bodies must be notified to the mailbox concerns.qualityandsafety.pow@wales.nhs.uk**

1 Safeguarding People

All serious incidents relating to the safeguarding of individuals, are to be brought to the attention of the PTHB Safeguarding Team.

Staff reporting the serious incident are required to complete the referral forms to safeguarding.

Details about the Health Board's safeguarding team and guidance for completing referrals can be found at:
<http://nww.powysthb.wales.nhs.uk/safeguarding>

2 Coroner

All deaths that fall into the following categories must be reported to the Coroner by the senior clinician involved:

- Death is unexpected or unexplained;
- A death occurs in suspicious circumstances;
- If the death cannot readily be certified as being entirely due to natural causes;
- The death is linked to an accident, regardless of when it occurs, and this includes medical or nursing mishaps;
- The death may be due to or contributed to by a fall or fracture;
- Any questions of self-neglect or neglect by others considered contributing to the cause of death;
- Apparent suicides;
- Drug related deaths;
- The deceased was detained under the Mental Health Act 1983;
- Death following an operation or before full recovery from anesthetic;
- The death is linked with termination of pregnancy; and
- The death could be due to or contributed to by industrial disease.

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There are other circumstances when a death should be reported to the Coroner but careful consideration must be given to such circumstances and advice sought from the Concerns Team if unsure.

Such examples are:

- Where a death is due to malnutrition or exposure to hypothermia
- The death may be due to lack of medical care
- The death occurs with 24 hours of admission to hospital, unless the admission was purely for medical care
- Careful consideration should be given to reporting a death where there is, or is likely to be, an allegation of a complaint.

Notification to the Coroner must be communicated to the Concerns Team via telephone (01874 712697/2699) or email concerns.qualityandsafety.pow@wales.nhs.uk to ensure early engagement for purposes of taking statements for the Coroner where requested.

3 Health and Safety Executive (HSE)

If a serious incident in the workplace is considered to be breaking health and safety law and is likely to cause serious harm and you consider it requires reporting to the Health and Safety Executive, during working hours the Health Board's health and safety manager/ advisor must be informed and they will onward report to the HSE.

Outside of normal working hours the Operational on call and Executive Lead will discuss action and communication.

The health and safety policy outline the steps to be taken and can be accessed via: <http://www.powysthb.wales.nhs.uk/health-and-safety-policies-and-guidance>
Website: <https://www.hse.gov.uk>

4 Police

Where a serious incident requires police involvement, the staff must ensure that they notify the Executive Lead and Concerns Team, this will support an early agreed approach to the serious incident investigation, ground rules to be set and identification of key contacts for communication in the Health Board.

The key contact for the police should be an Executive or his/ her representative.

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Timescales for police interviews, provision of medical records and arrangements for statements will be agreed early in the investigation process. The police should provide copies of all statements supplied to them as soon as possible to the investigating officer and Concerns Team. The Concerns Team will share these with NHS Wales Shared Services Legal & Risk Services.

5 Information Commissioner's Office (ICO)

There are certain incidents concerning patient safety that the Health Board may need to tell the Information Commissioner about.

Advice and guidance can be sought from the Information Governance Team as to the type of incidents that require reporting, they can be accessed via:

<http://nww.powysthb.wales.nhs.uk/information-governance>

The Information Governance Team will report serious IG incidents to the Information Commissioner's office.

Notification to the Concerns Team via telephone (01874 712697/2699) or email

concerns.qualityandsafety.pow@wales.nhs.uk is to ensure early communication and liaison for the purposes of reporting to both the ICO and Welsh Government.

Website: <https://ico.org.uk>

6 Healthcare Inspectorate Wales (HIW)

Healthcare Inspectorate Wales will carry out reviews of healthcare organisations or services in response to concerns arising from a particular incident or incidents, this is dependent on the seriousness and/ or frequency of occurrence.

A decision to undertake an investigation may be determined or influenced by the intelligence gathered.

Independent Healthcare Providers must notify HIW when a particular event occurs as stated in the Independent Healthcare (Wales) Regulations 2011.

Notification of radiation incidents, that is, any unintended or ill-advised event when using radiation apparatus or radioactive substances, which has the potential to result in, or exposure to radiation, to any person or the environment, outside the normal expected range requires reporting to Healthcare Inspectorate Wales. IR(ME)R incidents can be reported using the form shown in Appendix

2. Notification of all Serious Incidents is via the Concerns Team by telephoning (01874 712697/2699) or emailing concerns.qualityandsafety.pow@wales.nhs.uk to ensure prompt action and support and reporting to other bodies, that is, Welsh Government and consideration of reporting to the Health and Safety Executive.

Website: <https://hiw.org.uk>

Care Inspectorate Wales (CIW)

Services registered with Care Inspectorate Wales (CIW), that is registered under the Regulation and Inspection of Social Care Act (Wales) 2016, are required to report serious incidents that happen in services.

Notification to the Concerns Team via telephone (01874 712697/2699) or email concerns.qualityandsafety.pow@wales.nhs.uk to ensure prompt action, support and reporting.

Website: <https://careinspectoratewales>

8 Medicines and Healthcare Products Regulatory Agency (MHRA)

Any adverse incident involving a medical device or medicine must be reported to the MHRA. Incident reports should contain as much detail as possible but should not be delayed reporting for the sake of gathering more information.

Notify the adverse incident to the:

- Medical Devices Manager for medical device incidents
- Pharmacy Department for medicine incidents
- Concerns Team via telephone (01874 712697/2699) or email concerns.qualityandsafety.pow@wales.nhs.uk to ensure prompt action, support and reporting.

Website: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products>

9 Mothers and Babies - Reducing Risk through Audits and Confidential Enquiries (MBRRACE-UK)

Carry out surveillance and investigate the causes of maternal deaths, stillbirths and infant deaths. Reporting is via the midwifery services.

10 Human Tissue Authority

Serious incidents/ reactions linked to the procurement, testing, processing, storage and distribution of human tissues and cells for human application.

Notification to the Concerns Team via telephone (01874 712697/2699) or email concerns.qualityandsafety.pow@wales.nhs.uk to ensure prompt action, support and reporting.

Website: <https://www.hta.gov.uk/policies/serious-adverse-event-or-reaction-saears>

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Appendix 8



Grading of Concerns

The All Wales grading framework is based on a risk matrix (National Patient Safety Agency (2008). A risk matrix for risk managers, NPSA, London) and has been used to assess and manage risks and incidents. This approach underpins the development of a framework for determining the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across NHS Wales.

The impact or harm experienced by the patient is always the overriding factor for grading concerns. The harm grading is dynamic in nature and must be considered throughout the investigation. Due consideration should also be given to the potential for litigation, regardless of the harm grading. However, there may be situations where the grading of harm is low i.e. a grade 2, but there is indication there they will be pursuing a claim.

The examples listed are meant only to be a guide and not an exhaustive list. (Putting Things Right Guidance, 2013)

Grade	Examples of Concern	Potential for Qualifying Liability / Redress
1 No Harm	<ul style="list-style-type: none"> Concerns which normally involve issues that can be easily/speedily addressed, with no harm having arisen (e.g., outpatient appointment delayed but no consequences in terms of health, difficulty in car parking etc.) but have impacted on a positive patient experience. Labelling error in Pathology detected pre-analytically. 	Highly Unlikely.
2 Low Harm	<ul style="list-style-type: none"> Concerns regarding care and treatment which span a number of different aspects/specialties. Increase in length of stay by 1-3 days. Patient fall - requiring minor treatment. Requiring time off work - 3 days. Concern involves a single failure to meet internal standards but with minor implications for patient safety. 	Unlikely.

Grade	Examples of Concern	Potential for Qualifying Liability / Redress
	<ul style="list-style-type: none"> Return for minor treatment, e.g. requiring local anaesthetic, further treatment/monitoring by GP. Samples taken from the wrong patient – not acted upon but require repeat venepuncture. Pathology labelling error detected post analytically before further intervention 	
<p>3 Moderate Harm</p>	<ul style="list-style-type: none"> Clinical process/issues that have resulted in avoidable, semi-permanent injury or impairment of health or damage that requires intervention. Additional interventions required or treatment/appointments needed to be cancelled. Re-admission or return to surgery, e.g. requiring general anaesthetic. Necessity for transfer to another centre for treatment/care (e.g. for an incident in a GP Practice, admission to hospital). Increase in a length of stay by 4-15 days. RIDDOR reportable incident (moderate harm). Requiring time off work – 4-14 days. Concerns that outline more than one failure to meet internal standards. Moderate patient safety implication. Concerns that involve more than one organisation (e.g. cross border incidents that may involve English Providers or other Health Boards, incidents involving interface with Local Authority or Ambulance Trusts). 	Possible in some cases.
<p>4 Severe Harm</p>	<ul style="list-style-type: none"> Clinical process issues that have resulted in avoidable, semi-permanent harm or impairment of health or damage leading to incapacity or disability. Additional interventions required or treatment needed to be cancelled. 	Likely in many cases.

Grade	Examples of Concern	Potential for Qualifying Liability / Redress
	<ul style="list-style-type: none"> • Unexpected re-admission or unplanned return to surgery. • Increase in length of stay by more than 15 days. • Necessity for transfer to another centre for treatment/care. • Requiring time off work – more than 14 days. • A concern outlining non-compliance with national standards, with significant risk to patient safety. • RIDDOR reportable incident (significant harm). • Pathology: Specimen loss, labelling error detected post analytically following further intervention. • 'Wrong Blood' transfusion 	
5 Catastrophic Harm	<ul style="list-style-type: none"> • Concern leading to unexpected death, multiple harm or irreversible health effects. • Concern outlining gross failure to meet national standards. • Clinical/process issues that have resulted in avoidable, irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental wellbeing. • Clinical process or issues that have resulted in avoidable loss of life. • RIDDOR reportable incident (catastrophic harm). • Significant/consistent reporting errors i.e. malignant as benign. 	Very likely.

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Appendix 9

Levels of Investigation

The initial grading of a serious incident is undertaken on a case by case basis and will clarify the level of investigation required and monitoring approach. It is essential that the investigation is proportionate to the grade of the serious incident.

The table below provides a guide to the level of investigation required and outlines the recommended, standardised tools which should be used for different grades of concerns/ serious incident and who should investigate.

Grading	Application	Investigation Tools	Undertaken by	Timescales for Completion
<p>Putting Things Right (PTR) Grading of 4 and 5 (Possibly 3 where considered appropriate by the Health Board)</p> <p>Risk Rating of:</p> <ul style="list-style-type: none"> 8-12 high risk (Amber) 15-25 extreme risk (Red) <p>Patterson, Liz 05/26/2020 17:09:13</p>	<p>Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable</p> <p>Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or</p>	<p>Tabular Timeline (& brainstorming) with Classification Framework (& fishbone)</p> <p>and/or 5 Why's</p> <p>and/or Change Analysis Barrier Analysis</p> <p>Action Plan Report Writing Template</p>	<p>Investigation Team</p> <p>Examples are:</p> <p>Patient Safety Lead, Senior Investigation Manager, lay person, Senior Professional or Service staff external to the location and specialty of the serious incident.</p> <p>Expert in the specialty or location and of the serious incident.</p>	<p>NHS Organisations are required to provide Welsh Government with an assurance that a robust investigation has been completed and learning identified within 60 working days.</p> <p>Concerns Team involvement throughout. Duty of Candour. Timescales for draft written responses under PTR to affected patients/ family within 30 working days-6 months but regular communication to be agreed. ** To note some investigations</p>

Grading	Application	Investigation Tools	Undertaken by	Timescales for Completion
<div> Patterson, Liz 05/26/2020 17:09:13 </div>	number of organisations involved			<p>may complete within the 30- working day timescale.</p> <p><u>Timescales</u></p> <p>Executive Led Initial scoping / Terms of Reference 1-2 working days **Joint Investigations must be coordinated by Executive Leads in Health Boards/ NHS Trusts</p> <p>Investigation led by assigned Investigation Officer (IO) 3-25 working days</p> <p>Executive Lead Review 26-30 working days</p> <p>Additional Work 31-36 working days</p> <p>Executive Lead sign off 37-42 working days</p>

Grading	Application	Investigation Tools	Undertaken by	Timescales for Completion
				<p>Serious Incident Panel Review and Approval / Concerns Team involvement 42-47 working days</p> <p>Written draft responses to patient / families (Regulation 24/ 26 letter) Signed off by CEO via the Concerns Team.</p> <p>Assurance to Welsh Government within 60-working days.</p>
<p>PTR Grading of 1 and 2 (Possibly 3 where considered appropriate by the Health Board)</p> <p>Risk Rating of:</p> <ul style="list-style-type: none"> 1-3 negligible risk (Green) 4-6 minor risk (Yellow) 	Suited to less complex incidents which can be managed by individuals or a small group at a local level	<p>Tabular Timeline (& brainstorming)</p> <p>5 Whys</p> <p>Action Plan Report Writing Template</p>	Department/Ward/Community Team Manager & member of the local team.	<p>NHS Organisations are required to provide Welsh Government with an assurance that a robust investigation has been completed and learning identified within 60 working days.</p> <p>Concerns Team involvement throughout. Duty of Candour. Timescales for draft written</p>

Grading	Application	Investigation Tools	Undertaken by	Timescales for Completion
<p>Patterson, Liz 05/26/2020 17:09:13</p>				<p>responses under PTR to affected patients/ family within 30 working day timescale and regular communication to be agreed.</p> <p><u>Timescales</u> Senior Service Manager Initial review 1 working day **Joint Investigations must be coordinated by Senior Service Managers in Health Boards/ NHS Trusts</p> <p>Investigation and Service Manager Review 2-17 working days</p> <p>Executive Lead sign off 18-20 days</p> <p>Concerns Team 21-24 days</p>

Grading	Application	Investigation Tools	Undertaken by	Timescales for Completion
				<p>Written draft responses to patient / families (Regulation 24/ 26 letter) Signed off by CEO via the Concerns Team 25-28 days.</p> <p>Assurance to Welsh Government within 60-working days.</p>

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Appendix 10



Serious Incident Toolkit

Detailed investigation guidance and templates can be found within the Serious Incident Toolkit.

The serious incident toolkit contains the following:

- Executive Lead / Service Manager guidance
- Agenda template for serious incident meetings
- Terms of Reference template
- Serious Incident Forms
- Levels of Investigation
- Grading of Concerns (includes serious incidents)
- Investigation Booklet
- Investigation Report Template
- Joint Investigation Guidance for serious incidents involving:
 - NWIS
 - Welsh Ambulance Services NHS Trust
- Learning from Events Report
- Template letters for CEO response to patients, and/or their representatives

The toolkit can be accessed via: <http://www.powysthb.wales.nhs.uk/serious-incidents-reporting-investigatin>

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Agenda item: 2.5b

BOARD MEETING		Date of Meeting: 27 MAY 2020
Subject :	Management of Compensation Claims: Clinical Negligence & Personal Injury	
Approved and Presented by:	Alison Davies Executive Director Nursing & Midwifery	
Prepared by:	Wendy Morgan Assistant Director Quality & Safety	
Other Committees and meetings considered at:	Quality Governance Group 21 May 2020	

PURPOSE:

This paper provides the Board with the revised Management of Compensation Claims: Clinical Negligence & Personal Injury policy (see Appendix 1) for approval.

RECOMMENDATION(S):

The Board is asked to:

- **Approve** the Management of Compensation Claims: Clinical Negligence & Personal Injury policy.

Approval/Ratification/Decision	Discussion	Information
✓	x	x

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Management of Claims Policy

Board Meeting
27 May 2020
Agenda Item 2.5b

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	x
	2. Provide Early Help and Support	x
	3. Tackle the Big Four	x
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	x
	6. Promote Innovative Environments	x
	7. Put Digital First	x
	8. Transforming in Partnership	x
Health and Care Standards:	1. Staying Healthy	x
	2. Safe Care	✓
	3. Effective Care	x
	4. Dignified Care	x
	5. Timely Care	x
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

This paper provides the Board with the Management of Compensation Claims: Clinical Negligence & Personal Injury policy for approval. The policy has been reviewed and updated, and subject to consultation in December 2019, at which time it attracted two comments and further presented to the Quality Governance Group in May 2020. The policy has not required any additional amendments in response to the feedback provided.

DETAILED BACKGROUND AND ASSESSMENT:

A Management of Compensation Claims: Clinical Negligence & Personal Injury policy is required to be in place and effectively discharged for the purposes of managing compensation claims within Powys Teaching Health Board.

The policy describes systems and processes for handling of compensation claims, clinical negligence and personal injury, made against the health board.

The policy has been reviewed and updated to take account of learning from events, introduced by the Welsh Risk Pool Services in May 2019. All compensation claims considered for reimbursement will be scrutinised for evidence of lessons learnt and improvement actions taken by the health board. Reimbursement (both interim and final) will be deferred until the Welsh Risk Pool Committee is satisfied with learning and the actions taken.

Consultation

The Management of Compensation Claims: Clinical Negligence & Personal Injury policy was issued for consultation for a two-week period from 20 December 2019 to 9 January 2020.

Two comments received:

Section 10.2

Clarity of how the incident has been reported, that is, via Datix.

In considering the comments no changes were made to the policy. An incident may have occurred a number of years previous to a letter of claim being received. At the time of the incident, Datix may not have existed or another system may have been in use. With regards to this section, the incident will be identified in the letter of claim received by the health board, which will then prompt further enquiries.

Section 10.1 and 10.3

Do we need to include or add something surrounding a staff member who has submitted a claim? They may receive different advice from the solicitor and the information in these 2 sections could cause conflict.

In considering the comments no changes were made to the policy. If a staff member submits a claim, it will be through solicitors they have engaged to act on their behalf. Sections 10.1 and 10.3 relate to staff who are involved in incidents leading to a compensation claim.

Quality Governance Group

The policy was discussed at the Quality Governance Group 21 May 2020; the policy was supported for onward presentation to Board for approval.

NEXT STEPS:

- 1) Following approval, the Management of Compensation Claims: Clinical Negligence & Personal Injury policy is communicated to staff.
- 2) Action is taken to implement the policy.

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Management of Claims Policy

Board Meeting
27 May 2020
Agenda Item 2.5b

The following Impact Assessment must be completed for all reports requesting Approval, Ratification or Decision, in-line with the Health Board's Equality Impact Assessment Policy (HR075):

IMPACT ASSESSMENT				
Equality Act 2010, Protected Characteristics:				
	No impact	Adverse	Differential	Positive
Age	✓			
Disability	✓			
Gender reassignment	✓			
Pregnancy and maternity	✓			
Race	✓			
Religion/ Belief	✓			
Sex	✓			
Sexual Orientation	✓			
Marriage and civil partnership	✓			
Welsh Language	✓			

Risk Assessment:					
	Level of risk identified				Statement
	None	Low	Moderate	High	
Clinical	✓				If an approved policy is not in place to support the health board and its staff in the management of compensation claims, there is the potential for poor handling of compensation claims which could lead to both financial loss and reputational harm. This will further impact on any opportunity for learning and improvements to be put in place to mitigate against recurrent incidents resulting in further harm, prompting potential redress and compensation claims.
Financial		✓			
Corporate	✓				
Operational	✓				
Reputational		✓			

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Management of Claims Policy

Board Meeting
27 May 2020
Agenda Item 2.5b



MANAGEMENT OF COMPENSATION CLAIMS CLINICAL NEGLIGENCE & PERSONAL INJURY

Document Reference No:	PTHB / PEP 003	
Version No:	7	
Issue Date:	TBC	
Review Date:	March 2023	
Author:	Assistant Director Quality & Safety	
Document Owner:	Assistant Director Quality & Safety	
Accountable Executive:	Director of Nursing	
Approved By:		
Approval Date:		
Document Type:	Policy	Clinical / Non-clinical
Scope:	PTHB wide	

The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

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Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	2001
2	Revision following organisational change	OCT 2004
3	Review of existing policy	OCT 2007
4	Review & revision of existing policy <ul style="list-style-type: none"> Amended following organisational restructure Amended following Quality & Safety Unit restructure 	OCT 2012 DEC 2013
5	Review of existing policy	JUN 2015
6	Following an Internal Audit Recommendation amendments to Section 9 Compensation Claims Management Procedures have been made as follows: <ul style="list-style-type: none"> 9.1. Clarification that 'procedures' form part of this Policy document and are not being developed separately. 9.2. removal of the words "The Claims Management Procedure will" Removal of reference 9.3 	AUG 2016
7	Reviewed and updated. <ul style="list-style-type: none"> Amendment of coding from CP 025 to PEP 003 <i>as applied by Corporate Department in 2018.</i> Feedback received regarding clarification on Section 10 	DEC 2019

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ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation

Circulated to the following for Consultation

Date	Role / Designation
20/12/19	PTHB Wide Consultation sought via Powys Announcement.

Evidence Base

Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area?

- Section 8 PTR Guidance. Clinical Negligence and Personal Injury Litigation: Claims Handling: Putting Things Right, Guidance on dealing with concerns about the NHS from 1 April 2011 (Version 3 November 2013) which supersedes WHC(97)17 Clinical Negligence and Personal Injury Litigation: Structured Settlements
- The Civil Procedure Rules 1998
- Welsh Risk Pool Services (May, 2019) Case Reimbursement Procedure
- WHC(98)8 NHS Indemnity Arrangements for Handling Clinical Negligence Claims against NHS Staff
- WHC(99)128 Handling Clinical Negligence Claims: Pre-Action Protocol
- The Welsh Risk Pool Services Reimbursement Procedure and other Procedures
- The Health board Standing Orders and Standing Financial Instructions
- The Limitation Act 1980
- Health and Care Standards - [Standard 6.3 Listening & Learning from Feedback](#)

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IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	Adverse	Differential	Positive	Statement
Age	✓				<p>This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of age, disability, gender, sexual orientation, race, religion / belief or human rights.</p> <p>A redacted version can be uploaded to the internet in Welsh and English. The procedural sections apply to staff not the general public.</p>
Disability	✓				
Gender reassignment	✓				
Pregnancy and Maternity	✓				
Race	✓				
Religion or Belief	✓				
Sex	✓				
Sexual Orientation	✓				
Marriage and Civil Partnership	✓				
Welsh Language	✓				
Risk Assessment Summary					
<p>Have you identified any risks arising from the implementation of this policy / procedure / written control document?</p> <p>No risks have been identified from the implementation of this policy.</p>					
<p>Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?</p> <p>Information Governance policies & procedures are adhered to when managing compensation claims.</p>					
<p>Have you identified any training and / or resource implications as a result of implementing this?</p> <p>No specific training is required for staff in general. Update training for the Senior Putting Things Right Manager & Assistant Director Quality & Safety /Concerns Team may be required should there be any significant changes to current legislation in the UK.</p>					

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1. Policy Statement

- 1.1 This document describes the policy of Powys Teaching Health Board (herein referred to as the 'health board') for the management of negligence and personal injury claims made against the health board. The new General Medical Practice Indemnity Scheme is described in a separate policy.
- 1.2 Both the human costs of things going wrong and the financial costs of providing redress are powerful incentives for effective risk management. It is acknowledged that funds that are spent on addressing and compensating could otherwise contribute to the continuous improvements of healthcare services and working environments. Therefore, this Policy forms an integral part of the Health board's Risk Management, Putting Things Right and Organisational Learning Strategies and is intrinsically linked into the health board's systems for managing and learning from serious untoward incidents and concerns.
- 1.3 The health board aims to deal with all compensation claims made against it proactively, in an equitable, efficient and timely manner. In accordance with the Woolf Reforms, the health board will deal with each case on its own merits, taking advice from its legal advisors and others, as appropriate.
- 1.4 The health board will comply with the Pre-Action Protocols laid down by the Civil Procedure Rules in dealing with all legal claims ensuring a constructive and open approach to compensation claims that reduces delays and costs and the need for formal legal proceedings.
- 1.5 The health board will comply with the requirement for reimbursement of claims settled under NHS Indemnity (Welsh Risk Pool Services (May, 2019) Case Reimbursement Procedure).
- 1.6 The health board is committed to learning lessons from compensation claims to ensure the continued improvement in standards of patient and staff safety and services. The Senior Manager, Putting Things Right will support Directors, key managers and staff in this process through the provision of relevant information,

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which will assist in ensuring that lessons are learned and appropriate corrective and/or preventive action is taken and implemented in an effective manner.

2. Introduction

- 2.1 This Policy has been produced in accordance with the evidence base references for the management of the following:
- clinical negligence claims
 - redress claims
 - personal injury claims
 - property damages/losses and compensation claims
- 2.2 The health board has a legal duty of care towards those it treats, together with members of the general public and its staff. People who consider they have suffered harm from a breach of this duty can make a claim for compensation and damages against the health board.
- 2.3 For a claim to be successful, a claimant must prove:
- that he/she was owed a duty of care
 - that the duty was breached
 - that the breach of duty caused, or contributed materially to, the damage in question
 - that there were consequences and losses flowing from the damage
- 2.4 The Limitation Act 1980 requires that compensation claims be made within three years of the date of the incident or three years from the date a claimant became aware that he/she had suffered from an episode of negligence. With minors, the three-year limitation period becomes effective once they have reached the age of 18 years old.

There are no time limits for people with a disability who cannot manage their own affairs. Claims exceeding the three-year limitation period can, however, still be brought against the health board at the discretion of the Court

3. Definitions

The following provide definitions in respect of the types of compensation claims managed in accordance with this Policy.

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3.1 Clinical/ Medical Negligence: *"A breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgments made by members of those professions acting in their professional capacity in the course of employment, and which are admitted as negligent by the employer or are determined as such through the legal process."*

3.2 Redress Claims: *"Concerns raised under Putting Things Right involving a qualifying liability in tort resolved by the settlement of damages to a maximum of £25,000."*

3.3 Personal Injury: *"Any disease or impairment of a person's physical or mental condition."*

3.4 Property Damage/Losses and Special Payments: *"Bad debts, losses, damage to/or loss of personal belongings through no fault of the individual."*

4. Responsibilities

- 4.1 The Chief Executive is the Board member responsible for issues relating to clinical negligence and personal injury and for keeping the health board informed of major developments.
- 4.2 All Executive Directors and Heads of Service have a delegated accountability and responsibility within their service areas for the implementation and adherence to this policy.
- 4.3 A sub-group of the Board ('the Sub-Group'), to include the Chief Executive, one other Executive Director, the Assistant Director of Quality & Safety and the Senior Manager, Putting Things Right will meet, as required, to determine action in respect of significant claims valued in excess of the Chief Executive's delegated limits.
- 4.4 The Senior Manager, Putting Things Right is accountable via the Assistant Director Quality & Safety to the Chief Executive for the management of compensation claims for ensuring compliance with this policy, including compliance with delegated authority limits and for securing the most cost-effective resolution of claims.
- 4.5 All members of staff are encouraged to report adverse

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incidents, including those that may lead to claims for compensation, in line with the health board's promotion of a just blame free culture. Staff also have a duty towards the health board in the investigation and, where appropriate, defense of all compensation claims, and will assist the Senior Manager, Putting Things Right as necessary during the claim's management process.

- 4.6 The health board's organisational structure for the management of claims is set out in Appendix 2.
- 4.7 Approval of this strategic Policy on the Management of Compensation Claims will rest with the Board although subsequent Claims Management Procedures with supporting and associated responsibilities including reporting responsibilities there from will be delegated by the Board to the Executive Committee.

5. Delegated Limits

Delegation of Out of Court Settlement

- 5.1 The health board acknowledges that the Welsh Government has delegated its responsibility for the settlement of claims to a limit of £1 million to health board and that the health board continues to exercise this discretion subject to satisfaction with minimum requirements:
 - that it adopts a clear policy for the handling of claims which satisfies the requirements of Section 8 of Putting Things Right – Guidance on dealing with concerns about the NHS (Version 3 – November 2013) ('Section 8 PTR Guidance')
 - that the requirements of Section 8 PTR Guidance form the basis of the procedure for the day to day management of claims
 - Learning from Events reports are completed for all claims settled below the excess and within the delegated limit and submitted to the Welsh Risk Pool for consideration of reimbursement

Internal Delegated Limits

- 5.2 The health board has formal delegated responsibility from the Welsh Government for the management of compensation claims valued up to £1,000,000.

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- 5.3 The levels of delegated authority within the health board are those contained within the Health board Scheme of Delegation. Details are attached in Appendix 3.
- 5.4 For significant claims (over the Chief Executive's delegated limits) where settlement is advised, the health board Sub-Group will agree the range of value which the Chief Executive or nominated representative has discretion to negotiate. All settlements within the negotiated range will be reported to the next available meeting of the Board or nominated committee.
- 5.5 In situations where a decision is necessary and it is not possible to comply with the Scheme of Delegation limits because of time constraints, the Chief Executive, or nominated Executive Director, will contact the health board's Chairperson, or nominated Non-Executive Director and recommend a course of action. (Chairperson's Action). Any action taken under Chairperson's Action will be reported to the next available meeting of the Board, seeking retrospective approval.

6. Use of Legal Advisors

- 6.1 The health board will use legal advisors in the defense or settlement of clinical negligence and personal injury claims, through the services of NWSSP Legal & Risk Services.
- 6.2 Where external legal advice is sought, the health board will retain the responsibility to direct its solicitors in respect of liability admission, defense, settlement and general tactics. Delegated authority will be provided for some activities. However, the health board will always take due account of qualified legal advice in making such decisions. Legal advice will cover:
 - Liability and causation;
 - An assessment of the strength of the available defense and probability of success;
 - The likely valuation of quantum of damages including best and worst case scenarios; and
 - Estimates of legal costs for plaintiff and defense.
- 6.3 The final decision to settle a compensation claim or to continue with its defense should be taken by the Board, appropriate Manager or Claims Manager in accordance with the delegated limits.

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7. The Role of the Senior Manager, Putting Things Right (Claims Manager)

- 7.1 The health board will employ a dedicated Senior Manager, Putting Things Right (*referred to in Section 8 PTR Guidance as the Compensation Claims Specialist*) who holds relevant experience and/ or qualifications in claims management.
- 7.2 The Senior Manager, Putting Things Right will be required to demonstrate ongoing updating and continuing professional development in the area of claims management.
- 7.3 The health board will ensure that the Senior Manager, Putting Things Right is either given sufficient seniority within the Trust to achieve the objectives of Section 8 PTR Guidance or the organisational structure is sufficient to ensure that this occurs. The Board will support the Senior Manager, Putting Things Right in the furtherance of these objectives.
- 7.4 The Senior Manager, Putting Things Right can exercise direct access and report to the Chief Executive and Executive Team as necessary to achieve the objectives of Section 8 PTR Guidance for effective claims management.
- 7.5 The Board authorises the development of an appropriate escalation procedure to which it will give its full support to highlight the profile of the compensation claims management process and its support for the Senior Manager, Putting Things Right. The escalation procedure is designed to ensure that all members of staff, throughout the health board acknowledge the importance of the claims management process and Board support thereof and will provide all necessary support to the furtherance of the objectives set out in this policy to ensure that compensation claims are managed proactively equitably and in an efficient and timely manner.
- 7.6 The Senior Manager, Putting Things Right will ensure that all members of staff and/or their line managers involved in a compensation claim are kept informed of the progress and outcome of the claim.

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8. Reporting Requirements

- 8.1 The Board delegates its responsibilities to the Executive Committee as the duly authorised committee. The Executive Committee will receive and review six- monthly progress reports on the management and status of claims against the health board, in the format specified by Section 8 PTR Guidance. The minutes of the Executive Committee will be provided to the Board for information purposes. This compensation claims report will include information on:
- The health board compensation claims profile and claims management record
 - Key issues and/or major developments affecting the health board
 - Number of compensation claims
 - Aggregate value of compensation claims in progress
 - Details of any major compensation claims
 - Progress and likely outcome of ongoing compensation claims including expected settlement dates
 - Value of compensation claims settled and final outcomes
 - Relevant trends
 - Information regarding remedial action as appropriate
- 8.2 The Executive Committee will receive an Annual Report reporting on comparative issues at the end of the relevant financial year.
- 8.3 The Terms of Reference of the Executive Committee as the duly authorised Committee will reflect its role in relation to compensation claims.
- 8.4 The Chief Executive retains responsibility for compensation claims management within the health board and will ensure that the Board is kept informed of significant and major developments.
- 8.3 It is acknowledged that where a compensation claim has been identified as a Patient Safety Incident but during the course of investigation, it is identified that it was not previously reported through the incident reporting process, the health board will ensure that a procedure exists which is set out in the Compensation Claims Management procedure, to ensure that a retrospective report is made to the National Reporting and Learning System.

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- 8.4 The reporting requirements relating to the reimbursement process managed by the Welsh Risk Pool are set out in Paragraph 15 as follows.
- 8.5 The reporting requirements to the Welsh Government are set out in Paragraph 12 as follows.

9. Compensation Claims Management Procedure

- 9.1 The Compensation Claims Management Procedure forms part of this policy in support of Section 8 PTR Guidance.
- 9.2 It sets out the processes and procedures for the day to day practical management of claims and associated matters.

10. Involvement of Front Line Staff

- 10.1 The health board recognises that the co-operation of all staff involved in the incident leading to a compensation claim is crucial to the early collation of information to that case. The health board will ensure that such staff are encouraged to support the Senior Manager, Putting Things Right and any duly appointed legal advisors, in the handling of that compensation claim. All staff members are required to fully and openly co-operate with the investigation of any legal claims and to comply with this Policy and the Compensation Claims Management Procedure emanating there from.
- 10.2 Once an incident has been reported, the Senior Manager, Putting Things Right will establish an objective account of the original incident at the earliest available opportunity, taking advice from colleagues where appropriate.
- 10.3 Unless there are exceptional circumstances, any member of staff asked to do so should provide the Senior Manager, Putting Things Right with a witness statement and information regarding the investigation of the relevant compensation claim in a timely manner.
- 10.4 The health board recognises that providing a statement and giving evidence can be a stressful experience and will ensure that full support and guidance is provided to members of staff who are asked to give evidence on behalf of the health board.

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- 10.5 The health board will support an escalation procedure to be contained in the health board's Compensation Claims Management Procedure to secure this objective.
- 10.6 The health board will take full responsibility for managing and where appropriate settling compensation claims in clinical negligence cases meeting all financial obligations and will not seek to recover any costs from health professionals save in very exceptional cases, where the health professional was legally found to be acting outside of his/her remit.

11. Nuisance Compensation Claims

- 11.1 The health board will not settle compensation claims of doubtful merit, however small, purely on a 'nuisance' value basis although such compensation claims will not be inappropriately defended.
- 11.2 The decision to settle a compensation claim will always be based upon an assessment of the health board's legal liability and the risks and costs associated with the defense of that compensation claim, including the prospects of recovering those costs in the event that the defense is successful.

12. Reporting of Compensation Claims to Welsh Government

- 12.1 **Novel, Contentious or Repercussive Compensation Claims.** The Senior Manager, Putting Things Right will monitor the nature and type of compensation claims received to ensure that any which are novel, contentious or repercussive are reported in advance of settlement of the Welsh Government and any required approvals are obtained at relevant stages. These may include compensation claims involving some unusual and new features which, if not correctly handled, might set an unfortunate precedent for other NHS litigation or which appear to represent test cases for a potential class action, or cases which, although not formally part of a class action, appear to be very similar in kind to concurrent claims against other NHS bodies. In such cases, the Senior Manager, Putting Things Right will contact the Welsh Government for advice regarding management.

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- 12.2 **Compensation Claims Exceeding the Delegated Authority.** The Senior Manager, Putting Things Right will ensure that any compensation claims with damages and costs estimated to exceed the Health board delegated authority of £1 million are reported to the Welsh Government and prior approval is obtained in advance of liability being conceded and the compensation claim being settled.

13. Databases

The Health board will maintain two databases:

13.1 Datix

The health board's claims data-base will contain all relevant information on all compensation claims and also the information prescribed in the Compensation Claims Management Procedure.

13.2 LaSPaR

The Losses and Special Payments Register (LaSPaR) is a computerised database previously introduced by the National Assembly for Wales to replace previous paper based systems with a national standardised format for actioning write-offs or special payments approval. The main objectives of LaSPaR are to:

- Ensure that health bodies monitor all aspects of losses and special payments, from initial registration to final outcome, on a case by case basis
- Allow health bodies and the Welsh Government to identify settlement/ claimant costs, provisions, and defense or other administration costs provisions, and to action any subsequent adjustments
- Ensure that all payments and income recoveries are identified separately and that analyses can be performed on all transactions.

- 13.3 All compensation claims will be entered onto both databases by an authorised member of staff. Other losses and special payment details will be similarly input.

- 13.4 The health board will ensure that patient and staff

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confidentiality is maintained.

- 13.5 Information that is gathered during the course of a claim will be stored in a suitably secure manner in line with the health board policies and procedures on Records Management, Data Protection and Confidentiality in line with the General Data Protection Regulations.

14. Learning from Events

- 14.1 The health board is committed to learning lessons from all events.
- 14.2 The revised WRPS Case Reimbursement Procedure, issued in May 2019 outlines the introduction of early scrutiny of learning from events reports for all cases. All cases to be considered for reimbursement will be scrutinised for evidence of lessons learnt and improvement actions taken by the health board. Reimbursement (both interim and final) will be deferred until the WRP Committee is satisfied with learning and the actions taken in case.
- 14.3 It is important that lessons are learnt following every event which may include concerns, compensation claims, reports from the Public Ombudsman for Wales, Rule 43 letters arising out of inquests etc. Each Director has responsibility for liaising with appropriate staff and ensuring any identified and agreed actions are implemented and monitored.
- 14.4 The health board will develop a structure to support its learning from events agenda and ensure that a formal process and procedure to support the learning of lessons, monitoring of implementation of lessons learned, evaluation of the efficacy of lessons learned and thereafter the auditing of each component, is developed.

15. Liaison with Welsh Risk Pool Services

- 15.1 The Welsh Risk Pool Services (WRPS) is the risk pooling scheme run for the benefit of members of NHS Wales.
- 15.2 The Health board will comply with the various rules and procedures of the WRPS. The Senior Manager, Putting

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Things Right will ensure the health board's adherence to the same.

- 15.3 The Senior Manager, Putting Things Right will report details of compensation claims settled to the WRPS by completing appropriate checklists and forms, such as the Financial Case Management Record, Case Management Report and learning from events and submitting via the electronic system Welsh.RiskPool@wales.nhs.uk within four calendar months of reaching financial settlement.
- 15.4 In order to be reimbursed by the WRPS, the health board must adhere to the WRPS Case Reimbursement Procedure, issued in May 2019.
- 15.5 The health board acknowledges that the WRPS will periodically undertake claims reviews of compensation claims managed by the health board and will ensure the co-operation of its members of staff with such reviews through the development of a formal claims review procedure to be contained in the Claims Management Procedure.

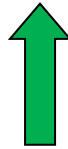
16. Review and Change Control

This document will be reviewed every three years or earlier should audit results or changes to legislation/ practice within PTHB indicate otherwise.

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RESPONSIBILITY FRAMEWORK

Chief Executive



Executive Director for Nursing



Assistant Director for Quality & Safety



Senior Manager, Putting Things Right

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**Appendix 2****SCHEME OF DELEGATION**

Approving individual losses and special payment claims in accordance with current Assembly Guidance:

Matter Delegated	Approving Officer
Up to £10,000	Assistant Director Quality & Safety
Up to £50,000	Executive Director of Nursing
Up to £100,000	Chief Executive Officer
Over £100,000 and Up to £500,000	Chief Executive Officer & Chairperson
Over £500,000 and Up to £1,000,000	Chief Executive Officer & Chairperson
Over £1,000,000	Welsh Government
<p>Notes:</p> <p>These limits relate to damages and / or costs payable.</p>	

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Agenda item: 2.6

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	Welsh Language Standards Update	
Approved and Presented by:	Claire Madsen, Director of Therapies & Health Sciences	
Prepared by:	Kathryn Cobley, Services Improvement Manager – Welsh Language	
Other Committees and meetings considered at:	Executive Committee, 06 May 2020	

PURPOSE:

The purpose of this paper is to provide an update to the Board on the Welsh Language Standards appeals process and to seek ratification following the decisions made by the Executive Committee held on 6 May 2020.

RECOMMENDATION:

The Board is asked to **RATIFY** and **NOTE** the update report.

Approval/Ratification/Decision	Discussion	Information
✓ Ratification		✓

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THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	✓
	2. Provide Early Help and Support	✗
	3. Tackle the Big Four	✗
	4. Enable Joined up Care	✗
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	✗
	8. Transforming in Partnership	✗
Health and Care Standards:	1. Staying Healthy	✗
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

This paper presents an update following the Welsh Language Standards appeals process which are likely to have some financial and resource implications for PTHB. Members are asked to ratify and note the decisions taken by the Executive Committee on 6 May 2020.

In November 2019, PTHB formally challenged the following standards:

Standards 10, 19, 50, 78, 106A and 107A

With the exception of Standard 19 and 78, full compliance with the Standards above will have significant resource and financial implications which would include the recruitment of 20+ Welsh speaking staff or the introduction of an entirely new telecoms system across the Health Board, and a higher volume and dependency on external translation services.

In February 2020, the Welsh Language Commissioner provided initial comments on our appeal to which PTHB was required to formally respond by 30 April 2020. The Commissioner has outlined his intention to reject our appeals and the expectation is for PTHB to achieve compliance with the Standards by 30 November 2019. (See attached Correspondence from the Welsh Language Commissioner in **Appendix 1**).

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In summary the Executive Committee has agreed to the following recommendations:

Standard 10 & Standard 50 relating to Welsh speaking staff at main reception areas

It was agreed to accept the risk of non-compliance and continue to offer training to existing staff at main reception posts, whilst implementing an action plan which will seek to recruit Welsh speaking staff to new and vacant posts as and when they arise. Current complaint rates in this area are 0%

Standard 19 relating to telephone calls made by PTHB and recording language choice of individuals

The Commissioner intends to grant a special condition making it easier for PTHB to comply with Standard 19 although some further work regarding the monitoring will be required.

Standard 78 relating to the need to develop a policy on Welsh language impact assessment for decisions relating to primary care services

A policy is under development to comply with Standard 78.

Standard 106A and 107A relating to the need to translate vacancy advertisements, job descriptions and person specifications

Since the appeals process a new Vacancy Approval Procedure has been developed and implemented across PTHB which will enable PTHB to comply with Standards 106A and 107A. There will be some financial implications relating to translation costs but these will be kept to a minimum with the new procedural guidelines.

Standards 37 and 110

PTHB did not formally challenge the standards 37 and 110, however, an Executive Decision was also sought to progress the implementation process.

Standard 37 refers to the need to publish information bilingually which would see a significant increase in translation costs. The Executive Committee agreed not to translate larger, technical documents and reports but instead to make them available in Welsh upon request. This is in line with the decisions of other Health Boards for practical reasons and in line with the principles of Prudent Healthcare.

Standard 110 refers to the requirement to publish a plan to increase the Health Board's capacity to undertake clinical consultations in Welsh. The draft plan was approved by the Executive Committee in May 2020.

The Health Board intends to accept the Commissioner's initial comments on its appeals process and continue to implement the agreed actions to work towards achieving compliance in the future.

BACKGROUND AND ASSESSMENT:

Implications and Risk of Non-compliance

Should a member of the public report a breach to the Welsh Language Commissioner, the following action could be taken:

- Welsh Language Commissioner initiates a Statutory Investigation within PTHB to look at a specific breach;
- PTHB will be expected to demonstrate the steps taken to work towards achieving compliance and develop new action plans to address areas of non-compliance;
- If the Welsh Language Commissioner remains unsatisfied with the findings of the Statutory Investigation, PTHB could receive a penalty fine of up to £5000 for each breach.

The Commissioner also has the authority to request information from Health Boards at any given time and can take the decision to instigate a statutory investigation.

Please note: PTHB will have the right to challenge and appeal any decisions made by the Commissioner and this process will be overseen by the Welsh Language Tribunal. This option could have potential financial and staffing resource implications due to the legal processes involved.

Implementation and Assessment of the Standards

Action plans have been developed for individual departments. Progress is monitored via the Welsh Language Service Leads Steering Group. This now means that PTHB can comply with the vast majority of the Welsh Language Standards and work continues to ensure that continuous improvements are being made to Welsh language service provision across all areas of the Health Board.

A full compliance assessment is underway and further updates will be presented to the Board's Experience Quality & Safety Committee on 4th June 2020.

In addition, an internal audit was undertaken in March / April 2020 on the implementation of the Welsh Language Standards and the findings presented to the Audit Committee in May 2020. Internal Audit provided the Board with a limited assurance rating with a number of recommendations made for improvement. The findings of the report recognised the progress made over the past 12 months. The audit highlighted the need to raise more awareness of the Standards across the Health Board and also noted a possible lack of staffing and resource capacity to implement the Standards as intended. However, this appears to be a common observation which has been noted within audits undertaken in other Health Boards and Trusts.

There remain several challenging Standards for which recommended actions were agreed by the Executive Committee in May 2020. Having explored possible options

for compliance and assessing the significant associated resource and financial implications, it was agreed that PTHB would continue to implement its agreed action plan to address areas of non-compliance and work towards achieving full compliance past the imposed compliance date. This means that PTHB is currently at risk of non-compliance. These risks will be included on the relevant service risk registers and will continue to be monitored by the Service Leads and the Board's Experience, Quality and Safety Committee.

NEXT STEPS:

The following actions will be taken forward:

- Respond to the Commissioner's initial comments;
- Update and monitor departmental action plans;
- Undertaken an assessment of current compliance rates;
- Continue to audit public materials and arrange for translation into Welsh;
- Continue to promote Welsh language resources available to help managers and staff;
- Monitor usage and availability of external translation services;
- Continue to roll out Welsh Language Awareness Sessions for staff groups;
- Prepare Welsh language annual reports for Welsh Government and the Commissioner;
- Develop and publish policies in line with Standards 78 and 110;
- Continue to liaise with Welsh Language Managers across NHS Wales and the Executive Leads to share best practice.

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Chief Executive
Powys Teaching Health Board

By e-mail: Kathryn.Cobley2@wales.nhs.uk

14/02/2020

Dear Chief Executive

Consultation in determining an application by Powys Teaching Health Board

I write to you to confirm that I have now considered your applications to challenge standards 10; 19; 50; 78; 106A and 107A. Before making final determinations, I must consult with you. The purpose of this letter therefore is to provide you an opportunity to respond to my initial comments and to the determinations I propose to make.

Please respond to the proposals within this letter, by noting whether or not you agree to them by **28 February 2020**. If you do not agree, please outline your reasons why and what further steps you wish to be taken. If I do not receive any response, I will move to determine in line with the proposals in this letter.

If you have any questions about the contents of this letter, your contact officer is James Whittaker.

Yours sincerely,

Aled Roberts
Welsh Language Commissioner

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The Welsh Language Commissioner's Initial Comments on the applications of Powys Teaching Health Board

1. Standard subject to challenge or challenged in a particular way:

Standard 10

When a person contacts you on your main telephone number (or numbers), or on any helpline numbers or call centre numbers, you must deal with the call in Welsh if that is the person's wish until such point as—

- (a) it is necessary to transfer the call to a member of staff who does not speak Welsh who can provide a service on a specific subject matter; and
- (b) no Welsh speaking member of staff is available to provide a service on that specific subject matter

Imposition day: 30/11/2019

Summary of the application

- 1.1** You claim that the requirement to comply with standard 10 is unreasonable and disproportionate. You are not asking for a complete departure from the standard. Instead, you are asking me to require you to comply with the standard in the following way:

'Where no Welsh speaking members of staff are currently employed to answer the main telephone number (or numbers) to deal with calls in Welsh, every effort will be made to recruit a Welsh speaker to those posts as and when they become vacant.'

The Commissioner's initial comments and proposed decision

- 1.2** Your application has not satisfied me that the requirement for you to comply with standard 10, as imposed, is unreasonable or disproportionate. The reasons for this are outlined below.

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- 1.3 Your evidence explains that all of your main telephone numbers are located in, and are answered by staff based in, a reception area. Currently, staff members, who would be able to deal with calls in Welsh, are not available in every one of these reception areas. For this reason, you consider the requirement of the standard to be unreasonable and disproportionate, until Welsh-speaking staff are located in these reception areas.
- 1.4 Your evidence on the unreasonableness and disproportionality of the standard as imposed concentrates on the argument that it would be unreasonable and disproportionate to ensure, by the imposition day, that Welsh-speaking staff are available to answer the telephone in each of the reception areas (where calls to your main phone numbers are currently answered).
- 1.5 I do not consider that the **only** way to ensure compliance with the standard is to ensure that Welsh-speaking staff are available to answer the telephone in each of these reception areas. This would be only one option to ensure compliance.
- 1.6 For that reason, I do not consider that the only way to make the requirements of the standard reasonable and proportionate is to agree to the imposition of a circumstance in the compliance that would mean that you would not have to comply with the standard in relation to a telephone number, if that number is currently answered in a reception area where there are no Welsh-speaking staff situated there.
- 1.7 However, even if the evidence had satisfied me that the only way to fully comply with the standard was to ensure that Welsh-speaking staff are available in each of the reception areas in question, I do not consider that the arguments that you have presented are sufficient to establish that it would have been unreasonable or disproportionate for you to ensure that by the imposition day that I imposed. See further clarification below.

High cost of recruiting additional staff

- 1.8 You suggested that it would be too costly to recruit the number of additional staff that you consider necessary to comply with the requirements of the standard. I do not consider that this argument confirms that it would have been unreasonable or disproportionate to ensure that Welsh-speaking staff were

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available in each reception area in question by the imposition day, in order to ensure compliance with the standard.

1.9 Apart from identifying what the estimated cost of employing these additional staff would be, the evidence did not explain what impact the expenditure, in terms of employing the additional staff, would have on the organisation, or why the impact of the expenditure would mean that the standard as imposed is unreasonable or disproportionate.

1.10 On that basis, I am unable to assess the extent and importance of any additional burden that would fall on you, had you decided to seek compliance with the standard by employing additional staff, for those reception areas where the telephone numbers are currently answered. As it is not possible for me to do so, it is not possible to assess the extent to which any additional burden would outweigh the positive contribution of the standard in securing rights for persons to use Welsh on the telephone.

1.11 Even if the evidence had enabled me to conclude that the cost of recruiting the number of Welsh speaking staff (you consider necessary to meet the requirements of the standard) would be an unreasonable or disproportionate amount of expenditure, the evidence did not prove the need for you to recruit as *many* additional staff in order to ensure compliance, if at all.

1.12 That is, the evidence did not establish why you were unable to plan your telephone services in a way that would have enabled you to comply with the standard, by using the Welsh-speaking staff that are already employed in the organisation. For example, you might have considered locating the telephone services in different areas or departments (to the locations where the main telephone numbers are currently located), where Welsh speaking staff would be available to answer the telephone number in question.

1.13 As the evidence does not confirm the need for you to recruit additional staff to ensure compliance, I do not consider that the argument regarding the cost of recruiting them necessarily proves the unreasonableness or disproportionality of the standard as imposed.

Current non-Welsh speaking reception staff have not accepted your offer to attend Welsh language training [to enable them to answer/deal with calls in Welsh]

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- 1.14 I do not consider that this argument establishes that it would have been unreasonable or disproportionate to ensure that Welsh-speaking staff were available in each reception area in question by the imposition day, in order to ensure compliance with the standard.
- 1.15 The evidence does not explain why staff have rejected your offer of receiving Welsh language training.
- 1.16 However, whatever the reasons for this, you have a responsibility to ensure sufficient Welsh-language capacity within the organisation to enable you to meet the legal requirements of this standard. A key influence on an organisation's ability to provide suitable Welsh language services is the number of its staff with Welsh language skills. I therefore consider that it is reasonable and proportionate for an organisation to improve the Welsh language skills of its existing workforce, if doing that is necessary in order to ensure compliance with a standard.
- 1.17 If you consider that providing Welsh language training for your existing staff would be a suitable means to ensure compliance with the standard, I consider that it would be reasonable and proportionate for you to deal with any barriers that prevent or hinder staff from choosing to attend the training in question.
- 1.18 In addition, without knowing what the barriers are, I am unable to begin to evaluate the magnitude of those barriers. I cannot therefore begin to assess the extent to which the decision of staff not to attend Welsh language training (and their reasons for not choosing to do so) confirms that the requirement of the standard as imposed is unreasonable or disproportionate.

Not possible for existing non-Welsh speaking reception staff to become sufficiently fluent to ensure compliance by the imposition day

- 1.19 I do not consider that this argument establishes that it would have been unreasonable or disproportionate to ensure that Welsh-speaking staff were available in each reception area in question by the imposition day, in order to ensure compliance with the standard.

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1.20 The evidence did not explain why it was not possible for you to ensure that the staff concerned became sufficiently fluent in Welsh by the imposition day, in order to ensure compliance with the requirements of the standard.

1.21 I am of the view that you should have been aware of the practical implications of implementing this standard for some time now. I therefore consider that, with so much notice of the need to ensure sufficient capacity to ensure compliance, you should have made the necessary preparations within the timeframe allowed, including increasing the Welsh-language skills of your existing staff, if you considered that this was necessary to comply with the requirements of the standard.

1.22 If, for whatever reason, it had not been possible to ensure compliance by increasing the Welsh language skills of your existing staff, I consider that you should have sought to make alternative arrangements to ensure compliance in another way. However, no evidence has been provided which confirms that this has occurred.

The replacement of non-Welsh-speaking staff [with staff who would be able to deal with calls in Welsh] would contravene employment law

1.23 I do not consider that this argument establishes that it would have been unreasonable or disproportionate to ensure that Welsh-speaking staff were available in each reception area by the imposition day, in order to ensure compliance with the standard.

1.24 The evidence does not explain in sufficient detail why, or exactly how, employment law prevents what you claim would need to be done in order to ensure compliance with the standard. It is therefore not possible to evaluate this argument in terms of the unreasonableness or disproportionality of the standard as it was imposed.

1.25 As I have already explained, ensuring that Welsh-speaking staff are available in each of the reception areas concerned is only one option to ensure compliance with the standard. Therefore, even if the above arguments had proved that it would be disproportionate to do so by the imposition day, it does not prove the unreasonableness or disproportionality of complying with the requirements of the standard in another way.

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- 1.26 It is not clear from the evidence whether the organisation has considered alternative options to ensure compliance with the standard, that would not have been reliant on the need for Welsh-speaking staff to be located in each of the reception areas concerned. For example, the evidence does not clarify whether you have considered taking, or attempted to take, reasonable and proportionate steps to revise the way in which Welsh language calls, to the telephone numbers in question, are dealt with and received.
- 1.27 Without any evidence to satisfy me that you have considered all other means of ensuring compliance with the requirements of the standard in relation to the main telephone numbers concerned, I do not consider that I am able to conclude that the only option available to ensure that those requirements are reasonable and proportionate is to exclude those duties from the notice completely (through the circumstance you request).
- 1.28 It should also be noted that the decision of the Welsh Language Tribunal (TYG/WLT/16/5) stated that "*the function of the Commissioner [...] is to consider what is reasonable and proportionate for the future, not to slavishly follow past practices.*" I imposed the standard the way that I did based on what I considered reasonable and proportionate for you to achieve in Welsh by 30/11/2019.
- 1.29 You were required to comply with the requirements by that date on the understanding and expectation that, during the period leading up to that date, you would be changing your arrangements to enable you to comply fully with the requirements in relation to each main telephone number, insofar as this was necessary to ensure full compliance.
- 1.30 The evidence does not confirm whether this has happened. Rather, it appears from the evidence that you consider the standard to be unreasonable and disproportionate to be implemented based on how you have always chosen to organise your telephone services, and on the expectation that you will continue to provide a telephone service in exactly the same way as you have been providing it before the requirements of the standard became operational, and on the expectation that you will seek to comply with the standard without increasing the Welsh language skills of your relevant staff.

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- 1.31 Finally, agreeing to your application for a circumstance, which would involve imposing an open-ended imposition day on you, until such time that certain conditions relating to the recruitment of staff are met, would create uncertainty for Welsh speakers. It is not clear when the staff posts who currently answer the telephone numbers would become vacant, or when staff able to answer them in Welsh would be appointed to fill those posts.
- 1.32 It is not clear when these conditions would be met, and therefore when the right to receive a Welsh language service, in accordance with the standard, would become operational. Agreeing to impose such a circumstance would therefore be in breach of one of the key aims of the standards of making it clear to Welsh speakers when they could expect to receive Welsh language services from organisations.
- 1.33 More importantly, I am legally unable to impose an unspecified imposition day in a compliance notice. In accordance with section 46 of the Welsh Language Measure, the imposition day must note a **specific** date in which the organisation must comply with the requirements of the standard. Therefore, allowing an application to not specify a specific date in which you must comply with the standard would mean that I would be operating in a way which is beyond my powers.
- 1.34 **Therefore, given the above, my proposed decision is that the requirement to comply with standard 10, as it was imposed, is not unreasonable or disproportionate.**

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2. Standard subject to challenge or challenged in a particular way:

Standard 19

When you telephone an individual ("A") for the first time you must ask A whether A wishes to receive telephone calls from you in Welsh, and if A responds to say that A wishes to receive telephone calls in Welsh you must keep a record of that wish, and conduct telephone calls made to A from then onwards in Welsh.

You must comply with standard 19 in every circumstance, except:

- where it is necessary for a member of staff who does not speak Welsh to provide a service on a specific subject matter; and
- where no Welsh speaking member of staff is available to provide a service on that specific subject matter.

The requirement under standard 19 to ask A whether A wishes to receive telephone calls from you in Welsh and to keep a record of A's wish applies each time a telephone call is made to A for the first time in relation to the specific matter of the call ("the matter in hand");

The requirement under standard 19 to conduct telephone calls made to A from then onwards in Welsh applies in relation to every call which involves the matter in hand.

Imposition day: 30/11/2019

Summary of the application

2.1 You claim that the requirement to comply with standard 19 is unreasonable and disproportionate. You are not asking for a complete departure from the standard. Instead, you are asking me to add an additional circumstance to the compliance notice in order to exempt you from having to comply with the standard in the following circumstances:

- where there are no appropriate means for keeping a record of A's wish
- where a one off telephone call is made to a patient in relation to booking or cancelling an appointment
- where A's records are inaccessible to a member of staff.

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The Commissioner's initial comments and proposed decision

2.2 I am satisfied that the requirement for you to comply with standard 19, as imposed, is unreasonable and disproportionate. The reasons for this are outlined below.

2.3 The evidence suggests that it would be unreasonable and disproportionate for you to enquire about language choice when you do not then make use of that information, and as you will not have contact with the individual again. Allowing the exception for a situation where one telephone call is made to arrange or cancel an appointment would therefore avoid the need to ask a question about language choice, when a subsequent call relating to that matter is unlikely to be made.

2.4 However, I do not consider that all further applications for an exception you have made are reasonable, as there is a risk that this would mean that it would not be necessary to enquire about and keep a record of language choice, at any time, if a suitable method is not in place and the records are not available to staff. I consider that the circumstance already imposed allows you to keep a record of information based on matters that arise within departments. You could limit this to matters within one department only.

2.5 **Therefore, given the above, my proposed decision is that the requirement to comply with standard 19 as it was imposed is unreasonable and disproportionate. However, I do not agree to vary the compliance notice in exactly the same way as you have requested. I am, instead, proposing to vary the compliance notice by adding the circumstance below to the standard:**

You must comply with standard 19 in every circumstance, except:

- where it is necessary for a member of staff who does not speak Welsh to provide a service on a specific subject matter;
- where no Welsh speaking member of staff is available to provide a service on that specific subject matter; and
- where a one off telephone call is made to a patient in relation to booking or cancelling an appointment.

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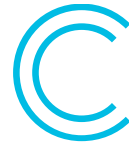
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The requirement under standard 19 to ask A whether A wishes to receive telephone calls from you in Welsh and to keep a record of A's wish applies each time a telephone call is made to A for the first time in relation to the specific matter of the call ("the matter in hand");

The requirement under standard 19 to conduct telephone calls made to A from then onwards in Welsh applies in relation to every call which involves the matter in hand.

Please confirm whether you agree to the above circumstance, so that further consultation is not needed in the case of this standard.

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3. Standard subject to challenge or challenged in a particular way:

Standard 50

Any reception service you make available in English at your reception must also be available in Welsh, and any person who requires a Welsh language reception service at your reception must not be treated less favourably than a person who requires an English language reception service.

You must comply with standard 50 in relation to the following by 30 May 2019:

- Machynlleth Community Hospital reception service
- Ystradgynlais Community Hospital main reception service
- Llanidloes Community Hospital main reception service.

You must comply with standard 50 in relation to the following by 30 November 2019:

- Every other reception service.

Imposition day: 30/05/2019

Summary of the application

3.1 You claim that the requirement to comply with standard 50 is unreasonable and disproportionate in relation to every reception service, apart from the reception service in Machynlleth Community Hospital and the main reception service in Ystradgynlais and Llanidloes Community Hospital, which are already in compliance. You are not asking for a complete departure from the standard. Instead, you are asking me to require you to comply with the standard in the following way for those other reception services:

'Where no Welsh speaking members of staff are currently employed to make available a Welsh language reception service, every effort will be made to recruit a Welsh speaker to those posts as and when they become vacant.'

The Commissioner's initial comments and proposed decision

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- 3.2 Your application has not satisfied me that the requirement for you to comply with standard 50, as imposed, is unreasonable or disproportionate. The reasons for this are outlined below.
- 3.3 As you know, your current situation is that there are no Welsh speaking staff available to provide a reception service in Welsh in all of your reception areas. You have confirmed that you can currently ensure a Welsh language reception service in those specific reception areas which were required to comply with the requirements of the standard by 30 May 2019.¹ However, in each of your other reception areas, your evidence suggests that you can only provide a reception service in English only.
- 3.4 You are therefore applying for me to impose a circumstance in the compliance notice that would mean that you do not have to comply with the standard at all in a particular reception area, if the staff, who are currently employed to serve that reception area, are unable to provide a reception service in Welsh. You request for that exception to continue in those English-only reception areas **until** staff, who would be able to provide a Welsh language reception service, are employed to serve them.
- 3.5 Your evidence on the unreasonableness and disproportionality of this standard, as imposed, concentrates on the same argument that you presented in relation to standard 10.
- 3.6 That is, you consider that it would be unreasonable and disproportionate by the imposition day for you to make staff available, who would be able to provide a Welsh language reception service, in the English-only reception areas in question,. To try to justify this position, you relied on the same evidence, and on the same arguments, as you had depended upon in relation to standard 10. As you know, those arguments included, but were not limited to, arguments about the perceived high cost of recruiting additional staff to ensure compliance with the standard.
- 3.7 Having considered these same arguments in relation to the requirement for you to comply with standard 50, I have come to the same conclusions as I did when

¹ Machynlleth Community Hospital reception service; Ystradgynlais Community Hospital main reception service and Llanidloes Community Hospital main reception service.

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considering them in connection with the requirements of standard 10.² Similarly therefore, I do not regard the arguments that you presented to be sufficient in order to confirm that it would have been unreasonable or disproportionate for you to ensure that Welsh-speaking staff were located in the English-language reception areas in question, by the imposition day I had imposed.

3.8 In addition, I would like to note that your previous Welsh language scheme commitments committed you to moving forward towards providing a bilingual service in your receptions. You were required to ensure this since 2010 – almost a decade before the duty of this standard became operational. The commitments meant that, well before the advent of the standards, you should have ensured that the staff, who serve each of your reception areas, have the appropriate Welsh language skills to provide a reception service in Welsh. On that basis, your evidence does not confirm that I did not allow sufficient time for your staff to become sufficiently fluent to be able to comply with the requirements of this standard.

3.9 Also, your evidence did not explain exactly how many receptions you have where there are no Welsh-speaking staff employed to serve them. Nor does the evidence explain how many members of staff are responsible for serving each of those receptions. It was therefore not possible to draw any conclusions in regards to the need for an additional 20 members of staff to meet the requirements of the standard. For that reason, I cannot even begin to draw any conclusions about the unreasonableness or disproportionality of the cost of recruiting additional Welsh speakers, to ensure compliance with the standard.

3.10 Also, even if the arguments had proved that it would be unreasonable and disproportionate to ensure that Welsh-speaking staff were located in the English-only reception areas in question by the imposition day, they do not necessarily prove the unreasonableness or disproportionality of complying with the requirements of the standard in another way. Ensuring that Welsh-speaking staff members are available in each of your reception areas in question is only one option to ensure compliance with the standard.

3.11 It is not clear from the evidence whether you have considered alternative options to ensure compliance with the standard. For example, the evidence does

² Please see clauses 2.8 – 2.24 of this document.



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not clarify whether you have considered taking, or have attempted to take, reasonable and proportionate steps to revise the way in which reception services are provided to the public, so that those services allow you to meet the requirements of the standard. For example, you may have considered the appropriateness of rationalising services, or of bringing various services together, to ensure that you have sufficient capacity around your reception areas to be able to provide a reception service in Welsh.

3.12 Without any evidence to satisfy me that you have considered all other means of ensuring compliance with the requirements of the standard in the reception areas in question, I do not consider that I can conclude that the only option available to ensure that those requirements are reasonable and proportionate is to exclude those duties from the notice completely (through the circumstance you request).

3.13 Also, as I have already explained in relation to standard 10, it appears from the evidence that you consider the standard to be unreasonable and disproportionate to be implemented based on how you have always chosen to organise your reception services, and on the expectation that you will continue to provide a reception service in exactly the same way as you have been providing it before the requirements of the standard became operational, and on the expectation that you will seek to comply with the standard without increasing the Welsh language skills of your staff.

1.35 Finally, agreeing to your application for a circumstance, which would involve imposing an open-ended imposition day until certain conditions relating to the recruitment of staff are met, would create uncertainty for Welsh speakers. As I have already explained in relation to standard 10, where you have applied for the same type of circumstance, agreeing to impose such a circumstance would be in breach of one of the key aims of the standards of making it clear to Welsh speakers when they could expect to receive Welsh language services from organisations.

1.36 You have not suggested any future date which would give me assurance of when Welsh-speaking staff would be appointed, and therefore when the imposition date, and through that the right to receive a Welsh language service in accordance with the standard, would become operational.

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1.37 More importantly, I am legally unable to impose an unspecified imposition day in a compliance notice. In accordance with section 46 of the Welsh Language Measure, the imposition day must note a specific date in which the organisation must comply with the duties of the standard. Therefore, allowing an application to not specify a specific date in which you must comply with the standard would mean that I would be operating in a way which is beyond my powers.

1.38 **Therefore, given the above, my proposed decision is that the requirement to comply with standard 50, as it was imposed, is not unreasonable or disproportionate.**

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4. Standard subject to challenge or challenged in a particular way:

Standard 78

You must publish a policy on providing a primary care service which requires you to take the following into account when you make decisions in relation to providing a primary care service—

- (a) what effects, if any (and whether positive or negative), the decision would have on—
 - (i) opportunities for persons to use the Welsh language, and
 - (ii) treating the Welsh language no less favourably than the English language;
- (b) how that decision could be taken or implemented so that it would have positive effects, or increased positive effects, on—
 - (i) opportunities for persons to use the Welsh language, and
 - (ii) treating the Welsh language no less favourably than the English language; and
- (c) how the decision could be taken or implemented so that it would not have adverse effects, or so that it would have decreased adverse effects on—
 - (i) opportunities for persons to use the Welsh language, and
 - (ii) treating the Welsh language no less favourably than the English language.

Imposition day: 30/11/2019

Summary of the application

- 4.1 You claim that the requirement to comply with standard 78 is unreasonable and disproportionate. You are not asking for a complete departure from the standard. Instead, you are asking me to extend the standard's imposition day from 30/11/2019 to 30/11/2020.

The Commissioner's initial comments and proposed decision

- 4.2 Your application has not satisfied me that the requirement for you to comply with standard 78, as imposed, is unreasonable or disproportionate. The reasons for this are outlined below.

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- 4.3 There are no sufficient arguments to prove that this standard is unreasonable or disproportionate. For example, I do not consider that the timing of the publication of the More Than Just Words framework is, in itself, a barrier to the formulation of the policy relevant to this standard. Whilst it is sensible to check that the implementation plan of that document does not contradict the content of any policy under standard 78, it would have been possible to refer to the plan within the policy.
- 4.4 Although that action plan is linked to the requirements to publish a policy as required by standard 78, the ability to comply with the standard is not dependent on that plan. And the fact that the action plan wasn't published until July 2019 was not a sufficient reason for why the policy has not been published by 30 November of the same year. Moreover, the actions stemming from More than Just Words are at a more practical level than what would be expected in a high-level policy.
- 4.5 The Welsh Language Standards (No 7) Regulations 2018, and the standard itself, do not require the policy to follow consultation and scrutiny processes. Even if it did, I consider that you would have been able to schedule this process within the year already allowed for compliance, before the duty to comply with the standard came into effect.
- 4.6 You chose to use a specific approach to compliance, which is to jointly formulate the policy with the other health boards and trusts in Wales. Whilst this bodes well in terms of efficiency, the fact that this approach has not come to fruition is not proof that the requirement is unreasonable or disproportionate. While the original intention to combine efforts and efficiency was commendable, the fact that those who had agreed to the work have not begun to draw up the policy was not due to the original imposition day.
- 4.7 Each health board and trust was given a 12-month imposition day from the date of the final compliance notice, in acknowledgement that it may be a requirement that was not part of every organisation's Welsh language scheme. You have been aware of the requirements for more than a year and therefore you could have been proactive in taking action even after it was understood that the primary care directors group had not been able to produce a joint policy. Furthermore, there is an argument that this standard, and its requirements, are

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going to differ from each organisation individually and are relevant to the way in which the organisation makes decisions in relation to the provision of primary care services within its own boundaries of jurisdiction.

4.8 It should be noted that this standard is one of only five standards that relate to primary care, within the regulations that came into force, despite it being the most common point of contact for people using the NHS. As a result, a large number of Welsh speakers will benefit from having the policy in place as soon as possible.

4.9 **Therefore, in light of the above, my proposed decision is that the requirement to comply with standard 78, as imposed, is not unreasonable or disproportionate.**

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5. Standard subject to challenge or challenged in a particular way:

Standard 106A

If you have categorised a post as one where Welsh language skills are essential, desirable or need to be learnt you must –

- (a) specify that when advertising the post, and
- (b) advertise the post in Welsh

Imposition day: 30/11/2019

Summary of the application

5.1 You claim that the requirement to comply with standard 106A is unreasonable and disproportionate. You are not asking for a complete departure from the standard. Instead, you are asking me to extend the standard's imposition day from 30/11/2019 to 30/11/2022 in relation to part (b) of the standard.

The Commissioner's initial comments and proposed decision

5.2 Your application has not satisfied me that the requirement for you to comply with standard 106A, as imposed, is unreasonable or disproportionate. The reasons for this are outlined below.

5.3 In regards to your extension to the imposition day, I am not satisfied that the evidence presented for standard 107A proves adequately that there is insufficient capacity within the NHS in Wales, or the current Framework, to meet the level of translation required by the health board in order to be able to comply with the standards. Even if your claim is correct, I do not consider, on the basis of the evidence that has been presented, that anything prevents the health board from procuring more translators (or that doing so) makes compliance with the standard by 30 November 2019 unreasonable or disproportionate.

5.4 In addition, the requirements of this standard are already limited. In other words, the standard only applies when you **advertise** posts. I consider that the translation of job advertisements into Welsh, as they are advertised, is a reasonable and proportionate requirement.

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5.5 Also, there is no specific requirement for me to ensure that the imposition days for standards 106A and 107A correspond with each other, and there is no evidence to support your comment that this would lead to complaints. I acknowledge that the publication of Welsh language advertisements and job descriptions at the same time would be ideal, and this was one of the reasons for deciding to impose the same imposition day for these standards in the final compliance notice. However, I am not convinced that this is necessary or that it would be misleading or lead to complaints.

5.6 Furthermore, the scope of standards 106A and 107A as set out in the regulations differs from each other. The scope of 106A is more limited than standard 107A, as there is no requirement to implement that standard in relation to posts **where Welsh language skills are not required**. This creates a compelling argument that the requirements of 106A and 107A should be treated separately. I do not therefore consider that the imposition days of these standards, or the way in which they are implemented, necessarily need to be consistent. Accordingly, an examination of the NHS Jobs website has highlighted that text for job advertisements does not come directly from job descriptions, and that it would therefore be necessary anyway to translate the text for job advertisements, in addition to translating any text for job descriptions. I therefore consider that the argument for imposing the same imposition days is even less compelling.

5.7 I have a duty to protect the rights of persons and to ensure that Welsh language services are available at the earliest opportunity. Ensuring that material is available in Welsh in recruitment processes is central to the success of the standards and to attracting more Welsh speakers to work and therefore the translation of those materials should be timetabled within any recruitment timescales as this is now an essential element of the process. I consider it my duty to protect the rights of those who wish to see job advertisements in Welsh. I therefore consider that any further delay in complying with any element of this standard would not be acceptable or reasonable.

5.8 There is no need to have a local library of advertisements before the standard can be implemented. Sufficient time has already been allowed to put arrangements in place or to take steps to facilitate and ensure compliance with this standard by the current imposition day with 12 months given to each health board and trust. You have therefore been given sufficient time to identify and take reasonable steps before the imposition day in order to ensure or facilitate

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compliance with this standard by the current imposition day. I do not consider that the fact you have not ensured that arrangements are in place before the imposition day to facilitate compliance with the standard, means or proves that the requirement to comply with the standard by the imposition day is unreasonable or disproportionate.

- 5.9 It appears that you have not considered or taken all reasonable steps possible to resolve any concerns or alleged difficulties in order to ensure compliance with this standard by the imposition day. I am of the view that nothing prevents the health boards or the trusts from co-ordinating the translation work to facilitate compliance with standard 106A(b), or having already begun to do so. Furthermore, it appears that you have not considered other ways of facilitating the requirement. For example, you would have been able to create and agree a standard template to use for advertisements in order to further reduce the burden. Another option would be to use or invest in translation memory.
- 5.10 The evidence for standard 107A(ch) highlights that **all** posts in the last 18 months have been advertised as Welsh 'essential' or 'desirable' only. It therefore appears that you do not carry out a meaningful assessment of what skills are really needed for jobs when advertised. I do not consider this to be the most effective way of operating or increasing the number of staff who can speak Welsh.
- 5.11 It is also of concern to see that only a small number of posts are advertised as being Welsh essential, with some organisations not advertising any posts as being Welsh essential during the periods in question. Therefore, based on current practice, allowing a 3-year extension for advertisements where Welsh is desirable and where skills are needed in Welsh would mean that it would be just a small number of advertisements needed in Welsh during that period, and I do not consider that to be acceptable. The health board should, when advertising a post, undertake a meaningful and comprehensive assessment of the need for Welsh language skills for that post. It would be good practice to note specifically which Welsh language skills and the level of Welsh needed for posts when advertising. For example, higher level verbal Welsh language skills may be required than writing skills for a reception post. It would also be an idea to note that training is available for candidates wishing to improve or refresh their Welsh.

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5.12 A further advantage of doing so is that any posts which do not require Welsh language skills could be identified in order to reduce the burden of implementing standard 106A (b).

5.13 I note your request that I discuss this standard jointly with each of the other organisations that have challenged this before responding with my final decision. I am happy to make arrangements to ensure this once you have had an opportunity to consider my initial comments and if you continue to wish for that to happen.

5.14 **Therefore, in light of the above, my proposed decision is that the requirement to comply with standard 106A, as imposed, is not unreasonable or disproportionate.**

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6. Standard subject to challenge or challenged in a particular way:

Standard 107A

If you publish –

- (a) application forms for posts;
 - (b) material that explains your procedure for applying for posts;
 - (c) information about your interview process, or about other assessment methods when applying for posts; or
 - (ch) job descriptions;
- you must publish them in Welsh; and you must ensure that the Welsh language versions of the documents are treated no less favourably than any English language versions of those documents.

Imposition day: 30/11/2019

Summary of the application

6.1 You claim that the requirement to comply with standard 107A is unreasonable and disproportionate. You are not asking for a complete departure from the standard. Instead, you are asking me to extend the standard's imposition day from 30/11/2019 to 30/11/2022 in relation to part (ch) of the standard.

6.2 You are also requesting that I impose a circumstance in the compliance notice to exclude the duty for you to publish job descriptions in Welsh when the post does not require any Welsh language skills.

The Commissioner's initial comments and proposed decision

6.3 Your application has not satisfied me that the requirement for you to comply with standard 107A, as imposed, is unreasonable or disproportionate. The reasons for this are outlined below.

6.4 It is unclear to me why you consider that the implementation of the standard without the circumstance that you request would make the requirements of the standard unreasonable or disproportionate. It appears that no posts have been advertised during the last 18 month period where no Welsh language skills are required. I therefore consider that the circumstance requested would have no impact on the requirement of the standard if you continue to operate in the same

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way as you have during the past 18 months. That is, by advertising every job with Welsh as 'desirable' as a minimum.

- 6.5 Your evidence regarding the number of posts advertised does not necessarily mean that the requirement to publish a job description in Welsh is the same, nor does it prove that the requirement is unreasonable or disproportionate. There is strong evidence in this case that a proportion of the numbers given represent the same posts or roles, and therefore, the total is actually lower, as they include duplicated posts. A job description could therefore be re-used in future to reduce the level and costs of translation. It is also not clear how much text is consistent from one job description to another. It is possible therefore that job descriptions may include standard text (for example, information about the organisation) in each of your job descriptions and therefore arrangements could be made to ensure that this type of text would only need to be translated once.
- 6.6 The evidence does not allow a meaningful assessment to be made of the impact of that on the reasonableness and proportionality of the standard as imposed. The evidence does not provide information on the percentage of those 'individual' jobs or how many 'individual' posts were advertised by you during the periods covered in the table. It is therefore possible that the number of job descriptions that need to be published in Welsh is even smaller. In addition, the evidence suggests that the translation of 15-20 job descriptions for nurses would be equivalent to 50% of all posts being advertised. It would have been useful in this case to see how those jobs compare and affect the number of jobs that you advertise.
- 6.7 What you consider to be unachievable or unrealistic does not necessarily mean that a requirement, as it has been imposed, is unreasonable or disproportionate. In addition, evidence about the impact of this standard on the NHS in Wales does not, in itself, mean that the requirement on individual organisations is unreasonable or disproportionate. While I consider that the impact of this standard on the NHS in Wales sets a context, I am of the view that it is not possible to rely on such evidence to accurately and fairly reflect the true impact that this standard has on individual organisations in order to make a meaningful assessment with regard to the alleged unreasonableness and disproportionality. For example, Health Education and Improvement Wales, one of the organisations listed in the table, is not under a duty to implement the standards. There would be no direct requirement under this standard for any job

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descriptions for Health Education and Improvement Wales posts to be available in Welsh.

- 6.8 An increase in the number of posts advertised, and the alleged costs involved, does not necessarily mean that the requirement of the standard is unreasonable or disproportionate. You do not appear to have considered and taken all reasonable steps possible to resolve any concerns or alleged difficulties in order to ensure compliance with this standard by the imposition day. You seem to be totally reliant on translation services and consider that recruiting translators to be the only way of meeting translation requirements. While I acknowledge that recruitment and procurement of translation services is one way of ensuring compliance, it is not the only option. I am not convinced that you have considered any alternative options to facilitate and ensure compliance with the standard by the current imposition day. If you have considered alternative options, the evidence does not cover this.
- 6.9 For example, during the period up to the imposition day, you would have been able to create templates and prepare standard text for staff preparing job descriptions to use, so that the number of words requiring translation is reduced. Another option would be to use or invest in translation memory in order to facilitate the identification of text already translated within other job descriptions.
- 6.10 The requirements of the standard are already limited to when an organisation publishes a job description. In other words, the job description need not have been translated until the post is advertised. I therefore consider that the requirement is already limited to that extent, and that to do so is a reasonable and proportionate requirement. This means that you and the NHS in Wales can increase over time the number of job descriptions available in Welsh, reducing the need for and the burden of translation over time.
- 6.11 The evidence does not adequately prove that there is insufficient capacity within the NHS in Wales or the current Framework to meet the level of translation required to be able to comply with the standards; that private translation companies would have to be used; or that the translation would have to be done as a matter of urgency and therefore entail additional costs. I acknowledge that this is not the only standard that requires the body to provide text in Welsh, and therefore it is reasonable to conclude that there are also other standards where the body would be required to undertake translation work in order to be able to

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comply with the standards. This was a consideration when issuing the final compliance notice and this was recognised by setting a 12 month imposition day to comply with some of the standards, including this standard, rather than the usual 6 months.

- 6.12 It is for the organisations using the Framework to identify and take action if the number of translators within the NHS in Wales and the framework is not sufficient to meet the translation needs of all the organisations that use it. I am not satisfied from the evidence that anything prevents you or the Framework from procuring more translators or taking other reasonable steps should it be necessary (or doing so) in order to comply with the standard by the current imposition day is unreasonable or disproportionate.
- 6.13 I am not convinced that you are unable to put arrangements in place to comply with the standard without compromising your ability to meet performance indicator targets. I do not consider that your tight timescale for advertising posts means that the requirement of this standard is unreasonable or disproportionate. Ensuring that key documents are available in Welsh in recruitment processes is central to the success of the standards and to attracting more Welsh speakers to work and therefore the translation of those documents should be timetabled within any recruitment timescales as this is now an essential element of the process.
- 6.14 Sufficient time has already been allowed to put arrangements in place or to take steps to facilitate and ensure compliance with this standard by the current imposition day with 12 months given to each health board and trust. You have been aware of the requirements for more than a year and so you could have proactively implemented a rolling programme of translation of job descriptions prior to the imposition day in order to reduce the alleged burden of having to translate every job description when advertising them.
- 6.15 You do not need a central library of job descriptions before the standard can be implemented. While I acknowledge your wish to co-ordinate translation and joint working to create a central library, I do not view that as meaning that the requirement of the standard as imposed is unreasonable or disproportionate, or prevents you from acting in this way by the current imposition day.

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- 6.16 I have a duty to protect the rights of persons and to ensure that Welsh language services are available at the earliest opportunity. Allowing an extension of a further 3 years would mean that there would be no requirement on any health board or trust to provide job descriptions in Welsh during that period. I do not consider that a further delay to the requirement would be reasonable.
- 6.17 Finally, there is no guarantee that all the organisations are going to work together or that the project is going to be implemented in the way that you have outlined. Not all organisations have challenged this standard and this therefore suggests that some already have arrangements in place to comply with the standard. While the project outlines actions to address common job descriptions, I note that you will be responsible for translating unique job descriptions. It does not appear therefore that the proposal is necessarily going to help with those kinds of job descriptions, and therefore it will still be necessary to ensure that there are separate local arrangements in place for the translation of unique job descriptions.
- 6.18 I note your request that I discuss this standard jointly with each of the other organisations that have challenged this before responding with my final decision. I am happy to make arrangements to ensure this once you have had an opportunity to consider my initial comments and if your request still stands.
- 6.19 **Therefore, in light of the above, my proposed decision is that the requirement to comply with standard 107A, as imposed, is not unreasonable or disproportionate.**

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Attachment

Summary of the proposed determinations:

Standard number Regulations Number 7	Commissioner's reference number	Commissioner's proposed determination	Proposed next steps
10	988-20191121-BIAP-10	That the requirement to comply with the standard is not unreasonable or disproportionate.	No change to the compliance notice.
19	990-20191121-BIAP-19	That the requirement to comply with the standard is unreasonable and disproportionate.	Vary the compliance notice in the following way: When you telephone an individual ("A") for the first time you must ask A whether A wishes to receive telephone calls from you in Welsh, and if A responds to say that A wishes to receive telephone calls in Welsh you must keep a record of that wish, and conduct telephone calls made to A from then onwards in Welsh. You must comply with standard 19 in every circumstance, except:

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			<p>where it is necessary for a member of staff who does not speak Welsh to provide a service on a specific subject matter; where no Welsh speaking member of staff is available to provide a service on that specific subject matter; and <u>where a one off telephone call is made to a patient in relation to booking or cancelling an appointment.</u></p> <p>The requirement under standard 19 to ask A whether A wishes to receive telephone calls from you in Welsh and to keep a record of A's wish applies each time a telephone call is made to A for the first time in relation to the specific matter of the call ("the matter in hand");</p> <p>The requirement under standard 19 to conduct telephone calls made to A from then onwards in Welsh applies in relation to every call which involves the matter in hand.</p>
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50	989-20191121-BIAP-50	That the requirement to comply with the standard is not unreasonable or disproportionate.	No change to the compliance notice.
78	991-20191121-BIAP-78	That the requirement to comply with the standard is not unreasonable or disproportionate.	No change to the compliance notice.
106A	992-20191121-BIAP-106A	That the requirement to comply with the standard is not unreasonable or disproportionate.	No change to the compliance notice.

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107A	993-20191121- BIAP-107A	That the requirement to comply with the standard is not unreasonable or disproportionate.	No change to the compliance notice.
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Agenda item: 2.7

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	Strategic Equality Plan 2020-2024	
Approved and Presented by:	Claire Madsen, Executive Director of Therapies and Health Sciences	
Prepared by:	Kathryn Cobley, Services Improvement Manager – Welsh Language & Equalities	
Other Committees and meetings considered at:	First draft to Executive Committee December 2019 EQS Committee February 2020 Final Draft to Executive Committee May 2020	

PURPOSE:

To present a final draft Strategic Equality Plan (SEP) to the Board for approval before publication.

RECOMMENDATION:

The Executive Committee is asked to **Approve** the SEP 2020-2024

Approval/Ratification/Decision	Discussion	Information
Approval		

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THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	✓
	2. Provide Early Help and Support	✓
	3. Tackle the Big Four	✓
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	x
	8. Transforming in Partnership	x
Health and Care Standards:	1. Staying Healthy	✓
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

Public Sector Bodies must publish a 4yr SEP in line with the requirements of the Public Sector Equality Duty Regulations. Powys THB's current 4yr SEP will expire and a new plan must be agreed and published by 30 September 2020. Please note, this date has been extended from 31 March 2020 due to the COVID19 pandemic.

BACKGROUND AND ASSESSMENT:

Extensive preparatory work has been undertaken to help Powys THB draft a new SEP for 2020-2024. A decision was made to adopt a joint approach to drafting a new SEP and a Regional SEP Collaboration was established across Powys, Ceredigion, Carmarthenshire and Pembrokeshire. The Steering Group consisted of Equality Leads and Managers from within the following organisations:

- Powys THB
- Hywel Dda UHB
- Powys County Council
- Ceredigion County Council
- Pembrokeshire County Council
- Carmarthenshire County Council
- Dyfed Powys Police and Crime Commissioner
- Mid and West Wales Fire and Rescue Service

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- Brecon Beacons National Park
- Pembrokeshire Coast National Park

Using the key themes within the *Is Wales Fairer?* Report as a guide, the Regional Collaboration Group undertook an extensive engagement exercise between May 2019 – June 2019. The survey, engagement and consultation exercise sought the opinions from the general public within Mid and West Wales, and also of those who have a protected characteristic under the Equality Act 2010. PTHB has used the analysis of the data collated by the Regional Collaboration Group to prepare a set of Equality Objectives for 2020-2024 with the aim of addressing the challenges set out in *Is Wales Fairer? 2018*.

The work of the Regional Collaboration Group discussed various approaches to developing a new SEP and chose to adopt a similar approach to Welsh Government's draft SEP 2020-2024 when setting our own equality objectives. This will ensure consistency across Wales and will help to create a collaborative approach to achieving fairness and equality for all on a regional and national level. Further meetings have taken place between Hywel Dda UHB and Powys THB to ensure consistency in setting objectives for our 2 Health Boards. Our equality objectives also reflect the aims and objectives set out within our IMTP 2020-23 and Annual Plan 2020-21 so that equality issues are embedded in everything we do.

Following the analysis of the survey responses and having received feedback from the Executive Committee in December, PTHB has developed 3 long-term equality objectives, these are:

**Long-term Aim 1:
Engagement**

To ensure strong and progressive equality and human rights protections for everyone in Powys.

PTHB Equality Objective 1:

We will promote a positive attitude towards equality and diversity across our organisation. Our processes of continuous engagement to develop and deliver services will be informed by local needs, with the aim of improving access to healthcare services and reducing inequalities.

**Long-term Aim 2:
Service Delivery**

The needs and rights of people who share protected characteristics are at the forefront of the design and delivery of our healthcare services

PTHB Equality Objective 2:

We will work with our population, staff and partners to shape the design and delivery of our services.

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**Long-term Aim 3:
Workforce**

PTHB is a leading, exemplar, inclusive and diverse organisation and employer

PTHB Equality Objective 3:

We will have an engaged workforce who have positive working relationships with their managers and colleagues in an environment where they feel safe and are supported to manage their own wellbeing.

The SEP Action Plan has been aligned to the objectives outlined in the IMTP 2020-2023 which include actions on how Powys THB will achieve the SEP objectives and work towards realising our long-term aims. Additional actions have also been identified for each of the SEP objectives which focus on specific areas of equality.

Please note: under Objective 3, Powys THB must include an action relating to the gender pay gap. EHRC has advised Health Boards that there will be a requirement to provide a more detailed analysis of gender pay for the financial year 2019/2020. This will include data on the number of males and females within particular staff roles e.g. nursing. A new national report template has been developed to help organisations present information on gender pay.

Consultation

The Equality Service Leads met in January 2020 to discuss the SEP and have approved the draft plan.

The public consultation on the draft SEP Objectives closed on 31 January 2020. The responses were analysed by the Director of Therapies and Health Sciences, the Assistant Director for Communications and Engagement and the Service Improvement Manager for Equality. The information received did not reveal any new areas of concern. The key challenges for PTHB in terms of Equality remains as follows:

- Access to services for those with a disability (both physical and learning);
- Access to services for those with a mental health condition;
- Access to services for our ageing population, in particular those with dementia and complex healthcare needs;
- EQIA in terms of strengthening existing procedures to provide better assurance; and
- Accessible communication for minority languages and those with specific communication needs.

Each of the above points will be addressed via the implementation of the IMTP objectives and the specific actions relating to the SEP Objectives.

In relation to the workforce, the following key themes have been identified as possible target areas for improvement:

- Reducing sexism in the workplace – raising awareness of the effects of 'banter' particularly that relating to gender and sexuality
- Increasing the use of Welsh within the workplace
- Improving opportunities for employees with a disability
- Ensuring staff received adequate training on Equality and Diversity

In addition, following the meeting with EHRC, it was noted that Powys THB needs to focus on improving the diversity of its workforce in terms of the staff employed.

NEXT STEPS:

The following actions will be taken forward:

- Publish SEP 2020 -2024
- Equality Service Leads to monitor progress against the SEP Objectives
- Progress to be recorded in the NHS Delivery Framework 6 monthly reports and the Equality Annual Monitoring Reports
- Update reports to be provided to the Executive Committee, Experience, Quality & Safety Committee and the Board as required

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The following Impact Assessment must be completed for all reports requesting Approval, Ratification or Decision, in-line with the Health Board's Equality Impact Assessment Policy (HR075):

IMPACT ASSESSMENT				
Equality Act 2010, Protected Characteristics:				
	No impact	Adverse	Differential	Positive
Age				X
Disability				X
Gender reassignment				X
Pregnancy and maternity				X
Race				X
Religion/ Belief				X
Sex				X
Sexual Orientation				X
Marriage and civil partnership				X
Welsh Language				X
<p>The SEP objectives aligned with the IMTP objectives will aim to enable improvements to service delivery and enhance service user experience for those with a protected characteristic under the Equality Act 2010.</p> <p>By incorporating Welsh Language into the SEP, this strategy will impact positively on our Welsh speaking service users and aim to improve bilingual service provision.</p>				
Risk Assessment:				
	Level of risk identified			
	None	Low	Moderate	High
Clinical	X			
Financial		X		
Corporate	X			
Operational	X			
Reputational	X			
<p>There may be some minor financial implications in terms of the funding required to implement initiatives relating to the SEP objectives within the workplace and also for any necessary changes to Estates to address physical access issues.</p>				

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Powys Teaching Health Board Strategic Equality Plan 2020-24

“Fairness & Equality for All”

This document is available in Welsh and English on the health board's website at www.powysthb.wales.nhs.uk/equalities-diversity-and-welsh-language

If you require a hard copy of this document or a copy in a different format, for example large print, audio version, word format for screen readers, please contact:

Email: Powys.geninfo@wales.nhs.uk

Tel: 01874 711661

Foreword

In Powys Teaching Health Board (PTHB) we have placed Equality at the heart of our planning and service delivery.

Fairness & Equality is one of the six core organisational values developed by our staff. Offering 'Fair Access' is one the core principles at the heart of our 10-year strategy for Health and Care in Powys

This Strategic Equality Plan applies across all sections of Powys Teaching Health Board and to all of the services that we plan and deliver. We also take careful consideration of equality needs and issues with our decision making and have embedded Equalities into our approach to impact assessment.

Powys Teaching Health Board has a key role to play in mainstreaming Equalities in the services that we provide, in the communities that we serve and with the people that we employ. We will aim to achieve this by implementing this Strategic Equality Plan and continuing to place Equalities at the heart of what we do.

Carol Shillabeer
Chief Executive

Professor Vivienne Harpwood
Chair



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- Appendix 2 – Action Plan – SEP Objective Actions
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- Appendix 4 – Further Information

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Introduction

Definition of Equality

The term 'equality' can mean different things to different people, so for clarity, when using this term, the Health Board will work to the definition provided by the Equalities Review "An equal society protects and promotes equality, real freedom and opportunity to live in the way people value and would choose, so that everyone can flourish. An equal society recognises people's different needs, situations and goals, and removes the barriers that limit what people can do and be."

Equality Act 2010

Section 149 of the Equality Act 2010 sets out the Public Sector Equality Duty (PSED) which, in summary, places a duty on public bodies to have due regard in exercising their functions to the need to:

- Eliminate discrimination, harassment, and victimisation;
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The PSED was developed to harmonise the previous equality duties regarding race, disability and gender equality, and to extend across all of the protected characteristics under the Equality Act 2010.

The 9 protected characteristics are:

- age
- disability
- gender reassignment
- pregnancy and maternity
- race
- religion or belief
- sex
- sexual orientation
- marriage and civil partnership (in relation to being treated differently at work).

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The Welsh Language

Although language is not a protected characteristic under the Equality Act 2010 and the protection of the Welsh language is taken forward under separate legislation (the Welsh Language (Wales) Measure 2011 and related Standards), it has long been recognised that the equality and Welsh language policies complement and inform each other and is further supported through the goal within the Wellbeing of Future Generations (Wales) Act 2015 – 'A Wales of vibrant culture and thriving Welsh language'. Our intention is to sustain and reinforce that principle through our new Strategic Equality Objectives and ensure that they serve to promote and protect the Welsh language.

Strategic Equality Plans

Under the Equality Act 2010, it is unlawful to **discriminate, harass or victimise** someone because they have, or are perceived to have, a "protected characteristic" or are associated with someone who has a protected characteristic.

The Act explains that having due regard for advancing equality involves:

- Removing or minimising disadvantages suffered by people due to their protected characteristics.
- Taking steps to meet the needs of people from protected characteristic groups where these are different from other people.
- Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.

The Equality Act describes fostering good relations as tackling prejudice and promoting understanding between people who share a protected characteristic and those who do not. Meeting the duty may involve treating some people more favourably than others, as long as this does not contravene other provisions within the Act.

Under these Regulations, listed bodies must prepare and publish a Strategic Equality Plan (SEP) every four years. In developing their equality objectives, organisations must involve people who represent the interests of people who share one or more of the protected characteristics and have an interest in the way that the organisation carries out its functions.

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Preparing for our SEP 2020-2024

In October 2018, the Equality and Human Rights Commission (EHRC) published a comprehensive review of how Wales is performing on equality and human rights within its report *Is Wales Fairer?* The review provides valuable data and evidence that will support the efforts of public bodies to reduce inequality in Wales.

The EHRC looked at six themes of life:

- education;
- health;
- living standards;
- justice and security;
- work; and
- participation

It compared outcomes for protected characteristic groups in areas such as pay gaps, educational attainment, and experiences of hate crime.

In order to strive for a consistent approach to developing an SEP, public sector bodies within Mid and West Wales have joined together to establish a Regional Collaboration Group which included representatives from the following organisations:

- Powys THB
- Hywel Dda UHB
- Powys County Council
- Ceredigion County Council
- Pembrokeshire County Council
- Carmarthenshire County Council
- Dyfed Powys Police and Crime Commissioner
- Mid and West Wales Fire and Rescue Service
- Brecon Beacons National Park
- Pembrokeshire Coast National Park

Using the key themes within the *Is Wales Fairer?* Report as a guide, the Regional Collaboration Group undertook an extensive engagement exercise in May and June 2019. The survey, engagement and consultation exercise sought the opinions from the general public within Mid and West Wales, and also of those who have a protected characteristic under the Equality Act 2010. PTHB has used the analysis of the data collected by the Regional Collaboration Group to prepare a set of Equality Objectives for 2020-2024 with the aim of addressing the challenges set out in *Is Wales Fairer? 2018*.

PTHB's SEP sets out how we will ensure that our actions are fair to all. Being treated fairly and with respect is relevant to all of us and to our families and friends.

Powys Teaching Health Board: Who we are, Where we live and What the Health Board does

Our Local Population

Powys is one of the most rural counties in the UK. Whilst the county is approximately 25% of the landmass of Wales, it has only 5% of the population. The population in Powys is older compared to the rest of Wales and the proportion of older people is growing. The working age adult population is smaller compared to rest of Wales and it is predicted that the number of young people and working age adults will decrease, whilst the number of older people will increase. The county has a strong network of small towns and villages with a high level of community commitment and a strong voluntary sector.

In terms of Equality and those with a protected characteristic, here are some statistics about Powys residents. This allows one to appreciate the diversity of our population and the need to treat one another with dignity and respect. It is important that we ensure that marginalised or seldom heard groups of people are involved and have access to services.

Powys has a population of 132,976 people.

22,893 (17%) aged 16 or under.

79,837 (60%) working age.

130,827 (98%) people from a white background and 2,149 (2%) from a non-white background

In 2016 Powys has seen a 10% rise in the number of domestic violence incidents being reported, compared with 2015. Domestic violence appears to be more prevalent in the north of Powys, where BME and LGBT groups are also more likely to be affected. Many crimes are still not reported, and the number of incidents is expected to rise over the coming years. This rise continues an existing trend with an overall increase of 75% since 2010.

In 2015, 5,900 people migrated into Powys and 5,500 migrated out of Powys, with about 400 of each of these two flows being international migrants. Migrants flowing out from Powys are usually aged 15-29, but the largest flows of people moving into Powys are also aged 15-29. About 2,000 people in these age groups migrated out of Powys and 1,500 moved in.

8% of the Powys population report being treated for depression or anxiety and it is one of the top three leading causes of disability.

19% of citizens said they could speak Welsh in 2011. The main pockets of Welsh speakers are found in the North West and South West of the county. Promotion of the Welsh language has continued, with an increase in the number of young Welsh speakers since 1991

It is estimated there are 4,256 people in Powys aged over 65 with dementia.

For every 100 people living within Powys, 5-7 people would be Lesbian, Gay or

Autistic spectrum disorders are the most common presentation of disability within children in Powys. In 2016, 155 open cases were referred to the team (a decrease of 13% since 2012). From our caseload, 52% of children with disabilities live in north Powys.

28,437 (21%) people with a limiting long term illness or disability

For every 100 people living within Powys, 12 of those are providing unpaid care

82,120 (62%) people are Christian, 2053 (1%) people are of other religion and 37,050 (28%) have no religion, 11,753 (9%) would prefer not to state their religion

41.6% of 59,215 households earn less than £20,000 per year

3.8% of 59,215 households earn over £80,000 per year

56,486 (42%) people over 18 are married or in a civil partnership
2,310 (2%) are separated but still legally married or in civil partnership
10,562 (8%) people are divorced
9,646 (7%) people are widowed
31,079 (23%) are people single

3,370 (3%) are living in lone parent households

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Our Workforce

As at October 2019, PTHB currently employs 2,248 members of staff who deliver a wide range of health care services in Powys. Equality is an integral component of the six core principles at the heart of our 10-year Health and Care Strategy for Powys:

- Do What Matters
- Do What Works
- Focus on Greatest Need
- Offer Fair Access
- Be Prudent
- Work with People and Communities

Our values and associated behaviours have been identified and developed by our staff and are central to everything that we do in Powys.

Our Values

- Our values are the things that we believe are important in the way we live and work. They are our “guiding principles”;
- All of the values have equal status;
- Values are usually invisible (like an iceberg, they are the ice below the water);
- Values on their own can be meaningless, if they are not matched to our behaviours.

Our Behaviours

- Behaviours are the things that we do and say, the way that we act;
- Behaviours are visible (like an iceberg, they are the ice above the water);
- Our behaviours impact on how we feel about ourselves and how we make others feel;
- When the things that you do and the way that you behave match our values, life is usually good – we are satisfied and content. When behaviours don’t match values, that’s when things feel wrong and can be a source of dissatisfaction and unhappiness.

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Developing our Equality Objectives

PTHB's SEP objectives have been informed by the following:

1. **Strategic Equality Plan Survey –Regional Collaboration Group**

Public Sector Bodies in Mid and West Wales joined together to ask the public their views on equality. This included a survey and engagement events. Using the *Is Wales Fairer?* Report as a guide, the survey gathered views on how people from each protected characteristic group experienced the following areas of life:

- Education
- Work
- Access to Care and Support
- Housing
- Access to transport
- Leisure access to the coast and countryside
- Health
- Crime
- Access to justice
- Influencing decisions
- Access to information and digital services
- Getting in together in a community

2. **Equality and Human Rights Commission's 'Is Wales Fairer 2018?'**

The report seeks to answer the question, '*Is Wales Fairer?*' The evidence points to five significant findings:

- Steps in the right direction have taken place
- Socio-economic disadvantage exists
- Disabled people are falling further behind
- Challenges to women's safety and career progression exist
- Race inequality persists

3. **Powys Teaching Health Board Strategic Equality Plan 2016-2020**

The plan included the following objectives:

- better more accessible information on services
- engagement
- attitude
- access to services
- working for us
- collating and analysing evidence
- healthy and sustainable communities
- communications
- gender pay and employment monitoring

4. The draft SEP Objectives for Welsh Government 2020-2024

These include:

- Elimination of inequality caused by poverty;
- Strong and progressive equality and human rights protections for Wales;
- That the needs and rights of people who share protected characteristics are at the forefront of the design and delivery of all public services in Wales;
- Wales is a world leader for gender equality;
- Elimination of identity-based abuse, harassment, hate-crime and bullying;
- A Wales of cohesive communities that are resilient, fair and equal;
- Everyone in Wales is able to participate in political, public and everyday life;
- The Welsh public sector leads the way as exemplar inclusive and diverse organisations and employers.

5. The integrated planning process in Powys

We work in partnership with service users, communities, staff and partners including Powys County Council, Powys Association of Voluntary Organisations, Powys Public Service Board and Powys Regional Partnership Board to develop an Area Plan, Well-being Plan, Health and Care Strategy and Integrated Medium Term Plan. The well-being objectives in our joint health and care strategy are:

- Focus on Wellbeing
- Early Help and Support
- Tackling the Big Four
- Joined Up Care
- Workforce Futures
- Innovative Environments
- Digital First
- Transforming in Partnership

6. The Well-being of Future Generations (Wales) Act 2015

PTHB has a duty to ensure the well-being of our local population and to work towards achieving the following well-being goals as set out in the Act:

- A globally responsible Wales
- A prosperous Wales
- A resilient Wales
- A Healthier Wales
- A more equal Wales
- A Wales of cohesive communities
- A Wales of vibrant culture and thriving Welsh language

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Setting our SEP Objectives

PTHB's long-term equality aims will be fundamental in helping PTHB to realise the well-being goals within our Integrated Medium-Term Plan, our Joint Health and Care Strategy and those included in the Well-being of Future Generations (Wales) Act, as they are all intricately linked. The Well-being Needs Assessment which was undertaken in 2017 has allowed PTHB to identify crucial information about our local population which has been used to prioritise our Equality Objectives.

The Regional Collaboration Group discussed various approaches to developing a new SEP. PTHB has chosen to adopt a similar approach to Welsh Government's draft SEP 2020-2024 when setting our own equality objectives. This will ensure consistency across Wales and will help to create a collaborative approach to achieving 'fairness and equality for all' on a regional and national level. Our equality objectives also reflect the aims and objectives set out within our Integrated Medium-Term Plan 2020-23 (IMTP) and Annual Plan 2020-21 so that equalities issues are embedded in everything we do.

Following the analysis of the survey responses and also considering the evidence and information available to us, PTHB has developed 3 long-term equality aims, with specific equality objective(s) under each long-term aim. These are:

Long-term Aim:	Equality Objective:
Engagement To ensure strong and progressive equality and human rights protections for everyone in Powys.	We will promote a positive attitude towards equality and diversity across our organisation. Our processes of continuous engagement to develop and deliver services will be informed by local needs, with the aim of improving access to healthcare services and reducing inequalities.
Long-term Aim:	Equality Objective:
Service Delivery The needs and rights of people who share protected characteristics are at the forefront of the design and delivery of our healthcare services	We will work with our population, staff and partners to shape the design and delivery of our services.
Long-term Aim:	Equality Objective:
Workforce PTHB is a leading, exemplar, inclusive and diverse organisation and employer	We will have an engaged workforce who have positive working relationships with their managers and colleagues in an environment where they feel safe and are supported to manage their own wellbeing.

Implementing our SEP Objectives

SEP Action Plan

Our equality objectives are fully embedded within our IMTP 2020-2023 and Annual Plan for 2020-2019, and their delivery will be monitored and reported through our corporate planning and performance assurance process. The SEP Action Plan may also be amended to incorporate future objectives within any subsequent annual plans.

Appendix 1 demonstrates how we intend to cross reference our SEP Objectives with our local IMTP objectives.

In addition, PTHB has identified additional actions based upon the long-term equality aims and equality objectives set out in this SEP. These actions will ensure a targeted approach to priority areas in terms of Equality within PTHB over the next 4 years.

Appendix 2 contains the additional actions.

Integrating our IMTP Objectives into our SEP means that all staff will be responsible for implementing the SEP Objectives across the various departments within PTHB. It also allows the Executive Committee and senior managers to monitor any necessary changes to operational procedures to address issues relating to implementation of the SEP Objectives and allows them to have an oversight of the progress made.

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Monitoring, Reviewing and Publishing Information

The Director of Therapies and Health Sciences, the Service Improvement Manager for Equality and the Equality Service Leads will oversee the implementation of the SEP. Opportunities will be provided routinely to report progress to the Board and Committees and to escalate any issues identified during the monitoring process.

Progress made against the IMTP objectives will be reported to Board and Committees through our integrated performance report.

The SEP will undergo review upon expiry in 2024.

Further information on Equality within PTHB can be found on our website. The following documents are available:

- PTHB Strategic Equality Plans (past and present)
- Information on the Equality Act 2010
- PTHB Annual Plan
- PTHB IMTP
- Powys Health and Care Strategy
- Gender Pay and Workforce Equality Data Report
- Welsh Language Standards

Alternative formats are available upon request. Please email Powys.geninfo@wales.nhs.uk or telephone 01874 711661.

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Appendix 1

Equality Objectives →			
IMTP Objectives ↓	Strong and progressive equality and human rights protections for everyone in Powys	The needs and rights of people who share protected characteristics are at the forefront of the design and delivery of our healthcare services	PTHB is a leading, exemplar, inclusive and diverse organisation and employer
Focus on Wellbeing	<p>Implement the Powys Wellbeing Plan as a partner of the Public Service Board</p> <p>Implement the health improvement and disease prevention programme – to include social equity in screening approach</p> <p>Deliver Community and Carers Support as per RPB Plan to include work with the third sector on Community Connectors, Info Engine and Dewis, accessible information, advice for wellbeing and signposting for those most vulnerable</p>	Implement the Sexual Health Improvement plan	
Early Help and Support	<p>Implement the transformation programme for primary and community care to include GP, dental services, eye care and medicines management</p> <p>Delivery of Start Well, Live Well and Age Well Programme to include Neighbourhood Nursing Model, Dementia and DOLS</p>	Improved proactive care for those with complex needs to include Care Plans for individuals deemed high risk, evaluation and extension of Community Resource Teams	
Tackling the Big Four		Delivery of the Mental Health Services Programme to include Service Model, improvement plan, psychological therapies, maternal and infant health, integration and CAMHS	

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Enable Joined Up Care	<p>Deliver the North Powys Wellbeing Programme and the Powys Model of Care</p> <p>Deliver the Powys Unscheduled Care Programme</p> <p>Deliver the Out of Hours Model</p> <p>Implementation of Quality Work Programme, shape around the Clinical Quality Framework</p>	<p>Deliver the Planned Care Programme to include</p> <ul style="list-style-type: none"> • priority workstreams for endoscopy, eye care, orthopaedics, ear, nose and throat • anticipatory care planning for people with long-term conditions, delivery of actions • delivery of actions in relation to safeguarding, the Violence Against Women, Domestic Abuse and Sexual Violence Strategy and the Sexual Assault Referral Centre 	
Develop Workforce Futures			<p>Implement the Powys Workforce Strategic Framework to include:</p> <ul style="list-style-type: none"> • Designing, Planning and Attracting the Workforce – Brand Powys, widening access to employment opportunities to those leaving care and these with advanced learning needs • Leading the Workforce – Cultural Development Programme, Compassionate Leadership Model, Managers' Programme and Assistant Director / Senior Management Programme • Engagement and Well-being – staff engagement, wellbeing initiatives and support • Education, Training and Development • Partnership and Citizenship – volunteering, work experience for young people, Rural Academy of learning
Promote Innovative Environments		<p>Deliver the Capital and Estates Programme to include long term estates strategy, capital developments, environmental sustainability, property and asset maintenance and investment</p>	

		Deliver Facilities Modernisation Programme to include waste and recycling, catering and transport	
Put Digital First		Develop and implement a Digital Strategic Framework to support self-management of citizens who have long term conditions to remain active	
Transforming In Partnership	<p>Deliver key partnership plans to include management of strategic change programmes, Regional Partnership Board, Mid Wales Joint Committee and the Regional Planning Fora</p> <p>Deliver continuous planning, performance and commissioning to include the delivery of the Improving Performance Framework, Strategic Planning and Commissioning</p>		

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Appendix 2 Action Plan

In addition to the actions outlined in our overarching IMTP and Annual Plans, the following actions have been identified in the action plan below

SEP Equality Objectives Action Plan

Long-term Aim 1: Strong and progressive equality and human rights protections for everyone in Powys	Equality Objective: We will promote a positive attitude towards equality and diversity across our organisation. Our processes of continuous engagement to develop and deliver services will be informed by local needs, with the aim of improving access to healthcare services and reducing inequalities.	
Action	Lead Person(s)	Progress
To review and strengthen EQIA procedures for PTHB to ensure that the needs of those with a protected characteristic will be considered when making strategic decisions and during policy development	Board Secretary Director of Planning and Performance	

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Long-term Aim 2: The needs and rights of people who share protected characteristics are at the forefront of the design and delivery of our healthcare services	Equality Objective: Working with our population, staff and partners will shape the design and delivery of our services	
To review EQIA procedures and commissioning guidelines for Capital and Estates programmes to ensure that the needs of individuals with a disability are considered early in the planning process	Head of Estates and Property	
To develop an Equality Information Hub for staff on the Intranet to ensure that staff have access to information and resources at all times	Director of Therapies and Health Sciences Equality Service Improvement Manager	
To assist in the national review of available mandatory e-learning Equality and Diversity Training programme	Equality Service Improvement Manager	

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Long-term Aim 3: PTHB is a leading, exemplar, inclusive and diverse organisation and employer	Equality Objective: We will have an engaged workforce who have positive working relationships with their managers and colleagues in an environment where they feel safe and are supported to manage their own wellbeing.	
Action	Lead Person(s)	Progress
To ensure that PTHB is proactive in its compliance with the Gender Pay Gap Review procedures	Director of Workforce and Organisational Development	
To source additional relevant training to increase knowledge and understanding of equality matters and help to develop a cultural awareness amongst staff		

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Appendix 3

Analysis of data from the Strategic Equality Plan Survey undertaken by the Regional Collaboration Group

Following a full analysis of the survey results within the Powys area, PTHB has paid close attention to the survey responses relating to the following:

- Access to Care and Support
- Health
- Influencing decisions

Survey Question: Do you consider people in the following groups generally have better or worst experiences of access to care and support?		
	Worst	Much worst
BME	25%	6%
Disabled	28%	25%
LGBT	16%	2%
Children and Young People	19%	9%
Older Persons	26%	16%
Females	8%	2%
Males	5%	0%
Transgender	16%	4%
Pregnant or recently given birth	13%	3%
Single	8%	2%
In a relationship	3%	0%
Welsh speakers	5%	0%
Population as a whole (referring to all those with a protected characteristic)	3%	1%

Survey Question: Do you consider people in the following groups generally have better or worst experiences of health?		
	Worst	Much worst
BME	32%	2%
Disabled	37%	20%
LGBT	12%	1%
Children and Young People	18%	5%
Older Persons	28%	15%
Females	10%	4%
Males	3%	2%
Transgender	24%	6%
Pregnant or recently given birth	12%	3%
Single	2%	4%
In a relationship	1%	3%
Welsh speakers	6%	5%
Population as a whole (referring to all those with a protected characteristic)	4%	2%

Survey Question: Do you consider people in the following groups generally have a better or worst experience of influencing decisions?		
	Worst	Much worst
BME	41%	14%
Disabled	40%	20%
LGBT	21%	6%

Children and Young People	45%	12%
Older Persons	27%	6%
Females	21%	6%
Males	2%	3%
Transgender	29%	5%
Pregnant or recently given birth	19%	4%
Single	10%	3%
In a relationship	5%	3%
Welsh speakers	8%	4%
Population as a whole (referring to all those with a protected characteristic)	11%	1%

Further information on the results of the Strategic Equality Plan Survey can be obtained by contacting:

Email: Powys.geninfo@wales.nhs.uk **Telephone:** 01874 711661

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Appendix 4

Further Information

For further on statistical census data for Powys please visit:

<https://en.powys.gov.uk/2011census>

For further information on the Well-being Needs Assessment please visit:

<https://en.powys.gov.uk/article/5794/Full-Well-being-assessment-analysis>

For information on household income details please visit:

www.caci.co.uk/products/product/paycheck

For information on LGBT* statistics please visit:

www.stonewallcymru.org.uk

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BOARD MEETING		Date of Meeting: 27 May 2020
Subject :	Pharmaceutical Applications Committee: Terms of Reference & Membership	
Approved and Presented by:	Rani Mallison, Board Secretary & Jamie Marchant, Director of Primary, Community Care and Mental Health	
Prepared by:	Rani Mallison, Board Secretary & Jamie Marchant, Director of Primary, Community Care and Mental Health	
Other Committees and meetings considered at:	None at the time of reporting	

PURPOSE:

This paper has been prepared to seek ratification of updated Terms of Reference of the health board's Pharmaceutical Applications Committee, which can be found at **Appendix 1**.

RECOMMENDATION(S):

The Board is asked to RATIFY updated Terms of Reference for its Pharmaceutical Applications Committee.

Approval/Ratification/Decision	Discussion	Information
✓	x	x

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY :

Section 2 of Powys Teaching Health Board's (referred to throughout this document as PTHB or the health board) Standing Orders provides that "The Board may and, where directed by the Welsh Government must, appoint Committees of the Board either to undertake specific functions on the Board's behalf or to provide advice and assurance to the Board in the exercise of its functions. The Board's commitment to openness and transparency in the conduct of all its business extends equally to the work carried out on its behalf by committees".

At its meeting in March 2017, the Board approved the establishment of a Pharmaceutical Applications Committee and its associated Terms of Reference and Operating Arrangements.

In light of Organisational Realignment, undertaken in 2019, the Terms of Reference and Membership have been reviewed and an updated version is presented to the Board for ratification.

BACKGROUND AND ASSESSMENT:

The requirement for the Board to make decisions in respect of Pharmaceutical Applications is set out in the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (**Appendix 2**). These decisions have been delegated to a Pharmaceutical Applications Committee. The purpose of which is to consider all applications to provide Pharmaceutical Services in the Powys area, and where appropriate to determine applications on behalf of PTHB.

The Committee is required to consider:

- All full applications for inclusion in the Pharmaceutical List of Powys Teaching Health Board;
- Applications for change of ownership;
- Applications from existing Pharmaceutical Contractors who wish to open additional premises;
- Applications from existing Pharmaceutical Contractors who wish to relocate their premises;
- Applications from existing Pharmaceutical Contractors who wish to provide additional services to those already provided;
- Applications from existing Pharmaceutical Contractors who wish to withdraw a service/services from existing premises;
- Applications by General Medical Practitioners to provide Pharmaceutical Services and to extend dispensing areas; and
- Applications in respect of rurality i.e. "Controlled Localities".

The Committee will also note:

- Serious Difficulty' applications which have been approved at officer level.
- Change of ownership applications which have been approved at officer level.

The Committee works as part of the structures and decision making processes of the organisation and will be accountable to the Board for its decisions in relation to pharmaceutical matters as outlined above.

Following approval of the establishment of the Pharmaceutical Applications Committee, the health board has undertaken an organisational realignment process. It was therefore felt necessary that the Terms of Reference and Membership were reviewed and updated accordingly. These are attached at **Appendix 1** for the Board's approval.

Pharmaceutical Applications Committee

Terms of Reference & Operating Arrangements

May 2020

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Status:
DRAFT – awaiting Board approval May 2020

1. INTRODUCTION

- 1.1 Section 2 of Powys Teaching Health Board's (referred to throughout this document as PTHB or the health board) Standing Orders provides that *"The Board may and, where directed by the Welsh Government must, appoint Committees of the THB either to undertake specific functions on the Board's behalf or to provide advice and assurance to the Board in the exercise of its functions. The Board's commitment to openness and transparency in the conduct of all its business extends equally to the work carried out on its behalf by committees"*.
- 1.2 In line with Standing Orders and PTHB's Scheme of Delegation, the Board has established a committee to be known as the **Pharmaceutical Applications Committee** (referred to throughout this document as 'the Committee'). The Committee has been established in order to consider all applications to provide Pharmaceutical Services in the Powys area and where appropriate determine such applications on behalf of the health board.
- 1.3 The requirement to establish a Pharmaceutical applications Committee is set out in the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013. Detailed Terms of Reference and the operating arrangements set by the Board in respect of this Committee are detailed below.

2 PURPOSE

- 2.1 The purpose of the Committee will be to consider all applications to provide Pharmaceutical Services in the Powys area, and where appropriate to determine applications in relation to the above matters, on behalf of PTHB.

3 DELEGATED POWERS AND AUTHORITY

- 3.1 With regard to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013, and the specific powers delegated to it by the Board the Committee will consider:
- All full applications for inclusion in the Pharmaceutical List of Powys Teaching Health Board;
 - Applications for change of ownership;

Status:

DRAFT – awaiting Board approval May 2020

- Applications from existing Pharmaceutical Contractors who wish to open additional premises;
- Applications from existing Pharmaceutical Contractors who wish to relocate their premises;
- Applications from existing Pharmaceutical Contractors who wish to provide additional services to those already provided;
- Applications from existing Pharmaceutical Contractors who wish to withdraw a service/services from existing premises;
- Applications by General Medical Practitioners to provide Pharmaceutical Services and to extend dispensing areas; and ▪ Applications in respect of rurality i.e. "Controlled Localities".

The Committee will also note:

- 'Serious Difficulty' applications which have been approved at officer level.
- Change of ownership applications which have been approved at officer level.

3.2 The Committee will work as part of the structures and decision making processes of the organisation and will be accountable to the Board for its decisions on behalf of the Board in relation to pharmaceutical matters as outlined above.

Authority

3.3 The Committee is authorised by the Board to undertake work on behalf of the health board in relation to the roles and responsibilities of the Committee outline in 3.1 above.

3.4 The Committee is authorised by the Board to obtain outside legal or other independent professional advice and to secure the attendance of outsiders with relevant experience and expertise if it considers it necessary, in accordance with the Board's procurement, budgetary and other requirements.

Access

3.5 The Head of Internal Audit shall have unrestricted and confidential access to the Chair of the Committee.

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- 3.6 The Chair of the Committee shall have reasonable access to Executive Directors and other relevant senior staff.

Sub Committees

- 3.7 The Committee may, subject to the approval of the Board, establish sub committees or task and finish groups to carry out on its behalf specific aspects of Committee business.

4 MEMBERSHIP

Members

- 4.1 Membership will comprise of the following members:

Chair	Vice Chair of the Health Board (with specific responsibilities for primary care, community and mental health services)
Vice Chair	Independent member of the Board (Community Member)
Members	Independent member of the Board (Finance) Executive Director of Primary Care, Community and Mental Health Services Chief Pharmacist Assistant Medical Director Assistant Director of Primary Care

- 5.2 In attendance:
The following will be in attendance at meetings of the Committee:

- NHS Wales Shared Services (NWSSP) – Primary Care Services representative

Representatives of the following organisations may be invited to attend at the request of the Chair.

- Community Pharmacy Wales (CPW) representative
- Dyfed Powys Local Medical Committee (LMC) representative

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The involvement of Independent Members will ensure a 'lay' perspective is included in the decision making of the Committee.

Other attendees will be co-opted as necessary and appropriate.

Secretariat

- 4.2 The secretariat for the Committee will be provided by the Primary Care Services Team, NHS Wales Shared Services.

Member Appointments

- 4.3 The membership of the Committee shall be determined by the Board, based on the recommendation of the Chair of the Board - taking account of the balance of skills and expertise necessary to deliver the Committee's remit and subject to any specific requirements or directions made by the Welsh Government.

Support to Committee Members

- 4.5 The Board Secretary, on behalf of the Committee Chair, shall arrange the provision of advice and support to committee members on any aspect related to the conduct of their role.

5. COMMITTEE MEETINGS

Quorum

- 5.1 At least four members must be present to ensure the quorum of the Committee, including:
- the Chair or Vice Chair;
 - one other Independent Member of the Board
 - the Executive Director of Primary Care, Community and Mental Health Services.
- 5.2 Where members notify the Committee Chair or Committee Secretariat that they are unable to attend a meeting, and there is a danger that the Committee will not be quorate the Chair can invite another independent member of the Board to become a temporary member of the Committee.

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Frequency of Meetings

5.3 The Committee shall meet as required to conduct its business.

Withdrawal of individuals in attendance and declarations of interest

5.4 The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of a particular matter.

5.5 No person who has any direct or indirect pecuniary interest in the application, or any other current personal interest, or who is associated with any person who has any current personal interest may take part in the proceedings at any stage. Any member who anticipates such an interest should declare it in advance in order that arrangements may be made for the attendance of a deputy.

6. RELATIONSHIP & ACCOUNTABILITIES WITH THE BOARD AND ITS COMMITTEES/GROUPS

- 6.1 Although the Board has delegated authority to the Committee for the exercise of certain functions as set out within these terms of reference. The Committee is directly accountable to the Board for its performance in exercising the functions set out in these terms of reference.
- 6.2 The Committee shall embed the health board's corporate standards, priorities and requirements, e.g., equality and human rights through the conduct of its business.

7. REPORTING AND ASSURANCE ARRANGEMENTS

7.1 The Committee Chair shall report its work and decisions to the Board.

8. APPLICABILITY OF STANDING ORDERS TO COMMITTEE BUSINESS

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-
- 8.1 The requirements for the conduct of business as set out in PTHB's Standing Orders are equally applicable to the operation of the Committee, except in the following areas:
- Quorum
 - Frequency of meetings
 - Issue of Committee papers
 - Committee will not hold meetings in public

9. CHAIR'S ACTION ON URGENT MATTERS

- 9.1 There may, occasionally, be circumstances where decisions which would normally be made by the Committee need to be taken between scheduled meetings, and it is not practicable to call a meeting of the Committee. In these circumstances, the Chair of the Committee, supported by the Board Secretary as appropriate, may deal with the matter on behalf of the Committee - after first consulting with at least three other Members of the Committee. The Board Secretary must ensure that any such action is formally recorded and reported to the next meeting of the Board for consideration and ratification.
- Chair's action may not be taken where the Chair has a personal or
- 9.2 business interest in the urgent matter requiring a decision.

10. REVIEW

- 10.1 These Terms of Reference shall be reviewed annually by the Committee. The Committee Chair will report any changes to the Board for ratification.

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OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2013 Rhif 898 (Cy.102)

2013 No. 898 (W.102)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

**Rheoliadau'r Gwasanaeth Iechyd
Gwladol (Gwasanaethau Fferyllol)
(Cymru) 2013**

**The National Health Service
(Pharmaceutical Services) (Wales)
Regulations 2013**

NODYN ESBONIADOL

EXPLANATORY NOTE

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

(This note is not part of the Regulations)

Mae'r Rheoliadau hyn yn dirymu ac yn disodli Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (O.S. 1992/662) (fel y'u diwygiwyd) ("Rheoliadau 1992") fel y Rheoliadau sydd, yng Nghymru, yn llywodraethu'r modd y darperir gwasanaethau fferyllol fel rhan o'r Gwasanaeth Iechyd Gwladol o dan Ran 7 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.

These Regulations revoke and replace the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I.1992/662) (as amended) ("the 1992 Regulations") as the Regulations which, in Wales, govern the provision of pharmaceutical services as part of the National Health Service under Part 7 of the National Health Service (Wales) Act 2006.

Mae Rhan 1 yn cynnwys darpariaethau rhagarweiniol.

Part 1 contains introductory provisions.

Mae Rhan 2 yn pennu'r gofynion bod pob Bwrdd Iechyd Lleol, yn paratoi a chynnal ar gyfer ei ardal—

Part 2 sets out the requirements for each Local Health Board to prepare and maintain for their area—

- (a) rhestrau fferyllol o fferyllwyr GIG a chontractwyr cyfarpar GIG sy'n ymrwymo i ddarparu gwasanaethau fferyllol o fangreoedd yn yr ardal; a
- (b) rhestrau meddygon fferyllol o feddygon sy'n ymrwymo i ddarparu gwasanaethau fferyllol o fangreoedd yn yr ardal.

- (a) pharmaceutical lists of NHS pharmacists and NHS appliance contractors who undertake to provide pharmaceutical services from premises in the area; and
- (b) dispensing doctor lists of doctors who undertake to provide pharmaceutical services from premises in the area.

Mae Rhan 2 hefyd yn pennu'r telerau gwasanaethu, sef y telerau y cynhwysir personau ar eu sail mewn rhestr fferyllol neu restr meddygon fferyllol, a'r telerau y mae'r personau hynny'n ymrwymo i ddarparu gwasanaethau fferyllol ar eu sail, fel rhan o'r Gwasanaeth Iechyd Gwladol.

It also sets out the terms of service, which are the terms on which persons are included in a pharmaceutical or dispensing doctor list and on which they undertake to provide pharmaceutical services as part of the National Health Service.

Mae Rhan 3 yn gwneud darpariaeth i'r Bwrdd Iechyd Lleol benderfynu, ei hunan neu ar gais Pwyllgor Meddygol Lleol neu Bwyllgor Fferyllol Lleol, pa un a yw ardal benodol, o fewn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer, oherwydd ei natur wledig, yn ardal reoledig neu'n rhan o ardal reoledig.

Part 3 makes provision for a Local Health Board itself, or on application from a Local Medical Committee or Local Pharmaceutical Committee, to determine whether or not a particular area within the area for which the Local Health Board is established is, because it is rural in character, a controlled locality or

Arwyddocâd penderfyniad bod ardal yn ardal reoledig yw y caiff meddygon, mewn amgylchiadau penodol, ddarparu gwasanaethau fferyllol i gleifion cymwys penodol (os yw'r meddygon hynny wedi eu cynnwys mewn rhestr meddygon fferyllol). Pennir y gweithdrefnau y mae'n rhaid i Fwrdd Iechyd Lleol eu dilyn, wrth benderfynu'r cwestiwn a yw ardal yn ardal reoledig neu'n rhan o ardal reoledig, yn Atodlen 2 i'r Rheoliadau. Pennir hawliau i apelio i Weinidogion Cymru ynghylch penderfyniadau a wneir gan Fyrdau Iechyd Lleol yn Atodlen 3.

Mae Rhan 4 yn nodi'r gwahanol fathau o geisiadau am gynnwys personau mewn rhestrau fferyllol, neu ddiwygio rhestrau fferyllol, a'r profion y mae'n rhaid i Fwrdd Iechyd Lleol eu cyflawni wrth benderfynu'r ceisiadau hynny. O dan reoliad 8 (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol) a rheoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol) ni chaiff Bwrdd Iechyd Lleol ganiatáu ceisiadau oni fodlonir ef fod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau darpariaeth ddigonol o'r cyfan, neu rai, o'r gwasanaethau a bennir yn y cais, yn y gymdogaeth y lleolir ynddi'r fangre a bennir yn y cais, (y prawf angenrheidiol neu hwylus). Yn ychwanegol, os yw'r fangre mewn ardal reoledig, mae'n rhaid, yn gyffredinol, bodloni'r Bwrdd Iechyd Lleol na fyddai caniatáu'r cais yn niweidio'r gwasanaethau meddygol sylfaenol, neu weinyddu neu'r gwasanaethau fferyllol mewn unrhyw ardal (y prawf niweidio). Gwneir eithriad i hyn os yw'r Bwrdd Iechyd Lleol yn penderfynu bod y fangre a bennir yn y cais mewn lleoliad neilltuedig (o dan reoliad 11 (lleoliadau mewn ardaloedd rheoledig sy'n lleoliadau neilltuedig)).

Mae rhai ceisiadau penodol ynglŷn â rhestrau fferyllol nad ydynt yn cael eu hasesu yn unol â'r prawf angenrheidiol neu hwylus, na'r prawf niweidio. Caiff person sydd wedi ei gynnwys eisoes mewn rhestr fferyllol wneud cais i adleoli'r fangre y mae'n darparu gwasanaethau fferyllol ohoni os gellir ystyried y symudiad yn adleoliad bach. Mae rheoliad 13 (ceisiadau sy'n ymwneud ag adleoliad bach o fewn ardal Bwrdd Iechyd Lleol) yn pennu amgylchiadau pan fo rhaid i Fwrdd Iechyd Lleol ganiatáu cais o'r fath. Yn yr un modd, nid asesir ceisiadau sy'n dod o fewn rheoliad 14 (ceisiadau sy'n ymwneud ag adleoliadau bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos), rheoliad 15 (ceisiadau sy'n ymwneud ag adleoli dros dro) a rheoliad 16 (ceisiadau sy'n ymwneud â newid perchnogaeth) yn unol â'r prawf angenrheidiol neu hwylus, na'r prawf niweidio. Mae'r gweithdrefnau y mae'n rhaid i Fwrdd Iechyd Lleol eu dilyn wrth benderfynu ceisiadau o dan Ran 4 wedi eu pennu yn Atodlen 2 i'r Rheoliadau, a'r hawliau i apelio i Weinidogion Cymru ynghylch penderfyniadau a wneir gan Fyrdau Iechyd Lleol wedi eu pennu yn Atodlen 3.

part of a controlled locality. The significance of a locality being determined to be a controlled locality is that, in certain circumstances, doctors can provide pharmaceutical services to certain of their eligible patients (if those doctors are included in a dispensing doctor list). The procedures that a Local Health Board must follow in determining a question as to whether an area is a controlled locality or part of a controlled locality are set out in Schedule 2 to the Regulations. Rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 3.

Part 4 sets out the types of applications in respect of inclusion in or amendment to pharmaceutical lists and the tests which a Local Health Board must apply to determine those applications. Under regulation 8 (applications to be included in or for amendment to a pharmaceutical list) and regulation 12 (applications for preliminary consent and effect of preliminary consent) applications can be granted only if the Local Health Board is satisfied that it is necessary or expedient to grant the application to secure in the neighbourhood in which the premises specified in the application are located, the adequate provision of all or some of the services specified in the application (the necessary or expedient test). In addition, the general position is that if the premises are situated in a controlled locality, the Local Health Board must be satisfied that to grant the application will not prejudice the proper provision of primary medical, dispensing or pharmaceutical services in any locality (the prejudice test). The exception to the general position is where the premises specified in an application are determined, by the Local Health Board, to be in a reserved location (under regulation 11 (locations in controlled localities that are reserved locations)).

Certain applications regarding pharmaceutical lists are not assessed in accordance with the necessary or expedient test or the prejudice test. A person already included in a pharmaceutical list can apply to relocate the premises from which he or she provides pharmaceutical services where the move can be considered to be a minor relocation. Regulation 13 (applications involving minor relocation within a Local Health Board's area) sets out when a Local Health Board must grant such an application. Similarly, applications that fall within regulation 14 (applications involving minor relocation between neighbouring Local Health Board areas), regulation 15 (applications involving a temporary relocation) and regulation 16 (applications involving a change of ownership) are not assessed in accordance with the necessary or expedient test or the prejudice test. The procedures that a Local Health Board must follow in determining applications under Part 4 are set out in Schedule 2 to the Regulations, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 3.

Mae Rhan 5 yn pennu'r ceisiadau y gall meddygon eu gwneud, i'w galluogi i gyflawni'r amodau, a fydd wedyn yn caniatáu iddynt wneud trefniadau gyda Bwrdd Iechyd Lleol i ddarparu gwasanaethau fferyllol i'w cleifion cymwys mewn ardaloedd rheoledig. Rhaid i feddygon wneud cais am gydsyniad amlinellol a chymeradwyaeth mangre o dan reoliad 24 (cydsyniad amlinellol a chymeradwyo mangre) a rhaid i Fyrddau Iechyd Lleol ystyried ceisiadau o'r fath yn unol â'r prawf angenrheidiol neu hwylus, y prawf niweidio a'r pellter rhwng y fangre y mae'r meddyg yn bwriadu darparu gwasanaethau fferyllol ohoni a fferyllfeydd cyfagos. Caiff meddyg, ar ôl cael cydsyniad amlinellol a chymeradwyaeth mangre, wneud trefniadau gyda Bwrdd Iechyd Lleol i ddarparu gwasanaethau fferyllol o dan reoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon). Pennir y gweithdrefnau y mae'n rhaid i Fwrdd Iechyd Lleol eu dilyn wrth benderfynu ceisiadau o dan Ran 5 yn Atodlen 2 i'r Rheoliadau, a'r hawliau i apelio i Weinidogion Cymru ynghylch penderfyniadau a wneir gan Fyrddau Iechyd Lleol yn Atodlen 3.

Mae Rhan 6 yn ymwneud â seiliau addasrwydd, ac â chynnwys personau mewn rhestrau fferyllol a'u tynnu ymaith o'r rhestrau. Mae'n darparu ar gyfer gohirio a gwrthod, ar sail addasrwydd, geisiadau am gynnwys person mewn rhestr fferyllol (rheoliadau 31 a 32), ac ar gyfer cynnwys person mewn rhestr fferyllol yn ddarostyngedig i amodau (rheoliad 33). Mewn rhai achosion addasrwydd, gan gynnwys achosion pan fo person wedi ei gollfarnu am drosedd yn y Deyrnas Unedig ac wedi ei ddedfrydu i garchar am gyfnod o fwy na chwe mis, rhaid i Fwrdd Iechyd Lleol dynnu enw'r person hwnnw o'r rhestr fferyllol yn unol â rheoliad 35 (tynnu ymaith oddi ar restr fferyllol am resymau eraill).

Mae Rhan 7 ymwneud â thaliadau i fferyllwyr GIG a chontractwyr cyfarpar GIG. Mae rheoliad 41 (y Tariff Cyffuriau a chydnabyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG) yn darparu ar gyfer cyhoeddi'r Tariff Cyffuriau, sef y prif ddatganiad o hawlogaethau ariannol fferyllwyr GIG a chontractwyr cyfarpar GIG, sy'n nodi'r penderfyniadau ar faterion o'r fath a wnaed gan Weinidogion Cymru fel yr awdurdod penderfynu. Mae rheoliad 42 (Byrddau Iechyd Lleol fel awdurdodau penderfynu) yn gwneud darpariaeth i'r Byrddau Iechyd Lleol fod yn awdurdodau penderfynu pan bennir hynny yn y Tariff Cyffuriau. Darperir hefyd ynghylch materion atodol, gan gynnwys gordaliadau a thaliadau i fferyllwyr GIG a chontractwyr cyfarpar GIG.

Mae Rhan 8 yn ymwneud â materion amrywiol, gan gynnwys darpariaethau trosiannol ar gyfer ceisiadau ac apelau a wnaed o dan Reoliadau 1992 cyn i'r Rheoliadau hyn ddod i rym.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar wneud Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, paratowyd

Part 5 sets out the applications which doctors can make in order to be able to fulfil the conditions on which they can then make arrangements with a Local Health Board to provide pharmaceutical services to their eligible patients in controlled localities. Doctors must apply for outline consent and premises approval under regulation 24 (outline consent and premises approval) and Local Health Boards must consider such applications in accordance with the necessary or expedient test, the prejudice test and the proximity of the premises from which the doctor wishes to provide pharmaceutical services to nearby pharmacies. A doctor who has been granted outline consent and premises approval may make arrangements with a Local Health Board to provide pharmaceutical services under regulation 20 (arrangements for the provision of pharmaceutical services by doctors). The procedures that a Local Health Board must follow in determining applications under Part 5 are set out in Schedule 2 to the Regulations, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 3.

Part 6 deals with fitness grounds and inclusion in and removal from pharmaceutical lists. It provides for the deferral and refusal of applications for inclusion in a pharmaceutical list on fitness grounds (regulations 31 and 32) together with an inclusion in a pharmaceutical list being subject to conditions (regulation 33). For certain fitness matters, including where a person has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over six months, a Local Health Board must remove a person from a pharmaceutical list pursuant to regulation 35 (removal from a pharmaceutical list for other reasons).

Part 7 deals with payments to NHS pharmacists and NHS appliance contractors. Regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliances contractors) provides for the publication of the Drug Tariff, the main statement of the financial entitlements of NHS pharmacists and NHS appliances contractors that sets out the determinations on such matters made by the Welsh Ministers as determining authority. Regulation 42 (Local Health Boards as determining authorities) makes provision for the Local Health Boards to be determining authorities where this is set out in the Drug Tariff. There are also provisions for supplemental matters including overpayments and payments to NHS pharmacists and NHS appliance contractors.

Part 8 deals with miscellaneous matters, including transitional provisions for applications and appeals made under the 1992 Regulations before these Regulations come into force.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to

asesiad effaith rheoleiddiol o'r costau a'r buddiannau sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn. Gellir cael copi ohono gan yr Adran Iechyd, Gwasanaethau Cymdeithasol a Phlant, Llywodraeth Cymru, Parc Cathays, Caerdydd, CF10 3NQ.

the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Department for Health, Social Services and Children, Welsh Government, Cathays Park, Cardiff, CF10 3NQ.

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2013 Rhif 898 (Cy.102)

2013 No. 898 (W.102)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

**Rheoliadau'r Gwasanaeth Iechyd
Gwladol (Gwasanaethau Fferyllol)
(Cymru) 2013**

**The National Health Service
(Pharmaceutical Services) (Wales)
Regulations 2013**

Gwnaed 17 Ebrill 2013

Made 17 April 2013

*Gosodwyd gerbron Cynulliad
Cenedlaethol Cymru* 18 Ebrill 2013

*Laid before the National
Assembly for Wales* 18 April 2013

Yn dod i rym 10 Mai 2013

Coming into force 10 May 2013

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41. Y Tariff Cyffuriau a chydnyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG

42. Byrddau Iechyd Lleol fel awdurdodau penderfynu

43. Gordaliadau

44. Cynllun gwobrwyo

45. Taliadau i fferyllwyr GIG a chontractwyr cyfarpar GIG sydd wedi eu hatal dros dro

RHAN 8

Amrywiol

46. Bwrdd Iechyd Lleol cartref

47. Cyhoeddi manylion

48. Arfer yr hawl i ddewis mewn achosion penodol

49. Darpariaethau trosiannol

50. Man ddiwygiadau, diwygiadau canlyniadol a dirymadau

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29. Premises approval: practice amalgamations

30. Appeals

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31. Deferral of applications on fitness grounds

32. Refusal of applications on fitness grounds

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37. Notification of decision to impose conditions

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ATODLEN 4 — Telerau gwasanaethu ar gyfer fferyllwyr GIG sy'n darparu gwasanaethau fferyllol yn benodol drwy ddarparu cyffuriau

ATODLEN 5 — Telerau gwasanaethu ar gyfer contractwyr cyfarpar GIG sy'n darparu gwasanaethau fferyllol drwy ddarparu cyfarpar yn unig

ATODLEN 6 — Telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanaethau fferyllol

ATODLEN 7 — Mân ddiwygiadau a digwyddiadau canlyniadol

ATODLEN 8 — Dirymadau

Mae Gweinidogion Cymru yn gwneud y Rheoliadau canlynol drwy arfer y pwerau a roddir gan adrannau 15, 80, 83, 84, 86, 88, 104, 107, 110, 115, 116, 118, 203(9) a (10) a 205 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1).

SCHEDULE 1 — Information to be included in applications to provide pharmaceutical services

SCHEDULE 2 — Procedures to be followed by Local Health Boards to determine applications under the Regulations

SCHEDULE 3 — Appeals to the Welsh Ministers

SCHEDULE 4 — Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provision of drugs

SCHEDULE 5 — Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances

SCHEDULE 6 — Terms of service for doctors providing pharmaceutical services

SCHEDULE 7 — Minor and consequential amendments

SCHEDULE 8 — Revocations

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 15, 80, 83, 84, 86, 88, 104, 107, 110, 115, 116, 118, 203(9) and (10) and 205 of the National Health Service (Wales) Act 2006(1).

RHAN 1

Cyflwyniad

Enwi, cychwyn a chymhwyso

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Cymru) 2013.

(2) Daw'r Rheoliadau hyn i rym ar 10 Mai 2013.

(3) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

Dehongli

2.—(1) Yn y Rheoliadau hyn—

ystyr "addasu cyfarpar stoma" ("*stoma appliance customisation*") yw addasu swp o fwy nag un cyfarpar stoma, pan fo—

(a) y cyfarpar stoma sydd i'w haddasu wedi eu rhestru yn Rhan IXC o'r Tariff Cyffuriau;

(1) 2006 c.42

PART 1

Introduction

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013.

(2) These Regulations come into force on 10 May 2013.

(3) These Regulations apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

"the 1992 Regulations" ("*Rheoliadau 1992*") means the National Health Service (Pharmaceutical Services) Regulations 1992(1), in force immediately before these Regulations come into force;

(1) 2006 c.42.

(2) S.I. 1992/662. Relevant amending instruments are S.I.2007/205 (W.19), S.I. 2009/1491 (W.144), S.I. 2010/868 (W.90), S.I. 2010/1648 (W.156) and S.I. 2011/2907 (W.311).

- (b) yr addasiad yn cynnwys newidiadau yn unol â'r un fanyleb, mewn darnau unfath lluosog sydd i'w defnyddio gyda phob cyfarpar unigol; ac
- (c) yr addasiad hwnnw'n seiliedig ar fesuriadau'r claf, neu gofnod o'r mesuriadau hynny, a phan fo'n briodol, templed;

ystyr "AEE" ("*EEA*") yw'r Ardal Economaidd Ewropeaidd a grëwyd gan y Cytundeb AEE;

ystyr "anghymhwysiad cenedlaethol" ("*national disqualification*") yw—

- (a) anghymhwysiad cenedlaethol yn yr ystyr a roddir i "national disqualification", a grybwyllir yn adran 115(2) a (3) o Ddeddf 2006 (anghymhwysiad cenedlaethol);
- (b) anghymhwysiad cenedlaethol yn yr ystyr a roddir i "national disqualification" a grybwyllir yn adran 159(2) a (3) o Ddeddf y Gwasanaeth Iechyd Gwladol 2006(1) (anghymhwysiad cenedlaethol);
- (c) unrhyw benderfyniad yn yr Alban neu Ogledd Iwerddon sy'n cyfateb i anghymhwysiad cenedlaethol o dan adran 115(2) a (3) o Ddeddf 2006; a
- (d) unrhyw benderfyniad arall a oedd yn anghymhwysiad cenedlaethol at ddibenion Rheoliadau 2005;

ystyr "ardal reoledig" ("*controlled locality*") yw ardal y penderfynodd Bwrdd Iechyd Lleol ei bod yn wledig yn unol â rheoliad 6 (ardaloedd sy'n ardaloedd rheoledig), y penderfynodd Gweinidogion Cymru yn dilyn apêl, yn unol â Rhannau 1 a 2 o Atodlen 3, ei bod yn wledig, neu sy'n ardal reoledig yn rhinwedd gweithredu rheoliad 6(1);

ystyr "Awdurdod Gwasanaethau Busnes y GIG" ("*NHS Business Services Authority*") yw'r Awdurdod Gwasanaethau Busnes y GIG (NHS Business Services Authority) a sefydlwyd gan Orchymyn Awdurdod Gwasanaethau Busnes y. GIG (NHS Business Services Authority) (Sefydlu a Chyfansoddiad) 2005(2);

ystyr "Bwrdd Iechyd Lleol" ("*Local Health Board*") yw Bwrdd Iechyd Lleol a sefydlwyd o dan adran 11 o Ddeddf 2006 (byrddau iechyd lleol);

mae i "cais am fferyllfa yn yr arfaeth" ("*outstanding pharmacy application*") yr ystyr a roddir iddo yn rheoliad 25(11) (cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith);

"the 2005 Regulations" ("*Rheoliadau 2005*") means the National Health Service (Pharmaceutical Services) Regulations 2005(1) as in force immediately before 1 September 2012;

"the 2006 Act" ("*Deddf 2006*") means the National Health Service (Wales) Act 2006;

"advanced electronic signature" ("*llofnod electronig uwch*") means an electronic signature which is—

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under his or her sole control; and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"APMS" ("*GMDdA*") means primary medical services provided in accordance with an APMS contract;

"APMS contract" ("*contract GMDdA*") means an arrangement to provide primary medical services made with a Local Health Board under section 41(2)(b) of the 2006 Act (primary medical services);

"APMS contractor" ("*contractwr GMDdA*") means a party to an APMS contract, other than a Local Health Board;

"appliance" ("*cyfarpar*") means an appliance which is included in a list approved by the Welsh Ministers for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);

"appliance use review service" ("*gwasanaeth adolygu defnyddio cyfarpar*") means arrangements made in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services) for an NHS pharmacist or NHS appliance contractor to review a person's use of any specified appliance;

"appropriate non-proprietary name" ("*enw amherchnogol priodol*") means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;

"associated batch issue" ("*swp-ddyrodidiad cysylltiedig*") means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

(1) 2006 p. 41. Mae adran 159 wedi ei diwygio gan O.S. 2010/22.

(2) O.S. 2005/2414 fel y'i diwygiwyd gan O.S. 2006/632.

(1) S.I. 2005/641. Revoked by S.I. 2012/1909.

ystyr "Cofrestr Nyrsio a Bydwreigiaeth" ("*Nursing and Midwifery Register*") yw'r gofrestr a gynhelir gan y Cyngor Nyrsio a Bydwreigiaeth o dan erthygl 5 o Orchymyn Nyrsio a Bydwreigiaeth 2001(1) (sefydlu a chynnal cofrestr);

ystyr "Cofrestr y Cyngor Fferyllol Cyffredinol" ("*General Pharmaceutical Council Register*") yw'r gofrestr a gynhelir o dan erthygl 19 o Orchymyn Fferylliaeth 2010(2) (Sefydlu a chynnal y Gofrestr a mynediad i'r Gofrestr);

ystyr "contract GMC" ("*GMS contract*") yw contract gwasanaethau meddygol cyffredinol o dan adran 42 o Ddeddf 2006 (contractau gwasanaethau meddygol cyffredinol: rhagarweiniol);

ystyr "contract GMDdA" ("*APMS contract*") yw trefniant i ddarparu gwasanaethau meddygol sylfaenol, a wnaed gyda Bwrdd Iechyd Lleol o dan adran 41(2)(b) o Ddeddf 2006 (gwasanaethau meddygol sylfaenol);

ystyr "contractwr cyfarpar GIG" ("*NHS appliance contractor*") yw person sydd wedi ei gynnwys mewn rhestr fferyllol o dan reoliad 3 (paratoi a chynnal rhestrau fferyllol) ar gyfer darparu gwasanaethau fferyllol drwy ddarparu cyfarpar yn unig;

ystyr "contractwr GMC" ("*GMS contractor*") yw parti mewn contract GMC, ac eithrio Bwrdd Iechyd Lleol;

ystyr "contractwr GMC perthnasol" ("*relevant GMS contractor*"), mewn perthynas ag unrhyw feddyg, yw'r contractwr GMC os yw'r meddyg yn contractwr GMC, neu, os nad yw'r meddyg yn contractwr GMC, y contractwr GMC y cyflogir y meddyg ganddo, neu y cymerwyd y meddyg ymlaen ganddo;

ystyr "contractwr GMDdA" ("*APMS contractor*") yw parti mewn contract GMDdA, ac eithrio Bwrdd Iechyd Lleol;

ystyr "contractwr GMDdA perthnasol" ("*relevant APMS contractor*"), mewn perthynas ag unrhyw feddyg, yw'r contractwr GMDdA os yw'r meddyg yn contractwr GMDdA, neu, os nad yw'r meddyg yn contractwr GMDdA, y contractwr GMDdA y cyflogir y meddyg ganddo, neu y cymerwyd y meddyg ymlaen ganddo;

ystyr "corff cyfatebol" ("*equivalent body*") yw Bwrdd Comisiynu'r Gwasanaeth Iechyd Gwladol yn Lloegr, Bwrdd Iechyd yn yr Alban, Bwrdd Iechyd a Gwasanaethau Cymdeithasol yng Ngogledd Iwerddon neu unrhyw gorff olynol yn Lloegr, yr Alban neu Ogledd Iwerddon ac, mewn

"bank holiday" ("*gwyl banc*") means any day that is specified or proclaimed as a bank holiday in Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(1);

"batch issue" ("*swp-ddyroddiad*") means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a NHS pharmacist or NHS appliance contractor to receive payment for the provision of repeat dispensing services which is in the required format, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

"Charges Regulations" ("*Rheoliadau Ffioedd*") means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(2);

"child" ("*plentyn*") means a person who has not attained the age of 16 years;

"Community Health Council" ("*Cyngor Iechyd Cymuned*") means a Community Health Council retained or established under section 182 of the 2006 Act (community health councils);

"conditional inclusion" ("*cynnwys yn amodol*") means inclusion in a pharmaceutical list or the grant of preliminary consent to be included in a pharmaceutical list subject to conditions imposed under Part 6 of these Regulations and "conditionally include" ("*cynnwys yn amodol*") is to be construed accordingly;

"contingent removal" ("*tynnu digwyddiadol*") means removal from a pharmaceutical list contingently, within the meaning of section 108 of the 2006 Act (contingent removal), and "contingently remove" ("*tynnu yn ddigwyddiadol*") is to be construed accordingly;

"controlled locality" ("*ardal reoledig*") means an area which a Local Health Board has determined to be rural in accordance with regulation 6 (areas that are controlled localities), which the Welsh

(1) O.S. 2002/253; fel y'i diwygiwyd gan O.S. 2009/1182.

(2) O.S. 2007/231.

(1) 1971 c.80.

(2) S.I. 2007/121 (W.11) amended by S.I. 2007/1112 (W.117), S.I. 2009/1175 (W.102), S.I. 2009/2607 (W.210), S.I. 2010/231 and S.I. 2010/1647 (W.155).

perthynas ag unrhyw adeg cyn 1 Ebrill 2003, Awdurdod Iechyd yng Nghymru, neu mewn perthynas ag unrhyw adeg cyn 1 Ebrill 2013 ac ar ôl 30 Medi 2002 Ymddiriedolaeth Gofal Sylfaenol yn Lloegr, neu mewn perthynas ag unrhyw adeg cyn 1 Hydref 2002 Awdurdod Iechyd yn Lloegr;

ystyr "corff trwyddedu neu reoleiddio" ("*licensing or regulatory body*") yw unrhyw gorff sy'n trwyddedu neu'n rheoleiddio unrhyw broffesiwn y mae neu y bu person yn aelod ohono, ac y mae'n cynnwys unrhyw gorff sy'n trwyddedu neu'n rheoleiddio unrhyw broffesiwn o'r fath mewn gwlad ac eithrio'r Deyrnas Unedig;

mae i "cyd-bwyllgor disgyblu" yr ystyr a roddir i "joint discipline committee" yn rheoliad 2 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thribiwnlys) 1992(1) (dehongli);

mae i "cydsyniad amlinellol" ("*outline consent*") yr ystyr a roddir iddo yn rheoliad 24(1)(a) (cydsyniad amlinellol a chymeradwyaeth mangre);

mae i "cydsyniad rhagarweiniol" ("*preliminary consent*") yr ystyr a roddir iddo yn rheoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol);

ystyr "cyfarpar" ("*appliance*") yw cyfarpar a gynhwysir mewn rhestr a gymeradwywyd gan Weinidogion Cymru at ddibenion adran 80 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol);

ystyr "cyfarpar argaeledd cyfyngedig" ("*restricted availability appliance*") yw cyfarpar a gymeradwywyd ar gyfer categorïau penodol o bersonau neu ddibenion penodol yn unig;

ystyr "cyfarpar penodedig" ("*specified appliance*") yw—

- (a) unrhyw un o'r cyfarpar canlynol a restrir yn Rhan IXA o'r Tariff Cyffuriau—
 - (i) cyfarpar cathetr (gan gynnwys ategolyn cathetr a hydoddiant cynnal),
 - (ii) cyfarpar laryngectomi neu gyfarpar traceostomi,
 - (iii) system ddyfrhau rhefrol,
 - (iv) pwmp gwactod neu fodrwy ddarwasgu ar gyfer diffyg ymgodol, neu
 - (v) bag draenio ar gyfer clwyf;
- (b) cyfarpar anymataliaeth a restrir yn Rhan IXB o'r Tariff Cyffuriau; neu
- (c) cyfarpar stoma a restrir yn Rhan IXC o'r Tariff Cyffuriau;

ystyr "cyfarwyddwr" ("*director*") yw—

Ministers have determined on appeal, in accordance with Parts 1 and 2 of Schedule 3, to be rural or which is a controlled locality by virtue of the operation of regulation 6(1);

"dentist" ("*deintydd*") means a dental practitioner;

"directed services" ("*gwasanaethau cyfeiriedig*") means additional pharmaceutical services provided in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services);

"director" ("*cyfarwyddwr*") means—

- (a) a director of a body corporate; or
- (b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

"dispensing doctor" ("*meddyg fferyllol*") means a doctor who provides pharmaceutical services under arrangements with a Local Health Board made under regulation 20 (arrangements for the provision of pharmaceutical services by doctors);

"dispensing doctor list" ("*rhestr meddygon fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 4 (preparation and maintenance of dispensing doctor lists);

"doctor" ("*meddyg*") means a registered medical practitioner;

"drugs" ("*cyffuriau*") includes medicines;

"Drug Tariff" ("*Tariff Cyffuriau*") has the meaning given to it in regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

"electronic communication" ("*cyfathrebiad electronig*") has the meaning given in section 15(1) of the Electronic Communications Act 2000(1) (general interpretation);

"electronic prescription" ("*presgripsiwn electronig*") means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" ("*ffurflen bresgripsiwn electronig*") means data created in an electronic form for the purpose of ordering a drug or appliance which—

- (a) is signed with a prescriber's advanced electronic signature;
- (b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service; and

(1) O.S. 1992/664. Mewnysodwyd y diffiniad o "joint discipline committee" gan O.S. 1996/703.

(1) 2000 c.7. The definition of "electronic communication" was amended by the Communications Act 2003 (c.21), Schedule 17 paragraph 158.

- (a) cyfarwyddwr corff corfforaethol; neu
- (b) aelod o'r corff o bersonau sy'n rheoli corff corfforaethol (boed yn bartneriaeth atebolrwydd cyfyngedig ai peidio);

mae i "cyfathrebiad electronig" yr ystyr a roddir i "electronic communication" yn adran 15(1) o Ddeddf Cyfathrebiadau Electronig 2000(1) (dehongli cyffredinol);

mae "cyflogaeth" ("*employment*") yn cynnwys cyflogaeth ddi-dâl a chyflogaeth o dan gontract am wasanaethau, ac mae "cyflogedig" ("*employed*"), "cyflogwr" ("*employer*") a "cyflogi" ("*employs*") i'w dehongli'n unol â hynny;

ystyr "cyffur Atodlen" ("*Scheduled drug*") yw cyffur neu sylwedd arall a bennir yn Atodlen 1 neu 2 i'r Rheoliadau Rhagnodi Cyffuriau (sy'n ymwneud â chyffuriau, meddyginiaethau a sylweddau eraill na chaniateir eu harchebu o dan gontract gwasanaethau meddygol cyffredinol, neu y caniateir eu harchebu mewn amgylchiadau penodol yn unig);

mae "cyffuriau" ("*drugs*") yn cynnwys meddyginiaethau;

ystyr "Cyngor Iechyd Cymuned" ("*Community Health Council*") yw Cyngor Iechyd Cymuned a gadwyd neu a sefydlwyd o dan adran 182 o Ddeddf 2006 (cynghorau iechyd cymuned);

mae i "cymeradwyaeth mangre" ("*premises approval*") yr ystyr a roddir iddo yn rheoliad 24(1)(b) (cydsyniad amlinellol a chymeradwyaeth mangre) ac y mae'n cynnwys cymeradwyaeth mangre dros dro a roddir o dan reoliad 28(13) (cymeradwyaeth mangre: mangre oedd ychwanegol a newydd wedi i'r cydsyniad amlinellol gael effaith) neu gymeradwyaeth mangre weddilliol a roddir o dan reoliad 29(9) (cymeradwyaeth mangre: cyfuno practisiau);

ystyr "cynllun GFfL1" ("*LPS scheme*") yw cynllun a wnaed gan Fwrdd Iechyd Lleol o dan adran 102 o Ddeddf 2006 (cynlluniau gwasanaethau fferyllo lleol);

mae i "cynllun peilot" ("*pilot scheme*") yr un ystyr a roddir i'r term "pilot scheme" yn adran 92(2) o Ddeddf 2006 (Cynlluniau peilot);

ystyr "cynnwys yn amodol" ("*conditional inclusion*", "*conditionally include*") yw cynnwys mewn rhestr fferyllo, neu roi cydsyniad rhagarweiniol ar gyfer cynnwys mewn rhestr fferyllo, yn ddarostyngedig i amodau a osodir o dan Ran 6 o'r Rheoliadau hyn;

ystyr "darparwr gwasanaethau meddygol sylfaenol" ("*provider of primary medical services*")

- (c) does not indicate that the drug or appliance ordered may be provided more than once;

"electronic repeatable prescription" ("*presgripsiwn amlroddadwy electronig*") means data created in an electronic form which—

- (a) is signed with a repeatable prescriber's advanced electronic signature;
- (b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service;
- (c) indicates that the drugs or appliances ordered may be provided more than once; and
- (d) specifies the number of occasions on which they may be provided;

"electronic signature" ("*llofnod electronig*") has the same meaning as in section 7 of the Electronic Communications Act 2000 (electronic signatures and related certificates);

"employment" ("*cyflogaeth*") includes unpaid employment and employment under a contract for services and "employed" ("*cyflogedig*"), "employer" ("*cyflogwr*") and "employs" ("*cyflogi*") are to be construed accordingly;

"equivalent body" ("*corff cyfatebol*") means the National Health Service Commissioning Board in England, a Health Board in Scotland, a Health and Social Services Board in Northern Ireland or any successor body in England, Scotland or Northern Ireland and, in relation to any time prior to 1 April 2003, a Health Authority in Wales or in relation to any time prior to 1 April 2013 and after 30 September 2002 a Primary Care Trust in England, or in relation to any time prior to 1 October 2002 a Health Authority in England;

"equivalent list" ("*rhestr gyfatebol*") means a list kept by an equivalent body;

"essential services" ("*gwasanaethau hanfodol*") for NHS pharmacists means the services specified in paragraph 3 of Schedule 4 and for NHS appliance contractors means the services specified in paragraphs 3 to 11 of Schedule 5;

"EEA" ("*AEE*") means the European Economic Area created by the EEA Agreement;

"ETP service" ("*gwasanaeth TPE*") means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;

(1) 2000 p.7. Diwygiwyd y diffiniad o "electronic communication" gan Ddeddf Cyfathrebiadau 2003 (p.21), Atodlen 17, paragraff 158.

yw contractwr GMC, contractwr GMDdA, neu bractis GMBILl;

ystyr "Deddf 2006" ("*the 2006 Act*") yw Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006;

ystyr "deintydd" ("*dentist*") yw ymarferydd deintyddol;

ystyr "digwyddiadau cychwynnol" ("*originating events*") yw'r digwyddiadau a arweiniodd at y gollfarn, yr ymchwiliad, yr achos cyfreithiol, yr atal dros dro, y gwrthod derbyn, y cynnwys yn amodol, y tynnu ymaith neu'r tynnu digwyddiadol a ddigwyddodd;

ystyr "enw amherchnogol" ("*non-proprietary name*") yw enw sy'n un o'r canlynol, neu'n amrywiad a ganiateir o un o'r canlynol—

- (a) Enw Amherchnogol Rhyngwladol (INN);
- (b) Enw Amherchnogol Rhyngwladol Addasedig (INNMe);
- (c) Enw Cymeradwy Prydeinig (BAN);
- (d) Enw Cymeradwy Prydeinig Addasedig (BANMe); neu
- (e) enw cymeradwy,

ac at y diben hwn, mae i'r enwau hyn (a'u hamrywiadau caniatadwy) yr un ystyr sydd iddynt mewn rhestr o enwau y mae Comisiwn Cyffurlyfr Prydain wedi ei pharatoi ac wedi peri ei chyhoeddi, ac nad yw wedi ei disodli(1);

ystyr "enw amherchnogol priodol" ("*appropriate non-proprietary name*") yw enw amherchnogol nas crybwyllir yn Atodlen 1 i'r Rheoliadau Rhagnodi Cyffuriau nac, ac eithrio pan fodlonir yr amodau ym mharagraff 42(2) o Atodlen 6 i'r Rheoliadau GMC, yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau;

ystyr "fferylfa" ("*pharmacy*") yw—

- (a) mangre restredig o dan reoliad 3 (paratoi a chynnal rhestrau fferyllo), lle y darperir gwasanaethau fferyllo gan fferyllydd GIG yn unol â threfniadau a wnaed o dan adran 80 o Ddeddf 2006; neu
- (b) mangre lle mae'r ystod o wasanaethau fferyllo a ddarperir o dan gynllun peilot fferylloeth o dan adran 92 o Ddeddf 2006 (Cynlluniau peilot), a'r oriau pan ddarperir y gwasanaethau

"General Pharmaceutical Council Register" ("*Cofrestr y Cyngor Fferyllo Cyffredinol*") means the register maintained under article 19 of the Pharmacy Order 2010(1) (Establishment, maintenance of and access to the Register);

"GMS contract" ("*contract GMC*") means a general medical services contract under section 42 of the 2006 Act (general medical services contracts: introductory);

"GMS contractor" ("*contractwr GMC*") means a party to a GMS contract, other than the Local Health Board;

"GMS Regulations" ("*Rheoliadau GMC*") means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(2);

"health care professional" ("*gweithiwr proffesiynol gofal iechyd*") means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Healthcare Professions Act 2002(3);

"independent nurse prescriber" ("*nyrs sy'n rhagnodi'n annibynnol*") means a person—

- (a) who is registered in the Nursing and Midwifery Register; and
- (b) against whose name in that register is recorded an annotation signifying that he or she is qualified to order drugs and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

"joint discipline committee" ("*cyd-bwyllgor disgyblu*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(4) (interpretation);

"LHBMS" ("*GMBIL*") means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act (primary medical services);

"LHBMS practice" ("*practis GMBIL*") means a practice providing LHBMS;

"licensing or regulatory body" ("*corff trwyddedu neu reoleiddio*") means any body that licenses or regulates any profession of which the person is or

(1) Y prif gasgliad o safonau ar gyfer cynhyrchion meddyginiaethol a sylweddau fferyllo y DU yw The British Pharmacopoeia 2013, sydd ar gael yn www.pharmacopoeia.co.uk.

(1) S.I. 2010/231.

(2) S.I. 2004/478 (W.48). Amending instruments include S.I. 2004/1017 (W.114), S.I. 2006/358 (W.46), S.I. 2006/945 (W.94), S.I. 2007/121 (W.11), S.I. 2007/205 (W.19), S.I. 2008/1329 (W.138), S.I. 2008/1425 (W.147), S.I. 2010/729 (W.70), S.I. 2010/1647 (W.155) and S.I. 2011/704 (W.108).

(3) 2002 c.17. Section 25 has been amended by the Health and Social Care Act 2008 (c.14).

(4) S.I. 1992/664. The definition of "joint discipline committee" was inserted by S.I. 1996/703.

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hynny, yn gymaradwy â fferyllfa sy'n dod o fewn is-baragraff (a);

ystyr "fferyllydd cofrestredig" ("*registered pharmacist*") yw person a gofrestrwyd yn Rhan 1 o Gofrestr y Cyngor Fferyllol Cyffredinol neu yn y gofrestr a gynhelir o dan Erthyglau 6 a 9 o Orchymyn Fferylliaeth (Gogledd Iwerddon) 1976;

ystyr "fferyllydd GIG" ("*NHS pharmacist*") yw—
(a) fferyllydd cofrestredig; neu
(b) person sy'n cynnal busnes fferyllfa fanwerthu yn gyfreithlon yn unol ag adran 69 o Ddeddf Meddyginiaethau 1968(1),

y mae ei enw wedi ei gynnwys mewn rhestr fferyllol o dan reoliad 3 (paratoi a chynnal rhestrau fferyllol) ar gyfer darparu gwasanaethau fferyllol yn benodol drwy ddarparu cyffuriau;

ystyr "fferyllydd-ragnodydd annibynnol" ("*pharmacist independent prescriber*") yw fferyllydd cofrestredig sydd â nodyn gyferbyn â'i enw yn Rhan 1 o Gofrestr y Cyngor Fferyllol Cyffredinol neu yn y gofrestr a gynhelir o dan Erthyglau 6 a 9 o Orchymyn Fferylliaeth (Gogledd Iwerddon) 1976(2)(sy'n ymwneud â chofrestrau a'r cofrestrydd), sy'n dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel fferyllydd-ragnodydd annibynnol;

ystyr "ffurflen bresgripsiwn" ("*prescription form*") yw—
(a) ffurflen a ddarperir gan Fwrdd Iechyd Lleol, Ymddiriedolaeth GIG, Ymddiriedolaeth Sefydledig GIG neu gorff cyfatebol ac a ddyroddir gan ragnodydd; neu
(b) ffurflen bresgripsiwn electronig,

sy'n galluogi person i gael gwasanaethau fferyllol ac nad yw'n cynnwys presgripsiwn amlroddadwy;

ystyr "ffurflen bresgripsiwn anelectronig" ("*non-electronic prescription form*") yw ffurflen bresgripsiwn sy'n dod o fewn is-baragraff (a) o'r diffiniad o "ffurflen bresgripsiwn";

ystyr "ffurflen bresgripsiwn electronig" ("*electronic prescription form*") yw data a grëwyd mewn ffurf electronig at y diben o archebu cyffur neu gyfarpar, ac—

(a) sy'n dwyn llofnod electronig uwch y rhagnodydd;
(b) a drawsyrir fel cyfathrebiad electronig at fferyllydd GIG, contractwr cyfarpar GIG neu feddyg fferyllol enwebedig drwy'r gwasanaeth TPE; ac

(c) nad ydynt yn dynodi y caniateir darparu'r cyffur neu'r cyfarpar a archebir fwy nag unwaith;

(1) 1968 p.67.13

(2) O.S. 1976/1213 (G.I. 22).

has been a member, and includes any body which licenses or regulates any such profession in a country other than the United Kingdom;

"list" ("*rhestr*"), unless the context otherwise requires, means a pharmaceutical list or a dispensing doctor list;

"listed premises" ("*mangre restredig*") means the premises that are included in—

(a) a pharmaceutical list; or
(b) a dispensing doctor list pursuant to regulation 4 (preparation and maintenance of dispensing doctor lists);

"Local Health Board" ("*Bwrdd Iechyd Lleol*") means a Local Health Board established under section 11 of the 2006 Act (local health boards);

"Local Medical Committee" ("*Pwyllgor Meddygol Lleol*") means a committee recognised under section 54 of the 2006 Act (local medical committees);

"Local Pharmaceutical Committee" ("*Pwyllgor Fferyllol Lleol*") means a committee recognised under section 90 of the 2006 Act (local pharmaceutical committees);

"local pharmaceutical services" ("*gwasanaethau fferyllol lleol*") means services of a kind which may be provided under section 80, or by virtue of section 81 of the 2006 Act, other than practitioner dispensing services, and which are provided under a pilot scheme;

"medical performers list" ("*rhestr cyflawnwyr meddygol*") means a list of doctors prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004(1);

"national disqualification" ("*anghymhwysiad cenedlaethol*") means—

(a) a national disqualification as mentioned in section 115 (2) and (3) of the 2006 Act (national disqualification);
(b) a national disqualification as mentioned in section 159 (2) and (3) of the National Health Service Act 2006(2) (national disqualification);
(c) any decision in Scotland or Northern Ireland corresponding to a national disqualification under section 115 (2) and (3) of the 2006 Act; and
(d) any other decision that was a national disqualification for the purposes of the 2005 Regulations;

(1) S.I. 2004/1020 (W.117).

(2) 2006 c.41. Section 159 has been amended by S.I. 2010/22.

ystyr "GMBILI" ("*LHBMS*") yw gwasanaethau meddygol sylfaenol a ddarperir gan Fwrdd Iechyd Lleol o dan adran 41(2)(a) o Ddeddf 2006 (gwasanaethau meddygol sylfaenol);

ystyr "GMDdA" ("*APMS*") yw gwasanaethau meddygol sylfaenol a ddarperir yn unol â chontract GMDdA;

ystyr "gwasanaeth adolygu defnyddio cyfarpar" ("*appliance use review service*") yw trefniadau a wneir yn unol â chyfarwyddiadau o dan adran 81 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol ychwanegol) i fferylllydd GIG neu gontractwr cyfarpar GIG adolygu'r modd y mae person yn defnyddio unrhyw gyfarpar penodedig;

ystyr "gwasanaeth TPE" ("*ETP service*") yw'r gwasanaeth presgripsiynau cod-bar 2-ddimensiwn sy'n rhan o'r systemau technoleg gwybodaeth mewn systemau rhagnodi a gweinyddu yng Nghymru, ac a ddefnyddir gan y gwasanaeth iechyd yng Nghymru i drosglwyddo a chadw gwybodaeth am bresgripsiynau mewn perthynas â chleifion;

ystyr "gwasanaethau amlweinyddu" ("*repeat dispensing services*") yw gwasanaethau fferyllol sy'n cynnwys darparu cyffuriau neu gyfarpar gan fferylllydd GIG neu gontractwr cyfarpar GIG yn unol â phresgripsiwn amlroddadwy;

ystyr "gwasanaethau cyfeiriedig" ("*directed services*") yw gwasanaethau fferyllol ychwanegol a ddarperir yn unol â chyfarwyddiadau o dan adran 81 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol ychwanegol);

ystyr "gwasanaethau fferyllol" ("*pharmaceutical services*") yw gwasanaethau fferyllol sy'n dod o fewn adran 80 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol) ac nid ydynt yn cynnwys gwasanaethau cyfeiriedig;

ystyr "gwasanaethau fferyllol lleol" ("*local pharmaceutical services*") yw gwasanaethau o fath y caniateir eu darparu o dan adran 80, neu yn rhinwedd adran 81 o Ddeddf 2006, ac eithrio gwasanaethau gweinyddu gan ymarferwyr, ac a ddarperir o dan gynllun peilot;

ystyr "gwasanaethau GIG" ("*NHS services*") yw gwasanaethau a ddarperir yn rhan o'r gwasanaeth iechyd yng Nghymru;

ystyr "gwasanaethau hanfodol" ("*essential services*") ar gyfer fferyllwyr GIG yw'r gwasanaethau a bennir ym mharagraff 3 o Atodlen 4, ac ar gyfer contractwyr cyfarpar GIG yr ystyr yw'r gwasanaethau a bennir ym mharagraffau 3 i 11 o Atodlen 5;

"NHS appliance contractor" ("*contractwr cyfarpar GIG*") means a person who is included in a pharmaceutical list under regulation 3 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;

"NHS Business Services Authority" ("*Awdurdod Gwasanaethau Busnes y GIG*") means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(1)

"NHS pharmacist" ("*fferylllydd GIG*") means—

- (a) a registered pharmacist; or
- (b) a person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(2),

whose name is included in a pharmaceutical list under regulation 3 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;

"NHS services" ("*gwasanaethau GIG*") means services provided as part of the health service in Wales;

"non-electronic prescription form" ("*ffurflen bresgripsiwn anelectronig*") means a prescription form which falls within sub-paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" ("*presgripsiwn amlroddadwy anelectronig*") means a prescription which falls within sub-paragraph (a)(i) of the definition of "repeatable prescription";

"non-proprietary name" ("*enw amherchnogol*") means a name which is, or which is a permitted variation of—

- (a) an International Nonproprietary Name (INN);
- (b) an International Nonproprietary Name Modified (INNMod);
- (c) a British Approved Name (BAN);
- (d) a British Approved Name Modified (BANMod); or
- (e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of

(1) S.I. 2005/2414 as amended by S.I. 2006/632.

(2) 1968 c.67.

ystyr "gweithiwr proffesiynol gofal iechyd" ("*health care professional*") yw person, ac eithrio gweithiwr cymdeithasol, sy'n aelod o broffesiwn a reoleiddir gan gorff a grybwyllir yn adran 25(3) o Ddeddf Diwygio'r Gwasanaeth Iechyd Gwladol a Phroffesiynau Gofal Iechyd 2002(1);

ystyr "Gwladwriaeth Ewropeaidd berthnasol" ("*relevant European State*") yw Gwladwriaeth AEE neu'r Swistir;

ystyr "gŵyl banc" ("*bank holiday*") yw unrhyw ddiwrnod a bennir neu a gyhoeddir yn ŵyl banc yng Nghymru yn unol ag adran 1 o Ddeddf Bancio a Thrafodion Ariannol 1971(2);

ystyr "hysbysiad" ("*notice*") yw hysbysiad ysgrifenedig ac mae "hysbysu" ("*notify*") i'w ddehongli'n unol â hynny;

mae i "lleoliad neilltuedig" ("*reserved location*") yr ystyr a roddir iddo gan reoliad 11(4) (lleoliadau mewn ardaloedd rheoledig sy'n lleoliadau neilltuedig);

mae i "llofnod electronig" yr ystyr a roddir i "electronic signature" yn adran 7 o Ddeddf Cyfathrebiadau Electronig 2000 (llofnodion electronig a thystysgrifau cysylltiedig);

ystyr "llofnod electronig uwch" ("*advanced electronic signature*") yw llofnod electronig—

- (a) sydd â chysylltiad unigryw â'r llofnodwr;
- (b) y gellir adnabod y llofnodwr oddi wrtho;
- (c) a grëwyd drwy ddefnyddio dull y gall y llofnodwr gadw dan ei reolaeth ei hunan yn unig; a
- (d) wedi ei gysylltu â'r data y mae'r llofnod yn perthyn iddynt mewn modd a fyddai'n gwneud unrhyw newid diweddarach yn y data yn ganfyddadwy;

ystyr "mangre practis" ("*practice premises*"), mewn perthynas â darparwr gwasanaethau meddygol sylfaenol, yw'r cyfeiriad neu'r cyfeiriadau a bennir yn y contract (yn achos contractwr GMC neu GMDdA) neu'r datganiad practis (yn achos practis GMBILl) lle y darperir gwasanaethau o dan y contract neu'r datganiad practis;

ystyr "mangre restredig" ("*listed premises*") yw'r fangre sydd wedi ei chynnwys mewn—

- (a) rhestr fferyllol; neu
- (b) rhestr meddygon fferyllol yn unol â rheoliad 4 (paratoi a chynnal rhestrau meddygon fferyllol);

(1) 2002 p.17. Diwygiwyd adran 25 gan Ddeddf Iechyd a Gofal Cymdeithasol 2008 (p.14).

(2) 1971 p.89

names which has been prepared and caused to be published by the British Pharmacopoeia Commission and which has not been superseded(1);

"notice" ("*hysbysiad*") means a notice in writing and "notify" ("*hysbysu*") is to be construed accordingly;

"nurse independent prescriber" ("*nyrs-ragnodydd annibynnol*") means a person—

- (a) whose name is registered in the Nursing and Midwifery Register;
- (b) against whose name in that register is recorded an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as:
 - (i) a nurse independent prescriber, or
 - (ii) a nurse independent/supplementary prescriber, and
- (c) who, in respect of a person practising in Wales on or after 19 July 2010, has passed an accredited course to practise as a nurse independent prescriber;

"Nursing and Midwifery Register" ("*Cofrestr Nyrsio a Bydwreigiaeth*") means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(2) (establishment and maintenance of register);

"optometrist independent prescriber" ("*optometrydd-ragnodydd annibynnol*") means a person—

- (a) who is an optometrist registered in the register of optometrists maintained under section 7 of the Opticians Act 1989(3) (which relates to the register of optometrists and the register of dispensing opticians) or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act; and
- (b) against whose name is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

"originating events" ("*digwyddiadau cychwynnol*") means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;

"outline consent" ("*cydsyniad amlinellol*") has the meaning given to it in regulation 24(1)(a) (outline consent and premises approval);

(1) The British Pharmacopoeia 2013 is the leading collection of standards for UK medicinal products and pharmaceutical substances and is available at www.pharmacopoeia.co.uk.

(2) S.I. 2002/253; as amended by S.I. 2009/1182.

(3) 1989 c.44; amended by S.I. 2005/848.

ystyr "meddyg" ("*doctor*") yw ymarferydd meddygol cofrestredig;

ystyr "meddyg fferyllol" ("*dispensing doctor*") yw meddyg sy'n darparu gwasanaethau fferyllol o dan drefniadau gyda Bwrdd Iechyd Lleol a wneir o dan reoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon);

ystyr "nyrs sy'n rhagnodi'n annibynnol" ("*independent nurse prescriber*") yw person—

- (a) sydd wedi ei gofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth; a
- (b) sydd â nodyn gyferbyn â'i enw yn y gofrestr honno yn dynodi ei fod yn gymwys i archebu cyffuriau a chyfarpar fel nyrs sy'n rhagnodi fel ymarferydd cymunedol, nyrs-ragnodydd annibynnol neu nyrs-ragnodydd annibynnol/atodol;

ystyr "nyrs-ragnodydd annibynnol" ("*nurse independent prescriber*") yw person—

- (a) sydd â'i enw wedi ei gofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth;
- (b) sydd â nodyn neu gofnod gyferbyn â'i enw yn y gofrestr honno yn dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel—
 - (i) nyrs-ragnodydd annibynnol, neu
 - (ii) nyrs-ragnodydd annibynnol/atodol; ac
- (c) sydd, mewn perthynas â pherson sy'n ymarfer yng Nghymru ar neu ar ôl 19 Gorffennaf 2010, wedi llwyddo mewn cwrs a achredwyd ar gyfer ymarfer fel nyrs-ragnodydd annibynnol;

ystyr "optometrydd-ragnodydd annibynnol" ("*optometrist independent prescriber*") yw person—

- (a) sy'n optometrydd a gofrestrwyd yn y gofrestr o optometryddion a gynhelir o dan adran 7 o Ddeddf Optometryddion 1989(1) (sy'n ymwneud â'r gofrestr o optometryddion a'r gofrestr o optegwyr fferyllol) neu'r gofrestr o optometryddion gwadd o Wladwriaethau Ewropeaidd perthnasol a gynhelir o dan adran 8B(1)(a) o'r Ddeddf honno; a
- (b) sydd â nodyn gyferbyn â'i enw yn dynodi bod yr optometrydd yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel optometrydd-ragnodydd annibynnol;

ystyr "plentyn" ("*child*") yw person nad yw wedi cyrraedd 16 mlwydd oed;

ystyr "practis GMBILI" ("*LHBMS practice*") yw practis sy'n darparu GMBILI;

"outstanding pharmacy application" ("*cais am fferyllfa yn yr arfaeth*") has the meaning given to it in regulation 25(11) (taking effect of outline consent and premises approval);

"patient list" ("*rhestr cleifion*") means a list of patients kept in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations or in respect of an APMS contractor or an LHBMS practice, in accordance with directions given by the Welsh Ministers under section 12(3) of the 2006 Act;

"pharmaceutical discipline committee" ("*pwyllgor disgyblu fferyllol*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(1);

"pharmaceutical list" ("*rhestr fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 3 (preparation and maintenance of pharmaceutical lists);

"pharmaceutical services" ("*gwasanaethau fferyllol*") means pharmaceutical services that fall within section 80 of the 2006 Act (arrangements for pharmaceutical services) and do not include directed services;

"pharmacist independent prescriber" ("*fferylllydd-ragnodydd annibynnol*") means a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(2) (which relates to registers and the registrar) is recorded an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"pharmacy" ("*fferyllfa*") means—

- (a) listed premises under regulation 3 (preparation and maintenance of pharmaceutical lists) at which pharmaceutical services are provided by an NHS pharmacist pursuant to arrangements made under section 80 of the 2006 Act; or
- (b) premises where under a pharmacy pilot scheme under section 92 of the 2006 Act (Pilot schemes) the range of pharmaceutical services and the hours on which they are provided are comparable to a pharmacy falling within subparagraph (a);

"pilot scheme" ("*cynllun peilot*") has the same meaning as in the term "pilot scheme" in section 92(2) of the 2006 Act (Pilot schemes);

"practice premises" ("*mangre practis*"), in relation to a provider of primary medical services, means

(1) 1989 p.44, diwygiwyd gan O.S. 2005/848.

(1) S.I. 1992/664. The definition of "pharmaceutical discipline committee" was inserted by S.I. 1996/703.

(2) S.I. 1976/1213 (N.I. 22).

ystyr "presgripsiwn amlroddadwy" ("*repeatable prescription*") yw presgripsiwn a gynhwysir mewn ffurflen a ddarparwyd gan Fwrdd Iechyd Lleol—

(a) sydd naill ai—

- (i) wedi ei chynhyrchu gan gyfrifiadur ond wedi ei llofnodi gan ragnodydd amlroddadwy, neu
 - (ii) yn ffurflen a grëwyd mewn fformat electronig, a adwaenir drwy ddefnyddio cod rhagnodydd amlroddadwy ac a drawsyrir fel cyfathrebiad electronig at fferylllydd GIG, contractwr cyfarpar GIG neu feddyg fferyllol enwebedig drwy'r gwasanaeth TPE;
- (b) a ddyroddir neu a grëir i alluogi person i gael gwasanaethau fferyllol; ac
- (c) sy'n dynodi y caniateir darparu'r cyffuriau neu'r cyfarpar a archebir ar y ffurflen honno fwy nag unwaith, ac yn pennu'r nifer o droeon y caniateir eu darparu;

ystyr "presgripsiwn amlroddadwy anelectronig" ("*non-electronic repeatable prescription*") yw presgripsiwn sy'n dod o fewn is-baragraff (a)(i) o'r diffiniad o "presgripsiwn amlroddadwy";

ystyr "presgripsiwn amlroddadwy electronig" ("*electronic repeatable prescription*") yw data a grëwyd mewn ffurf electronig—

- (a) sy'n dwyn llofnod electronig uwch y rhagnodydd amlroddadwy;
- (b) a drawsyrir fel cyfathrebiad electronig at fferylllydd GIG, contractwr cyfarpar GIG neu feddyg fferyllol enwebedig drwy'r gwasanaeth TPE;
- (c) sy'n dynodi y caniateir darparu'r cyffuriau neu'r cyfarpar a archebir fwy nag unwaith; a
- (d) sy'n pennu'r nifer o droeon y caniateir darparu'r cyffuriau neu'r cyfarpar;

ystyr "presgripsiwn electronig" ("*electronic prescription*") yw ffurflen bresgripsiwn electronig neu bresgripsiwn amlroddadwy electronig;

mae i "pwyllgor disgyblu fferyllol" yr ystyr a roddir i "pharmaceutical discipline committee" yn rheoliad 2 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thribiwnlys) 1992(1);

ystyr "Pwyllgor Fferyllol Lleol" ("*Local Pharmaceutical Committee*") yw pwyllgor a gydnabyddir o dan adran 90 o Ddeddf 2006 (pwyllgorau fferyllol lleol);

ystyr "Pwyllgor Meddygol Lleol" ("*Local Medical Committee*") yw pwyllgor a gydnabyddir o dan

the address or addresses specified in the contract (in the case of a GMS or APMS contractor) or practice statement (in the case of an LHBMS practice) at which services are to be provided under the contract or practice statement;

"preliminary consent" ("*cydsyniad rhagarweiniol*") has the meaning given to it in regulation 12 (applications for preliminary consent and effect of preliminary consent);

"premises approval" ("*cymeradwyaeth mangre*") has the meaning given to it in regulation 24(1)(b) (outline consent and premises approval) and includes temporary premises approval granted under regulation 28(13) (premises approval: additional and new premises after outline consent has taken effect) or residual premises approval granted under regulation 29(9) (premises approval: practice amalgamations);

"prescriber" ("*rhagnodydd*") means a doctor, dentist, pharmacist independent prescriber, independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber or a supplementary prescriber;

"prescription form" ("*ffurflen bresgripsiwn*") means—

- (a) a form provided by a Local Health Board, an NHS Trust, an NHS Foundation Trust or an equivalent body and issued by a prescriber; or
- (b) an electronic prescription form,

that enables a person to obtain pharmaceutical services and does not include a repeatable prescription;

"Prescription of Drugs Regulations" ("*Rheoliadau Rhagnodi Cyffuriau*") means the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(1);

"provider of primary medical services" ("*darparwr gwasanaethau meddygol sylfaenol*") means a GMS contractor, APMS contractor, or an LHBMS practice;

"registered pharmacist" ("*fferylllydd cofrestredig*") means a person who is registered in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

"relevant APMS contractor" ("*contractwr GMDda perthnasol*"), in relation to any doctor, means the APMS contractor, where the doctor is an APMS contractor, or where he or she is not, the APMS contractor by whom the doctor is employed or engaged;

(1) O.S. 1992/664. Mewnosodwyd y diffiniad o "pharmaceutical discipline committee" gan O.S. 1996/703.

(1) S.I. 2004/1022 (W.119) amended by S.I. 2005/366 (W.32), S.I. 2009/1838 (W.166) and S.I. 2009/1977 (W.176).

adran 54 o Ddeddf 2006 (pwyllgorau meddygol lleol);

ystyr "rhagnodydd" ("*prescriber*") yw meddyg, deintydd, fferyllydd-ragnodydd annibynnol, nyrs sy'n rhagnodi'n annibynnol, nyrs-ragnodydd annibynnol, optometrydd-ragnodydd annibynnol neu ragnodydd atodol;

ystyr "rhagnodydd amlroddadwy" ("*repeatable prescriber*") yw person sydd—

- (a) yn contractwr GMC sy'n darparu gwasanaethau amlweinyddu o dan y telerau yn ei contract sy'n rhoi effaith i baragraff 40 (gwasanaethau amlweinyddu) o Atodlen 6 i'r Rheoliadau GMC;
- (b) yn contractwr GMDdA sy'n darparu gwasanaethau amlweinyddu o dan y telerau yn ei gytundeb sy'n rhoi effaith i ddarpariaeth mewn cyfarwyddiadau a wnaed gan Weinidogion Cymru o dan adran 12(3) o Ddeddf 2006 mewn perthynas â chontractau GMDdA, sy'n ddarpariaeth gyfatebol i baragraff 40 o Atodlen 6 i'r Rheoliadau GMC; neu
- (c) yn gyflogedig neu wedi ei gymryd ymlaen gan—
 - (i) contractwr GMC sy'n darparu gwasanaethau amlweinyddu o dan y telerau mewn contract sy'n rhoi effaith i baragraff 40 o Atodlen 6 i'r Rheoliadau GMC,
 - (ii) contractwr GMDdA sy'n darparu gwasanaethau amlweinyddu o dan y telerau mewn cytundeb sy'n rhoi effaith i ddarpariaeth mewn cyfarwyddiadau a wnaed gan Weinidogion Cymru o dan adran 12(3) o Ddeddf 2006 mewn perthynas â chontractau GMDdA, sy'n ddarpariaeth gyfatebol i baragraff 40 o Atodlen 6 i'r Rheoliadau GMC, neu
 - (iii) Bwrdd Iechyd Lleol at ddibenion darparu gwasanaethau meddygol sylfaenol mewn practis GMBILl sy'n darparu presgripsiynu amlroddadwy yn unol â darpariaeth mewn cyfarwyddiadau a wnaed gan Weinidogion Cymru o dan adran 12(3) o Ddeddf 2006 mewn perthynas â GMBILl, sy'n ddarpariaeth gyfatebol i baragraff 40 o Atodlen 6 i'r Rheoliadau GMC;

ystyr "rhagnodydd atodol" ("*supplementary prescriber*") yw—

- (a) fferyllydd cofrestredig y mae nodyn gyferbyn â'i enw yn Rhan 1 o Gofrestr y Cyngor

"relevant European State" ("*Gwladwriaeth Ewropeaidd perthnasol*") means an EEA State or Switzerland;

"relevant GMS contractor" ("*contractwr GMC perthnasol*"), in relation to any doctor, means the GMS contractor, where the doctor is a GMS contractor or, where he or she is not, the GMS contractor by whom the doctor is employed or engaged;

"relevant list" ("*rhestr berthnasol*") means—

- (a) a pharmaceutical list or an equivalent list; or
- (b) a list maintained by a Local Health Board or an equivalent body of approved performers or providers of primary medical, dental or ophthalmic services;

"relevant patient list" ("*rhestr cleifion berthnasol*") means, in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or APMS contractor, the patient list for that contractor or, where the doctor is not a contractor, means the patient list for the GMS contractor or APMS contractor by whom the doctor is employed or engaged or for the LHBMS practice within which the doctor provides primary medical services;

"Remission of Charges Regulations" ("*Rheoliadau Peidio â Chodi Tâl*") means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007(1);

"repeat dispensing services" ("*gwasanaethau amlweinyddu*") means pharmaceutical services which involve the provision of drugs or appliances by an NHS pharmacist or an NHS appliance contractor in accordance with a repeatable prescription;

"repeatable prescriber" ("*rhagnodydd amlroddadwy*") means a person who is—

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 (repeatable prescribing services) of Schedule 6 to the GMS Regulations;
- (b) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations; or
- (c) employed or engaged by—

(1) S.I. 2007/1104 (W.116) amended by S.I. 2008/1480 (W.153), S.I. 2008/2568 (W.226), S.I. 2009/54 (W.18), S.I. 2009/709 (W.61), S.I. 2009/1824 (W.165), S.I. 2009/2365 (W.193), S.I. 2010/1237 (W.107), S.I. 2010/2759 (W.231), S.I. 2011/681 (W.100), S.I. 2011/1940 (W.208) and S.I. 2012/800 (W.109).

Fferyllol Cyffredinol neu yn y gofrestr a gynhelir o dan Erthyglau 6 a 9 o Orchymyn Fferylliaeth (Gogledd Iwerddon) 1976 sy'n dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel rhagnodydd atodol;

(b) person y mae ei enw wedi ei gofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth, ac y mae nodyn gyferbyn â'i enw yn y Gofrestr honno sy'n dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel nyrs-ragnodydd annibynnol/atodol;

(c) person—

(i) sydd wedi ei gofrestru mewn rhan o'r gofrestr a gynhelir o dan erthygl 5 o Orchymyn Proffesiynau Iechyd a Gwaith Cymdeithasol 2001(1) (sefydlu a chynnal cofrestr) sy'n ymwneud â chiropodyddion a phodiatriyddion, ffisiotherapyddion neu radiograffwyr, a

(ii) y mae nodyn gyferbyn â'i enw yn y gofrestr honno sy'n dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel rhagnodydd atodol; neu

(d) optometrydd y mae nodyn gyferbyn â'i enw yn y gofrestr o optometryddion a gynhelir o dan adran 7 neu 8B(1)(a) o Ddeddf Optegwyr 1989 sy'n dynodi bod yr optometrydd yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel rhagnodydd atodol;

ystyr "Rheoliadau 1992" ("*the 1992 Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(2), a oedd mewn grym yn union cyn i'r Rheoliadau hyn ddod i rym;

ystyr "Rheoliadau 2005" ("*the 2005 Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 2005(3) fel yr oeddent mewn grym yn union cyn 1 Medi 2012;

ystyr "Rheoliadau Ffioedd" ("*Charges Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007(4);

(i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations,

(ii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations, or

(iii) a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to LHBMS which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations;

"repeatable prescription" ("*presgripsiwn amlroddadwy*") means a prescription contained in a form provided by a Local Health Board which—

(a) is either—

(i) generated by computer but signed by a repeatable prescriber, or

(ii) a form created in an electronic format, identified using a repeatable prescriber's code and transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service;

(b) is issued or created to enable a person to obtain pharmaceutical services; and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

"reserved location" ("*lleoliad neilltuedig*") has the meaning given to it by regulation 11(4) (locations in controlled localities that are reserved locations);

(1) O.S. 2002/254. Diwygiwyd erthygl 5 gan O.S. 2009/1182. Mae'r Gorchymyn wedi ei ailenwi gan adran 213(4) a (6) o Ddeddf Iechyd a Gofal Cymdeithasol 2012 (p.7)

(2) O.S. 1992/662. Yr offerynnau perthnasol sy'n diwygio yw O.S.2007/205 (Cy.19), O.S. 2009/1491 (Cy.144), O.S. 2010/868 (Cy.90), O.S. 2010/1648 (Cy.156) ac O.S. 2011/2907 (Cy.311).

(3) O.S. 2005/641. Dirymwyd gan O.S. 2012/1909.

(4) O.S. 2007/121 (Cy.11) a ddiwygiwyd gan O.S. 2007/1112 (Cy.117), O.S. 2009/1175 (Cy.102), O.S. 2009/2607 (Cy.210), O.S. 2010/231 ac O.S. 2010/1647 (Cy.155).

ystyr "Rheoliadau GMC" ("*GMS Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004(1);

ystyr "Rheoliadau Peidio â Chodi Tâl" ("*Remission of Charges Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Treuliau Teithio a Pheidio â Chodi Tâl) (Cymru) 2007(2);

ystyr "Rheoliadau Rhagnodi Cyffuriau" ("*Prescription of Drugs Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Rhagnodi Cyffuriau etc) (Cymru) 2004(3);

ystyr "rhestr" ("*list*"), oni fydd y cyd-destun yn mynnu'n wahanol, yw rhestr fferyllol neu restr meddygon fferyllol;

ystyr "rhestr berthnasol" ("*relevant list*") yw—

- (a) rhestr fferyllol neu restr gyfatebol; neu
- (b) rhestr, a gynhelir gan Fwrdd Iechyd Lleol neu gorff cyfatebol, o gyflawnwyr cymeradwy neu ddarparwyr gwasanaethau meddygol sylfaenol, deintyddol neu offthalmig;

ystyr "rhestr cleifion" ("*patient list*") yw rhestr o gleifion a gedwir yn unol â pharagraff 14 (rhestr o gleifion) o Atodlen 6 i'r Rheoliadau GMC neu, mewn perthynas â chontractwr GMDdA neu bractis GMBILl, yn unol â chyfarwyddiadau a roddir gan Weinidogion Cymru o dan adran 12(3) o Ddeddf 2006;

ystyr "rhestr cleifion berthnasol" ("*relevant patient list*"), mewn perthynas â meddyg sy'n contractwr GMC neu'n contractwr GMDdA (neu sy'n gyfranddaliwr cyfreithiol a llesianol mewn cwmni sy'n contractwr o'r fath), yw'r rhestr cleifion ar gyfer y contractwr hwnnw, neu, pan nad yw'r meddyg yn contractwr, yw'r rhestr cleifion ar gyfer y contractwr GMC neu'r contractwr GMDdA y cyflogir y meddyg ganddo neu y cymerwyd y meddyg ymlaen ganddo neu ar gyfer y practis GMBILl y mae'r meddyg yn darparu gwasanaethau meddygol sylfaenol ynddo;

ystyr "rhestr cyflawnwyr meddygol" ("*medical performers list*") yw rhestr o feddygon, a baratowyd ac a gyhoeddwyd yn unol â rheoliad 3(1) o Reoliadau'r Gwasanaeth Iechyd Gwladol

"restricted availability appliance" ("*cyfarpar argaeledd cyfyngedig*") means an appliance which is approved for particular categories of persons or particular purposes only;

"Scheduled drug" ("*cyffur Atodlen*") means a drug or other substance specified in Schedule 1 or 2 to the Prescription of Drugs Regulations (which relate to drugs, medicines and other substances not to be ordered under a general medical services contract or that may be ordered only in certain circumstances);

"specified appliance" ("*cyfarpar penodedig*") means—

- (a) any of the following appliances listed in Part IXA of the Drug Tariff—
 - (i) a catheter appliance (including a catheter accessory and maintenance solution),
 - (ii) a laryngectomy or tracheostomy appliance,
 - (iii) an anal irrigation system,
 - (iv) a vacuum pump or constrictor ring for erectile dysfunction, or
 - (v) a wound drainage pouch;
- (b) an incontinence appliance listed in Part IXB of the Drug Tariff; or
- (c) a stoma appliance listed in Part IXC of the Drug Tariff;

"stoma appliance customisation" ("*addasu cyfarpar stoma*") means the customisation of a quantity of more than one stoma appliance, where—

- (a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;
- (b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and
- (c) that modification is based on the patient's measurements or a record of those measurements and, if applicable, a template;

"superintendent" ("*uwcharolygydd*") has the same meaning as in section 71 of the Medicines Act 1968(1) (bodies corporate);

"supplementary prescriber" ("*rhagnodydd atodol*")

(1) O.S. 2004/478 (Cy.48). Mae'r offerynnau sy'n diwygio yn cynnwys O.S. 2004/1017 (Cy.114), O.S. 2006/358 (Cy.46), O.S. 2006/945 (Cy.94), O.S. 2007/121 (Cy.11), O.S. 2007/205 (Cy.19), O.S. 2008/1329 (Cy.138), O.S. 2008/1425 (Cy.147), O.S. 2010/729 (Cy.70), O.S. 2010/1647 (Cy.155) ac O.S. 2011/704 (Cy.108).

(2) O.S. 2007/1104 (Cy.116) a ddiwygiwyd gan O.S. 2008/1480 (Cy.153), O.S. 2008/2568 (Cy.226), O.S. 2009/54 (Cy.18), O.S. 2009/709 (Cy.61), O.S. 2009/1824 (Cy.165), O.S. 2009/2365 (Cy.193), O.S. 2010/1237 (Cy.107), O.S. 2010/2759 (Cy.231), O.S. 2011/681 (Cy.100), O.S. 2011/1940 (Cy.208) ac O.S. 2012/800 (Cy.109).

(3) O.S. 2004/1022 (Cy.119) a ddiwygiwyd gan O.S. 2005/366 (Cy.32), O.S. 2009/1838 (Cy.166) ac O.S. 2009/1977 (Cy.176).

(1) Section 71 was substituted by section 28 of the Health Act 2006 (c.28).

(Rhestrï Cyflawnwyr) (Cymru) 2004(1);

ystyr "rhestr fferyllol" ("*pharmaceutical list*") yw rhestr y mae'n ofynnol bod Bwrdd Iechyd Lleol yn ei pharatoi a'i chynnal o dan reoliad 3 (paratoi a chynnal rhestrau fferyllol);

ystyr "rhestr gyfatebol" ("*equivalent list*") yw rhestr a gedwir gan gorff gyfatebol;

ystyr "rhestr meddygon fferyllol" ("*dispensing doctor list*") yw rhestr y mae'n ofynnol i Fwrdd Iechyd Lleol ei pharatoi a'i chynnal o dan reoliad 4 (paratoi a chynnal rhestrau meddygon fferyllol);

ystyr "swp-ddyroddiad" ("*batch issue*") yw ffurflen, a ddarparwyd gan Fwrdd Iechyd Lleol ac a ddyroddir gan ragnodydd amlroddadwy ar yr un pryd â phresgripsiwn amlroddadwy anelectronig i alluogi fferylllydd GIG neu gontractwr cyfarpar GIG i dderbyn tâl am ddarparu gwasanaethau amlweinyddu, ac sydd yn y fformat gofynnol, ac—

- (a) a gynhyrchir gan gyfrifiadur ac nas llofnodir gan ragnodydd amlroddadwy;
- (b) sy'n ymwneud â phresgripsiwn amlroddadwy anelectronig penodol ac yn cynnwys yr un dyddiad â'r presgripsiwn hwnnw;
- (c) a ddyroddir fel un o ddilyniant o ffurflenni sydd â'u nifer yn hafal i nifer y troeon y caniateir darparu'r cyffuriau neu'r cyfarpar a archebwyd ar y presgripsiwn amlroddadwy anelectronig; a
- (d) sy'n pennu rhif i ddynodi ei safle yn y dilyniant y cyfeirir ato yn is-baragraff (c);

ystyr "swp-ddyroddiad cysylltiedig" ("*associated batch issue*"), mewn perthynas â phresgripsiwn amlroddadwy anelectronig, yw un o'r swp-ddyroddiadau sy'n ymwneud â'r presgripsiwn hwnnw ac yn cynnwys yr un dyddiad â'r presgripsiwn hwnnw;

mae i "Tariff Cyffuriau" ("*Drug Tariff*") yr ystyr a roddir iddo yn rheoliad 41 (y Tariff Cyffuriau a chydabyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG);

ystyr "Tribiwnlys" ("*Tribunal*") yw Tribiwnlys yr Haen Gyntaf a sefydlwyd o dan Ddeddf Tribiwnlysoedd, Llysoedd a Gorfodi 2007(2);

ystyr "tynnu digwyddiadol" ("*contingent removal*") yw tynnu oddi ar restr fferyllol yn ddigwyddiadol, o fewn yr ystyr a roddir i "contingent removal" gan adran 108 o Ddeddf 2006 (tynnu digwyddiadol) ac mae "tynnu yn ddigwyddiadol" ("*contingently remove*") i'w ddehongli'n unol â hynny; ac

means—

- (a) a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Article 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber;
- (b) a person whose name is registered in the Nursing and Midwifery Register and against whose name in that Register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a nurse independent/supplementary prescriber;
- (c) a person—
 - (i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001(1) (establishment and maintenance of register) which relates to chiropodists and podiatrists, physiotherapists or radiographers, and
 - (ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber; or
- (d) an optometrist against whose name in the register of optometrists maintained under section 7 or 8B(1)(a) of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as a supplementary prescriber; and

"Tribunal" ("*Tribiwnlys*") means the First-tier Tribunal established under the Tribunals, Courts and Enforcement Act 2007(2).

(2) Where reference is made in these Regulations to a decision of a Local Health Board and that decision is changed on appeal, unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision changed on appeal.

(3) In these Regulations—

- (a) the term "pharmaceutical services" ("*gwasanaethau fferyllol*") in relation to a doctor means those services referred to in regulation 20; and
- (b) the term "dispensing services" ("*gwasanaethau gweinyddu*"), in relation to a doctor or GMS contractor means any

(1) O.S. 2004/1020 (Cy.117).

(2) 2007 p.13.13

(1) S.I. 2002/254. Article 5 has been amended by S.I. 2009/1182. The Order was renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c.7).

(2) 2007 c.15.

mae i "uwcharolygydd" yr un ystyr a roddir i "superintendent" yn adran 71 o Ddeddf Meddyginiaethau 1968(1) (cyrff corfforaethol).

(2) Os cyfeirir yn y Rheoliadau hyn at benderfyniad gan Fwrdd Iechyd Lleol ac os newidir y penderfyniad hwnnw yn dilyn apêl, onid yw'r cyd-destun yn mynnu fel arall, mae'r cyfeiriad at y penderfyniad hwnnw i'w ddehongli fel cyfeiriad at y penderfyniad fel y'i newidiwyd yn dilyn yr apêl.

(3) Yn y Rheoliadau hyn—

(a) ystyr y term "gwasanaethau fferyllol" ("*pharmaceutical services*") mewn perthynas â meddyg yw'r gwasanaethau hynny y cyfeirir atynt yn rheoliad 20; a

(b) ystyr y term "gwasanaethau gweinyddu" ("*dispensing services*"), mewn perthynas â meddyg neu gontractwr GMC yw unrhyw wasanaeth cyfatebol a ddarperir, nid fel gwasanaethau fferyllol, ond o dan y telerau mewn contract GMC sy'n rhoi effaith i baragraffau 47 i 51 o Atodlen 6 i'r Rheoliadau GMC.

(4) Ac eithrio pan ddarperir yn benodol i'r gwrthwyneb, caniateir rhoi neu anfon unrhyw ddogfen y mae'n ofynnol, neu yr awdurdodir, ei rhoi neu ei hanfon i berson neu gorff o dan y Rheoliadau hyn drwy ddanfon y ddogfen i'r person neu, yn achos corff, i ysgrifennydd neu reolwr cyffredinol y corff hwnnw, neu drwy anfon y ddogfen mewn llythyr rhagdaledig wedi ei gyfeirio at y person hwnnw neu, yn achos corff, at ysgrifennydd neu reolwr cyffredinol y corff hwnnw, yn ei gyfeiriad arferol neu ei gyfeiriad olaf sy'n hysbys, ac mae danfon y ddogfen yn cynnwys ei hanfon yn electronig i gyfeiriad electronig a hysbyswyd gan y person hwnnw at y diben hwnnw.

(5) Pan fo'r term "community practitioner nurse prescriber" yn ymddangos yn Rheoliadau Meddyginiaethau Dynol 2012(2) neu yn y Gofrestr Nyrsio a Bydwreigiaeth, rhaid ei ddehongli at ddibenion y Rheoliadau hyn fel cyfeiriad at "nyrs sy'n rhagnodi'n annibynnol".

corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations.

(4) Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations may be given or sent by delivering it to the person or, in the case of a body, to the secretary or general manager of that body, or by sending it in a pre-paid letter addressed to that person or, in the case of a body, to the secretary or general manager of that body at his usual or last known address, and delivering it includes sending it electronically to an electronic address which that person has notified for the purpose.

(5) Where the term "community practitioner nurse prescriber" appears in the Human Medicines Regulations 2012(1) or the Nursing and Midwifery Register it is to be construed for the purposes of these Regulations as a reference to an "independent nurse prescriber".

(1) Amnewidiwyd adran 71 gan adran 28 o Ddeddf Iechyd 2006 (p.28).

(2) S.I. 2012/1916.

(1) S.I. 2012/1916.

RHAN 2

Rhestrau fferyllol a rhestrau meddygon fferyllol

Paratoi a chynnal rhestrau fferyllol

3.—(1) Rhaid i bob Bwrdd Iechyd Lleol baratoi a chynnal rhestrau fferyllol o'r fferyllwyr GIG a chontractwyr cyfarpar GIG sydd wedi gwneud cais yn unol â Rhan 4 o'r Rheoliadau hyn ac Atodlen 1 i ddarparu gwasanaethau fferyllol o fangreoedd yn ardal y Bwrdd Iechyd Lleol ac y cymeradwywyd eu ceisiadau gan y Bwrdd Iechyd Lleol yn unol ag Atodlen 2 neu, yn dilyn apêl, gan Weinidogion Cymru yn unol ag Atodlen 3, ac sydd wedi eu hawdurdodi—

- (a) i ddarparu gwasanaethau fferyllol yn benodol drwy ddarparu cyffuriau; neu
- (b) i ddarparu gwasanaethau fferyllol drwy ddarparu cyfarpar yn unig.

(2) Rhaid i bob rhestr fferyllol gynnwys—

- (a) cyfeiriad y fangre lle mae'r person a restrir wedi ymrwymo i ddarparu gwasanaethau fferyllol;
- (b) y diwrnodau a'r amseroedd pan fydd y person a restrir yn darparu gwasanaethau fferyllol yn y fangre honno; ac
- (c) disgrifiad o'r gwasanaethau fferyllol y mae'r person a restrir wedi ymrwymo i'w darparu, gan gynnwys unrhyw wasanaethau cyfeiriedig y mae'r person a restrir wedi cytuno i'w darparu.

(3) Mae Rhan 6 o'r Rheoliadau hyn yn gwneud darpariaeth ar gyfer tynnu personau oddi ar restrau fferyllol.

(4) Bydd rhestr fferyllol Bwrdd Iechyd Lleol, sy'n rhestr gyfredol yn union cyn i'r Rheoliadau hyn ddod i rym, yn rhestr fferyllol gyfredol hefyd pan ddaw'r Rheoliadau hyn i rym, oni fydd yn ofynnol bod y Bwrdd Iechyd Lleol yn rhoi effaith i benderfyniad, a wnaed cyn y dyddiad dod i rym, i newid, tynnu ymaith neu gynnwys cofnod yn y rhestr o ddechrau'r dyddiad dod i rym, neu oni fydd hawl gan y Bwrdd Iechyd Lleol i wneud hynny, ac mewn achos o'r fath, y rhestr gyfredol ar ddechrau'r dyddiad dod i rym fydd y rhestr fel y'i haddaswyd i roi effaith i'r penderfyniad hwnnw.

Paratoi a chynnal rhestrau meddygon fferyllol

4.—(1) Rhaid i bob Bwrdd Iechyd Lleol baratoi a chynnal rhestr meddygon fferyllol o'r meddygon y gwnaeth y Bwrdd Iechyd Lleol drefniant gyda hwy yn unol â rheoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon) i ddarparu

PART 2

Pharmaceutical lists and dispensing doctor lists

Preparation and maintenance of pharmaceutical lists

3.—(1) Each Local Health Board must prepare and maintain pharmaceutical lists of NHS pharmacists and NHS appliance contractors who have applied in accordance with Part 4 of these Regulations and Schedule 1, to provide pharmaceutical services from premises in the Local Health Board's area and whose applications have been approved by the Local Health Board in accordance with Schedule 2 or on appeal by the Welsh Ministers in accordance with Schedule 3 and who are authorised—

- (a) to provide pharmaceutical services in particular by way of the provision of drugs; or
- (b) to provide pharmaceutical services only by way of the provision of appliances.

(2) Each pharmaceutical list must include—

- (a) the address of the premises at which the listed person has undertaken to provide pharmaceutical services;
- (b) the days on which and times at which at those premises the listed person provides pharmaceutical services; and
- (c) a description of the pharmaceutical services that the listed person has undertaken to provide, including any directed services the listed person has agreed to provide.

(3) Part 6 of these Regulations makes provision for the removal of persons from pharmaceutical lists.

(4) A pharmaceutical list of a Local Health Board that is the current list immediately before these Regulations come into force is also the current pharmaceutical list when these Regulations come into force, unless the Local Health Board is required or entitled to give effect to a decision reached before the coming into force date to change, remove or include an entry from the list from the start of the coming into force date, in which case the current list at the start of the coming into force date is the list as modified to give effect to that decision.

Preparation and maintenance of dispensing doctor lists

4.—(1) Each Local Health Board must prepare and maintain a dispensing doctor list of doctors with whom the Local Health Board has made an arrangement in accordance with regulation 20 (arrangements for the provision of pharmaceutical services by doctors) to

gwasanaethau fferyllol i'w cleifion o fangre yn ardal y Bwrdd Iechyd Lleol.

(2) Rhaid i bob rhestr meddygon fferyllol gynnwys—

(a) enw'r meddyg—

- (i) y mae ei gais o dan Ran 5 am gydsyniad amlinellol a chymeradwyaeth mangre wedi ei gymeradwyo gan y Bwrdd Iechyd Lleol yn unol ag Atodlen 2 neu, yn dilyn apêl, gan Weinidogion Cymru yn unol ag Atodlen 3, a
- (ii) sydd wedi gwneud trefniadau gyda'r Bwrdd Iechyd Lleol o dan reoliad 20 i ddarparu gwasanaethau fferyllol;
- (b) yr ardal y rhoddwyd cydsyniad amlinellol mewn perthynas â hi a'r dyddiad y cafodd y cydsyniad amlinellol effaith;
- (c) cyfeiriad y fangre practis y rhoddwyd cymeradwyaeth mangre iddi, gan bennu—
 - (i) y dyddiad y cafodd y gymeradwyaeth mangre effaith neu, os nad yw eto wedi cael effaith, y dyddiad y'i rhoddwyd, a
 - (ii) os yw cymeradwyaeth y fangre yn gymeradwyaeth dybiedig, dros dro neu weddilliol, y ffaith honno;
- (d) cyfeiriad unrhyw fangreoedd practis y gwnaeth y meddyg geisiadau am gymeradwyaeth mangre mewn perthynas â hwy, sy'n dal yn yr arfaeth; ac
- (e) pan fo meddyg y cynhwysir ei enw yn y rhestr meddygon fferyllol yn darparu gwasanaethau meddygol sylfaenol gyda phractis GMBILl, enw a chyfeiriad y Bwrdd Iechyd Lleol.

(3) Caiff meddyg sydd wedi ei gynnwys mewn rhestr meddygon fferyllol a gynhelir gan Fwrdd Iechyd Lleol ac sy'n ddarparwr gwasanaethau meddygol sylfaenol, neu a gyflogir, neu a gymerwyd ymlaen, gan ddarparwr gwasanaethau meddygol sylfaenol, wneud cais i'r Bwrdd Iechyd Lleol hwnnw am i feddyg arall sy'n ddarparwr gwasanaethau meddygol sylfaenol, neu a gyflogir neu a gymerwyd ymlaen gan ddarparwr gwasanaethau meddygol sylfaenol gael ei gynnwys yn y rhestr meddygon fferyllol yn ei le.

(4) Rhaid i Fwrdd Iechyd Lleol sy'n cael cais a ddisgrifir ym mharagraff (3) gytuno â'r cais hwnnw, ac—

- (a) rhaid i'r Bwrdd Iechyd Lleol gynnwys y meddyg arall ("y meddyg newydd") yn lle'r meddyg a wnaeth y cais ("y meddyg gwreiddiol") yn y rhestr meddygon fferyllol a gynhelir gan y Bwrdd Iechyd Lleol;
- (b) bydd y trefniadau a oedd gan y Bwrdd Iechyd Lleol gyda'r meddyg gwreiddiol yn dod yn drefniadau gyda'r meddyg newydd; ac

provide pharmaceutical services to their patients from premises in the area of the Local Health Board.

(2) Each dispensing doctor list must include—

(a) the name of the doctor—

- (i) whose application under Part 5 for outline consent and premises approval has been approved by the Local Health Board in accordance with Schedule 2 or, on appeal by the Welsh Ministers in accordance with Schedule 3, and
- (ii) who has made arrangements with the Local Health Board under regulation 20 to provide pharmaceutical services;
- (b) the area in relation to which outline consent has been granted and the date on which the outline consent took effect;
- (c) the address of the practice premises which have been granted premises approval, specifying—
 - (i) the date on which premises approval took effect or where it has not taken effect the date on which it was granted, and
 - (ii) if premises approval is deemed, temporary or residual, that this is the case;
- (d) the address of any practice premises in relation to which the doctor has outstanding applications for premises approval; and
- (e) where the doctor whose name is included in the dispensing doctor list provides primary medical services with an LHBMS practice, the name and address of the Local Health Board.

(3) A doctor included in a dispensing doctor list maintained by a Local Health Board who is a provider of primary medical services or who is employed or engaged by a provider of primary medical services may make a request to that Local Health Board for another doctor who is a provider of primary medical services or who is employed or engaged by a provider of primary medical services to be included in the dispensing doctor list in his or her place.

(4) A Local Health Board that receives a request described in paragraph (3) must agree to that request and—

- (a) the doctor that made the request ("the original doctor") must be substituted by the other doctor ("the new doctor") by the Local Health Board in the dispensing doctor list that it maintains;
- (b) the arrangements that the Local Health Board had with the original doctor become arrangements with the new doctor; and

- (c) bydd cydsyniadau amlinellol a chymeradwyaethau mangre y meddyg gwreiddiol yn dod yn gydsyniadau amlinellol a chymeradwyaethau mangre y meddyg newydd.

(5) Rhaid i Fwrdd Iechyd Lleol dynnu meddyg rhestredig oddi ar restr meddygon fferyllol—

- (a) os bu farw'r meddyg;
- (b) os nad yw'r meddyg bellach yn cyflawni gwasanaethau meddygol sylfaenol o fewn ardal y Bwrdd Iechyd Lleol;
- (c) os yw'r cydsyniad amlinellol a chymeradwyaeth mangre wedi mynd yn ddi-rym o dan reoliad 26 (cydsyniad amlinellol a chymeradwyaeth mangre yn mynd yn ddi-rym);
- (d) os yw'r meddyg wedi ei dynnu oddi ar y rhestr cyflawnwyr meddygol; neu
- (e) os aeth mwy na 12 mis heibio er pan ddarparwyd cyffuriau, meddyginiaethau neu gyfarpar ddiwethaf gan y meddyg o dan drefniant a wnaed yn unol â rheoliad 20.

(6) Bydd rhestr meddygon fferyllol Bwrdd Iechyd Lleol, sy'n rhestr gyfredol yn union cyn i'r Rheoliadau hyn ddod i rym, yn rhestr meddygon fferyllol gyfredol hefyd pan ddaw'r Rheoliadau hyn i rym, oni fydd yn ofynnol bod y Bwrdd Iechyd Lleol yn rhoi effaith i benderfyniad, a wnaed cyn y dyddiad dod i rym, i newid, tynnu ymaith neu gynnwys cofnod yn y rhestr o ddechrau'r dyddiad dod i rym, neu oni fydd hawl gan y Bwrdd Iechyd Lleol i wneud hynny, ac mewn achos o'r fath, y rhestr gyfredol ar ddechrau'r dyddiad dod i rym fydd y rhestr fel y'i haddaswyd i roi effaith i'r penderfyniad hwnnw.

Telerau gwasanaethu

5.—(1) Y telerau y cynhwysir person ar eu sail mewn rhestr fferyllol (ac felly, telerau gwasanaethu'r person) yw'r telerau sydd wedi eu cynnwys—

- (a) yn y telerau gwasanaethu—
 - (i) ar gyfer fferyllwyr GIG sy'n darparu gwasanaethau fferyllol yn benodol drwy ddarparu cyffuriau, a bennir yn Atodlen 4; neu
 - (ii) ar gyfer contractwyr cyfarpar GIG sy'n darparu gwasanaethau fferyllol drwy ddarparu cyfarpar yn unig, a bennir yn Atodlen 5,

y caniateir eu hamrywio gan amodau a osodir gan Fwrdd Iechyd Lleol yn rhinwedd rheoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd);

- (b) yn y Tariff Cyffuriau i'r graddau y mae'r hawliau a'r rhwymedigaethau yn y Tariff Cyffuriau yn ymwneud â fferyllwyr GIG neu gcontractwyr cyfarpar GIG ac yn gynnwys yn

- (c) the outline consents and premises approvals of the original doctor become the outline consents and premises approvals of the new doctor.

(5) A Local Health Board must remove a listed doctor from a dispensing doctor list if—

- (a) the doctor has died;
- (b) the doctor is no longer performing primary medical services within the area of the Local Health Board;
- (c) outline consent and premises approval has lapsed under regulation 26 (lapse of outline consent and premises approval);
- (d) the doctor has been removed from the medical performers list; or
- (e) more than 12 months have elapsed since the doctor last provided drugs, medicines or appliances under an arrangement made pursuant to regulation 20.

(6) A dispensing doctor list of a Local Health Board that is the current list immediately before these Regulations come into force is also the current dispensing doctor list when these Regulations come into force unless the Local Health Board is required or entitled to give effect to a decision reached before the coming into force date to change, remove or include an entry in the list from the start of the coming into force date, in which case the current list at the start of the coming into force date is the list as modified to give effect to that decision.

Terms of service

5.—(1) The terms on which a person is included in a pharmaceutical list (and therefore the person's terms of service) are those that are included—

- (a) in the terms of service—
 - (i) for NHS pharmacists who provide pharmaceutical services in particular by the provision of drugs, set out in Schedule 4; or
 - (ii) for NHS appliance contractors who provide pharmaceutical services only by way of the provision of appliances, set out in Schedule 5,

as may be varied by conditions imposed by a Local Health Board by virtue of regulation 33 (conditional inclusion relating to fitness grounds);

- (b) in the Drug Tariff, in so far as the rights and liabilities in the Drug Tariff relate to NHS pharmacists or NHS appliance contractors and are applicable in the case of the NHS

achos y fferylllydd GIG neu'r contractwr cyfarpar GIG; ac

- (c) mewn trefniant a wnaed gan Fwrdd Iechyd Lleol gyda'r fferylllydd GIG neu gontractwr cyfarpar GIG ar gyfer darparu unrhyw wasanaethau cyfeiriedig.

(2) Y telerau y cynhwysir person ar eu sail mewn rhestr meddygon fferyllol (ac felly, telerau gwasanaethu'r person) yw'r telerau—

- (a) a gynhwysir yn y telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanaethau fferyllol, a bennir yn Atodlen 6;
- (b) yn unol ag unrhyw amodau a osodir ynglŷn â gohirio neu derfynu darparu gwasanaethau fferyllol i gleifion cymwys, a wnaed o dan baragraff 6 o Atodlen 2, paragraff 13 o Atodlen 2 neu reoliad 11(6); ac
- (c) yn unol ag unrhyw amodau a osodir mewn perthynas â gallu'r meddyg fferyllol i ddarparu gwasanaethau fferyllol yn rhinwedd rheoliad 9(7) o Reoliadau 1992(1).

RHAN 3

Penderfynu ar ardaloedd rheoledig

Ardaloedd sy'n ardaloedd rheoledig

6.—(1) Mae unrhyw ardal, a oedd yn ardal reoledig neu'n rhan o ardal reoledig at ddibenion Rheoliadau 1992—

- (a) yn union cyn i'r Rheoliadau hyn ddod i rym; neu
- (b) yn dilyn penderfyniad a wnaed yn unol â rheoliad 49(2)

yn parhau'n ardal reoledig neu'n rhan o ardal reoledig at ddibenion y Rheoliadau (hyn oni phenderfynir, neu hyd nes penderfynir nad yw'r ardal bellach yn ardal reoledig nac yn rhan o ardal reoledig).

(2) Yn ddarostyngedig i baragraff (3), rhaid i Fwrdd Iechyd Lleol, wrth ymateb i gais a gyflwynwyd mewn ysgrifen gan Bwyllgor Meddygol Lleol neu Bwyllgor Fferyllol Lleol, ystyried y cwestiwn pa un a yw unrhyw ardal benodol o fewn yr ardal y sefydlwyd y Bwrdd ar ei chyfer, oherwydd ei chymeriad gwledig, yn ardal reoledig neu'n rhan o ardal reoledig; neu ar unrhyw adeg arall a benderfynir gan y Bwrdd, caiff y Bwrdd ystyried hynny.

(3) Pan fo'r cwestiwn pa un a yw unrhyw ardal benodol yn ardal reoledig neu'n rhan o ardal reoledig

(1) Cyn ei ddiddymu, mewnosodwyd rheoliad 9(7) yn Rheoliadau 1992 gan O.S. 2009/1491 (Cy.144).

pharmacist or NHS appliance contractor; and

- (c) in an arrangement made by a Local Health Board with the NHS pharmacist or NHS appliance contractor for the provision of any directed services.

(2) The terms on which a person is included in a dispensing doctor list (and therefore the person's terms of service) are those that are—

- (a) included in the terms of service for doctors providing pharmaceutical services set out in Schedule 6;
- (b) in accordance with any conditions imposed regarding the postponement or termination of the provision of pharmaceutical services to eligible patients made under paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or regulation 11(6); and
- (c) in accordance with any conditions imposed in relation to the dispensing doctor's ability to provide pharmaceutical services by virtue of regulation 9(7) of the 1992 Regulations(1)

PART 3

Determination of controlled localities

Areas that are controlled localities

6.—(1) Any area that was, or was part of, a controlled locality for the purposes of the 1992 Regulations—

- (a) immediately before these Regulations come into force; or
- (b) following a determination made in accordance with regulation 49(2),

continues to be, or to be part of, a controlled locality for the purposes of these Regulations (unless or until it is determined that the area is no longer, or is no longer part of, a controlled locality).

(2) Subject to paragraph (3), a Local Health Board must in response to an application submitted in writing by a Local Medical Committee or a Local Pharmaceutical Committee, or may at any other time that it may decide, consider the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality.

(3) Where the question of whether or not any particular area is or is part of a controlled locality has

(1) Prior to its repeal, regulation 9(7) was inserted into the 1992 Regulations by S.I. 2009/1491 (W.144).

wedi ei benderfynu gan Fwrdd Iechyd Lleol neu gan Weinidogion Cymru yn dilyn apêl (boed hynny o dan y Rheoliadau hyn neu Reoliadau 1992), rhaid peidio ag ystyried y cwestiwn hwnnw drachefn mewn perthynas â'r ardal benodol honno—

- (a) am gyfnod o bum mlynedd, sy'n cychwyn gyda dyddiad y penderfyniad gan y Bwrdd Iechyd Lleol neu, os apeliwyd yn erbyn y penderfyniad hwnnw, dyddiad y penderfyniad ar yr apêl; oni bai
- (b) y bodlonir y Bwrdd Iechyd Lleol (o fewn y cyfnod hwnnw o bum mlynedd) fod newid sylweddol wedi digwydd mewn amgylchiadau sy'n effeithio ar yr ardal er pan benderfynwyd y cwestiwn ddiwethaf.

(4) Mae Rhannau 1 a 2 o Atodlen 2 yn pennu'r gweithdrefnau sydd i'w dilyn gan Fwrdd Iechyd Lleol wrth benderfynu a yw ardal yn ardal reoledig o dan y rheoliad hwn ai peidio.

Apelau yn erbyn penderfyniadau o dan Ran 3

7. Mae Rhannau 1 a 2 o Atodlen 3 yn gwneud darpariaeth ar gyfer apelau i Weinidogion Cymru mewn perthynas â phenderfyniadau a wneir o dan y Rhan hon.

RHAN 4

Ceisiadau gan fferyllwyr GIG a chontractwyr cyfarpar GIG am eu cynnwys mewn rhestrau fferyllol neu ddiwygio rhestrau fferyllol

Ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol

8.—(1) Caiff person gyflwyno cais i Fwrdd Iechyd Lleol os yw'r person hwnnw—

- (a) yn dymuno cael ei gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol;
- (b) eisoes wedi ei gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol ond yn dymuno, o fewn ardal y Bwrdd—
 - (i) agor mangre ychwanegol i ddarparu'r un gwasanaethau fferyllol neu wasanaethau fferyllol gwahanol ohoni;
 - (ii) adleoli i fangre wahanol ac, yn y fangre honno, ddarparu'r un gwasanaethau fferyllol neu wasanaethau fferyllol gwahanol; neu
 - (iii) darparu, o'r un fangre restredig, wasanaethau fferyllol o ddisgrifiad gwahanol i'r gwasanaethau a restrwyd eisoes mewn perthynas â'r person hwnnw; neu
- (c) wedi ei gynnwys eisoes mewn rhestr fferyllol a

been determined by a Local Health Board or on appeal by the Welsh Ministers (whether under these Regulations or the 1992 Regulations) that question must not be considered again in relation to the particular area—

- (a) for five years, beginning on the date of the determination of the Local Health Board or, if that determination was appealed, the date of the decision on the appeal; unless
- (b) the Local Health Board is satisfied (within that five years) that there has been a substantial change in circumstances affecting the area since the question was last determined.

(4) Parts 1 and 2 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining whether or not an area is a controlled locality under this regulation.

Appeals against decisions under Part 3

7. Parts 1 and 2 of Schedule 3 make provision for appeals to the Welsh Ministers in respect of decisions made under this Part.

PART 4

Applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to pharmaceutical lists

Applications to be included in or for amendment to a pharmaceutical list

8.—(1) A person may submit an application to a Local Health Board where that person—

- (a) wishes to be included in a pharmaceutical list maintained by the Local Health Board;
- (b) is already included in a pharmaceutical list maintained by the Local Health Board but wishes, within the Board's area, to—
 - (i) open additional premises from which to provide the same or different pharmaceutical services;
 - (ii) relocate to different premises, and at those premises to provide the same or different pharmaceutical services; or
 - (iii) provide from the listed premises pharmaceutical services that are of a different description to those services already listed in relation to that person; or
- (c) is already included in a pharmaceutical list

gynhelir gan Fwrdd Iechyd Lleol cyfagos, ond yn dymuno adleoli i fangre wahanol sydd yn ardal y Bwrdd Iechyd Lleol y gwneir cais iddo ac, yn y fangre honno, ddarparu'r un gwasanaethau fferyllol.

(2) Rhaid i gais a wneir i Fwrdd Iechyd Lleol o dan y rheoliad hwn fod mewn ysgrifen, a rhaid iddo ddarparu'r wybodaeth a bennir yn Rhan 1 o Atodlen 1.

(3) Yn ddarostyngedig i reoliad 46 (Bwrdd Iechyd Lleol cartref), rhaid i berson sy'n gwneud cais o dan baragraff (1)(a) ddarparu'r wybodaeth a'r ymrwymadau a bennir yn Rhan 2 o Atodlen 1.

(4) Rhaid i Fwrdd Iechyd Lleol ddychwelyd cais os nad yw'n cynnwys yr holl wybodaeth sy'n ofynnol o dan baragraffau (2) a (3).

(5) Rhaid gwrthod cais gan berson, nad yw eisoes wedi ei gynnwys mewn rhestr fferyllol, am gael ei gynnwys yn y rhestr honno, os yw'r ceisydd yn unigolyn a gymhwysodd fel fferylllydd yn y Swistir neu mewn Gwladwriaeth AEE ac eithrio'r Deyrnas Unedig, oni fydd yr unigolyn hwnnw'n bodloni'r Bwrdd Iechyd Lleol fod ganddo'r lefel o wybodaeth o Saesneg sydd, er budd yr unigolyn hwnnw a'r personau sy'n defnyddio'r gwasanaethau y mae'r cais yn ymwneud â hwy, yn angenrheidiol ar gyfer darparu'r gwasanaethau hynny yn ardal y Bwrdd Iechyd Lleol.

(6) Bydd yr holl geisiadau a wneir o dan reoliad 8(1) yn cael eu penderfynu o dan reoliad 9 (penderfynu ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), ac eithrio ceisiadau y mae—

- (a) rheoliad 13 (ceisiadau sy'n ymwneud ag adleoliad bach o fewn ardal Bwrdd Iechyd Lleol);
- (b) rheoliad 14 (ceisiadau sy'n ymwneud ag adleoliad bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos);
- (c) rheoliad 15 (ceisiadau sy'n ymwneud ag adleoli dros dro); neu
- (d) rheoliad 16 (ceisiadau sy'n ymwneud â newid perchnogaeth),

yn gymwys iddynt ac a benderfynir o dan y rheoliadau hynny.

(7) Mae Rhannau 1 a 3 o Atodlen 2 yn pennu'r gweithdrefnau sydd i'w dilyn gan Fwrdd Iechyd Lleol wrth benderfynu ceisiadau a wnaed o dan y Rhan hon.

Penderfynu ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol

9.—(1) Yn ddarostyngedig i reoliad 10 (penderfynu ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol: effaith penderfyniadau cynharach), pan nad yw'r fangre a bennir mewn cais o

maintained by a neighbouring Local Health Board but wishes to relocate to different premises in the area of the Local Health Board to which the application is made, and at those premises to provide the same pharmaceutical services.

(2) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 1 of Schedule 1.

(3) Subject to regulation 46 (home Local Health Board), a person making an application under paragraph (1)(a) must provide the information and undertakings specified in Part 2 of Schedule 1.

(4) A Local Health Board must return an application if it does not contain all of the information required under paragraphs (2) and (3).

(5) An application to be included in a pharmaceutical list by a person not already included must be refused if the applicant is an individual who qualified as a pharmacist in Switzerland or an EEA state other than the United Kingdom, unless that individual satisfies the Local Health Board that he or she has the level of knowledge of English which, in the interests of that individual and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the Local Health Board.

(6) All applications made under regulation 8(1) will be determined under regulation 9 (determination of applications to be included in or for amendment to a pharmaceutical list) except for applications to which—

- (a) regulation 13 (applications involving minor relocation within a Local Health Board's area);
- (b) regulation 14 (applications involving minor relocation between neighbouring Local Health Board areas);
- (c) regulation 15 (applications involving temporary relocation); or
- (d) regulation 16 (applications involving a change of ownership),

applies and which are determined under those regulations.

(7) Parts 1 and 3 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining applications made under this Part.

Determination of applications to be included in or for amendment to a pharmaceutical list

9.—(1) Subject to regulation 10 (determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations), where the premises specified in an application are not

fewn ardal reoledig, rhaid i'r Bwrdd Iechyd Lleol beidio â chaniatáu'r cais oni fodlonir y Bwrdd fod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau darpariaeth ddigonol, gan bersonau a gynhwysir mewn rhestr fferyllol, o'r gwasanaethau a bennir yn y cais, neu rai o'r gwasanaethau hynny, yn y gymdogaeth y lleolir ynddi'r fangre (y "prawf angenrheidiol neu hwylus").

(2) Yn ddarostyngedig i reoliad 10, pan fo'r fangre a bennir mewn cais o fewn ardal reoledig ond nid mewn lleoliad neilltuedig (fel y'i diffinnir yn rheoliad 11(4)), rhaid i'r Bwrdd Iechyd Lleol—

- (a) gwrthod y cais os yw o'r farn y byddai ei ganiatáu yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau gweinyddu neu wasanaethau fferyllol yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn y cais (y "prawf niweidio"); a
- (b) pan nad yw cais wedi ei wrthod o dan y prawf niweidio, wrthod y cais oni fodlonir ef fod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau darpariaeth ddigonol, gan bersonau a gynhwysir mewn rhestr fferyllol, o'r gwasanaethau a bennir yn y cais, neu rai o'r gwasanaethau hynny, yn y gymdogaeth y lleolir ynddi'r fangre (y "prawf angenrheidiol neu hwylus").

(3) Nid yw'r prawf niweidio yn gymwys pan fo Bwrdd Iechyd Lleol yn penderfynu cais a'r fangre a bennir yn y cais mewn lleoliad neilltuedig.

(4) Rhaid i Fwrdd Iechyd Lleol wrthod cais nad yw'r ceisydd yn cynnig ynddo ddarparu pob un o'r gwasanaethau hanfodol, ond caiff ganiatáu cais mewn perthynas â'r cyfan neu rai yn unig o'r gwasanaethau cyfeiriedig a bennir ynddo.

(5) Wrth benderfynu cais o dan y rheoliad hwn, a wnaed o dan reoliad 8(1)(a) (ac eithrio pan fo'r cais wedi ei wneud gan berson y rhoddwyd iddo gydsyniad rhagarweiniol yn unol â rheoliad 12 a'r cydsyniad rhagarweiniol hwnnw'n ddilys yn unol â rheoliad 12(5)); neu o dan reoliad 12 pan nad yw'r ceisydd eisoes wedi ei gynnwys yn rhestr fferyllol y Bwrdd Iechyd Lleol hwnnw, caiff Bwrdd Iechyd Lleol—

- (a) gohirio ystyried y cais ar sail addasrwydd o dan reoliad 31 (gohirio ceisiadau ar sail addasrwydd);
- (b) gwrthod y cais ar sail addasrwydd o dan reoliad 32 (gwrthod ceisiadau ar sail addasrwydd); neu
- (c) gosod amodau ar ganiatáu'r cais o dan reoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd).

in a controlled locality, the Local Health Board must grant the application only if it is satisfied that it is necessary or expedient to do so in order to secure in the neighbourhood in which the premises are located the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application (the "necessary or expedient test").

(2) Subject to regulation 10, where the premises specified in an application are in a controlled locality but not in a reserved location (as defined in regulation 11(4)) the Local Health Board—

- (a) must refuse the application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality within which the premises specified in the application are situated (the "prejudice test"); and
- (b) must, where the application has not been refused under the prejudice test, grant the application only if it is satisfied that it is necessary or expedient to do so to secure in the neighbourhood in which the premises are located the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application (the "necessary or expedient test").

(3) The prejudice test does not apply to the Local Health Board's determination of an application where the premises specified in an application are situated in a reserved location.

(4) A Local Health Board must refuse an application in which the applicant does not offer to provide all of the essential services but may grant an application in respect of all or some only of the directed services specified in it.

(5) In determining an application under this regulation which has been made under regulation 8(1)(a), (except where the application is made by a person who has been granted preliminary consent under regulation 12 which is valid in accordance with regulation 12(5)); or under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Penderfynu ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol: effaith penderfyniadau cynharach

10. Os oedd y prawf angenrheidiol neu hwylus o dan reoliad 9, wedi ei ystyried wrth benderfynu cais cynharach am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol, mewn perthynas â'r gymdogaeth y bodlonir y Bwrdd Iechyd Lleol y lleolir ynddi'r fangre a bennir yn y cais sydd dan ystyriaeth, ac os penderfynwyd nad oedd yn angenrheidiol neu'n hwylus caniatáu'r cais blaenorol er mwyn sicrhau darpariaeth ddigonol o wasanaethau fferyllol yn y gymdogaeth, rhaid peidio ag ystyried y prawf angenrheidiol neu hwylus drachefn mewn perthynas â'r gymdogaeth honno—

- (a) am gyfnod o dair blynedd, sy'n cychwyn gyda'r dyddiad y penderfynwyd y cais cynharach gan y Bwrdd Iechyd Lleol neu, os apeliwyd yn erbyn y penderfyniad hwnnw, y dyddiad y penderfynwyd yr apêl; oni bai
- (b) bod y Bwrdd Iechyd Lleol wedi ei fodloni bod newid sylweddol wedi digwydd mewn perthynas â'r gymdogaeth er pan ystyriwyd y prawf angenrheidiol neu hwylus ddiwethaf.

Lleoliadau mewn ardaloedd rheoledig sy'n lleoliadau neilltuedig

11.—(1) Rhaid i Fwrdd Iechyd Lleol benderfynu, pan fo mangre a bennir mewn cais a gyflwynwyd i'r Bwrdd o dan reoliad 8 (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), neu fangre neu'r lleoliad perthnasol y mae'r ceisydd yn dymuno darparu gwasanaethau fferyllol ohono a bennir mewn cais a gyflwynwyd i'r Bwrdd o dan reoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol), mewn ardal reoledig, pa un a yw hefyd mewn lleoliad neilltuedig.

(2) Pan fo penderfyniad wedi ei wneud gan y Bwrdd Iechyd Lleol neu, yn dilyn apêl, gan Weinidogion Cymru (o dan baragraff (1) ac Atodlen 3 yn eu trefn) neu yn unol â rheoliad 11ZA neu 13 o Reoliadau 1992, mewn perthynas â mangre neu leoliad perthnasol y darperir neu y bwriedir darparu gwasanaethau fferyllol ohoni neu ohono, i'r perwyl bod y fangre honno neu'r lleoliad perthnasol hwnnw mewn lleoliad neilltuedig, caiff y person a gynhwysir yn y rhestr fferyllol mewn perthynas â'r fangre honno neu'r lleoliad perthnasol hwnnw, wneud cais mewn ysgrifen i'r Bwrdd Iechyd Lleol, am i'r Bwrdd Iechyd Lleol wneud penderfyniad pellach pa un a yw'r fangre honno neu'r lleoliad perthnasol hwnnw, ar ddyddiad y cais, mewn lleoliad neilltuedig.

(3) At ddibenion y rheoliad hwn, ystyr "lleoliad perthnasol" ("relevant location"), pan fo lleoliad y fangre y bwriedir darparu gwasanaethau fferyllol ohoni wedi ei bennu mewn ysgrifen gan y ceisydd cyn i'r Bwrdd Iechyd Lleol wneud ei benderfyniad, yw'r

Determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations

10. Where in determining an earlier application for inclusion in or amendment to a pharmaceutical list the necessary or expedient test under regulation 9 was considered in relation to the neighbourhood in which the Local Health Board is satisfied the premises specified in the application under consideration are located and it was decided that it was not necessary or expedient to grant the earlier application to secure in the neighbourhood the adequate provision of pharmaceutical services, the necessary or expedient test must not be considered again in relation to that neighbourhood—

- (a) for three years, beginning on the date on which the earlier application was determined by the Local Health Board or, if that determination was appealed, the date of the decision on the appeal; unless
- (b) the Local Health Board is satisfied that there has been a substantial change of circumstances in relation to the neighbourhood since the necessary or expedient test was last considered.

Locations in controlled localities that are reserved locations

11.—(1) A Local Health Board must determine whether premises specified in an application submitted to it under regulation 8 (applications to be included in or for amendment to a pharmaceutical list) or premises or the relevant location from which the applicant wishes to provide pharmaceutical services, specified in an application submitted to it under regulation 12 (applications for preliminary consent and effect of preliminary consent) that are in a controlled locality are also in a reserved location.

(2) Where it has been determined by the Local Health Board, or on appeal the Welsh Ministers (under paragraph (1) and Schedule 3 respectively) or pursuant to regulation 11ZA or 13 of the 1992 Regulations, in relation to premises or a relevant location, from which pharmaceutical services are to be or are being provided, that those premises are or the relevant location is in a reserved location, the person included in the pharmaceutical list in relation to those premises, or that relevant location, may make an application in writing to the Local Health Board to make a further determination as to whether, on the date of the application, those premises are, or that relevant location is, in a reserved location.

(3) For the purposes of this regulation the "relevant location" ("lleoliad perthnasol") means, where the location of the premises from which the pharmaceutical services are to be provided, is specified in writing by the applicant before the Local Health

lleoliad hwnnw, a phan nad yw'r lleoliad wedi ei bennu felly, yr amcan gorau y gall y Bwrdd Iechyd Lleol ei wneud o'r man lle byddai'r fangre honno.

(4) Yn ddarostyngedig i baragraff (5), lleoliad neilltuedig yw lleoliad mewn ardal reoledig lle mae nifer yr unigolion ar y rhestrau cleifion ar gyfer yr ardal sydd o fewn 1.6 cilometr i'r fangre neu leoliad y fangre yn llai na 2,750 o bersonau.

(5) Nid yw lleoliad yn lleoliad neilltuedig o dan baragraff (4) os yw'r Bwrdd Iechyd Lleol o'r farn, pe bai fferyllfa yn gweithredu o'r lleoliad, y defnyddid hi i raddau cyffelyb neu raddau mwy nag y byddid yn disgwyl pe bai nifer yr unigolion ar y rhestrau cleifion ar gyfer yr ardal sydd o fewn 1.6 cilometr i'r fangre neu'r lleoliad yn hafal i neu'n fwy na 2,750 o bersonau.

(6) Pan fo'r Bwrdd Iechyd Lleol, wrth wneud penderfyniad pellach y gwnaed cais amdano yn unol â pharagraff (2), yn penderfynu nad yw'r fangre honno neu'r lleoliad perthnasol hwnnw mewn lleoliad neilltuedig, neu os apelir yn erbyn penderfyniad gan y Bwrdd Iechyd Lleol a phenderfynir yn yr apêl nad yw'r fangre neu nad yw'r lleoliad perthnasol mewn lleoliad neilltuedig—

- (a) caiff y Bwrdd Iechyd Lleol benderfynu bod y fangre i'w thrin, neu'r lleoliad perthnasol i'w drin, at ddibenion y Rheoliadau hyn fel pe bai mewn lleoliad neilltuedig, os yw o'r farn y byddai peidio â gwneud hynny yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol (ac eithrio'r rhai a ddarperir gan y Bwrdd Iechyd Lleol ei hunan), gwasanaethau gweinyddu neu wasanaethau fferyllol mewn unrhyw ardal reoledig; neu
- (b) os yw'r Bwrdd Iechyd Lleol o'r farn ei bod yn debygol yr effeithir yn anffafriol ar y ddarpariaeth o wasanaethau meddygol sylfaenol gan ddarparwr gwasanaethau meddygol sylfaenol (ac eithrio un a gyflogir gan y Bwrdd Iechyd Lleol), gwasanaethau fferyllol gan fferylllydd GIG neu gontractwr cyfarpar GIG, gwasanaethau fferyllol lleol a ddarperir o dan gynllun peilot neu wasanaethau fferyllol a ddarperir gan feddyg, oherwydd penderfyniad nad yw'r fangre mewn lleoliad neilltuedig, caiff y Bwrdd Iechyd Lleol wneud y cyfryw benderfyniad ond caiff osod amodau i ohirio, am ba bynnag gyfnod y tybia'n briodol, gwneud neu derfynu trefniadau o dan reoliad 20 (neu'r hyn sy'n cyfateb iddo o dan y Rheoliadau GMC) ar gyfer darpariaeth, gan feddyg neu gontractwr GMC, o wasanaethau fferyllol neu wasanaethau gweinyddu i gleifion.

Board makes its determination, that location, and where that location is not so specified, the best estimate the Local Health Board is able to make of where those premises may be

(4) Subject to paragraph (5), a reserved location is a location in a controlled locality in respect of which the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location of the premises is less than 2,750 persons.

(5) A location is not a reserved location under paragraph (4) if the Local Health Board considers that if a pharmacy were to operate from the location the extent to which it would be used would be similar to or greater than might be expected if the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location were equal to or more than 2,750 persons.

(6) Where in making a further determination applied for in accordance with paragraph (2) the Local Health Board determines that those premises are, or the relevant location is, not in a reserved location, or there is an appeal against a determination by the Local Health Board and it is determined on appeal that the premises are not, or that the relevant location is not, in a reserved location—

- (a) the Local Health Board may determine that the premises are, or the relevant location is to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Local Health Board itself), dispensing services or pharmaceutical services in any controlled locality; or
- (b) if the Local Health Board considers that the provision of primary medical services by a provider of primary medical services (other than one employed by the Local Health Board), pharmaceutical services by a NHS pharmacist or NHS appliance contractor, local pharmaceutical services provided under a pilot scheme or pharmaceutical services provided by a doctor is likely to be adversely affected by a determination that the premises are not in a reserved location, it may make such determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients.

Patterson, Liz
05/26/2020 17:09:13

Ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol

12.—(1) Caiff person, sy'n dymuno cael yr hawl i'w gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol pan gyflwynir cais dilynol gan y person hwnnw o dan reoliad 8(1)(a) neu 8(1)(b)(i) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), gyflwyno cais i Fwrdd Iechyd Lleol am gydsyniad rhagarweiniol o dan y rheoliad hwn.

(2) Rhaid i gais a wneir o dan y rheoliad hwn fod mewn ysgrifen, a rhaid iddo ddarparu'r wybodaeth a'r ymrwymadau a bennir yn—

(a) Rhan 1 o Atodlen 1; a

(b) yn ddarostyngedig i reoliad 46, Rhan 2 o Atodlen 1.

(3) Rhaid i Fwrdd Iechyd Lleol ddychwelyd cais os nad yw'n cynnwys yr holl wybodaeth sy'n ofynnol o dan baragraff (2).

(4) Rhaid i Fwrdd Iechyd Lleol benderfynu cais am gydsyniad rhagarweiniol fel pe bai'n gais a wnaed o dan reoliad 8(1)(a) neu 8(1)(b)(i).

(5) Bydd cydsyniad rhagarweiniol yn ddilys am gyfnod o chwe mis o'r dyddiad y'i rhoddir, sef y diweddaraaf o naill ai—

(a) 30 diwrnod ar ôl anfon hysbysiad o benderfyniad y Bwrdd Iechyd Lleol ar y cais yn unol â pharagraff 14 o Atodlen 2; neu

(b) pan fo apêl wedi ei gwneud yn erbyn penderfyniad y Bwrdd Iechyd Lleol, y dyddiad y rhoddir hysbysiad gan Weinidogion Cymru o'u penderfyniad ar yr apêl yn unol â pharagraff 8 o Atodlen 3.

(6) Rhaid i Fwrdd Iechyd Lleol ganiatáu cais dilynol a wneir o dan reoliad 8(1)(a) neu 8(1)(b)(i) gan berson y rhoddwyd cydsyniad rhagarweiniol iddo—

(a) os yw'r dyddiad y daeth y cais i law'r Bwrdd Iechyd Lleol o fewn y cyfnod a bennir ym mharagraff (5);

(b) os yw'r gwasanaethau a bennir yn y cais yr un rhai ag a bennwyd yn y cais am gydsyniad rhagarweiniol; ac

(c) os yw'r fangre a bennir yn y cais yn yr un man â'r fangre a bennwyd yn y cais am gydsyniad rhagarweiniol, neu yng nghymdogaeth y fangre a bennwyd yn y cais am gydsyniad rhagarweiniol.

(7) Pan fo is-baragraffau (a) a (b) o baragraff (6) wedi eu bodloni, ond lleoliad y fangre a bennir yn y cais yn wahanol i'r lleoliad y rhoddwyd cydsyniad rhagarweiniol mewn perthynas ag ef, rhaid i'r Bwrdd Iechyd Lleol drin y cais fel pe bai'n gais o dan reoliad

Applications for preliminary consent and effect of preliminary consent

12.—(1) A person who wishes to be granted the right to be included in a pharmaceutical list maintained by the Local Health Board on a subsequent application under regulation 8(1)(a) or 8(1)(b)(i) (applications to be included in or for amendment to a pharmaceutical list) may submit an application to a Local Health Board for preliminary consent under this regulation.

(2) An application made under this regulation must be made in writing and must provide the information and undertakings set out in—

(a) Part 1 of Schedule 1; and

(b) subject to regulation 46, Part 2 of Schedule 1.

(3) A Local Health Board must return an application if it does not contain all of the information required under paragraph (2).

(4) A Local Health Board must determine an application for preliminary consent as if it were an application made under regulation 8(1)(a) or 8(1)(b)(i).

(5) A preliminary consent will be valid for a period of six months from the date on which it is granted, which is the later of either—

(a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 2; or

(b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers give notice of their decision on the appeal under paragraph 8 of Schedule 3.

(6) A Local Health Board must grant a subsequent application made under regulation 8(1)(a) or 8(1)(b)(i) by a person who has been granted preliminary consent if—

(a) the date on which the application was received by the Local Health Board is within the period specified in paragraph (5);

(b) the services specified in the application are the same as those that were specified in the application for preliminary consent; and

(c) the premises specified in the application are in the same location as the premises or the locality of the premises specified in the application for preliminary consent.

(7) Where sub-paragraphs (a) and (b) of paragraph (6) are satisfied but the premises specified in the application have a different location from that in respect of which preliminary consent was granted, the Local Health Board must treat the application as

8(1)(b)(ii).

(8) Rhaid i'r penderfyniad i ganiatáu cais o dan baragraff (6) fod yn ddarostyngedig i unrhyw amodau a osodwyd gan y Bwrdd Iechyd Lleol, neu gan Weinidogion Cymru yn dilyn apêl, mewn perthynas â'r penderfyniad terfynol i ganiatáu'r cydsyniad rhagarweiniol cyfatebol.

(9) Wrth benderfynu cais o dan y rheoliad hwn, gan berson nad yw'n gynwysedig eisoes yn rhestr fferyllol y Bwrdd Iechyd Lleol (ac eithrio cais gan berson sydd â chydsyniad rhagarweiniol dilys yn unol â pharagraff (5)), caiff Bwrdd Iechyd Lleol—

- (a) gohirio ystyried y cais ar sail addasrwydd o dan reoliad 31 (gohirio ceisiadau ar sail addasrwydd);
- (b) gwrthod y cais ar sail addasrwydd o dan reoliad 32 (gwrthod ceisiadau ar sail addasrwydd); neu
- (c) gosod amodau ar ganiatáu'r cais o dan reoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd).

Ceisiadau sy'n ymwneud ag adleoliad bach o fewn ardal Bwrdd Iechyd Lleol

13.—(1) Caiff person sydd wedi gwneud cais o dan reoliad 8(1)(a) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), ar unrhyw adeg ar ôl gwneud y cais ond cyn diwedd y cyfnod perthnasol (fel y'i diffinnir yn rheoliad 17(3)(b) (gweithdrefn yn dilyn caniatáu cais)), hysbysu'r Bwrdd Iechyd Lleol ei fod yn dymuno newid y fangre y mae'n bwriadu darparu'r gwasanaethau fferyllol a bennir yn y cais ohoni, a chaiff y Bwrdd Iechyd Lleol ddiwygio'r fangre a bennir yn y cais gwreiddiol os bodlonir y Bwrdd—

- (a) mai adleoliad bach yw'r newid;
- (b) y bydd y gwasanaethau fferyllol, a bennir yn y cais ac y byddid wedi eu darparu yn y fangre a bennwyd yn y cais gwreiddiol, yn cael eu darparu yn y fangre newydd; ac
- (c) ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre bresennol, nad yw lleoliad y fangre newydd yn llai hygyrch i raddau sylweddol.

(2) Rhaid i Fwrdd Iechyd Lleol ganiatáu cais a wneir gan berson o dan reoliad 8(1)(b)(ii), i adleoli o fangre restredig i fangre newydd lle mae'r person hwnnw'n bwriadu darparu'r un gwasanaethau fferyllol, os bodlonir y Bwrdd—

- (a) mai adleoliad bach yw'r newid;
- (b) ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre

though it were an application under regulation 8(1)(b)(ii).

(8) The grant of an application under paragraph (6) must be subject to any conditions that were imposed by the Local Health Board, or the Welsh Ministers on appeal, in relation to the final grant of the corresponding preliminary consent.

(9) In determining an application under this regulation from a person who is not already included in the Local Health Board's pharmaceutical list (apart from an application from a person who has a valid preliminary consent in accordance with paragraph (5)), a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Applications involving minor relocation within a Local Health Board's area

13.—(1) A person who has made an application under regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list) may at any time after making the application but before the end of the relevant period (as defined in regulation 17(3)(b) (procedure following grant of an application)) notify the Local Health Board that he or she wishes to change the premises from which he or she intends to provide the pharmaceutical services specified in the application and the Local Health Board may amend the premises specified in the original application if it is satisfied that—

- (a) the change is a minor relocation;
- (b) the pharmaceutical services specified in the application that would have been provided at the premises specified in the original application will be provided at the new premises; and
- (c) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible.

(2) A Local Health Board must grant an application made by a person under regulation 8(1)(b)(ii) to relocate from listed premises to new premises at which the person intends to provide the same pharmaceutical services if it is satisfied that—

- (a) the change is a minor relocation;
- (b) for the patients who are accustomed to accessing pharmaceutical services at the

bresennol, nad yw lleoliad y fangre newydd yn llai hygyrch i raddau sylweddol;

- (c) y darperir yr un gwasanaethau fferyllol yn y fangre newydd ag a ddarperir yn y fangre restredig;
- (d) na fydd unrhyw doriad yn y ddarpariaeth o wasanaethau fferyllol (ac eithrio am ba bynnag gyfnod a ganiateir am reswm da gan y Bwrdd Iechyd Lleol); ac
- (e) nad yw'r fangre a bennir yn y cais fel y fangre y mae'r person yn dymuno adleoli ohoni yn fangre y mae'r person wedi adleoli iddi dros dro o dan reoliad 15 (ceisiadau sy'n ymwneud ag adleoli dros dro).

(3) Ni chaiff person, y caniatwyd cais ganddo o dan y rheoliad hwn, gyflwyno cais arall ar gyfer ei benderfynu o dan y rheoliad hwn nac o dan reoliad 14 o fewn deuddeng mis ar ôl dyddiad caniatáu'r cais (fel y'i diffinnir yn rheoliad 17(3)(a)).

Ceisiadau sy'n ymwneud ag adleoliad bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos

14.—(1) Rhaid i Fwrdd Iechyd Lleol, ganiatáu cais a wneir iddo gan berson o dan reoliad 8(1)(c) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), i adleoli o fangre restredig yn ardal Bwrdd Iechyd Lleol cyfagos i fangre newydd yn ardal y Bwrdd Iechyd Lleol y gwneir y cais iddo, ac yn y fangre honno mae'r person yn bwriadu darparu'r un gwasanaethau fferyllol—

- (a) os bodlonir y Bwrdd Iechyd Lleol y gwneir y cais iddo—
 - (i) mai adleoliad bach yw'r newid,
 - (ii) ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre bresennol, nad yw lleoliad y fangre newydd yn llai hygyrch i raddau sylweddol,
 - (iii) y darperir yr un gwasanaethau fferyllol yn fangre newydd ag a ddarperir yn y fangre restredig,
 - (iv) na fydd unrhyw doriad yn y ddarpariaeth o wasanaethau fferyllol (ac eithrio am ba bynnag gyfnod a ganiateir am reswm da gan y Bwrdd Iechyd Lleol),
 - (v) nad yw'r fangre a bennir yn y cais fel y fangre y mae'r person yn dymuno adleoli ohoni yn fangre y mae'r person wedi adleoli iddi dros dro o dan reoliad 15 (ceisiadau sy'n ymwneud ag adleoli dros dro); a
- (b) os yw'r person hwnnw yn cytuno i'w enw gael ei dynnu oddi ar y rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol y lleolir y fangre

existing premises, the location of the new premises is not significantly less accessible;

- (c) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises;
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow); and
- (e) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 15 (applications involving temporary relocation).

(3) A person who has had an application granted under this regulation may not, within twelve months of the date of the grant of the application (as defined in regulation 17(3)(a)) submit another application for determination under this regulation or under regulation 14.

Applications involving minor relocation between neighbouring Local Health Board areas

14.—(1) A Local Health Board must grant an application made by a person under regulation 8(1)(c) (applications to be included in or for amendment to a pharmaceutical list) to relocate from listed premises in the area of a neighbouring Local Health Board to new premises in the area of the Local Health Board to which the application is made, and at those premises the person intends to provide the same pharmaceutical services, if—

- (a) the Local Health Board to which the application is made is satisfied that—
 - (i) the change is a minor relocation,
 - (ii) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,
 - (iii) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises,
 - (iv) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow),
 - (v) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 15 (applications involving temporary relocation); and
- (b) the person consents to the removal of his or her name from the pharmaceutical list maintained by the Local Health Board in whose area the

restredig bresennol yn ei ardal, gydag effaith o'r dyddiad y bydd y ddarpariaeth o wasanaethau fferyllol o'r fangre newydd yn cychwyn.

(2) Ni chaiff person, y caniatwyd cais ganddo o dan y rheoliad hwn, gyflwyno cais arall am benderfyniad o dan y rheoliad hwn nac o dan reoliad 13 o fewn deuddeng mis ar ôl dyddiad caniatáu'r cais (fel y'i diffinnir yn rheoliad 17(3)(a)).

Ceisiadau sy'n ymwneud ag adleoli dros dro

15.—(1) Caiff Bwrdd Iechyd Lleol ddiwygio cofnod mewn rhestr fferyllol dros dro drwy ganiatáu cais a wneir gan berson o dan reoliad 8(1)(b)(ii) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol) i adleoli i fangre wahanol dros dro, os bodlonir y Bwrdd—

- (a) bod yr amgylchiadau pan wneir y cais yn ei gwneud yn ofynnol ddarparu gwasanaethau fferyllol yn hyblyg;
- (b) ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre bresennol, nad yw lleoliad y fangre dros dro yn llai hygyrch i raddau sylweddol;
- (c) y darperir yr un gwasanaethau fferyllol yn y fangre dros dro ag a ddarperir yn y fangre restredig; ac
- (d) na fydd unrhyw doriad yn y ddarpariaeth o wasanaethau fferyllol (ac eithrio am ba bynnag gyfnod a ganiateir am reswm da gan y Bwrdd Iechyd Lleol).

(2) Bydd diwygiad dros dro mewn cofnod yn y rhestr fferyllol yn cael effaith o'r dyddiad y cymeradwyodd y Bwrdd Iechyd Lleol y cais a wnaed iddo, a bydd yn ddilys am ba bynnag gyfnod o hyd at chwe mis, ac unrhyw gyfnodau pellach o hyd at dri mis, a ystyrir yn angenrheidiol gan y Bwrdd Iechyd Lleol.

(3) Caiff person ddychwelyd i'r cofnod a ddisodlwyd yn y rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol cyn diwedd y cyfnod a benderfynir gan y Bwrdd Iechyd Lleol o dan baragraff (2), drwy roi i'r Bwrdd Iechyd Lleol 7 diwrnod, o leiaf, o rybudd ysgrifenedig.

(4) Pan ddisodlir cofnod mewn rhestr fferyllol gan ddiwygiad dros dro yn unol â'r rheoliad hwn, ni fydd y disodliad hwnnw'n effeithio ar unrhyw weithrediadau mewn perthynas â'r trefniadau a ddisodlwyd (er, hwyrach y bydd angen eu hatal am resymau eraill), ac os bydd angen diwygio'r trefniadau a ddisodlwyd cyn diwedd y diwygiad dros dro, o ganlyniad i'r gweithrediadau hynny, bydd rhaid dychwelyd, ar ddiwedd y diwygiad dros dro, i'r trefniadau a ddisodlwyd fel y'u diwygiwyd o ganlyniad i'r gweithrediadau hynny.

current listed premises are located with effect from the date on which the provision of pharmaceutical services from the new premises commences.

(2) A person who has had an application granted under this regulation may not, within twelve months of the date of the grant of the application (as defined in regulation 17(3)(a)) submit another application for determination under this regulation or under regulation 13.

Applications involving temporary relocation

15.—(1) A Local Health Board may make a temporary amendment to an entry in a pharmaceutical list by granting an application made by a person under regulation 8(1)(b)(ii) (applications to be included in or for amendment to a pharmaceutical list) to relocate to different premises on a temporary basis if it is satisfied that—

- (a) the circumstances in which the application is made require the flexible provision of pharmaceutical services;
- (b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the temporary premises is not significantly less accessible;
- (c) the same pharmaceutical services will be provided at the temporary premises as are provided at the listed premises; and
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) A temporary amendment to an entry in the pharmaceutical list will have effect from the date on which the Local Health Board approved the application made to it and will be valid for such period of up to six months and any further periods of up to three months each that the Local Health Board considers necessary.

(3) A person may revert to the overridden entry in the pharmaceutical list maintained by the Local Health Board before the end of the period determined by the Local Health Board under paragraph (2) on giving the Local Health Board at least 7 days notice in writing.

(4) Where, in accordance with this regulation, an entry in a pharmaceutical list is overridden by a temporary amendment any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed for other reasons), and if, as a result of those proceedings the overridden arrangements require amendment before the end of the temporary amendment, the reversion to the overridden arrangements is to be to the original overridden amendments as amended as a result of those proceedings.

Ceisiadau sy'n ymwneud â newid perchnogaeth

16.—(1) Rhaid i Fwrdd Iechyd Lleol ganiatáu cais a wneir gan berson o dan reoliad 8(1)(a), (b)(i) neu (ii) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol) sy'n bwriadu darparu gwasanaethau fferyllol mewn mangre lle darperir y gwasanaethau hynny, ar yr adeg y gwneir y cais, gan berson arall sydd wedi ei gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol o dan reoliad 3 (paratoi a chynnal rhestrau fferyllol), os bodlonir y Bwrdd Iechyd Lleol—

- (a) bod y fangre wedi ei chynnwys eisoes mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol;
- (b) y parheir i ddarparu'r un gwasanaethau fferyllol o'r fangre; ac
- (c) na fydd toriad yn y ddarpariaeth o wasanaethau fferyllol (ac eithrio am ba bynnag gyfnod a ganiateir am reswm da gan y Bwrdd Iechyd Lleol).

(2) Wrth benderfynu cais o dan y rheoliad hwn, a wnaed o dan reoliad 8(1)(a) (ac eithrio pan fo'r cais wedi ei wneud gan berson y rhoddwyd iddo gydsyniad rhagarweiniol o dan reoliad 12 a'r cydsyniad rhagarweiniol hwnnw'n ddilys yn unol â rheoliad 12(5)) neu o dan reoliad 12 pan nad yw'r ceisydd eisoes wedi ei gynnwys yn rhestr fferyllol y Bwrdd Iechyd Lleol hwnnw, caiff Bwrdd Iechyd Lleol—

- (a) gohirio ystyried y cais ar sail addasrwydd o dan reoliad 31 (gohirio ceisiadau ar sail addasrwydd);
- (b) gwrthod y cais ar sail addasrwydd o dan reoliad 32 (gwrthod ceisiadau ar sail addasrwydd); neu
- (c) gosod amodau ar ganiatáu'r cais o dan reoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd).

Gweithdrefn yn dilyn caniatáu cais

17.—(1) Yn dilyn y dyddiad y caniateir cais a wneir o dan reoliad 8 (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), rhaid i Fwrdd Iechyd Lleol beidio â chynnwys person mewn rhestr fferyllol na diwygio rhestr fferyllol oni fydd—

- (a) yr amod ym mharagraff (2) wedi ei fodloni; a
- (b) gofynion rheoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd), os oes rhai, wedi eu bodloni o ran gosod amodau ar unrhyw berson.

(2) Bydd person yn cael ei gynnwys yn y rhestr fferyllol berthnasol, neu diwygir y rhestr fferyllol berthnasol fel y bo'n briodol, os bydd y person hwnnw, ddim llai na 14 diwrnod cyn diwedd y cyfnod

Applications involving a change of ownership

16.—(1) A Local Health Board must grant an application made by a person under regulation 8(1)(a), (b)(i) or (ii) (applications to be included in or for amendment to a pharmaceutical list) who intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by another person who is included in a pharmaceutical list maintained by the Local Health Board under regulation 3 (preparation and maintenance of pharmaceutical lists) if the Local Health Board is satisfied that—

- (a) the premises are already included in a pharmaceutical list maintained by the Local Health Board;
- (b) the same pharmaceutical services will continue to be provided from the premises; and
- (c) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) In determining an application under this regulation which has been made under regulation 8(1)(a) (except where the application has been made by a person who has been granted preliminary consent under regulation 12 which is valid in accordance with regulation 12(5)), or under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Procedure following grant of an application

17.—(1) Following the date of the grant of an application made under regulation 8 (applications to be included in or for amendment to a pharmaceutical list), a Local Health Board must not include a person in a pharmaceutical list or amend a pharmaceutical list unless—

- (a) the condition in paragraph (2) is satisfied; and
- (b) the requirements of regulation 33 (conditional inclusion relating to fitness grounds), if any, are met as regards the imposition of conditions on any person.

(2) A person will be included in the relevant pharmaceutical list or the relevant pharmaceutical list will be amended as appropriate if, not less than 14 days before the end of the relevant period, he or she notifies

perthnasol, gan ddarparu'r wybodaeth a bennir yn Rhan 3 o Atodlen 1, yn hysbysu'r Bwrdd Iechyd Lleol, mewn ysgrifen, y bydd y person hwnnw, o fewn y 14 diwrnod nesaf, yn cychwyn darparu, yn y fangre, y gwasanaethau a bennwyd yn y cais.

(3) At ddibenion y rheoliad hwn a phan fo'n berthnasol, rheoliad 18—

(a) "y dyddiad y caniateir cais" ("*the date of the grant of an application*") yw'r dyddiad diweddaraf o naill ai—

(i) 30 diwrnod ar ôl anfon hysbysiad o benderfyniad y Bwrdd Iechyd Lleol ar y cais, gan y Bwrdd Iechyd Lleol yn unol â pharagraff 14 o Atodlen 2; neu

(ii) y dyddiad y penderfynir unrhyw apêl a ddygir yn erbyn penderfyniad y Bwrdd Iechyd Lleol,

ac mae "caniatawyd" ("*granted*") i'w ddehongli'n unol â hynny; a

(b) "y cyfnod perthnasol" ("*the relevant period*") yw—

(i) y cyfnod o chwe mis o'r dyddiad y caniatawyd cais; neu

(ii) pa bynnag gyfnod pellach yn ychwanegol at yr hyn a bennir yn is-baragraff (a), ac na fydd yn hwy na thri mis, y caiff y Bwrdd Iechyd Lleol ei ganiatáu am reswm da.

Cais am estyn y cyfnod perthnasol

18.—(1) Cyn diwedd y cyfnod perthnasol, caiff person wneud cais i'r Bwrdd Iechyd Lleol am estyn y cyfnod perthnasol.

(2) Yn unol â rheoliad 17(3)(b)(ii) caiff y person wneud cais am estyniad o hyd at dri mis.

(3) Rhaid i gais a wneir i'r Bwrdd Iechyd Lleol o dan y rheoliad hwn fod mewn ysgrifen, a rhaid iddo nodi'n llawn pam y gofynnir am estyniad o'r cyfnod perthnasol.

(4) Mae Rhannau 1 a 3 o Atodlen 2 yn pennu'r gweithdrefnau sydd i'w dilyn gan Fwrdd Iechyd Lleol wrth benderfynu ceisiadau a wneir o dan y rheoliad hwn.

(5) At ddibenion y rheoliad hwn, ystyr "person" ("*person*") yw'r person y byddai hawl ganddo i ddarparu hysbysiad i Fwrdd Iechyd Lleol yn unol â rheoliad 17(2) o gychwyn darparu gwasanaethau fferyllol.

Apelau

19.—(1) Mae Atodlen 3 yn gwneud darpariaeth ar gyfer apelau i Weinidogion Cymru mewn perthynas â

the Local Health Board in writing, providing the information specified in Part 3 of Schedule 1, that he or she will within the next 14 days commence the provision at the premises of the services that were specified in the application.

(3) For the purposes of this regulation and, where relevant, regulation 18—

(a) "the date of the grant of an application" ("*y dyddiad y caniateir cais*") is the date which is the later of either—

(i) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 2; or

(ii) the date of the determination of any appeal that is brought against the decision of the Local Health Board,

and "granted" ("*caniatawyd*") is to be construed accordingly; and

(b) "the relevant period" ("*cyfnod perthnasol*") is—

(i) the period of six months from the date an application is granted; or

(ii) such further period in addition to that specified in sub-paragraph (a) not exceeding three months that the Local Health Board may for good cause allow.

Application to extend the relevant period

18.—(1) Before the expiry of the relevant period, a person may make an application to the Local Health Board to extend the relevant period.

(2) In accordance with regulation 17(3)(b)(ii) the person may apply for an extension of up to three months.

(3) An application to the Local Health Board under this regulation must be in writing and must set out in full why an extension of the relevant period is sought.

(4) Parts 1 and 3 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining applications made under this regulation.

(5) For the purposes of this regulation, "person" ("*person*") means the person who would be entitled to provide notification to a Local Health Board in accordance with regulation 17(2) of commencement of provision of pharmaceutical services.

Appeals

19.—(1) Schedule 3 makes provision for appeals to the Welsh Ministers in respect of decisions of Local

phenderfyniadau a wneir gan Fyrddau Iechyd Lleol o dan y Rhan hon.

(2) Nid oes hawl i apelio o dan y Rheoliadau hyn mewn perthynas â phenderfyniad gan Fwrdd Iechyd Lleol i ddiwygio dros dro neu beidio â'i diwygio dros dro neu estyn diwygiad dros dro, mewn rhestr fferyllol o dan reoliad 15 (ceisiadau sy'n ymwneud ag adleoli dros dro).

RHAN 5

Ceisiadau gan feddygon am eu cynnwys mewn rhestrau meddygon fferyllol neu ddiwygio rhestrau meddygon fferyllol

Trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon

20.—(1) Caiff Bwrdd Iechyd Lleol wneud trefniant gyda meddyg sy'n dod o fewn paragraff (8) er mwyn i'r meddyg ddarparu gwasanaethau fferyllol i glaf sydd wedi ei gynnwys ar restr cleifion y meddyg neu restr cleifion darparwr gwasanaethau meddygol sylfaenol sy'n cyflogi'r meddyg neu wedi ei gymryd ymlaen, os bodlonir yr amodau canlynol—

- (a) byddai'n ddifrifol o anodd i'r claf gael unrhyw gyffuriau neu gyfarpar angenrheidiol o fferyllfa, oherwydd pellter neu foddion cyfathrebu annigonol a bodlonir yr amodau ym mharagraff (2);
- (b) bod y claf yn preswyllo mewn ardal reoledig, a hynny'n bellter o fwy nag 1.6 cilometr o unrhyw fferyllfa, a bodlonir yr amodau a bennir ym mharagraff (4); neu
- (c) bod y claf yn preswyllo mewn ardal reoledig, a phenderfynwyd bod unrhyw fferyllfa, sydd o fewn pellter o 1.6 cilometr i'r man lle mae'r claf yn byw, mewn lleoliad neilltuedig ac na newidiwyd y penderfyniad hwnnw mewn apêl na thrwy benderfyniad pellach, a bodlonir yr amodau a bennir ym mharagraff (4).

(2) Yr amodau y cyfeirir atynt ym mharagraff (1)(a) yw—

- (a) bod y claf wedi gwneud cais mewn ysgrifen i'r Bwrdd Iechyd Lleol am i'r meddyg ddarparu gwasanaethau fferyllol iddo, am y rhesymau a bennir ym mharagraff (1)(a); a
- (b) bod y Bwrdd Iechyd Lleol wedi ei fodloni y byddai'n ddifrifol o anodd i'r claf gael unrhyw gyffuriau neu gyfarpar angenrheidiol am y rhesymau hynny.

(3) With i'r Bwrdd Iechyd Lleol wneud trefniant gyda meddyg o dan baragraff (1)(a) i'r meddyg ddarparu gwasanaethau fferyllol i glaf o fangre practis,

Health Boards made under this Part.

(2) There is no right of appeal under these Regulations in respect of a decision of a Local Health Board to make or not to make, or to extend a temporary amendment to a pharmaceutical list under regulation 15 (applications involving temporary relocation).

PART 5

Applications by doctors for inclusion in or amendment to dispensing doctor lists

Arrangements for the provision of pharmaceutical services by doctors

20.—(1) A Local Health Board may make an arrangement with a doctor who falls within paragraph (8) for the doctor to provide pharmaceutical services to a patient included on the doctor's patient list or the patient list of a provider of primary medical services by whom the doctor is employed or engaged if the patient—

- (a) would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy because of distance or inadequacy of means of communication, and the conditions in paragraph (2) are satisfied;
- (b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy, and the conditions specified in paragraph (4) are satisfied; or
- (c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination and the conditions specified in paragraph (4) are satisfied.

(2) The conditions referred to in paragraph (1)(a) are—

- (a) the patient has made a request in writing to the Local Health Board for the doctor to provide him or her with pharmaceutical services for the reasons specified in paragraph (1)(a); and
- (b) the Local Health Board is satisfied that the patient would have serious difficulty in obtaining any necessary drugs or appliances for those reasons.

(3) In making an arrangement with a doctor for the doctor to provide a patient under paragraph (1)(a) with pharmaceutical services from practice premises, the

rhaid i'r Bwrdd Iechyd Lleol roi i'r meddyg mewn ysgrifen, gyfnod rhesymol o rybudd o'r dyddiad y bydd y trefniant yn cael effaith, oni fydd y meddyg wedi bodloni'r Bwrdd Iechyd Lleol—

- (a) nad yw'r meddyg fel arfer yn darparu gwasanaethau fferyllol i gleifion; neu
- (b) na fyddai'n ddifrifol o anodd i'r claf gael cyffuriau a chyfarpar o fferyllfa oherwydd pellter neu foddion cyfathrebu annigonol.

(4) Yr amodau y cyfeirir atynt ym mharagraff (1)(b) ac (c) yw—

- (a) bod cydsyniad amlinellol wedi ei roi i'r meddyg neu i'r darparwr gwasanaethau meddygol sylfaenol sy'n cyflogi'r meddyg neu wedi ei gymryd ymlaen;
- (b) bod cymeradwyaeth mangre wedi ei rhoi mewn perthynas â'r fangre y bydd y meddyg yn darparu gwasanaethau fferyllol ohoni i'r claf hwnnw;
- (c) bod y cydsyniad amlinellol a'r gymeradwyaeth mangre wedi cael effaith o dan reoliad 25 (cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith); a
- (d) bod unrhyw amodau a osodir o dan y Rheoliadau hyn mewn cysylltiad â rhoi cydsyniad amlinellol neu gymeradwyaeth mangre yn rhai sy'n caniatáu gwneud trefniadau o dan y rheoliad hwn ar gyfer darparu gwasanaethau fferyllol gan y meddyg hwnnw i gleifion o dan baragraff (1)(b) neu (c).

(5) Mae cyfeiriadau ym mharagraff (4) at gydsyniad amlinellol, cymeradwyaeth mangre ac amodau a osodir yn cynnwys cyfeiriadau at rai a oedd wedi cael effaith o dan Reoliadau 1992.

(6) Caiff meddyg, y gwnaed trefniant gydag ef i ddarparu gwasanaethau fferyllol i glaf o dan y rheoliad hwn, gyda chydsyniad y claf, yn hytrach na darparu'r cyffuriau neu gyfarpar ei hunan, archebu'r cyffuriau neu gyfarpar drwy ddyroddi presgripsiwn i'r claf.

(7) Os oedd trefniant bod meddyg yn darparu gwasanaethau fferyllol i glaf wedi cael effaith yn union cyn i'r Rheoliadau hyn ddod i rym, bydd y trefniant hwnnw'n cael effaith fel pe bai wedi ei wneud o dan y rheoliad hwn, hyd yn oed os na fodlonir yr amodau ym mharagraff (4).

(8) Mae meddyg yn dod o fewn y paragraff hwn os yw—

- (a) yn contractwr GMC neu'n contractwr GMDdA;

- (b) wedi ei gymryd ymlaen neu'n gyflogedig gan contractwr GMC neu contractwr GMDdA; neu

Local Health Board must give reasonable notice in writing to the doctor of when the arrangement is to take effect unless the doctor satisfies the Local Health Board that—

- (a) the doctor does not normally provide pharmaceutical services to patients; or
- (b) the patient would not have serious difficulty in obtaining drugs and appliances from a pharmacy because of distance or inadequacy of means of communication.

(4) The conditions referred to in paragraph (1)(b) and (c) are that—

- (a) outline consent has been granted to the doctor or the provider of primary medical services by whom the doctor is employed or engaged;
- (b) premises approval has been granted in relation to the premises from which the doctor will provide pharmaceutical services to that patient;
- (c) the outline consent and premises approval has taken effect under regulation 25 (taking effect of outline consent and premises approval); and
- (d) any conditions imposed under these Regulations in connection with the grant of outline consent or premises approval are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to patients under paragraph (1)(b) or (c).

(5) References in paragraph (4) to outline consent, premises approval and conditions imposed include references to those in effect under the 1992 Regulations.

(6) A doctor with whom an arrangement has been made to provide pharmaceutical services to a patient under this regulation may, with the consent of the patient, instead of providing the drugs or appliances himself or herself order them by issuing a prescription to the patient.

(7) Where an arrangement for a doctor to provide pharmaceutical services to a patient was in effect immediately before these Regulations came into force, that arrangement will have effect as though made under this regulation notwithstanding that the conditions in paragraph (4) are not satisfied.

(8) A doctor falls within this paragraph if he or she is—

- (a) a GMS contractor or an APMS contractor;
- (b) engaged or employed by a GMS contractor or an APMS contractor; or

(c) wedi ei gymryd ymlaen gan Fwrdd Iechyd Lleol at y diben o ddarparu gwasanaethau meddygol sylfaenol i bractis GMBILI.

(9) Caiff meddyg apelio i Weinidogion Cymru yn erbyn penderfyniad gan Fwrdd Iechyd Lleol o dan baragraff (3). Rhaid gwneud yr apêl mewn ysgrifen o fewn cyfnod o 30 diwrnod sy'n cychwyn gyda'r dyddiad yr anfonwyd hysbysiad o'r penderfyniad at y meddyg, a rhaid i'r apêl gynnwys datganiad cryno o seiliau'r apêl.

(10) Rhaid i Weinidogion Cymru, ar ôl cael unrhyw hysbysiad o apêl o dan baragraff (9), anfon copi o'r hysbysiad hwnnw at y Bwrdd Iechyd Lleol a'r contractwr GMC neu'r contractwr GMDdA perthnasol, a chaiff y Bwrdd Iechyd Lleol a'r contractwr GMC neu'r contractwr GMDdA perthnasol, o fewn 30 diwrnod o'r dyddiad yr anfonodd Gweinidogion Cymru gopi o'r hysbysiad o apêl, gyflwyno sylwadau ysgrifenedig i Weinidogion Cymru.

(11) Caiff Gweinidogion Cymru benderfynu apêl yn unol â pharagraff (9) ym mha bynnag fodd y gwelant yn briodol, gan gymryd i ystyriaeth y materion rhagarweiniol yn Rhan 1 o Atodlen 3.

(12) Rhaid i Weinidogion Cymru, wedi iddynt benderfynu unrhyw apêl o dan baragraff (9), roi hysbysiad o'u penderfyniad mewn ysgrifen, ynghyd â'r rhesymau am y penderfyniad, i'r apelydd, i'r Bwrdd Iechyd Lleol ac i'r contractwr GMC neu'r contractwr GMDdA perthnasol.

Gwasanaethau angenrheidiol ar gyfer cleifion dros dro

21. Caiff meddyg, sy'n darparu gwasanaethau fferyllol i gleifion ar restr cleifion drwy drefniant a wneir gyda Bwrdd Iechyd Lleol o dan reoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon), ddarparu gwasanaethau fferyllol angenrheidiol i berson sydd wedi ei dderbyn gan y meddyg fel claf dros dro.

Darparu gwasanaethau fferyllol ar gyfer rhoi triniaeth ar unwaith neu eu rhoi neu eu defnyddio ar y claf gan y meddyg ei hunan

22.—(1) Yn ddarostyngedig i baragraff (2), caiff meddyg y mae ei enw wedi ei gynnwys mewn rhestr cyflawnwyr meddygol—

(a) darparu i glaf unrhyw gyfarpar neu gyffur, nad yw'n gyffur Atodlen, pan fo angen darpariaeth o'r fath ar gyfer trin y claf hwnnw ar unwaith, cyn y gellir cael darpariaeth rywfodd arall; a

(b) darparu i glaf unrhyw gyfarpar neu gyffur, nad yw'n gyffur Atodlen, a roddir i'r claf hwnnw, neu a osodir ar y claf hwnnw, gan y meddyg ei hunan.

(c) is engaged by a Local Health Board for the purposes of providing primary medical services to a LHBMS practice.

(9) A doctor may appeal to the Welsh Ministers against a decision of a Local Health Board under paragraph (3). The appeal must be made in writing within 30 days beginning with the date on which notice of the decision was sent to the doctor and must contain a concise statement of the grounds of appeal.

(10) The Welsh Ministers must, on receipt of any notice of appeal under paragraph (9), send a copy of that notice to the Local Health Board and the relevant GMS contractor or APMS contractor, and the Local Health Board and the relevant GMS contractor or APMS contractor may, within 30 days from the date on which the Welsh Ministers sent a copy of the notice of appeal, make representations in writing to the Welsh Ministers.

(11) The Welsh Ministers may determine an appeal pursuant to paragraph (9) in such manner as they see fit, taking into consideration the preliminary matters in Part 1 of Schedule 3.

(12) The Welsh Ministers must, upon determination by them of any appeal under paragraph (9), give notice of their decision in writing, together with the reasons for it, to the appellant, to the Local Health Board, and to the relevant GMS contractor or relevant APMS contractor.

Necessary services for temporary patients

21. A doctor who provides pharmaceutical services to patients on a patient list by arrangement made with a Local Health Board under regulation 20 (arrangements for the provision of pharmaceutical services by doctors) may provide necessary pharmaceutical services to a person who has been accepted by the doctor as a temporary patient.

Provision of pharmaceutical services for immediate treatment or personal administration

22.—(1) Subject to paragraph (2), a doctor whose name is included in a medical performers list may—

(a) provide to a patient any appliance or drug, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and

(b) provide to a patient any appliance or drug, not being a Scheduled drug, which he or she personally administers or applies to that patient.

(2) Ni chaiff meddyg ddarparu cyfarpar argaeledd cyfyngedig ac eithrio ar gyfer person neu ddiben a bennir yn y Tariff Cyffuriau.

Terfynu trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon

23.—(1) Rhaid i'r Bwrdd Iechyd Lleol roi cyfnod rhesymol o rybudd mewn ysgrifen i feddyg, i'r perwyl y bydd rhaid i'r meddyg roi'r gorau i ddarparu gwasanaethau fferyllol i glaf o dan drefniant yn unol â rheoliad 20 os nad yw'r claf hwnnw bellach yn dod o fewn rheoliad 20(1)(a), (b) neu (c).

(2) Mae hysbysiad a roddir o dan baragraff (1)—

- (a) yn ddarostyngedig i unrhyw ohirio neu derfynu'r trefniadau ar gyfer darparu gwasanaethau fferyllol i'r person hwnnw gan y meddyg hwnnw, a wnaed o dan baragraff 6 o Atodlen 2, paragraff 13 o Atodlen 2 neu reoliad 11(6); a
- (b) rhaid peidio â'i roi—
 - (i) os oes unrhyw apêl yn yr arfaeth yn erbyn penderfyniad gan y Bwrdd Iechyd Lleol i ohirio gwneud, neu derfynu'r trefniant; neu
 - (ii) pan fo paragraff 5 o Atodlen 2 yn gymwys

Cydsyniad amlinellol a chymeradwyaeth mangre

24.—(1) Rhaid i feddyg, sy'n ddarparwr gwasanaethau meddygol sylfaenol neu a gymerwyd ymlaen neu a gyflogir gan ddarparwr gwasanaethau meddygol sylfaenol ac sy'n dymuno gwneud trefniant gyda Bwrdd Iechyd Lleol i ddarparu gwasanaethau fferyllol i gleifion o dan reoliad 20(1)(b) neu (c) (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon), gyflwyno cais mewn ysgrifen i'r Bwrdd Iechyd Lleol, am—

- (a) cydsyniad, gan bennu'r ardal y mae'r meddyg yn dymuno darparu gwasanaethau fferyllol ynddi ("cydsyniad amlinellol"); a
- (b) cymeradwyaeth i unrhyw fangre practis y mae'r meddyg yn dymuno gweinyddu ohoni ("cymeradwyaeth mangre").

(2) Ni chaiff meddyg, y mae ganddo gydsyniad amlinellol sydd wedi cael effaith o dan reoliad 25 (cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith), gyflwyno cais am gymeradwyaeth mangre ac eithrio mewn perthynas ag—

- (a) mangre practis ychwanegol y bwriedir darparu gwasanaethau fferyllol ohoni; neu
- (b) mangre practis y mae'r meddyg yn dymuno adleoli iddi o fangre restredig.

(3) Rhaid i gais a wneir i Fwrdd Iechyd Lleol o dan y rheoliad hwn fod mewn ysgrifen, a rhaid iddo ddarparu'r wybodaeth a bennir yn Rhan 4 o Atodlen 1.

(2) A doctor may only provide a restricted availability appliance if it is for a person or a purpose specified in the Drug Tariff.

Discontinuation of arrangements for the provision of pharmaceutical services by doctors

23.—(1) A Local Health Board must give reasonable notice in writing to a doctor that he or she must discontinue the provision of pharmaceutical services to a patient under an arrangement pursuant to regulation 20 where the patient no longer falls within regulation 20(1)(a), (b) or (c).

(2) A notice given under paragraph (1)—

- (a) is subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or regulation 11(6); and
- (b) must not be given—
 - (i) pending any appeal against a decision of the Local Health Board to postpone the making of or the termination of the arrangement.; or
 - (ii) where paragraph 5 of Schedule 2 applies.

Outline consent and premises approval

24.—(1) A doctor who is a provider of primary medical services or who is engaged or employed by a provider of primary medical services and who wishes to make an arrangement with a Local Health Board to provide pharmaceutical services to patients under regulation 20(1)(b) or (c) (arrangements for the provision of pharmaceutical services by doctors) must submit an application in writing to the Local Health Board for—

- (a) consent specifying the area in which the doctor wishes to provide pharmaceutical services ("outline consent"); and
- (b) approval of any practice premises from which the doctor wishes to dispense ("premises approval").

(2) A doctor who has outline consent which has taken effect under regulation 25 (taking effect of outline consent and premises approval) may submit an application for premises approval only in relation to—

- (a) additional practice premises from which to provide pharmaceutical services; or
- (b) practice premises to which the doctor wishes to relocate from listed premises.

(3) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 4 of Schedule 1.

(4) Rhaid i Fwrdd Iechyd Lleol ddychwelyd cais os nad yw'r cais yn cynnwys yr holl wybodaeth sy'n ofynnol o dan baragraff (3).

(5) O ran y Bwrdd Iechyd Lleol—

- (a) rhaid iddo wrthod cydsyniad amlinellol mewn perthynas ag unrhyw ran o'r ardal a bennir yn y cais nad yw mewn ardal reoledig, neu sydd o fewn 1.6 cilometr i unrhyw fferyllfa;
- (b) rhaid iddo wrthod cymeradwyaeth mangre mewn perthynas ag unrhyw fangre a bennir yn y cais sydd o fewn 1.6 cilometr i unrhyw fferyllfa;
- (c) rhaid iddo wrthod cais os yw o'r farn y byddai ei ganiatáu yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau gweinyddu neu wasanaethau fferyllol yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn y cais (y "prawf niweidio");
- (d) yn ddarostyngedig i baragraff (7) a phan nad yw cais wedi ei wrthod o dan y prawf niweidio, rhaid iddo wrthod y cais oni fodlonir ef fod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau darpariaeth ddigonol, gan bersonau a gynhwysir mewn rhestr, o'r gwasanaethau a bennir yn y cais, neu rai o'r gwasanaethau hynny, yn yr ardal y gwnaeth y meddyg gais am gydsyniad amlinellol mewn perthynas â hi; ac
- (e) pan fo'r Bwrdd Iechyd Lleol wedi ystyried dau neu ragor o geisiadau ar y cyd ac mewn perthynas â'i gilydd, caiff wrthod un neu ragor ohonynt (hyd yn oed rhai y byddid wedi eu caniatáu pe baent wedi eu penderfynu ar eu pen eu hunain) os yw nifer y ceisiadau yn peri y byddai caniatáu pob un ohonynt neu fwy nag un ohonynt yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau gweinyddu neu wasanaethau fferyllol mewn unrhyw ardal reoledig.

(6) Caiff unrhyw wrthodiad o gais, fel a amlinellir yn is-baragraffau (a) i (e) uchod, ymwneud â'r cyfan neu unrhyw ran o'r ardal sydd o fewn yr ardal reoledig neu, yn ôl fel y digwydd, yr holl fangreodd neu rai o'r mangreodd y gofynnir am gymeradwyaeth ar eu cyfer.

(7) Os, wrth benderfynu cais blaenorol a wnaed o dan y rheoliad hwn, gwrthodwyd y cais hwnnw o dan baragraff (5)(d), rhaid peidio ag ystyried y cwestiwn o dan baragraff (5)(d) drachefn mewn perthynas â'r un ardal a bennwyd yn y cais blaenorol—

- (a) am gyfnod o dair blynedd, sy'n cychwyn gyda'r dyddiad y penderfynwyd y cais blaenorol gan y Bwrdd Iechyd Lleol, neu, os apeliwyd yn erbyn y penderfyniad hwnnw, dyddiad y penderfyniad ar yr apêl; oni bai
- (b) bod y Bwrdd Iechyd Lleol wedi ei fodloni bod

(4) A Local Health Board must return an application if it does not contain all of the information required under paragraph (3).

(5) The Local Health Board—

- (a) must refuse outline consent in relation to any part of the area specified in the application which is not in a controlled locality or which is within 1.6 kilometres of any pharmacy;
- (b) must refuse premises approval in relation to any premises specified in the application which are within 1.6 kilometres of any pharmacy;
- (c) must refuse an application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality within which the premises specified in the application are situated (the "prejudice test");
- (d) subject to paragraph (7) and where an application has not been refused under the prejudice test, must refuse the application unless it is satisfied that it is necessary or expedient to grant the application in order to secure in the area in respect of which the doctor has applied for outline consent the adequate provision, by persons included in a list, of the services, or some of the services, specified in the application; and
- (e) may, where the Local Health Board has considered two or more applications together and in relation to each other, refuse one or more of them (notwithstanding that it would, if determining the applications in isolation, grant them) where the number of applications is such that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any controlled locality.

(6) Any refusal of an application outlined at subparagraphs (a) to (e) above may relate to all or any part of the area within the controlled locality, or, as the case may be, all or some of the premises for which approval is sought.

(7) Where in determining an earlier application made under this regulation that application was refused under paragraph (5)(d), the question under paragraph (5)(d) must not be considered again in relation to the same area as was specified in the earlier application—

- (a) for three years, beginning on the date on which the earlier application was determined by the Local Health Board or, if that determination was appealed, the date of the decision on the appeal; unless
- (b) the Local Health Board is satisfied that there

newid sylweddol wedi digwydd yn yr amgylchiadau mewn perthynas â'r ardal y gwnaeth y meddyg gais am gydsyniad amlinellol mewn perthynas â hi, er pan ystyriwyd ddiwethaf y cwestiwn o dan baragraff (5)(d).

(8) Yn ddarostyngedig i unrhyw ofynion penodol a gynhwysir yn y Rhan hon, mae Rhannau 1 a 3 o Atodlen 2 yn pennu'r gweithdrefnau sydd i'w dilyn gan Fwrdd Iechyd Lleol wrth benderfynu ceisiadau o dan y Rhan hon.

(9) Mae cais o dan y rheoliad hwn yn cael ei ganiatáu ar ba bynnag ddyddiad yw'r diweddaraf o—

- (a) 30 diwrnod ar ôl anfon hysbysiad o benderfyniad y Bwrdd Iechyd Lleol ar y cais, gan y Bwrdd Iechyd Lleol yn unol â pharagraff 15 o Atodlen 2; neu
- (b) os gwneir apêl yn erbyn penderfyniad y Bwrdd Iechyd Lleol, y dyddiad y rhoddwyd hysbysiad gan Weinidogion Cymru o'u penderfyniad ar yr apêl o dan baragraff 8 o Atodlen 3.

Cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith

25.—(1) Wrth ganiatáu cais a wneir o dan reoliad 24 (cydsyniad amlinellol a chymeradwyaeth mangre), rhaid i'r Bwrdd Iechyd Lleol benderfynu ar ba ddyddiad y bydd y cydsyniad amlinellol a'r gymeradwyaeth mangre yn cael effaith.

(2) Os nad oes ceisiadau am fferyllfa yn yr arfaeth (fel y'u diffinnir ym mharagraff (11)), mae'r cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith ar y dyddiad y caniateir y cais.

(3) Os oes ceisiadau am fferyllfa yn yr arfaeth ar y diwrnod cyn y caniateir y cais o dan reoliad 24, rhaid penderfynu'r dyddiad y bydd y cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith yn unol â pharagraffau (4) i (9).

(4) Rhaid i'r Bwrdd Iechyd Lleol, mewn perthynas â chais y mae paragraff (3) yn gymwys iddo, hysbysu'r meddyg a wnaeth y cais o dan reoliad 24, a Gweinidogion Cymru os yw'r cais yn destun apêl, ynghylch—

- (a) unrhyw geisiadau am fferyllfa yn yr arfaeth;
- (b) tynnu'n ôl unrhyw geisiadau am fferyllfa yn yr arfaeth;
- (c) y dyddiad dros dro (fel y'i diffinnir ym mharagraff (11)) pan gaiff y meddyg ofyn i'r Bwrdd Iechyd Lleol benderfynu y dylai'r cydsyniad amlinellol a chymeradwyaeth mangre gael effaith; a
- (d) cais y meddyg am gydsyniad amlinellol a chymeradwyaeth mangre yn mynd yn ddi-rym os ddechreuir darparu gwasanaethau fferyllol,

has been a substantial change of circumstances in relation to the area in respect of which the doctor has applied for outline consent since the question under paragraph (5)(d) was last considered.

(8) Subject to any specific requirements that are contained within this Part, Parts 1 and 3 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining applications under this Part.

(9) An application under this regulation is granted on the date which is the later of—

- (a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 15 of Schedule 2; or
- (b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers gave notice of their decision on the appeal under paragraph 8 of Schedule 3.

Taking effect of outline consent and premises approval

25.—(1) When granting an application made under regulation 24 (outline consent and premises approval), the Local Health Board must determine the date on which outline consent and premises approval are to take effect.

(2) Where there are no outstanding pharmacy applications (as defined in paragraph (11)) outline consent and premises approval take effect on the date on which the application is granted.

(3) Where there are outstanding pharmacy applications on the day before the application under regulation 24 is granted, the date on which outline consent and premises approval take effect is to be determined in accordance with paragraphs (4) to (9).

(4) The Local Health Board must in respect of an application to which paragraph (3) applies notify the doctor who made the application under regulation 24, and the Welsh Ministers if the application is subject to appeal, of—

- (a) any outstanding pharmacy applications;
- (b) the withdrawal of outstanding pharmacy applications;
- (c) the provisional date (as defined in paragraph 11) on which the doctor can request the Local Health Board to determine that outline consent and premises approval should come into effect; and
- (d) the lapse of the doctor's application for outline consent and premises approval if, before the provisional date, the provision of

cyn y dyddiad dros dro, o fangre a oedd yn destun cais am fferyllfa yn yr arfaeth sydd wedi ei ganiatáu;

(5) Ar y dyddiad dros dro, neu mor fuan ag y bo'n rhesymol ymarferol ar ôl y dyddiad dros dro, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r meddyg a wnaeth y cais o dan reoliad 24—

- (a) y caiff y meddyg, o fewn tri mis ar ôl yr hysbysiad gan y Bwrdd Iechyd Lleol, gyflwyno cais ysgrifenedig i'r Bwrdd Iechyd Lleol yn gofyn iddo benderfynu a ddylai'r cydsyniad amlinellol a chymeradwyaeth mangre gael effaith; a
- (b) bod rhaid i'r Bwrdd Iechyd Lleol benderfynu'r cais cyn gynted ag y bo'n ymarferol ac yn unol â pharagraffau (6) a (7).

(6) Os yw'r fangre y ceisir cymeradwyaeth mangre mewn perthynas â hi, ar ddyddiad y penderfyniad o dan baragraff (5), yn fangre practis, rhaid i'r Bwrdd Iechyd Lleol benderfynu y bydd y cydsyniad amlinellol a chymeradwyaeth mangre mewn perthynas â'r fangre honno yn cael effaith ar y dyddiad hwnnw.

(7) Os nad yw'r fangre y ceisir cymeradwyaeth mangre mewn perthynas â hi, ar ddyddiad y penderfyniad o dan baragraff (5), yn fangre practis, bydd y cydsyniad amlinellol a chymeradwyaeth mangre yn mynd yn ddi-rym.

(8) Rhaid i'r Bwrdd Iechyd Lleol roi hysbysiad o'i benderfyniad o dan baragraff (5) i'r ceisydd ac i'r personau hynny yr oedd yn ofynnol, o dan baragraff 8 o Atodlen 2, roi hysbysiad iddynt o'r cais o dan reoliad 24.

(9) Pan fo'r Bwrdd Iechyd Lleol wedi penderfynu y bydd cydsyniad amlinellol a chymeradwyaeth mangre yn mynd yn ddi-rym yn rhinwedd paragraff (7) neu yr estynnir y dyddiad dros dro o dan baragraff (11), caiff y meddyg a wnaeth y cais o dan reoliad 24 apelio i Weinidogion Cymru.

(10) Yn yr amgylchiadau a amlinellir ym mharagraff (9), os cyflwynir hysbysiad o apel i Weinidogion Cymru, bydd Rhan I o Atodlen 3 a'r paragraffau canlynol o Atodlen 3 yn gymwys:

- (a) 6(4)(b) ac (c);
- (b) 7(2) a (4); ac
- (c) 8,

fel pe bai'r hysbysiad o apel wedi ei gyflwyno o dan baragraff 6(2) o Atodlen 3.

(11) Yn y rheoliad hwn—

ystyr "cais am fferyllfa yn yr arfaeth" ("*outstanding pharmacy application*") yw cais a wneir o dan reoliad 8 (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol) neu reoliad 12 (ceisiadau am gydsyniad rhagarweiniol

pharmaceutical services is commenced from the premises which were the subject of an outstanding pharmacy application which has been granted;

(5) On, or as soon as reasonably practicable after, the provisional date, the Local Health Board must notify the doctor who made the application under regulation 24 that—

- (a) the doctor may within three months of the Local Health Board's notification submit a request in writing to the Local Health Board asking it to determine whether the outline consent and premises approval should come into effect; and
- (b) the Local Health Board must determine the request as soon as practicable and in accordance with paragraphs (6) and (7).

(6) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are practice premises, the Local Health Board must determine that the outline consent and premises approval in respect of those premises will come into effect on that date.

(7) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are not practice premises outline consent and premises approval will lapse.

(8) The Local Health Board must notify its determination under paragraph (5) to the applicant and those persons to whom notice of the application under regulation 24 was required to be given under paragraph 8 of Schedule 2.

(9) Where the Local Health Board has determined that outline consent and premises approval will lapse by virtue of paragraph (7) or that the provisional date is to be extended under paragraph (11), the doctor who made the application under regulation 24 may appeal to the Welsh Ministers.

(10) If, in the circumstances outlined in paragraph (9), a notice of appeal is submitted to the Welsh Ministers, Part I of Schedule 3 and the following paragraphs of Schedule 3 will apply:

- (a) 6(4)(b) and (c);
- (b) 7(2) and (4); and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(2) of Schedule 3.

(11) In this regulation—

"outstanding pharmacy application" ("*cais am fferyllfa yn yr arfaeth*") means an application made under regulation 8 (applications to be included in or for amendment to a pharmaceutical list) or regulation 12 (applications for preliminary consent

ac effaith cydsyniad rhagarweiniol)—

- (a) pan fo'r fangre a bennir yn y cais hwnnw o fewn 1.6 cilometr i'r fangre y ceisir cymeradwyaeth mangre ar ei chyfer; a
- (b) sydd naill ai—
 - (i) wedi ei wneud ond eto heb ei benderfynu, gan gynnwys yn dilyn apêl, neu
 - (ii) wedi ei ganiatáu fel y diffinnir "caniatawyd" yn rheoliad 17 (gweithdrefn yn dilyn caniatáu cais) ond darparu gwasanaethau fferyllol o'r fangre honno heb gychwyn eto; ac
- (c) ystyr "dyddiad dros dro" ("*provisional date*") yw'r diwrnod ar ôl diwedd cyfnod o un flwyddyn, neu pa bynnag gyfnod pellach o ddim mwy na thri mis a benderfynir gan y Bwrdd Iechyd Lleol (a rhaid iddo hysbysu'r meddyg a wnaeth y cais o dan reoliad 24 o unrhyw estyniad) sy'n cychwyn gyda'r dyddiad y caniateir y cais yn unol â rheoliad 24(9).

Cydsyniad amlinellol a chymeradwyaeth mangre yn mynd yn ddi-rym

26.—(1) Bydd cydsyniad amlinellol yn peidio â chael effaith—

- (a) os na fydd darparu gwasanaethau gweinyddu wedi cychwyn o fewn deuddeg mis wedi i gydsyniad amlinellol neu gymeradwyaeth mangre gael effaith o dan reoliad 25 (cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith);
- (b) pan fo mwy na 12 mis wedi mynd heibio er pan ddarparwyd gwasanaethau gweinyddu ddiwethaf;
- (c) pan fo practisiau'n cyfuno ac ar ôl cyfuno nid oes mangre practis sydd â chymeradwyaeth mangre; neu
- (d) pan fo cydsyniad amlinellol wedi mynd yn ddi-rym o dan reoliad 25.

(2) Bydd cymeradwyaeth mangre yn peidio â chael effaith mewn perthynas ag—

- (a) mangre restredig sydd, yn barhaol, wedi peidio â bod yn fangre practis;
- (b) mangre restredig nas defnyddiwyd ar gyfer gweinyddu gan unrhyw feddyg a awdurdodwyd i weinyddu o'r fangre honno am gyfnod o chwe mis, neu pa bynnag gyfnod hwy a ganiateir am reswm da gan y Bwrdd Iechyd Lleol;
- (c) mangre restredig lle mae'r meddyg, y rhestrwyd y fangre o dan ei enw yn y rhestr meddygon fferyllol, wedi hysbysu'r Bwrdd Iechyd Lleol fod yr holl feddygon sydd ag

and effect of preliminary consent)—

- (a) where the premises specified in that application are within 1.6 kilometres of the premises for which premises approval has been sought; and
- (b) which has either—
 - (i) been made but not yet determined, including on appeal, or
 - (ii) has been granted as defined in regulation 17 (procedure following grant of an application) but the provision of pharmaceutical services from those premises has not been commenced; and
- (c) "provisional date" ("*dyddiad dros dro*") means the day after the end of a period of one year or such further period not exceeding three months as the Local Health Board may determine (and it must notify the doctor who made the application under regulation 24 of any extension) beginning with the date on which the application is granted in accordance with regulation 24(9).

Lapse of outline consent and premises approval

26.—(1) Outline consent will cease to have effect—

- (a) where the provision of dispensing services has not commenced within twelve months of outline consent or premises approval taking effect under regulation 25 (taking effect of outline consent and premises approval);
- (b) where more than twelve months have elapsed since the last provision of dispensing services;
- (c) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval; or
- (d) where outline consent has lapsed under regulation 25.

(2) Premises approval will cease to have effect in relation to—

- (a) listed premises which have permanently ceased to be practice premises;
- (b) listed premises which have not been used for dispensing by any doctor authorised to dispense from those premises for six months or such longer period as the Local Health Board may for good cause allow;
- (c) listed premises where the doctor under whose name those premises are listed in the dispensing doctors list has notified the Local Health Board that all the doctors who have

awdurdod i weinyddu o'r fangre honno wedi rhoi'r gorau i wneud hynny;

- (d) mangre restredig lle nad oes meddyg sydd â chymeradwyaeth mangre mewn perthynas â'r fangre honno yn weddill ar y rhestr meddygon fferyllol; neu
- (e) mangre restredig y caniatawyd cymeradwyaeth mangre iddi o dan reoliad 29(3), os nad oes cyfuno practisiau yn digwydd o fewn y cyfnod a bennir yn rheoliad 29(7).

(3) Bydd cymeradwyaeth mangre yn peidio â chael effaith pan yw'r cydsyniad amlinellol perthnasol yn peidio â chael effaith.

Cymeradwyaeth mangre: newid mangre cyn bo cydsyniad amlinellol yn cael effaith

27.—(1) Pan fo—

- (a) cydsyniad amlinellol wedi ei roi ond heb ddod i rym eto o dan reoliad 25 (rhoi cydsyniad amlinellol a chymeradwyaeth mangre mewn grym); a
- (b) cyn y dyddiad dros dro a ddiffinnir yn rheoliad 25(11), y meddyg yn bwriadu newid y fangre practis y dymuna ddarparu gwasanaethau fferyllol ohoni,

caiff y meddyg wneud cais ysgrifenedig i'r Bwrdd Iechyd Lleol, gan ddarparu'r wybodaeth a bennir yn Rhan 4 o Atodlen 1, am i'r Bwrdd Iechyd Lleol benderfynu a ddylid rhoi cymeradwyaeth mangre mewn perthynas â'r fangre newydd, a rhaid i'r Bwrdd Iechyd Lleol wneud y penderfyniad yn unol â pharagraff (2).

(2) Os yw'r Bwrdd Iechyd Lleol wedi ei fodloni mai adleoliad bach yw'r newid mangre, caiff ganiatáu'r gymeradwyaeth mangre ar gyfer y fangre newydd, ond os nad yw wedi ei fodloni felly, rhaid gwrthod cymeradwyaeth mangre ar gyfer y fangre newydd.

(3) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r personau hynny yr oedd yn ofynnol rhoi hysbysiad iddynt o'r cais a wnaed o dan reoliad 24 (cydsyniad amlinellol a chymeradwyaeth mangre) o'i benderfyniad o dan baragraff (2).

(4) Caiff y ceisydd apelio i Weinidogion Cymru yn erbyn penderfyniad y Bwrdd Iechyd Lleol o dan baragraff (2).

(5) Yn yr amgylchiadau a amlinellir ym mharagraff (4), os cyflwynir hysbysiad o apel i Weinidogion Cymru, bydd Rhan I o Atodlen 3 a'r paragraffau canlynol o Atodlen 3 yn gymwys:

- (a) 6(4)(b) ac (c);
- (b) 7(2) a (4); ac
- (c) 8

authority to dispense from those premises have ceased to do so;

- (d) listed premises where there is no doctor with premises approval in respect of them remaining on the dispensing doctor list; or
- (e) listed premises which were granted premises approval under regulation 29(3), where no practice amalgamation takes place within the period specified in regulation 29(7).

(3) Premises approval will cease to have effect where the related outline consent ceases to have effect.

Premises approval: change of premises before outline consent takes effect

27.—(1) Where—

- (a) outline consent has been granted but has not yet taken effect under regulation 25 (taking effect of outline consent and premises approval); and
- (b) before the provisional date defined in regulation 25(11) the doctor intends to change the practice premises from which he or she wishes to provide pharmaceutical services,

he or she may apply in writing to the Local Health Board providing the information set out in Part 4 of Schedule 1 for the Local Health Board to determine whether premises approval should be given in relation to the new premises, and the Local Health Board must make the determination in accordance with paragraph (2).

(2) If the Local Health Board is satisfied that the change of premises is a minor relocation it may grant the premises approval for those new premises, but if it is not so satisfied premises approval for those new premises must be refused.

(3) The Local Health Board must notify those persons to whom notice of the application made under regulation 24 (outline consent and premises approval) was required to be given of its determination under paragraph (2).

(4) The determination by the Local Health Board under paragraph (2) may be appealed by the applicant to the Welsh Ministers.

(5) If, in the circumstances outlined in paragraph (4), a notice of appeal is submitted to the Welsh Ministers, Part I of Schedule 3 and the following paragraphs of Schedule 3 will apply:

- (a) 6(4)(b) and (c);
- (b) 7(2) and (4); and
- (c) 8,

fel pe bai'r hysbysiad o apêl wedi ei gyflwyno o dan baragraff 6(2) o Atodlen 3.

Cymeradwyaeth mangre: mangreoedd ychwanegol a newydd wedi i'r cydsyniad amlinellol gael effaith

28.—(1) Caiff meddyg y mae ganddo gydsyniad amlinellol sydd wedi cael effaith, ac sy'n dymuno cael cymeradwyaeth mangre ar gyfer mangre yn ychwanegol at y fangre honno y rhoddwyd cymeradwyaeth mangre ar ei chyfer ("mangre ychwanegol") wneud cais ysgrifenedig, gan ddarparu'r wybodaeth a bennir yn Rhan 4 o Atodlen 1, i bob un o'r Byrddau Iechyd Lleol priodol, a bydd y cais yn cael ei benderfynu gan y Bwrdd Iechyd Lleol perthnasol yn unol â pharagraff (2).

(2) Rhaid i gais am fangre ychwanegol gael ei benderfynu gan y Bwrdd Iechyd Lleol perthnasol yn unol â rheoliad 24 (cydsyniad amlinellol a chymeradwyaeth mangre) a rheoliad 25 (cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith).

(3) At ddibenion y rheoliad hwn—

- (a) y "Byrddau Iechyd Lleol priodol" ("*appropriate Local Health Boards*") yw'r rheini sy'n cynnal y rhestrau meddygol fferyllol y cynhwysir ynddynt y meddyg sy'n gwneud y cais; a
- (b) y "Bwrdd Iechyd Lleol perthnasol" ("*relevant Local Health Board*") yw'r Bwrdd Iechyd Lleol y lleolir y fangre ychwanegol yn ei ardal.

(4) Caiff meddyg sy'n dymuno cael cymeradwyaeth mangre mewn perthynas â mangre ("mangre newydd") lle mae'r meddyg yn dymuno gweinyddu, yn lle mangre restredig, wneud cais, gan ddarparu'r wybodaeth a bennir yn Rhan 4 o Atodlen 1, i bob un o'r Byrddau Iechyd Lleol priodol, a bydd y cais yn cael ei benderfynu gan y Bwrdd Iechyd Lleol perthnasol yn unol â pharagraffau (5) a (6).

(5) Yn achos cais am fangre newydd, rhaid i'r Bwrdd Iechyd Lleol perthnasol roi hysbysiad o'r cais yn unol â pharagraff 9 o Atodlen 2 a rhaid i gynnwys yr hysbysiad gydymffurfio â pharagraff 10 o'r Atodlen honno.

(6) Yn achos cais am fangre newydd, rhaid i'r Bwrdd Iechyd Lleol perthnasol—

- (a) caniatáu'r cais os yw wedi ei fodloni—
 - (i) ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre bresennol, nad yw lleoliad y fangre newydd yn llai hygyrch i raddau sylweddol, a
 - (ii) na fyddai caniatáu'r cais yn achosi newid sylweddol yn y trefniadau ar gyfer darparu gwasanaethau fferyllol neu wasanaethau gweinyddu mewn unrhyw ran o'r ardal

as if the notice of appeal were submitted under paragraph 6(2) of Schedule 3.

Premises approval: additional and new premises after outline consent has taken effect

28.—(1) A doctor who has outline consent which has taken effect and who wishes to be granted premises approval for premises in addition to those premises in respect of which premises approval has been given ("additional premises") may apply in writing providing the information set out in Part 4 of Schedule 1 to all of the appropriate Local Health Boards and the application will be determined by the relevant Local Health Board in accordance with paragraph (2).

(2) An application for additional premises must be determined by the relevant Local Health Board in accordance with regulation 24 (outline consent and premises approval) and regulation 25 (taking effect of outline consent and premises approval).

(3) For the purpose of this regulation—

- (a) the "appropriate Local Health Boards" ("*Byrddau Iechyd Lleol priodol*") are those who hold the dispensing doctor lists on which the doctor making the application is included; and
- (b) the "relevant Local Health Board" ("*Bwrdd Iechyd Lleol perthnasol*") is the Local Health Board in whose area the additional premises are situated.

(4) A doctor wishing to be granted premises approval in relation to premises ("new premises") where he or she wishes to dispense instead of listed premises may apply to all the appropriate Local Health Boards providing the information set out in Part 4 of Schedule 1 and the application will be determined by the relevant Local Health Board in accordance with paragraphs (5) and (6).

(5) In the case of an application for new premises the relevant Local Health Board must give notice of the application in accordance with paragraph 9 of Schedule 2 and the content of the notification must comply with paragraph 10 of that Schedule.

(6) In the case of an application for new premises the relevant Local Health Board must—

- (a) grant an application where it is satisfied that—
 - (i) for the patients that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible, and
 - (ii) granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical or dispensing services to any part of the

reoleddig y lleolir y fangre newydd ynddi;
neu

- (b) mewn unrhyw achos arall, penderfynu'r cais fel cais am gymeradwyaeth mangre a wneir o dan reoliad 24(1)(b).

(7) Rhaid i Fwrdd Iechyd Lleol, oni fydd ganddo reswm da dros beidio â gwneud hynny, wrthod cais o dan baragraff (1) neu (4) os oes cais a wnaed gan y meddyg wedi ei ganiatáu o dan baragraff (6)(a) yn ystod y deuddeg mis cyn cyflwyno'r cais o dan baragraff (1) neu (4).

(8) Rhaid i'r Bwrdd Iechyd Lleol roi hysbysiad o'i benderfyniad o dan baragraff (2) neu baragraff (6)(b) i'r personau hynny y mae'n ofynnol rhoi hysbysiad o'r cais iddynt yn unol â rheoliad 24 a pharagraff 8 o Atodlen 2.

(9) Rhaid i'r Bwrdd Iechyd Lleol roi hysbysiad o'i benderfyniad o dan baragraff (6)(a) i'r personau hynny y mae'n ofynnol rhoi hysbysiad iddynt yn unol â pharagraff 15 o Atodlen 2.

(10) Caiff y personau a restrir ym mharagraff 6(2) o Atodlen 3 apelio i Weinidogion Cymru yn erbyn penderfyniad gan y Bwrdd Iechyd Lleol o dan baragraff (2), (6)(a) neu (6)(b).

(11) Yn ddarostyngedig i baragraff (12) bydd y gymeradwyaeth mangre ar gyfer mangre ychwanegol neu newydd yn cael effaith o ddyddiad yr hysbysiad o ganiatáu'r gymeradwyaeth mangre, sef—

- (a) os na wneir apêl yn erbyn penderfyniad y Bwrdd Iechyd Lleol, y dyddiad ar ôl diwedd y cyfnod o 30 diwrnod sy'n cychwyn gyda'r dyddiad y rhoddir hysbysiad o'r penderfyniad hwnnw o dan baragraff (8) neu baragraff (9); neu
- (b) os gwneir apêl o'r fath, y dyddiad y bydd Gweinidogion Cymru yn rhoi hysbysiad o'u penderfyniad ar yr apêl honno.

(12) Pan fo—

- (a) cymeradwyaeth mangre wedi ei roi mewn perthynas â mangre ychwanegol; a
- (b) mewn perthynas â'r fangre y rhoddir y gymeradwyaeth ar ei chyfer, ceisiadau am fferyllfa yn yr arfaeth (fel y'u diffinnir yn rheoliad 25(11)), ar y dyddiad y rhoddiwyd y gymeradwyaeth,

y dyddiad y bydd y gymeradwyaeth mangre yn cael effaith fydd y diwrnod ar ôl diwedd cyfnod o un flwyddyn, neu pa bynnag gyfnod pellach (o ddim mwy na thri mis) y caiff y Bwrdd Iechyd Lleol ei ganiatáu am reswm da, ar ôl penderfynu yn derfynol unrhyw cais am fferyllfa yn yr arfaeth.

(13) Caiff y Bwrdd Iechyd Lleol roi cymeradwyaeth mangre dros dro i feddyg sydd â chydysyniad amlinellol a chymeradwyaeth mangre mewn perthynas â mangre

controlled locality in which the new premises are located; or

- (b) in any other case determine the application as an application for premises approval made under regulation 24(1)(b).

(7) A Local Health Board must, unless it has good cause not to do so, refuse an application under paragraph (1) or (4) if an application made by the doctor has been granted under paragraph (6)(a) during the twelve months before the application was submitted under paragraph (1) or (4).

(8) The Local Health Board must notify its determination under paragraph (2) or paragraph (6)(b) to the persons to whom notice of the application is required to be given in accordance with regulation 24 and paragraph 8 of Schedule 2.

(9) The Local Health Board must notify its determination under paragraph (6)(a) to those persons to whom notification is required to be given in accordance with paragraph 15 of Schedule 2.

(10) A determination by the Local Health Board under paragraph (2), (6)(a) or (6)(b) may be appealed to the Welsh Ministers by the persons listed in paragraph 6(2) of Schedule 3.

(11) Subject to paragraph (12) the premises approval for the additional or new premises will take effect from the date of notification of the grant of premises approval, which is—

- (a) where no appeal is made against the decision of the Local Health Board, the date after the expiry of 30 days beginning with the date on which notice of that decision is given under paragraph (8) or paragraph (9); or
- (b) where such an appeal is made, the date on which the Welsh Ministers give notice of their decision on that appeal.

(12) Where—

- (a) the premises approval is granted in relation to additional premises; and
- (b) in relation to the premises for which the approval is granted there were, at the date of the grant, outstanding pharmacy applications (as defined in regulation 25(11)),

the premises approval will take effect on the date which is the day after the end of a period of one year, or such further period (not exceeding three months) as the Local Health Board may for good cause allow, from the final resolution of any outstanding pharmacy application.

(13) The Local Health Board may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new

ychwanegol neu fangre newydd os yw'r Bwrdd o'r farn ei bod yn angenrheidiol neu'n hwylus gwneud hynny er mwyn sicrhau darpariaeth ddigonol o wasanaethau fferyllol yn yr ardal a wasanaethir gan y fangre ychwanegol neu'r fangre newydd, ac adnewyddu unrhyw gymeradwyaeth dros dro o'r fath a roddwyd, er mwyn sicrhau darpariaeth ddigonol, ac os yw'r Bwrdd yn gwneud hynny rhaid iddo—

- (a) hysbysu'r personau hynny yr oedd yn ofynnol, o dan baragraff 8 o Atodlen 2, rhoi hysbysiad o'r cais iddynt o dan reoliad 24 (cydsyniad amlinellol a chymeradwyaeth mangre) a'r ceiswyr mewn perthynas â'r ceisiadau am fferyllfa yn yr arfaeth;
- (b) datgan am ba gyfnod y bydd y gymeradwyaeth mangre dros dro mewn grym; ac
- (c) cynnwys y fangre honno yn y rhestr meddygon fferyllol mewn perthynas â'r meddyg hwnnw.

(14) Caniateir rhoi cymeradwyaeth mangre dros dro am gyfnod o ddim mwy na deuddeng mis, a chaniateir ei adnewyddu am gyfnod pellach o ddim mwy na thri mis.

(15) Caiff y ceisydd apelio i Weinidogion Cymru yn erbyn penderfyniad gan y Bwrdd Iechyd Lleol o dan baragraff (13).

(16) Yn yr amgylchiadau a amlinellir ym mharagraff (15), os cyflwynir hysbysiad o apel i Weinidogion Cymru, bydd Rhan I o Atodlen 3 a'r paragraffau canlynol o Atodlen 3 yn gymwys:

- (a) 6(4)(b) ac (c);
- (b) 7(2) a (4); ac
- (c) 8,

fel pe bai'r hysbysiad o apel wedi ei gyflwyno o dan baragraff 6(2) o Atodlen 3.

Cymeradwyaeth mangre: cyfuno practisiau

29.—(1) Mae cyfuno practisiau yn digwydd pan fo dau neu ragor o ddarparwyr gwasanaethau meddygol sylfaenol yn uno fel un darparwr gwasanaethau meddygol sylfaenol, ac, o ganlyniad, dwy neu ragor o restrau cleifion yn cael eu cyfuno.

(2) Yn dilyn cyfuno practisiau, os yw pob un o fangreoeedd practis y darparwr gwasanaethau meddygol sylfaenol sengl yn fangreoeedd a oedd, yn union cyn cyfuno'r practisiau, yn fangreoeedd rhestredig, bydd y cymeradwyaethau mangre ar gyfer y fangreoeedd hynny a'r cydsyniadau amlinellol perthynol yn parhau i gael effaith.

(3) Yn dilyn cyfuno practisiau, os nad yw paragraff (2) yn gymwys ond yr oedd gan un neu ragor o'r meddygon a ymunodd â'i gilydd fel darparwr gwasanaethau meddygol sylfaenol sengl, yn union cyn cyfuno, y gymeradwyaeth mangre ar gyfer fangreoeedd—

premises where it considers it is necessary or expedient to do so to secure the adequate provision of pharmaceutical services in the area served by the additional or new premises, and renew any such temporary approval granted, to secure such adequate provision, and where it does so it must—

- (a) notify those persons to whom notice of the application under regulation 24 (outline consent and premises approval) was required to be given under paragraph 8 of Schedule 2 and the applicants in relation to the outstanding pharmacy applications;
- (b) state the period during which the temporary premises approval is to apply; and
- (c) include those premises in the dispensing doctor list in relation to that doctor.

(14) Temporary premises approval may be granted for a period not exceeding twelve months, and may be renewed for a further period not exceeding three months.

(15) The determination by the Local Health Board under paragraph (13) may be appealed by the applicant to the Welsh Ministers.

(16) If, in the circumstances outlined in paragraph (15), a notice of appeal is submitted to the Welsh Ministers, Part I of Schedule 3 and the following paragraphs of Schedule 3 will apply:

- (a) 6(4)(b) and (c);
- (b) 7(2) and (4); and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(2) of Schedule 3.

Premises approval: practice amalgamations

29.—(1) A practice amalgamation occurs where two or more providers of primary medical services amalgamate as a single provider of primary medical services as a result of which two or more patient lists are combined.

(2) Following a practice amalgamation, if the practice premises of the single provider of primary medical services are all premises that immediately prior to the practice amalgamation were listed premises, the premises approvals for those premises and the related outline consents will continue to have effect.

(3) Following a practice amalgamation, if paragraph (2) does not apply but one or more of the doctors coming together as the single provider of primary medical services had, immediately prior to amalgamation, premises approval for premises—

(a) os daw unrhyw rai o'r mangreoedd hynny yn fangreoedd practis y darparwr gwasanaethau meddygol sylfaenol sengl—

(i) bydd y cymeradwyaethau mangre ar gyfer y mangreoedd a'r cydsyniadau amlinellol perthynol yn parhau i gael effaith, a

(ii) rhaid trin unrhyw geisiadau am gymeradwyaethau mangre i fangreoedd practis eraill fel ceisiadau am fangreoedd ychwanegol o dan reoliad 28 (cymeradwyo mangre: mangreoedd ychwanegol a newydd wedi i'r cydsyniad amlinellol gael effaith);

(b) os nad oes yr un o'r mangreoedd hynny yn dod yn fangre practis y darparwr gwasanaethau meddygol sylfaenol sengl—

(i) caiff meddyg gyflwyno cais am gymeradwyaeth mangre ar gyfer mangre o dan reoliad 24 (cydsyniad amlinellol a chymeradwyaeth mangre) a chael trin y cais hwnnw fel adleoliad o fangre restredig meddyg a oedd yn rhan o'r cyfuno practisiau; a

(ii) rhaid trin unrhyw geisiadau am gymeradwyaeth mangre mewn perthynas â mangreoedd practis eraill y darparwr gwasanaethau meddygol sylfaenol sengl fel ceisiadau am fangreoedd ychwanegol o dan reoliad 28.

(4) Caniateir gwneud cais a grybwyllir ym mharagraff (3) cyn neu ar ôl cyfuno'r practisiau, ac os bydd cyfuno'r practisiau yn cael effaith cyn bo'r cais wedi ei benderfynu yn derfynol—

(a) bydd unrhyw gymeradwyaeth mangre sydd wedi cael effaith ar ddyddiad cyfuno'r practisiau yn cael effaith o ddyddiad y cyfuno ymlaen fel pe bai'n gymeradwyaeth mangre dros dro o dan reoliad 28(13) am gyfnod a ddatgenir gan y Bwrdd Iechyd Lleol, o ddim mwy nag un flwyddyn; a

(b) bydd y practis newydd yn cael cymeradwyaeth mangre dros dro o ddyddiad cyfuno'r practisiau ymlaen i weinyddu o unrhyw fangre a grybwyllir yn y cais am gyfnod a ddatgenir gan y Bwrdd Iechyd Lleol, o ddim mwy nag un flwyddyn.

(5) Pan fo cyfuno practisiau yn cael effaith, rhaid i'r meddygon hysbysu'r holl Fyrddau Iechyd Lleol y lleolir y practis cyfunedig yn eu hardaloedd fod y cyfuno practisiau wedi digwydd.

(6) Yn ddarostyngedig i baragraff (7), pan fo cais a wnaed o dan baragraff (3) wedi ei ganiatáu cyn i'r cyfuno practisiau ddigwydd, bydd y gymeradwyaeth mangre yn cael effaith o ddyddiad cyfuno'r practisiau ymlaen.

(a) if any of those premises become practice premises of the single provider of primary medical services—

(i) the premises approvals for the premises and the related outline consents will continue to have effect, and

(ii) any applications for premises approvals for other practice premises must be treated as applications for additional premises under regulation 28 (premises approval: additional and new premises after outline consent has taken effect);

(b) if none of those premises become practice premises of the single provider of primary medical services—

(i) a doctor may submit an application for premises approval for premises under regulation 24 (outline consent and premises approval) and have that application treated as a relocation from listed premises of a doctor who was part of the practice amalgamation; and

(ii) any applications for premises approval in respect of other practice premises of the single provider of primary medical services are to be treated as applications for additional premises under regulation 28.

(4) An application mentioned in paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

(a) any premises approval in effect at the date of the practice amalgamation will have effect from the date of the amalgamation as if it were a temporary premises approval under regulation 28(13) for a period stated by the Local Health Board not exceeding one year; and

(b) the new practice will have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Local Health Board not exceeding one year.

(5) When the practice amalgamation takes effect the doctors must notify all Local Health Boards in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to paragraph (7), where an application made under paragraph (3) was granted before the practice amalgamation takes place, premises approval will take effect from the date of the practice amalgamation.

(7) Pan fo cais wedi ei wneud o dan baragraff (3) cyn i'r cyfuno practisiau ddigwydd, ac nad yw'r cyfuno practisiau wedi digwydd cyn diwedd cyfnod o un flwyddyn sy'n cychwyn gyda'r dyddiad y rhoddwyd cymeradwyaeth mangre o dan y paragraff hwnnw, bydd y gymeradwyaeth mangre honno'n mynd yn ddi-rym.

(8) Os gwrthodir cais o dan baragraff (3) am gymeradwyaeth mangre, naill ar gyfer pob un neu unrhyw rai o'r mangreoedd a bennir yn y cais, boed hynny cyn neu ar ôl i'r cyfuno practisiau ddigwydd, bydd gan y meddygon yr oedd ganddynt gymeradwyaeth mangre cyn gwneud y cais ac unrhyw feddyg arall yn y practis newydd ar ôl y dyddiad hwnnw gymeradwyaeth mangre weddilliol.

(9) At ddibenion y rheoliad hwn, ystyr "cymeradwyaeth mangre weddilliol" ("*residual premises approval*") yw cymeradwyaeth mangre i ddarparu gwasanaethau fferyllol—

(a) o fangre yr oedd gan y meddyg hwnnw, neu feddyg arall yn ei bractis, gymeradwyaeth mangre ar ei chyfer ar yr adeg y gwnaed y cais mewn perthynas â chyfuno practisiau; a

(b) i glaf sy'n dod o fewn rheoliad 20(1) ac y mae'r meddyg sy'n gwneud y cais yn darparu gwasanaethau fferyllol iddo, ond gan eithrio unrhyw glaf o'r fath sy'n peidio â bod yn glaf a grybwyllir yn rheoliad 20(1)(b) neu (c).

(10) At ddibenion paragraff (9), mae rheoliad 20(1)(b) neu (c) i'w ddarllen fel pe bai'r geiriau "a bodlonir yr amodau a bennir ym mharagraff (4)" wedi eu hepgor.

(11) Pan fo Bwrdd Iechyd Lleol wedi penderfynu cais am gymeradwyaeth mangre o dan baragraff (3), penderfynir ar y personau a gaiff wneud apêl i Weinidogion Cymru yn unol ag—

(a) rheoliad 28 mewn perthynas â chais o dan baragraff (3)(a)(ii) neu (b)(ii); neu

(b) rheoliad 24 mewn perthynas â chais o dan baragraff (3)(b)(i).

(12) Pan fo Bwrdd Iechyd Lleol wedi penderfynu cais o dan baragraff (4), caiff y ceisydd apelio i Weinidogion Cymru.

(13) Yn yr amgylchiadau a amlinellir ym mharagraff (12), os cyflwynir hysbysiad o apêl i Weinidogion Cymru, bydd Rhan I o Atodlen 3 a'r paragraffau canlynol o Atodlen 3 yn gymwys:

(a) 6(4)(b);

(b) 7(2) a (4); ac

(c) 8,

fel pe bai'r hysbysiad o apêl wedi ei gyflwyno o dan baragraff 6(2) o Atodlen 3.

(7) Where an application was made under paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted under that paragraph, that grant will lapse.

(8) Where an application under paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the doctors who had premises approval prior to making the application, and any other doctor in the new practice after that date will have residual premises approval.

(9) For the purposes of this regulation "*residual premises approval*" ("*cymeradwyaeth mangre weddilliol*") means premises approval to provide pharmaceutical services—

(a) from premises in respect of which the doctor or another doctor in his or her practice had premises approval at the time of the application in relation to the practice amalgamation; and

(b) to a patient falling within regulation 20(1) to whom the doctor making the application provides pharmaceutical services, but excluding any such patient who ceases to be a patient mentioned in regulation 20(1)(b) or (c).

(10) For the purposes of paragraph (9), regulation 20(1)(b) or (c) is to be read as if the words "and the conditions specified in paragraph (4) are satisfied" were omitted.

(11) Where a Local Health Board has determined an application for premises approval under paragraph (3), the persons who may make an appeal to the Welsh Ministers will be determined in accordance with—

(a) regulation 28 in respect of an application under paragraph (3)(a)(ii) or (b)(ii); or

(b) regulation 24 in respect of an application under paragraph (3)(b)(i).

(12) Where a Local Health Board has determined an application under paragraph (4), the applicant may make an appeal to the Welsh Ministers.

(13) If, in the circumstances outlined in paragraph (12), a notice of appeal is submitted to the Welsh Ministers, Part I of Schedule 3 and the following paragraphs of Schedule 3 will apply:

(a) 6(4)(b);

(b) 7(2) and (4); and

(c) 8,

as if the notice of appeal were submitted under paragraph 6(2) of Schedule 3.

Apelau

30. Yn ddarostyngedig i unrhyw ddarpariaethau penodol a gynhwysir yn y Rhan hon, mae Atodlen 3 yn darparu ar gyfer apelau i Weinidogion Cymru mewn perthynas â phenderfyniadau a wneir gan Fyrddau Iechyd Lleol o dan y Rhan hon.

RHAN 6

Seiliau addasrwydd, cynnwys mewn rhestrau fferyllol a thynnu ymaith o restrau fferyllol

Gohirio ceisiadau ar sail addasrwydd

31.—(1) Mae'r rheoliad hwn yn gymwys i geisiadau a wneir o dan—

- (a) rheoliad 8(1)(a) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), ac eithrio pan wneir y cais gan berson sydd â chydsyniad rhagarweiniol dilys yn unol â rheoliad 12(5); a
- (b) rheoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol) pan nad yw'r ceisydd eisoes wedi ei gynnwys yn rhestr fferyllol y Bwrdd Iechyd Lleol hwnnw.

(2) Caiff Bwrdd Iechyd Lleol ohirio ystyried neu benderfynu cais—

- (a) os oes achos troseddol yn y Deyrnas Unedig neu achos yn rhywle arall yn y byd sy'n ymwneud ag ymddygiad a fyddai, yn y Deyrnas Unedig, yn gyfystyr â throsedd, mewn perthynas ag—
 - (i) y ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, mewn perthynas â'r ceisydd neu gyfarwyddwr neu uwcharolygydd y ceisydd), neu
 - (ii) corff corfforaethol y mae'r ceisydd yn gyfarwyddwr neu'n uwcharolygydd ohono, neu y bu'r ceisydd yn gyfarwyddwr neu'n uwcharolygydd ohono yn ystod y chwe mis blaenorol neu ar adeg y digwyddiadau cychwynnol,

a fyddai, pe bai'n arwain at gollfarn, neu'r hyn sy'n gyfystyr â chollfarn, yn debygol o beri tynnu'r ceisydd ymaith o restr fferyllol y Bwrdd Iechyd Lleol, pe bai'r ceisydd wedi ei gynnwys ynddi;

- (b) os oes ymchwiliad mewn unrhyw le yn y byd gan gorff sy'n trwyddedu neu'n rheoleiddio'r ceisydd (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), neu unrhyw ymchwiliad arall (gan gynnwys ymchwiliad gan Fwrdd Iechyd Lleol neu gorff cyfatebol

Appeals

30. Subject to any specific provisions that are contained within this Part, Schedule 3 makes provision for appeals to the Welsh Ministers in respect of determinations of Local Health Boards made under this Part.

PART 6

Fitness grounds and inclusion in and removal from pharmaceutical lists

Deferral of applications on fitness grounds

31.—(1) This regulation applies to applications made under—

- (a) regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 12(5); and
- (b) regulation 12 (applications for preliminary consent and effect of preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.

(2) A Local Health Board may defer consideration or determination of an application where—

- (a) there are criminal proceedings in the United Kingdom or proceedings elsewhere in the world relating to conduct which in the United Kingdom would constitute a criminal offence in respect of—
 - (i) the applicant (and where the applicant is a body corporate, in respect of the applicant or a director or superintendent of the applicant), or
 - (ii) a body corporate of which the applicant is, or has in the preceding six months been, or was at the time of the originating events, a director or superintendent,

which, if they resulted in a conviction or the equivalent of a conviction, would be likely to lead to the applicant's removal from the Local Health Board's pharmaceutical list, if the applicant had been included in it;

- (b) there is an investigation anywhere in the world by the applicant's (or where the applicant is a body corporate, any director or superintendent of the applicant) licensing or regulatory body or any other investigation (including one by another Local Health Board or equivalent body) relating to the applicant's professional

arall) ynglŷn â gallu proffesiynol y ceisydd, a fyddai, pe bai'r canlyniad yn anffafriol yn debygol o beri tynnu'r ceisydd ymaith o restr fferyllol y Bwrdd Iechyd Lleol, pe bai'r ceisydd wedi ei gynnwys ynddi;

- (c) os yw'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) yn cael ei atal dros dro o restr berthnasol;
- (d) os yw corff corfforaethol yr oedd y ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), ar adeg y digwyddiadau cychwynnol, yn gyfarwyddwr neu'n uwcharolygydd ohono yn cael ei atal dros dro o restr berthnasol;
- (e) os yw'r Tribiwnlys yn ystyried apêl gan y ceisydd (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) yn erbyn penderfyniad gan Fwrdd Iechyd Lleol neu gorff cyfatebol—
 - (i) i wrthod cais gan y ceisydd am ei gynnwys mewn rhestr berthnasol, neu
 - (ii) i gynnwys yn amodol neu dynnu ymaith, neu dynnu yn ddigwyddiadol, y ceisydd o restr berthnasol, neu
 - (iii) i wrthod cais gan y ceisydd am gydsyniad rhagarweiniol ar gyfer ei gynnwys mewn rhestr fferyllol a gynhelir gan Fwrdd Iechyd Lleol neu gorff cyfatebol,

a phe bai'r apêl honno'n aflwyddiannus, byddai'r Bwrdd Iechyd Lleol yn debygol o dynnu'r ceisydd ymaith o'r rhestr fferyllol pe bai'r ceisydd wedi ei gynnwys ynddi;

- (f) os yw'r Tribiwnlys yn ystyried apêl gan gorff corfforaethol yr oedd y ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), ar adeg y digwyddiadau cychwynnol, neu yn ystod y chwe mis blaenorol yn gyfarwyddwr neu'n uwcharolygydd ohono, yn erbyn penderfyniad gan Fwrdd Iechyd Lleol neu gorff cyfatebol—
 - (i) i wrthod cais gan y corff corfforaethol hwnnw am ei gynnwys mewn rhestr berthnasol;
 - (ii) i wrthod cais gan y corff corfforaethol hwnnw am gydsyniad rhagarweiniol ar gyfer ei gynnwys mewn rhestr fferyllol a gynhelir gan Fwrdd Iechyd Lleol neu gorff cyfatebol; neu
 - (iii) i'w gynnwys yn amodol neu i'w dynnu ymaith, neu i'w dynnu yn ddigwyddiadol o unrhyw restr berthnasol,

a phe bai'r apêl honno'n aflwyddiannus, byddai'r Bwrdd Iechyd Lleol yn debygol o dynnu'r ceisydd ymaith o'r rhestr fferyllol pe bai'r ceisydd wedi ei

capacity, that if the outcome of which was adverse would be likely to lead to the removal of the applicant from the Local Health Board's pharmaceutical list, if the applicant had been included in it;

- (c) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is suspended from a relevant list;
- (d) a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is suspended from a relevant list;
- (e) the Tribunal is considering an appeal by the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) against a decision of a Local Health Board or an equivalent body—
 - (i) to refuse an application by the applicant for inclusion in a relevant list,
 - (ii) to conditionally include or remove or contingently remove the applicant from a relevant list, or
 - (iii) to refuse an application from the applicant for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body,

and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if he or she were to be included in it;

- (f) the Tribunal is considering an appeal by a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent, against a decision of a Local Health Board or equivalent body—
 - (i) to refuse an application by that body corporate for inclusion in a relevant list;
 - (ii) to refuse an application by that corporate body for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body; or
 - (iii) to conditionally include it in, or to remove or contingently remove it from any relevant list,

and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if he or she were to be

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gynnwys ynddi;

- (g) os yw'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) yn destun ymchwiliad mewn perthynas ag unrhyw dwyll, ac y byddai'r canlyniad, pe bai'n anffafriol, yn debygol o beri tynnu'r ceisydd ymaith o'r rhestr fferyllol pe bai'r ceisydd wedi ei gynnwys ynddi;
- (h) os yw corff corfforaethol yr oedd y ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), ar adeg y digwyddiadau cychwynnol, yn gyfarwyddwr neu'n uwcharolygydd ohono yn destun ymchwiliad mewn perthynas â thwyll, ac y byddai'r canlyniad, pe bai'n anffafriol, yn debygol o beri tynnu'r ceisydd ymaith o'r rhestr fferyllol pe bai'r corff corfforaethol wedi ei gynnwys ynddi; neu
- (i) os yw'r Tribiwnlys yn ystyried cais gan Fwrdd Iechyd Lleol neu gorff cyfatebol am anghymhwysiad cenedlaethol o'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) neu o gorff corfforaethol yr oedd y ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) ar adeg y digwyddiadau cychwynnol, yn gyfarwyddwr neu'n uwcharolygydd ohono;
- (j) os yw Bwrdd Iechyd Lleol neu gorff cyfatebol, am reswm mewn perthynas â thwyll, anaddasrwydd neu effeithlonrwydd y ddarpariaeth o wasanaethau—
 - (i) yn ystyried tynnu'r ceisydd (ac eithrio ei dynnu yn wirfoddol) neu dynnu'r ceisydd yn ddigwyddiadol oddi ar restr berthnasol; neu
 - (ii) wedi gwneud penderfyniad i dynnu'r ceisydd (ac eithrio ei dynnu yn wirfoddol) neu dynnu'r ceisydd yn ddigwyddiadol oddi ar restr berthnasol ond nad yw'r penderfyniad hwnnw eto wedi cael effaith.

(3) Ni chaiff Bwrdd Iechyd Lleol ohirio penderfyniad o dan baragraff (2) ac eithrio hyd nes bo'r achos, yr ymchwiliadau neu'r ceisiadau a grybwyllir yn y paragraff hwnnw wedi eu cwblhau, neu'r rheswm dros ohirio yn peidio â bodoli.

(4) Rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol, hysbysu'r ceisydd mewn ysgrifen o benderfyniad i ohirio ystyried neu benderfynu y cais, ac o'r rhesymau am hynny.

(5) Unwaith y bydd yr achos, yr ymchwiliadau neu'r ceisiadau a grybwyllir ym mharagraff (2) wedi eu cwblhau, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r ceisydd y bydd rhaid i'r ceisydd, o fewn 30 diwrnod ar ôl dyddiad yr hysbysiad, (neu pa bynnag gyfnod hwy a gytunir gan y Bwrdd)—

included in it;

- (g) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is being investigated in relation to any fraud, where the outcome, if adverse, would be likely to lead to the removal of the applicant from the pharmaceutical list if the applicant had been included in it;
- (h) a body corporate, of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is being investigated in relation to fraud, where the outcome if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if the body corporate had been included in it; or
- (i) the Tribunal is considering an application from a Local Health Board or equivalent body for a national disqualification of the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) or of a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent;
- (j) a Local Health Board or equivalent body, for a reason relating to fraud, unsuitability or efficiency of service provision—
 - (i) is considering removal (other than voluntary removal) or contingent removal of the applicant from a relevant list; or
 - (ii) has taken a decision to remove (other than voluntary removal) or contingently remove the applicant from a relevant list but that decision has yet to take effect .

(3) A Local Health Board may only defer a decision under paragraph (2) until the proceedings, investigations or applications mentioned in that paragraph are concluded or the reason for the deferral no longer exists.

(4) A Local Health Board must, as soon as is practicable, notify the applicant in writing of a decision to defer consideration or determination of the application, and the reasons for this.

(5) Once the proceedings, investigations or applications mentioned in paragraph (2) are concluded, the Local Health Board must notify the applicant that he or she within 30 days of the date of the notification (or such longer period as it may agree)—

- (a) cadarnhau mewn ysgrifen ei fod yn dymuno mynd ymlaen â'r cais; a
- (b) y caiff ddiweddarau ei gais os yw'n dymuno.

(6) Os nad yw'r ceisydd yn cadarnhau, yn unol â pharagraff (5), ei fod yn dymuno mynd ymlaen, rhaid i'r Bwrdd Iechyd Lleol ystyried bod y cais wedi ei dynnu'n ôl gan y ceisydd.

Gwrthod ceisiadau ar sail addasrwydd

32.—(1) Mae'r rheoliad hwn yn gymwys i geisiadau a wneir o dan—

- (a) rheoliad 8(1)(a) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), ac eithrio pan wneir y cais gan berson sydd â chydsyniad rhagarweiniol dilys yn unol â rheoliad 12(5); a
- (b) rheoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol) pan nad yw'r ceisydd eisoes wedi ei gynnwys yn rhestr fferyllol y Bwrdd Iechyd Lleol hwnnw.

(2) Caiff Bwrdd Iechyd Lleol wrthod caniatáu cais os yw'r Bwrdd Iechyd Lleol—

- (a) ar ôl ystyried yr wybodaeth a'r ymrwymadau sy'n ofynnol gan Ran 2 o Atodlen 1 ac unrhyw wybodaeth arall sydd yn ei feddiant mewn perthynas â'r cais, o'r farn bod y ceisydd yn anaddas i'w gynnwys yn ei restr fferyllol;
- (b) ar ôl cysylltu â'r canolwyr enwebwyd gan y ceisydd yn unol â Rhan 2 o Atodlen 1, heb ei fodloni gan y geiradon a roddwyd;
- (c) ar ôl gwirio gydag Awdurdod Gwasanaethau Busnes y GIG unrhyw ffeithiau yr ystyria'r Awdurdod yn berthnasol ynglŷn ag ymchwiliadau i dwyll, presennol neu yn y gorffennol, sy'n ymwneud neu sy'n gysylltiedig â'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), ac ar ôl ystyried y ffeithiau hynny ac unrhyw ffeithiau eraill yn ei feddiant ynglŷn â thwyll sy'n ymwneud neu sy'n gysylltiedig â'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), o'r farn eu bod yn cyfiawnhau gwrthodiad o'r fath;
- (d) ar ôl gwirio gyda Gweinidogion Cymru unrhyw ffeithiau yr ystyria'n berthnasol ynglŷn ag ymchwiliadau neu achosion, presennol neu yn y gorffennol, sy'n ymwneud neu sy'n gysylltiedig â'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), ac ar ôl ystyried y ffeithiau hynny ac unrhyw ffeithiau eraill yn ei feddiant sy'n ymwneud

- (a) must confirm in writing that the applicant wishes to proceed with the application; and
- (b) may update the application if the applicant wishes.

(6) If the applicant fails to confirm that he or she wishes to proceed in accordance with paragraph (5), the Local Health Board must deem the application as having been withdrawn by the applicant.

Refusal of applications on fitness grounds

32.—(1) This regulation applies to applications made under—

- (a) regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 12(5); and
- (b) regulation 12 (applications for preliminary consent and effect of preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.

(2) A Local Health Board may refuse to grant an application where—

- (a) having considered the information and undertakings required by Part 2 of Schedule 1 and any other information in its possession in relation to the application, the Local Health Board considers that the applicant is unsuitable to be included in its pharmaceutical list;
- (b) having contacted the referees nominated by the applicant in accordance with Part 2 of Schedule 1, it is not satisfied with the references given;
- (c) having checked with the NHS Business Services Authority for any facts that it considers relevant relating to past or current fraud investigations involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), and having considered these and any other facts in its possession relating to fraud involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal;
- (d) having checked with the Welsh Ministers for any facts that they consider relevant relating to past or current investigations or proceedings involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) and having considered these and any other facts in its possession involving or relating to the applicant (and where the applicant is a body

neu sy'n gysylltiedig â'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), o'r farn eu bod yn cyfiawnhau gwrthodiad o'r fath; neu

- (e) o'r farn y byddai derbyn y ceisydd i'r rhestr yn niweidio effeithlonrwydd y gwasanaeth y byddai'r ceisydd yn ymrwymo i'w ddarparu.

(3) Rhaid i Fwrdd Iechyd Lleol wrthod caniatáu cais os yw—

- (a) y ceisydd (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) wedi ei gollfarnu yn y Deyrnas Unedig am lofruddiaeth;
- (b) y ceisydd (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) wedi ei gollfarnu yn y Deyrnas Unedig am drosedd ac eithrio llofruddiaeth, a gyflawnwyd ar ôl y dyddiad y daeth y Rheoliadau hyn i rym, ac wedi ei ddedfrydu i gyfnod hwy na chwe mis o garchar;
- (c) y ceisydd yn destun anghymhwysiad cenedlaethol; neu
- (d) y Tribiwnlys, yn dilyn apêl, yn penderfynu y caniateir cynnwys y ceisydd mewn rhestr fferyllol, yn ddarostyngedig i amodau, ond nad yw'r ceisydd, o fewn 30 diwrnod i'r penderfyniad hwnnw, wedi hysbysu'r Bwrdd Iechyd Lleol ei fod wedi cytuno â gosod yr amodau.

(4) Pan fo'r Bwrdd Iechyd Lleol yn ystyried gwrthod cais o dan baragraff (2), rhaid iddo gymryd i ystyriaeth yr holl ffeithiau sy'n ymddangos iddo yn berthnasol, ac yn benodol, mewn perthynas â pharagraff (2)(a), (c) a (d), rhaid iddo ystyried—

- (a) natur unrhyw drosedd, ymchwiliad neu ddigwyddiad;
- (b) yr amser a aeth heibio ers unrhyw drosedd, digwyddiad, collfarn neu ymchwiliad;
- (c) a oes yna unrhyw droseddau, digwyddiadau neu ymchwiliadau eraill i'w hystyried;
- (d) unrhyw gamau a gymerwyd neu gosb a osodwyd gan unrhyw gorff trwyddedu neu reoleiddio, gan yr heddlu neu'r llysoedd o ganlyniad i unrhyw drosedd, digwyddiad neu ymchwiliad o'r fath;
- (e) pa mor berthnasol yw unrhyw drosedd, digwyddiad neu ymchwiliad i'r ddarpariaeth gan y ceisydd o wasanaethau fferyllol ac unrhyw risg debygol i ddefnyddwyr gwasanaethau fferyllol neu i arian cyhoeddus;
- (f) a oedd unrhyw drosedd yn drosedd rywiol y mae Rhan 2 o Ddeddf Troseddau Rhywiol 2003(1) yn gymwys iddi, neu y byddai wedi

corporate any director or superintendent of the applicant), it considers that these justify such a refusal; or

- (e) it considers that admitting the applicant to the list would be prejudicial to the efficiency of the service which he or she would undertake to provide.

(3) A Local Health Board must refuse to grant an application where—

- (a) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of murder;
- (b) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of a criminal offence, other than murder, which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over six months;
- (c) the applicant is the subject of a national disqualification; or
- (d) on appeal the Tribunal determines that the applicant may be included in the pharmaceutical list subject to conditions but the applicant has not, within 30 days of that decision notified the Local Health Board that he or she agrees to the imposition of conditions.

(4) Where the Local Health Board is considering a refusal of an application under paragraph (2), it must consider all facts which appear to it to be relevant and must, in particular, take into consideration in relation to paragraph (2)(a), (c) and (d)—

- (a) the nature of any offence, investigation or incident;
- (b) the length of time since any offence, incident, conviction or investigation;
- (c) whether there are other offences, incidents or investigations to be considered;
- (d) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
- (e) the relevance of any offence, investigation or incident to the provision by the applicant of pharmaceutical services and any likely risk to users of pharmaceutical services or public finances;
- (f) whether any offence was a sexual offence to which Part 2 of the Sexual Offences Act 2003(1) applies, or if it had been committed in

(1) 2003 p.42.

(1) 2003 c.42.

bod yn gymwys pe bai'r drosedd wedi ei chyflawni yng Nghymru neu Loegr;

- (g) a yw'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) wedi ei wrthod rhag ei gynnwys mewn unrhyw restr neu restr gyfatebol, neu wedi ei gynnwys yn amodol, neu ei dynnu, neu ei dynnu yn ddigwyddiadol, neu ar hyn o bryd wedi ei atal oddi arni dros dro ar seiliau addasrwydd i ymarfer, ac os felly, ffeithiau'r mater a arweiniodd at weithredu felly, a'r rhesymau a roddwyd gan y Bwrdd Iechyd Lleol neu gorff cyfatebol dros weithredu felly; neu
- (h) a fu'r ceisydd (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) ar adeg y digwyddiadau cychwynnol, neu yn ystod y chwe mis blaenorol, yn gyfarwyddwr neu'n uwcharolygydd corff corfforaethol y gwrthodwyd ei gynnwys mewn unrhyw restr neu restr gyfatebol, neu a gynhwyswyd yn amodol mewn rhestr o'r fath, neu a dynnwyd, neu a dynnwyd yn ddigwyddiadol oddi arni, neu sydd ar hyn o bryd wedi ei atal oddi arni dros dro, ar seiliau addasrwydd i ymarfer, ac os felly, beth oedd y ffeithiau ym mhob achos o'r fath, a'r rhesymau a roddwyd gan y Bwrdd Iechyd Lleol neu gorff cyfatebol ym mhob achos.

(5) Pan fo'r Bwrdd Iechyd Lleol yn cymryd i ystyriaeth y materion a bennir ym mharagraff (4), rhaid iddo ystyried effaith gyffredinol y materion a ystyrir.

(6) Os yw Bwrdd Iechyd Lleol yn gwrthod cais y mae'r rheoliad hwn yn gymwys iddo, ar seiliau ym mharagraff (2) neu (3), rhaid i'r Bwrdd Iechyd Lleol hysbysu'r ceisydd o'r penderfyniad hwnnw, a chynnwys gyda'r hysbysiad esboniad o'r canlynol—

- (a) y rhesymau am y penderfyniad;
- (b) hawl y ceisydd i apelio i'r Tribiwnlys yn erbyn y penderfyniad, a bod rhaid arfer yr hawl honno o fewn 30 diwrnod o'r dyddiad yr hysbyswyd y ceisydd o'r penderfyniad; ac
- (c) o fewn pa derfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008(1), y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl.

Cynnwys yn amodol mewn perthynas â seiliau addasrwydd

33.—(1) Caiff Bwrdd Iechyd Lleol sy'n cael cais gan person—

- (a) o dan reoliad 8(1)(a) (ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol), ac eithrio pan wneir y cais gan

England and Wales would have applied;

- (g) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from any list or equivalent list on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Local Health Board or equivalent body for such action; or
- (h) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from any list or equivalent list, or is currently suspended from any such list on fitness to practise grounds, and if so, what the facts were in each such case and the reasons given by the Local Health Board or equivalent body in each case.

(5) When the Local Health Board takes into account the matters set out in paragraph (4), it must consider the overall effect of the matters being considered.

(6) If a Local Health Board refuses an application to which this regulation applies under grounds in paragraph (2) or (3), the Local Health Board must notify the applicant of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) the applicant's right of appeal against the decision to the Tribunal; and
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(1), the application notice must be sent to the Tribunal if an appeal is to be brought.

Conditional inclusion relating to fitness grounds

33.—(1) A Local Health Board that receives an application from a person—

- (a) under regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the

(1) O.S. 2008/2699 (Cyfr.16), gweler rheol 19 o'r Rheolau hynny.

(1) S.I. 2008/2699 (L.16), see rule 19 of those Rules.

person y rhoddwyd cydsyniad rhagarweiniol iddo o dan reoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol) a'r cydsyniad rhagarweiniol yn ddilys yn unol â rheoliad 12(5); neu

- (b) o dan reoliad 12 pan nad yw'r ceisydd eisoes wedi ei gynnwys yn rhestr fferyllol y Bwrdd Iechyd Lleol hwnnw,

benderfynu y bydd y person hwnnw, tra bo wedi ei gynnwys yn y rhestr fferyllol neu tra bo'i gydsyniad rhagarweiniol yn ddilys, yn ddarostyngedig i amodau a osodir gan roi sylw i ofynion adran 104 (cynnwys yn amodol mewn rhestrau offthalmig a fferyllol) o Ddeddf 2006.

(2) Caiff Bwrdd Iechyd Lleol amrywio'r telerau gwasanaethu y cynhwysir person yn unol â hwy yn y rhestr fferyllol at ddiben paragraff (1).

(3) Rhaid i amod a osodir o dan baragraff (1) fod yn amod a osodir gyda'r bwriad o—

- (a) rhwystro unrhyw niwed i effeithlonrwydd y gwasanaethau neu unrhyw un neu rai o'r gwasanaethau, y mae'r person wedi ymgymryd â'u darparu; neu
- (b) rhwystro unrhyw weithred neu anweithred o fewn adran 107(3)(a) o Ddeddf 2006 (anghymhwyso ymarferwyr).

(4) Os yw Bwrdd Iechyd Lleol yn penderfynu caniatáu cais yn ddarostyngedig i amod a osodir o dan baragraff (1), rhaid iddo hysbysu'r person o'r penderfyniad hwnnw a rhaid iddo gynnwys gyda'r hysbysiad esboniad o'r canlynol—

- (a) y rhesymau am y penderfyniad;
- (b) hawl y person i apelio i'r Tribiwnlys yn erbyn ei benderfyniad;
- (c) o fewn pa derfyn amser yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008, y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl; a
- (d) effaith paragraff (5).

(5) Os yw'r person, yn unol â rheoliad 17(2), yn darparu hysbysiad o gychwyn cyn bo'r Tribiwnlys wedi penderfynu apêl yn erbyn amod a osodwyd o dan baragraff (1), rhaid cynnwys y person hwnnw yn y rhestr fferyllol yn ddarostyngedig i'r amod, ond yn unig hyd nes canlyniad yr apêl os bydd yr apêl yn llwyddiannus.

(6) Bydd yr apêl ar ffurf ailbenderfynu—

- (a) penderfyniad y Bwrdd Iechyd Lleol i osod yr amod; a
- (b) os yw'r person, ar yr adeg y penderfynir yr apêl, wedi ei gynnwys yn y rhestr fferyllol,

application is made by a person who has been granted preliminary consent under regulation 12 (applications for preliminary consent and effect of preliminary consent) and which is valid in accordance with regulation 12(5); or

- (b) under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list,

may determine that the person, whilst he or she is included in the pharmaceutical list or whilst his or her preliminary consent is valid, is to be subject to the imposition of conditions having regard to the requirements of section 104 (conditional inclusion in ophthalmic and pharmaceutical lists) of the 2006 Act.

(2) A Local Health Board may vary the terms of service on which a person is included in the pharmaceutical list for the purpose of paragraph (1).

(3) A condition imposed under paragraph (1) must be a condition imposed with a view to—

- (a) preventing any prejudice to the efficiency of the services, or any of the services, which the person has undertaken to provide; or
- (b) preventing any act or omission within section 107(3)(a) of the 2006 Act (disqualification of practitioners).

(4) If a Local Health Board decides to grant an application subject to a condition imposed under paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) the person's right of appeal against its decision to the Tribunal;
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (d) the effect of paragraph (5).

(5) If the person, in accordance with regulation 17(2), provides a notice of commencement before the Tribunal has determined an appeal against a condition imposed under paragraph (1), that person is to be included in the pharmaceutical list subject to the condition, but only until the outcome of the appeal if the appeal is successful.

(6) The appeal is to be by way of redetermination of—

- (a) the decision of the Local Health Board to impose the condition; and
- (b) if the person has, at the time the appeal is determined, been included in the

unrhyw benderfyniad o dan baragraff (2) i amrywio telerau gwasanaethu'r person hwnnw at y diben o osod yr amod neu mewn cysylltiad â'i osod.

(7) Os nad yw'r person wedi ei gynnwys yn y rhestr fferyllol ar yr adeg y penderfynir yr apêl ac—

- (a) y Tribiwnlys yn cadarnhau penderfyniad y Bwrdd Iechyd Lleol; neu
- (b) yn gosod amod gwahanol,

rhaid i'r person, o fewn 30 diwrnod ar ôl ei hysbysu o benderfyniad y Tribiwnlys, hysbysu'r Bwrdd Iechyd Lleol o ba un a yw'r person yn dymuno tynnu ei gais yn ôl ai peidio.

(8) Os yw'r person, yn yr amgylchiadau a ddisgrifir ym mharagraff (7), yn methu â hysbysu'r Bwrdd Iechyd Lleol o fewn y cyfnod hwnnw o 30 diwrnod nad yw'n dymuno tynnu ei gais yn ôl, bydd y penderfyniad i ganiatáu cais y person hwnnw yn mynd yn ddi-rym.

(9) Pan fo person yn dymuno tynnu ei enw oddi ar restr fferyllol, rhaid i'r person hwnnw hysbysu'r Bwrdd Iechyd Lleol, o leiaf 30 diwrnod cyn y dyddiad hwnnw—

- (a) os gosodwyd amod o dan baragraff (1);
- (b) os yw'r person yn apelio i'r Tribiwnlys yn erbyn yr amod hwnnw;
- (c) os yw'r Tribiwnlys, yn dilyn apêl, yn cadarnhau'r penderfyniad i osod yr amod hwnnw neu'n gosod amod arall; a
- (d) os yw'r person, o fewn 30 diwrnod ar ôl ei hysbysu o benderfyniad y Tribiwnlys, yn hysbysu'r Bwrdd Iechyd Lleol o'i ddymuniad i dynnu ei enw oddi ar restr fferyllol y Bwrdd,

onid yw'n anymarferol i'r person wneud hynny, ac os felly, rhaid i'r person hysbysu'r Bwrdd Iechyd Lleol cyn gynted ag y bo'n ymarferol iddo wneud hynny.

Tynnu ymaith o restr fferyllol am dorri amodau mewn cysylltiad â seiliau addasrwydd neu osod neu amrywio neu osod amodau newydd o dan adran 108 o Ddeddf 2006

34.—(1) Pan fo Bwrdd Iechyd Lleol yn ystyried—

- (a) tynnu enw person o'r rhestr fferyllol o dan adran 107 (datgymhwyso ymarferwyr) o Ddeddf 2006, ac eithrio mewn achosion a bennir yn rheoliad 35 (tynnu ymaith oddi ar restr fferyllol am resymau eraill);
- (b) tynnu enw person o'r rhestr fferyllol yn ddigwyddiadol o dan adran 108 (tynnu digwyddiadol) o Ddeddf 2006;
- (c) tynnu enw person o'r rhestr fferyllol am dorri amod a osodwyd o dan adran 108 o Ddeddf 2006;

pharmaceutical list, any decision under paragraph (2) to vary the terms of service of that person for the purpose of or in connection with the imposition of the condition.

(7) If at the time the appeal is determined, the person has not been included in the pharmaceutical list and

- (a) the Tribunal confirms the decision of the Local Health Board; or
- (b) imposes a different condition,

the person must, within 30 days of being notified of the Tribunal's decision, notify the Local Health Board as to whether or not the person wishes to withdraw his or her application.

(8) If the person fails, in the circumstances described in paragraph (7), to notify the Local Health Board within that 30 days that he or she does not wish to withdraw his or her application, the grant of that person's application lapses.

(9) Where a person wishes to withdraw from a pharmaceutical list, that person must notify the Local Health Board at least 30 days in advance of that date, if—

- (a) a condition is imposed under paragraph (1);
- (b) the person appeals that condition to the Tribunal;
- (c) on appeal, the Tribunal confirms the imposition of that condition or imposes another condition; and
- (d) within 30 days of being informed of the decision of the Tribunal the person notifies the Local Health Board that he or she wishes to withdraw from its pharmaceutical list,

unless it is impracticable for the person to do so in which case the person must notify the Local Health Board as soon as it is practicable to do so.

Removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act

34.—(1) Where a Local Health Board is considering—

- (a) removing a person's name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act, other than in cases specified in regulation 35 (removal from a pharmaceutical list for other reasons);
- (b) contingently removing a person's name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act;
- (c) removing a person's name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act;

- (d) gosod unrhyw amod penodol o dan adran 108 o Ddeddf 2006, neu amrywio unrhyw amod neu osod amod gwahanol o dan yr adran honno, neu amrywio telerau gwasanaethu person o dan adran 108(4) o Ddeddf 2006; neu
- (e) tynnu enw person o'r rhestr fferyllol am dorri amod o dan reoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd),

ar sail addasrwydd, rhaid i'r Bwrdd ddilyn y weithdrefn a bennir yn y rheoliad hwn.

(2) Cyn gweithredu fel a bennir ym mharagraff (1), rhaid i'r Bwrdd Iechyd Lleol roi i'r person—

- (a) hysbysiad o unrhyw honiad a wnaed yn ei erbyn;
- (b) hysbysiad o'r camau y mae'r Bwrdd Iechyd Lleol yn ystyried eu cymryd, ac ar ba sail;
- (c) cyfle i wneud sylwadau ysgrifenedig o fewn cyfnod o 30 diwrnod sy'n cychwyn gyda'r dyddiad y rhoddir yr hysbysiad o dan y paragraff hwn; a
- (d) y cyfle i gyflwyno'i achos mewn gwrandawriad llafar gerbron y Bwrdd Iechyd Lleol, os yw'r person yn gofyn am wrandawriad o'r fath o fewn y cyfnod o 30 diwrnod a grybwyllir yn is-baragraff (c).

(3) Os yw'r Bwrdd Iechyd Lleol yn cael sylwadau neu gais am wrandawriad llafar o fewn y cyfnod a bennir ym mharagraff (2)(c), rhaid iddo gymryd y sylwadau i ystyriaeth neu gynnal y gwrandawriad, yn ôl fel y digwydd, cyn cyrraedd ei benderfyniad.

(4) Unwaith y bydd y Bwrdd Iechyd Lleol wedi cyrraedd penderfyniad, rhaid iddo hysbysu'r person o'r penderfyniad hwnnw, a chynnwys gyda'r hysbysiad esboniad o'r canlynol—

- (a) y rhesymau am y penderfyniad;
- (b) hawl y person i apelio i'r Tribiwnlys yn erbyn ei benderfyniad; ac
- (c) o fewn pa derfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008, y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apel.

(5) Os yw'r Bwrdd Iechyd Lleol wedi penderfynu tynnu enw person yn ddigwyddiadol, rhaid iddo hysbysu'r person o'i hawl i gael adolygiad o'r penderfyniad yn unol ag adran 113 (adolygu penderfyniadau) o Ddeddf 2006.

(6) Rhaid i'r Bwrdd Iechyd Lleol beidio â thynnu enw person o'r rhestr fferyllol, na thynnu ei enw yn ddigwyddiadol, hyd nes bo'r amser ar gyfer gwneud apel wedi dod i ben neu, os gwneir apel, hyd nes bo'r apel wedi ei phenderfynu gan y Tribiwnlys.

- (d) imposing any particular condition under section 108 of the 2006 Act, or varying any condition or imposing a different condition under that section, or varying a person's terms of service under section 108(4) of the 2006 Act; or
- (e) removing a person's name from the pharmaceutical list for breach of a condition under regulation 33 (conditional inclusion relating to fitness grounds),

on fitness grounds, it must follow the procedure set out in this regulation.

(2) Before taking an action specified in paragraph (1), the Local Health Board must give the person—

- (a) notice of any allegation against him or her;
- (b) notice of what action the Local Health Board is considering and on what grounds;
- (c) the opportunity to make written representations within 30 days beginning on the date on which the notification is given under this paragraph; and
- (d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(3) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (2)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(4) Once the Local Health Board has reached a decision it must notify the person of that decision and it must include with that notification an explanation of—

- (a) the reasons for the decision;
- (b) the person's right of appeal against its decision to the Tribunal; and
- (c) the time limit within which in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(5) Where the Local Health Board has decided to impose a contingent removal, it must inform the person of their right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(6) The Local Health Board must not remove a person's name from the pharmaceutical list, or impose a contingent removal, until the time for bringing an appeal has expired or, where an appeal is made, it has been determined by the Tribunal.

(7) Os yw'r Tribiwnlys yn hysbysu'r Bwrdd Iechyd Lleol fod y Tribiwnlys wedi ystyried—

- (a) apêl gan berson yn erbyn tynnu digwyddiadol a bod y Tribiwnlys wedi penderfynu yn hytrach dynnu'r person oddi ar y rhestr fferyllol; neu
- (b) apêl gan berson sy'n ddarostyngedig i amodau o dan reoliad 33, a bod y Tribiwnlys wedi penderfynu yn hytrach beidio â chynnwys y person yn y rhestr fferyllol honno,

rhaid i'r Bwrdd Iechyd Lleol dynnu'r person oddi ar ei restr fferyllol a hysbysu'r person, ar unwaith, ei fod wedi gwneud hynny.

Tynnu ymaith o restr fferyllol am resymau eraill

35.—(1) Yn ddarostyngedig i baragraff (2), rhaid i Fwrdd Iechyd Lleol dynnu person oddi ar restr fferyllol a gynhelir ganddo os daw'n ymwybodol bod y person (ac os yw'r person yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y corff hwnnw)—

- (a) wedi ei gollfarnu yn y Deyrnas Unedig o lofruddiaeth;
- (b) wedi ei gollfarnu yn y Deyrnas Unedig o drosedd a gyflawnwyd ar ôl y dyddiad y daw'r Rheoliadau hyn i rym ac wedi ei ddedfrydu i garchar am dymor hwy na chwe mis; neu
- (c) o dan anghymhwysiad cenedlaethol.

(2) Pan fo'r Bwrdd Iechyd Lleol yn ystyried tynnu person oddi ar ei restr fferyllol ar seiliau a gynhwysir ym mharagraff (1), rhaid i'r Bwrdd Iechyd Lleol, cyn cyrraedd ei benderfyniad—

- (a) hysbysu'r person o'r camau y mae'n ystyried eu cymryd a'r seiliau dros ystyried cymryd y camau hynny; a
- (b) fel rhan o'r hysbysiad—
 - (i) hysbysu'r person am unrhyw honiadau a wnaed yn ei erbyn; a
 - (ii) rhoi gwybod i'r person y caiff wneud—
 - (aa) sylwadau ysgrifenedig i'r Bwrdd Iechyd Lleol ynghylch y camau hynny ar yr amod bod y Bwrdd Iechyd Lleol yn cael y sylwadau hynny o fewn 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad gan y Bwrdd Iechyd Lleol: a
 - (bb) sylwadau llafar i'r Bwrdd Iechyd Lleol ynghylch y camau hynny, ar yr amod bod y person yn hysbysu'r Bwrdd Iechyd Lleol o'i ddymuniad i wneud sylwadau llafar o fewn 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad gan y Bwrdd Iechyd

(7) Where a Local Health Board is notified by the Tribunal that it has considered—

- (a) an appeal by a person against a contingent removal and the Tribunal has decided to remove the person from the pharmaceutical list instead; or
- (b) an appeal by a person who is subject to conditions under regulation 33 and the Tribunal has decided not to include the person in that pharmaceutical list,

the Local Health Board must remove the person from its pharmaceutical list and must notify the person immediately that it has done so.

Removal from a pharmaceutical list for other reasons

35.—(1) Subject to paragraph (2), a Local Health Board must remove a person from a pharmaceutical list that it maintains where it becomes aware that the person (and where the person is a body corporate, any director or superintendent of that body)—

- (a) has been convicted in the United Kingdom of murder;
- (b) has been convicted in the United Kingdom of a criminal offence which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over six months; or
- (c) is subject to a national disqualification.

(2) Where a Local Health Board is considering removing a person from its pharmaceutical list under grounds contained in paragraph (1), the Local Health Board must, before reaching its decision—

- (a) notify the person of the action that it is considering taking and the grounds for considering taking that action; and
- (b) as part of that notification—
 - (i) inform the person of any allegation made against him or her; and
 - (ii) advise the person that he or she may make—
 - (aa) written representations to the Local Health Board with regard to that action provided such representations are received by the Local Health Board within 30 days beginning with the date of notification by the Local Health Board; and
 - (bb) oral representations to the Local Health Board with regard to that action, provided the person notifies the Local Health Board of his or her wish to make oral representations within 30 days beginning with the date of the notification by the Local

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Lleol, a bod y person (neu gynrychiolydd) yn bresennol yn y gwrandawriad y mae'r Bwrdd Iechyd Lleol yn ei drefnu at ddibenion clywed y sylwadau hynny; ac

- (c) mewn achos y mae paragraff (1)(a) neu (b) yn gymwys iddo, os yw'r person yn gorff corfforaethol, rhoi gwybod iddo na fydd y Bwrdd Iechyd Lleol yn tynnu'r corff corfforaethol oddi ar ei restr fferyllol o ganlyniad i baragraff (1)(a) neu (b) (heb niweidio unrhyw gamau eraill y caiff y Bwrdd eu cymryd), ar yr amod—
 - (i) bod y cyfarwyddwr neu uwcharolygydd dan sylw yn peidio â bod yn gyfarwyddwr neu'n uwcharolygydd y corff corfforaethol o fewn y cyfnod o 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad; a
 - (ii) bod y corff corfforaethol yn hysbysu'r Bwrdd Iechyd Lleol, o fewn y cyfnod hwnnw, am y dyddiad y mae'r cyfarwyddwr neu'r uwcharolygydd wedi peidio â bod, neu y bydd yn peidio â bod, yn gyfarwyddwr neu'n uwch-arolygydd y corff corfforaethol.

(3) Rhaid i Fwrdd Iechyd Lleol dynnu person oddi ar restr fferyllol—

- (a) os nad yw'r person, yn ystod y chwe mis blaenorol, wedi darparu gwasanaethau fferyllol o'r fangre y mae'r person wedi ei gynnwys yn y rhestr fferyllol mewn perthynas â hi (ond wrth gyfrifo'r cyfnod o chwe mis ni ddylid cynnwys unrhyw gyfnod pan oedd y person wedi ei atal); neu
- (b) os bu farw'r person, ond nid os yw cynrychiolydd y person hwnnw yn parhau i gynnal ei fusnes ar ôl ei farwolaeth o dan adran 72 o Ddeddf Meddyginiaethau 1968 (cynrychiolydd fferyllol mewn achos o farwolaeth neu anabledd) cyn belled â bod y cynrychiolydd yn cynnal y busnes yn unol â darpariaethau'r Ddeddf honno, ac yn cytuno i gael ei rwymo gan y telerau gwasanaethu; neu
- (c) os nad yw'r person bellach yn fferyllol cofrestredig.

(4) Cyn tynnu person oddi ar restr fferyllol o dan baragraff (3) rhaid i'r Bwrdd Iechyd Lleol—

- (a) rhoi i'r person, neu i gynrychiolydd y person a grybwyllir o dan baragraff (3)(b), 30 diwrnod o rybudd o'i fwriad i dynnu'r person oddi ar y rhestr fferyllol;
- (b) rhoi cyfle i'r person, neu i gynrychiolydd y person a grybwyllir o dan baragraff (3)(b), wneud sylwadau mewn ysgrifen neu, os yw'n dymuno hynny, yn bersonol yn ystod y cyfnod hwnnw; ac
- (c) ymgynghori â'r Pwyllgor Fferyllol Lleol.

Health Board and the person (or a representative) attends the hearing that the Local Health Board arranges for the purposes of hearing those representations; and

- (c) in a case to which paragraph (1)(a) or (b) applies, if the person is a body corporate, advise the person that the Local Health Board will not remove the body corporate from its pharmaceutical list as a consequence of paragraph (1)(a) or (b) (without prejudice to any other action that it may take), provided that—
 - (i) the director or superintendent concerned ceases to be a director or superintendent of the body corporate within the period of 30 days commencing with the date of the notice; and
 - (ii) within that period, the body corporate notifies the Local Health Board of the date on which the director or superintendent has ceased or is to cease to be a director or superintendent of the body corporate.

(3) A Local Health Board must remove a person from a pharmaceutical list—

- (a) if the person has not, in the preceding six months, provided pharmaceutical services from the premises in respect of which the person is included in the pharmaceutical list (but a period during which the person has been suspended does not count towards calculating the six month period); or
- (b) if the person has died, but not if that person's business is carried on after his or her death by a representative under section 72 of the Medicines Act 1968 (representative of pharmacist in case of death or disability) so long as the business is carried on by the representative in accordance with the provisions of that Act, and the representative agrees to be bound by the terms of service; or
- (c) if the person is no longer a registered pharmacist.

(4) Before removing a person from a pharmaceutical list under paragraph (3) the Local Health Board must—

- (a) give the person or the person's representative mentioned under paragraph (3)(b) 30 days notice of its intention to remove the person from the pharmaceutical list;
- (b) give the person or the person's representative mentioned under paragraph (3)(b) the opportunity to make representations in writing or, if he or she so desires, in person, during that period; and
- (c) consult the Local Pharmaceutical Committee.

(5) Unwaith y bydd y Bwrdd Iechyd Lleol wedi gwneud penderfyniad i dynnu person oddi ar y rhestr fferyllol ar sail a gynhwysir ym mharagraff (1), rhaid iddo hysbysu'r person o'r penderfyniad hwnnw, a chynnwys gyda'r hysbysiad esboniad o'r canlynol—

- (a) y rhesymau am y penderfyniad;
- (b) hawl y person i apelio i'r Tribiwnlys yn erbyn ei benderfyniad; ac
- (c) o fewn pa derfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008, y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl.

(6) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r person ar unwaith mewn ysgrifen, o benderfyniad y Bwrdd o dan baragraff (3) i dynnu'r person oddi ar y rhestr fferyllol, ac o hawl y person i apelio o dan baragraff (7).

(7) Caiff person a hysbysir o dan baragraff (6), o fewn 30 diwrnod ar ôl cael yr hysbysiad, apelio yn erbyn y penderfyniad drwy roi hysbysiad ysgrifenedig i Weinidogion Cymru, gan nodi seiliau'r apêl.

(8) Ar ôl cael apêl o dan baragraff (7) rhaid i Weinidogion Cymru hysbysu'r Bwrdd Iechyd Lleol fod apêl wedi ei gael.

(9) Rhaid i Weinidogion Cymru benderfynu apêl, y rhoddwyd hysbysiad o apêl dilys mewn perthynas â hi yn unol â pharagraff (7) yn y cyfryw fodd (gan gynnwys o ran gweithdrefnau) a ystyrir yn briodol gan Weinidogion Cymru.

(10) Wrth benderfynu apêl o dan baragraff (9), caiff Gweinidogion Cymru—

- (a) cadarnhau penderfyniad y Bwrdd Iechyd Lleol; neu
- (b) yn lle'r penderfyniad hwnnw, gwneud unrhyw benderfyniad arall y gallai'r Bwrdd Iechyd Lleol fod wedi ei wneud pan wnaeth y penderfyniad hwnnw.

(11) Rhaid i Fwrdd Iechyd Lleol beidio â thynnu enw person oddi ar y rhestr fferyllol—

- (a) os na wneir apêl, hyd nes i'r cyfnod ar gyfer dwyn apêl yn erbyn y penderfyniad ddod i ben; neu
- (b) os gwneir apêl, hyd nes bo'r apêl wedi ei phenderfynu.

(12) Os yw apêl yn cael ei chadarnhau, rhaid i'r Bwrdd Iechyd Lleol beidio â thynnu enw'r person oddi ar y rhestr fferyllol.

Atal dros dro o restr fferyllol

36.—(1) Cyn gwneud penderfyniad o dan adran 110(1) (atal dros dro) neu adran 111(2) (atal dros dro tra'n aros am apêl) o Ddeddf 2006, rhaid i'r Bwrdd

(5) Once the Local Health Board has taken a decision to remove the person from the pharmaceutical list on grounds contained in paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) the person's right of appeal against its decision to the Tribunal; and
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(6) The Local Health Board must notify the person immediately in writing of its decision under paragraph (3) to remove the person from the pharmaceutical list and of the person's right of appeal under paragraph (7).

(7) A person notified under paragraph (6) may, within 30 days of receiving the notice appeal the decision by notice in writing to the Welsh Ministers setting out the grounds of appeal.

(8) Upon receipt of an appeal under paragraph (7) the Welsh Ministers must notify the Local Health Board that an appeal has been received.

(9) The Welsh Ministers may determine the appeal in respect of which a valid notice of appeal has been given in accordance with paragraph (7) in such manner (including with regard to procedures) as the Welsh Ministers think fit.

(10) On determining an appeal under paragraph (9), the Welsh Ministers may—

- (a) confirm the decision of the Local Health Board; or
- (b) substitute for that decision any decision that the Local Health Board could have taken when it took that decision.

(11) A Local Health Board must not remove the person's name from the pharmaceutical list until—

- (a) if no appeal is made, the period for bringing an appeal against the decision has elapsed; or
- (b) if an appeal is made, the appeal is determined.

(12) Where an appeal is upheld, the Local Health Board must not remove the person's name from the pharmaceutical list.

Suspension from a pharmaceutical list

36.—(1) Before making a decision under section 110(1) (suspension) or section 111(2) (suspension pending appeal) of the 2006 Act, the Local Health

Iechyd Lleol roi i'r person—

- (a) hysbysiad o unrhyw honiad a wnaed yn ei erbyn;
- (b) hysbysiad o'r camau y mae'r Bwrdd Iechyd Lleol yn ystyried eu cymryd, ac ar ba seiliau;
- (c) cyfle i wneud sylwadau ysgrifenedig o fewn 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad a roddir o dan y paragraff hwn; a
- (d) y cyfle i wneud sylwadau mewn gwrandawriad llafar gerbron y Bwrdd Iechyd Lleol, ar yr amod bod y person yn hysbysu'r Bwrdd Iechyd Lleol o'i ddymuniad i wneud sylwadau o fewn cyfnod penodedig (o ddim llai na 24 awr).

(2) Rhaid i'r Bwrdd Iechyd Lleol gymryd i ystyriaeth unrhyw sylwadau a wneir gan y person cyn cyrraedd ei benderfyniad.

(3) Rhaid i'r Bwrdd Iechyd Lleol, unwaith y bydd wedi cyrraedd penderfyniad, hysbysu'r person o'r penderfyniad hwnnw, mewn ysgrifen, cyn gynted ag y bo'n rhesymol ymarferol, gan roi'r rhesymau am y penderfyniad (a chan nodi unrhyw ffeithiau y dibynnwyd arnynt).

(4) Pan fo'r Bwrdd Iechyd Lleol wedi atal person o'r rhestr fferyllol dros dro, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r person o'r rhesymau am y penderfyniad ac, yn achos ataliad o dan adran 110(1) o Ddeddf 2006, o'i hawl i gael adolygiad o'r penderfyniad yn unol ag adran 113 (adolygu penderfyniadau) o Ddeddf 2006.

(5) Caiff y Bwrdd Iechyd Lleol, ar unrhyw adeg, ddirymu'r ataliad a hysbysu'r person o'i benderfyniad.

Hysbysiad o benderfyniad i osod amodau

37.—(1) Pan fo Bwrdd Iechyd Lleol yn penderfynu—

- (a) gwrthod caniatáu cais gan berson o dan reoliad 32;
- (b) gosod amodau ar berson o dan reoliad 33;
- (c) tynnu person ymaith o restr fferyllol y Bwrdd o dan reoliad 34 neu 35;
- (d) atal person dros dro o restr fferyllol y Bwrdd o dan reoliad 36;
- (e) gosod neu amrywio amod o dan reoliad 38; neu
- (f) gosod neu amrywio amod o dan reoliad 39,

rhaid iddo hysbysu'r personau a'r cyrff a bennir ym mharagraff (2) ac yn ychwanegol hysbysu'r rhai a bennir ym mharagraff (3), os gofynnir iddo wneud felly gan y personau neu'r cyrff hynny mewn ysgrifen (gan gynnwys yn electronig), ynghylch y materion a bennir ym mharagraff (4).

Board must give the person—

- (a) notice of any allegation against him or her;
- (b) notice of the action the Local Health Board is considering and on what grounds;
- (c) the opportunity to make written representations within 30 days beginning with the date the notification is given under this paragraph; and
- (d) the opportunity to make representations at an oral hearing before the Local Health Board, provided the person notifies the Local Health Board that he or she wishes to make representations within a specified period (of not less than 24 hours).

(2) The Local Health Board must take into account any representations made by the person before it reaches its decision.

(3) Once the Local Health Board has reached a decision it must as soon as is reasonable practicable notify the person in writing of its decision and the reasons for it (including any facts relied upon).

(4) Where the Local Health Board has suspended a person from the pharmaceutical list, it must inform the person of the reasons for the decision and, in the case of a suspension under section 110(1) of the 2006 Act, of his or her right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(5) The Local Health Board may at any time revoke the suspension and notify the person of its decision.

Notification of decision to impose conditions

37.—(1) Where a Local Health Board decides to—

- (a) refuse to grant an application from a person under regulation 32;
- (b) impose conditions on a person under regulation 33;
- (c) remove a person from its pharmaceutical list under regulation 34 or 35;
- (d) suspend a person from its pharmaceutical list under regulation 36,
- (e) impose or vary a condition under regulation 38; or
- (f) impose or vary a condition under regulation 39

it must notify the persons and bodies specified in paragraph (2) and additionally notify those specified in paragraph (3), if requested to do so by those persons or bodies in writing (including electronically), of the matters set out in paragraph (4).

(2) Y personau sydd i'w hysbysu yw—

- (a) Gweinidogion Cymru;
- (b) unrhyw Fwrdd Iechyd Lleol arall neu gorff cyfatebol, y gŵyr y Bwrdd Iechyd Lleol sy'n hysbysu ei fod wedi cynnwys y ceisydd ar restr berthnasol;
- (c) Gweinidogion yr Alban;
- (d) yr Ysgrifennydd Gwladol;
- (e) Gweithrediaeth Gogledd Iwerddon;
- (f) y Cyngor Fferyllol Cyffredinol, Cymdeithas Fferyllol Gogledd Iwerddon neu unrhyw gorff rheoleiddio priodol arall;
- (g) y Pwyllgor Fferyllol Lleol ar gyfer ardal y Bwrdd Iechyd Lleol;
- (h) y Bwrdd Comisiynu'r Gwasanaeth Iechyd Gwladol; ac
- (i) yn achos twyll, Awdurdod Gwasanaethau Busnes y GIG.

(3) Y personau neu'r cyrff a gaiff ofyn am eu hysbysu yn ychwanegol yn unol â pharagraff (1) yw—

(a) personau neu gyrff a all ddangos—

- (i) eu bod, neu y buont, yn cyflogi'r person, yn defnyddio neu wedi defnyddio ei wasanaethau (neu os yw'r person yn gorff corfforaethol, wedi defnyddio gwasanaethau unrhyw gyfarwyddwr neu uwcharolygydd y corff corfforaethol hwnnw) mewn swydd broffesiynol, neu
 - (ii) yn ystyried cyflogi neu ddefnyddio gwasanaethau'r person (neu os yw'r person yn gorff corfforaethol, defnyddio gwasanaethau unrhyw gyfarwyddwr neu uwcharolygydd y corff corfforaethol hwnnw) mewn swydd broffesiynol; a
- (b) partneriaeth y mae unrhyw un o'i haelodau yn darparu neu'n cynorthwyo i ddarparu gwasanaethau fferyllol, ac sy'n gallu dangos bod y person, neu y bu'r person, yn aelod o'r bartneriaeth, neu fod y bartneriaeth yn ystyried ei wahodd i fod yn aelod.

(4) Y materion y cyfeirir atynt ym mharagraff (1) yw—

- (a) os yw'r person yn unigolyn neu'n bartneriaeth—
 - (i) enw, cyfeiriad a dyddiad geni'r person neu bob aelod o'r bartneriaeth;
 - (ii) rhif cofrestru proffesiynol y person neu bob aelod o'r bartneriaeth;
 - (iii) dyddiad penderfyniad y Bwrdd Iechyd Lleol a chopi o'r penderfyniad; a
 - (iv) enw person cyswllt yn y Bwrdd Iechyd

(2) The persons to be notified are—

- (a) the Welsh Ministers;
- (b) any other Local Health Board or equivalent body that to the knowledge of the notifying Local Health Board has the applicant included in a relevant list;
- (c) the Scottish Ministers;
- (d) the Secretary of State;
- (e) the Northern Ireland Executive;
- (f) the General Pharmaceutical Council, the Pharmaceutical Society of Northern Ireland or any other appropriate regulatory body;
- (g) the Local Pharmaceutical Committee for the Local Health Board's area;
- (h) the National Health Service Commissioning Board; and
- (i) in the case of fraud, the NHS Business Services Authority.

(3) The persons or bodies who may request to be additionally notified in accordance with paragraph (1) are—

(a) persons or bodies that can establish that they—

- (i) are or were employing the person, are using or have used his or her services (or where the person is a body corporate, have used the services of any director or superintendent of that body corporate) in a professional capacity, or
 - (ii) are considering employing or using the services of the person (or where the person is a body corporate, using the services of any director or superintendent of that body corporate) in a professional capacity; and
- (b) a partnership any of whose members provide or assist in the provision of pharmaceutical services and can establish that the person is or was a member of the partnership or that it is considering inviting the person to become a member.

(4) The matters referred to in paragraph (1) are—

- (a) where the person is an individual or a partnership—
 - (i) the person's, or each member of the partnership's name, address and date of birth;
 - (ii) the person's or each member of the partnership's, professional registration number;
 - (iii) the date and copy of the decision of the Local Health Board; and
 - (iv) a contact name of a person in the Local

Lleol ar gyfer ymholiadau pellach.

(b) os yw'r person yn gorff corfforaethol—

- (i) enw'r corff corfforaethol, ei rif cofrestru cwmni a chyfeiriad ei swyddfa gofrestredig;
- (ii) rhif cofrestru proffesiynol uwcharolygydd y corff corfforaethol a rhif cofrestru proffesiynol unrhyw gyfarwyddwr y corff corfforaethol sy'n fferylllydd cofrestredig;
- (iii) dyddiad penderfyniad y Bwrdd Iechyd Lleol a chopi o'r penderfyniad; a
- (iv) enw person cyswllt yn y Bwrdd Iechyd Lleol ar gyfer ymholiadau pellach.

(5) Rhaid i'r Bwrdd Iechyd Lleol anfon copi at berson o unrhyw wybodaeth a ddarperir amdano i'r personau neu'r cyrff a bennir ym mharagraffau (2) a (3), ac unrhyw ohebiaeth gyda'r personau neu'r cyrff hynny ynglŷn â'r wybodaeth honno.

(6) Pan fo'r Bwrdd Iechyd Lleol wedi hysbysu unrhyw un o'r personau neu'r cyrff a bennir ym mharagraff (2) neu (3) o'r materion a bennir ym mharagraff (4), caiff y Bwrdd, yn ychwanegol, os gofynnir iddo gan y person neu'r corff hwnnw, hysbysu'r person neu'r corff hwnnw o unrhyw dystiolaeth a ystyriwyd, gan gynnwys sylwadau a wnaed gan y person.

(7) Pan hysbysir Bwrdd Iechyd Lleol gan y Tribiwnlys, fod y Tribiwnlys wedi gosod anghymhwysiad cenedlaethol ar berson a dynnwyd gan y Bwrdd Iechyd Lleol oddi ar ei restr fferyllol, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r personau neu'r cyrff a bennir ym mharagraff (2)(b), (g), (h) ac (i) a pharagraff (3).

(8) Pan newidir penderfyniad o ganlyniad i adolygiad neu apêl, neu pan fo ataliad yn mynd yn ddi-rym, rhaid i'r Bwrdd Iechyd Lleol hysbysu unrhyw berson neu gorff, a hysbyswyd o'r penderfyniad gwreiddiol, ynghylch y penderfyniad diweddarach neu ynghylch yr ataliad yn mynd yn ddi-rym.

Adolygu penderfyniad i osod ataliad dros dro o dan adran 110 o Ddeddf 2006 neu dynnu yn ddigwyddiadol o dan adran 108 o Ddeddf 2006

38.—(1) Pan fo rhaid i Fwrdd Iechyd Lleol, yn unol ag adran 113 (adolygu penderfyniadau) o Ddeddf 2006, adolygu ei benderfyniad i dynnu person yn ddigwyddiadol oddi ar y rhestr fferyllol neu atal person dros dro o'r rhestr fferyllol o dan adran 110 (atal dros dro) o Ddeddf 2006, neu pan fo'r Bwrdd yn penderfynu adolygu penderfyniad o'r fath, rhaid iddo roi i'r person hwnnw—

- (a) hysbysiad o'i fwriad i adolygu ei benderfyniad;
- (b) hysbysiad o'r penderfyniad y mae'n ystyried ei wneud o ganlyniad i'r adolygiad, a'r rhesymau am y penderfyniad;

Health Board for further enquiries.

(b) where the person is a body corporate—

- (i) the body corporate's name, company registration number and the address of the registered office;
- (ii) the professional registration number of body corporate's superintendent and of any director of the body corporate who is a registered pharmacist;
- (iii) the date and copy of the decision of the Local Health Board; and
- (iv) a contact name of a person in the Local Health Board for further enquiries.

(5) The Local Health Board must send to the person a copy of any information about him or her provided to the persons or bodies specified in paragraphs (2) and (3) and any correspondence with those persons or bodies relating to that information.

(6) Where the Local Health Board has notified any of the persons or bodies specified in paragraph (2) or (3) of the matters set out in paragraph (4), it may in addition, if so requested by that person or body, notify that person or body of any evidence that was considered, including representations made by the person .

(7) Where a Local Health Board is notified by the Tribunal that it has imposed a national disqualification on a person whom the Local Health Board has removed from its pharmaceutical list, the Local Health Board must notify the persons or bodies specified in paragraph (2)(b), (g), (h) and (i) and paragraph (3).

(8) Where a decision is changed on review or appeal, or a suspension lapses, the Local Health Board must notify any person or body that was notified of the original decision of the later decision, or of the fact that the suspension has lapsed.

Review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act

38.—(1) Where in accordance with section 113 (review of decisions) of the 2006 Act, a Local Health Board must review its decision to contingently remove a person from the pharmaceutical list or suspend a person from the pharmaceutical list under section 110 (suspension) of the 2006 Act, or where it decides to review such a decision, it must give that person—

- (a) notice that it intends to review its decision;
- (b) notice of the decision that it is minded to take upon review, and the reasons for it;

(c) cyfle i wneud sylwadau ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn y cyfnod o 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad o dan is-baragraff (a); a

(d) cyfle i gyflwyno'i achos mewn gwrandawriad llafar gerbron y Bwrdd Iechyd Lleol, os yw'r person yn gofyn am hynny, o fewn y cyfnod o 30 diwrnod a grybwyllir yn is-baragraff (c).

(2) Yn dilyn adolygiad o'r fath, caiff y Bwrdd Iechyd Lleol—

(a) cadarnhau'r tynnu digwyddiadol neu'r ataliad dros dro;

(b) yn achos ataliad dros dro, ei derfynu;

(c) yn achos tynnu digwyddiadol, amrywio'r amodau, gosod amodau gwahanol, dirymu'r tynnu digwyddiadol, neu dynnu'r ymarferydd oddi ar y rhestr.

(3) Ni chaiff person a ataliwyd dros dro o restr fferyllol o dan adran 110 o Ddeddf 2006 neu a dynnwyd yn ddigwyddiadol oddi ar restr fferyllol o dan adran 108 o Ddeddf 2006 ofyn am adolygiad cyn diwedd —

(a) cyfnod o dri mis sy'n cychwyn gyda dyddiad penderfyniad y Bwrdd Iechyd Lleol i dynnu yn ddigwyddiadol; neu

(b) cyfnod o chwe mis sy'n cychwyn gyda dyddiad y penderfyniad ar yr adolygiad blaenorol.

(4) Os yw'r Bwrdd Iechyd Lleol yn cael sylwadau neu gais am wrandawriad llafar o fewn y cyfnod a bennir ym mharagraff (1)(c), rhaid iddo gymryd y sylwadau i ystyriaeth neu gynnal y gwrandawriad llafar, yn ôl fel y digwydd, cyn cyrraedd ei benderfyniad.

(5) Unwaith y bydd y Bwrdd Iechyd Lleol wedi gwneud penderfyniad o dan adran 113(3) o Ddeddf 2006, rhaid iddo hysbysu'r person o'i benderfyniad a chynnwys gyda'r hysbysiad esboniad o'r canlynol—

(a) y rhesymau am y penderfyniad;

(b) os oes hawl gan y person i apelio mewn perthynas â'r penderfyniad—

(i) yr hawl sydd gan y person i apelio mewn perthynas â'r penderfyniad hwnnw o dan adran 114 o Ddeddf 2006 (apelau)(1), a

(ii) o fewn pa derfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008, y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl; ac

(1) Sylwer nad oes hawl i apelio i'r Tribiwnlys yn erbyn penderfyniad i atali ymarferydd dros dro, nac i adolygu penderfyniad ynghylch atal dros dro. Fodd bynnag, mae hawl i apelio i'r Tribiwnlys yn erbyn unrhyw benderfyniad gan Fwrdd Iechyd Lleol ynghylch adolygiad o dynnu digwyddiadol o dan adran 113 o Ddeddf 2006. *Gweler* adran 114 o Ddeddf 2006.

(c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a); and

(d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(2) On such a review the Local Health Board may—

(a) confirm the contingent removal or suspension;

(b) in the case of a suspension terminate it;

(c) in the case of a contingent removal, vary the conditions, impose different conditions, revoke the contingent removal, or remove the practitioner from the list.

(3) A person who has been suspended from a pharmaceutical list under section 110 of the 2006 Act or contingently removed from a pharmaceutical list under section 108 of the 2006 Act cannot request a review until the expiry of—

(a) three months beginning with the date of the decision of the Local Health Board to contingently remove; or

(b) six months beginning with the date of the decision on the previous review.

(4) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account or hold the oral hearing, as the case may be, before reaching its decision.

(5) Once the Local Health Board has made a decision under section 113(3) of the 2006 Act, it must notify the person of its decision and it must include with the notification of its decision an explanation of—

(a) the reasons for the decision;

(b) if the person has a right of appeal in relation to the decision—

(i) the right of appeal that the person has in relation to that decision under section 114 of the 2006 Act (appeals)(1), and

(ii) the time limit within which, in accordance with the Tribunal Procedure (First Tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought; and

(1) Note there is no right of appeal to the Tribunal against a decision to suspend a practitioner or to review a decision on suspension. However, there is a right of appeal to the Tribunal against any decision of a Local Health Board on a review of a contingent removal under section 113 of the 2006 Act. *See* section 114 of the 2006 Act.

- (c) os yw'r person wedi ei atal dros dro neu wedi ei dynnu yn ddigwyddiadol neu os yw'r person yn parhau felly, y trefniadau ar gyfer adolygu'r ataliad dros dro neu'r amodau o dan adran 113(1) o Ddeddf 2006.

Adolygu penderfyniad i osod amodau

39.—(1) Pan fo Bwrdd Iechyd Lleol wedi gwneud penderfyniad i osod amodau yn unol â rheoliad 33, caiff adolygu penderfyniad o'r fath, naill ai o'i ddewis ei hunan neu os gofynnir iddo wneud hynny gan y person y caniatwyd ei gais yn ddarostyngedig i amodau.

(2) Ni chaiff person y caniatwyd ei gais yn ddarostyngedig i amodau ofyn am adolygiad o benderfyniad Bwrdd Iechyd Lleol cyn diwedd cyfnod o dri mis sy'n cychwyn gyda'r dyddiad y mae'r Bwrdd Iechyd Lleol—

- (a) yn cynnwys enw'r person yn ei restr fferyllol; neu
- (b) yn caniatáu cydsyniad rhagarweiniol i'r person,

ac ni chaiff ofyn am adolygiad o fewn chwe mis ar ôl penderfyniad ar adolygiad blaenorol.

(3) Rhaid i Fwrdd Iechyd Lleol roi i'r person y caniatwyd ei gais yn ddarostyngedig i amodau—

- (a) hysbysiad o'i fwriad i adolygu ei benderfyniad;
- (b) hysbysiad o'r penderfyniad y mae'n ystyried ei wneud o ganlyniad i'r adolygiad, a'r rhesymau am y penderfyniad;
- (c) cyfle i wneud sylwadau ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn y cyfnod o 30 diwrnod sy'n cychwyn gyda dyddiad yr hysbysiad o dan is-baragraff (a); a
- (d) cyfle i gyflwyno'i achos mewn gwrandawriad llafar gerbron y Bwrdd Iechyd Lleol, os yw'r person yn gofyn am hynny, o fewn y cyfnod o 30 diwrnod a grybwyllir yn is-baragraff (c).

(4) Os yw'r Bwrdd Iechyd Lleol yn cael sylwadau neu gais am wrandawriad llafar o fewn y cyfnod a bennir ym mharagraff (3)(c), rhaid iddo gymryd y sylwadau i ystyriaeth neu gynnal y gwrandawriad llafar, yn ôl fel y digwydd, cyn cyrraedd ei benderfyniad.

(5) Yn dilyn adolygiad o'r fath, caiff y Bwrdd Iechyd Lleol—

- (a) parhau'r amodau cyfredol;
- (b) gosod amodau newydd;
- (c) amrywio telerau gwasanaethu'r person;
- (d) amrywio'r amodau; neu
- (e) os yw'r person wedi torri amod, tynnu'r person

- (c) if the person has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 113(1) of the 2006 Act.

Review of a decision to impose conditions

39.—(1) Where a Local Health Board has made a decision to impose conditions in accordance with regulation 33, it may review such a decision either of its own volition or at the request of the person whose application has been granted subject to conditions.

(2) A person whose application has been granted subject to conditions may not request a review of a Local Health Board's decision until the expiry of a three month period beginning with the date the Local Health Board—

- (a) includes the person's name on its pharmaceutical list; or
- (b) grants the person preliminary consent,

and cannot request a review within six months of a decision on a previous review.

(3) A Local Health Board must give the person whose application has been granted subject to conditions—

- (a) notice that it intends to review its decision;
- (b) notice of the decision that it is minded to take upon review, and the reasons for it.
- (c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a); and
- (d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(4) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (3)(c), it must take the representations into account or hold the oral hearing, as the case may be, before reaching its decision.

(5) Upon review the Local Health Board may—

- (a) maintain the current conditions;
- (b) impose new conditions;
- (c) vary the person's terms of service;
- (d) vary the conditions; or
- (e) where the person has breached a condition,

oddi ar y rhestr fferyllol.

(6) Cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r person o'i benderfyniad, a rhaid iddo gynnwys gyda'r hysbysiad o'i benderfyniad esboniad o'r canlynol—

- (a) y rhesymau am y penderfyniad;
- (b) yr hawl sydd gan y person i apelio i'r Tribiwnlys; ac
- (c) o fewn pa derfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008, y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl.

Apelau

40.—(1) Pan fo person, ac eithrio person a hysbysir o dan reoliad 37, wedi ei hysbysu o benderfyniad gan Fwrdd Iechyd Lleol bod y Bwrdd—

- (a) yn bwriadu—
 - (i) gwrthod caniatáu cais y mae rheoliad 32 (gwrthod ceisiadau ar sail addasrwydd) yn gymwys iddo ar seiliau a gynhwysir ym mharagraffau (2) neu (3) o'r rheoliad hwnnw;
 - (ii) gosod amodau ar y person yn rhinwedd rheoliad 33 (cynnwys yn amodol mewn perthynas â seiliau addasrwydd), neu amrywio telerau gwasanaethu'r person yn unol â'r rheoliad hwnnw;
 - (iii) yn unol â rheoliad 34 (tynnu ymaith o restr fferyllol am dorri amodau mewn cysylltiad â seiliau addasrwydd neu osod neu amrywio neu osod amodau newydd o dan adran 108 o Ddeddf 2006)—
 - (aa) tynnu enw'r person oddi ar y rhestr fferyllol o dan adran 107 (anghymhwyso ymarferwyr) o Ddeddf 2006;
 - (bb) tynnu enw'r person yn ddigwyddiadol oddi ar y rhestr fferyllol o dan adran 108 (tynnu digwyddiadol) o Ddeddf 2006;
 - (cc) tynnu enw person oddi ar y rhestr fferyllol am dorri amod a osodwyd o dan adran 108 o Ddeddf 2006;
 - (dd) gosod unrhyw amod penodol o dan adran 108 o Ddeddf 2006, amrywio unrhyw amod, gosod amod gwahanol neu amrywio telerau gwasanaethu'r person o dan yr adran honno;
 - (ee) tynnu enw'r person oddi ar y rhestr fferyllol am dorri amod a osodwyd o

remove the person from the pharmaceutical list.

(6) As soon as practicable after reaching a decision, the Local Health Board must notify the person of its decision, and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision;
- (b) the right of appeal that the person has to the Tribunal; and
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

Appeals

40.—(1) A person, other than a person notified under regulation 37, who has been notified by a Local Health Board of its decision that it—

- (a) intends to—
 - (i) refuse to grant an application to which regulation 32 (refusal of applications on fitness grounds) applies under grounds contained in paragraph (2) or (3) of that regulation;
 - (ii) impose conditions on the person by virtue of regulation 33 (conditional inclusion relating to fitness grounds), or vary the person's terms of service pursuant to that regulation;
 - (iii) in accordance with regulation 34 (removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act)—
 - (aa) remove the person's name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act;
 - (bb) contingently remove the person's name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act;
 - (cc) remove the person's name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act;
 - (dd) impose any particular condition under section 108 of the 2006 Act, vary any condition, impose a different condition or vary the person's terms of service under that section;
 - (ee) remove the person's name from the pharmaceutical list for breach of a

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dan reoliad 33; neu

(iv) tynnu'r person oddi ar y rhestr fferyllol ar sail a gynhwysir yn rheoliad 35(1); neu

(b) wedi adolygu penderfyniad i osod amodau o dan reoliad 39 (adolygu penderfyniad i osod amodau) ac wedi penderfynu cymryd un o'r camau gweithredu yn rheoliad 39(5); neu

(c) wedi adolygu penderfyniad i dynnu'r person yn ddigwyddiadol oddi ar restr fferyllol yn rhinwedd rheoliad 38 (adolygu penderfyniad i osod ataliad dros dro o dan adran 110 o Ddeddf 2006 neu dynnu yn ddigwyddiadol o dan adran 108 o Ddeddf 2006), ac wedi—

(i) cadarnhau'r tynnu digwyddiadol;

(ii) amrywio'r amodau sy'n gysylltiedig â'r tynnu digwyddiadol neu wedi gosod amodau gwahanol; neu

(iii) wedi tynnu'r person oddi ar y rhestr fferyllol,

caiff y person apelio yn erbyn y penderfyniad hwnnw i'r Tribiwnlys.

(2) Rhaid gwneud apêl o dan baragraff (1) mewn ysgrifen, gan nodi'r seiliau dros wneud yr apêl, a rhaid ei chyflwyno i'r Tribiwnlys o fewn y terfyn amser, yn unol â Rheolau Gweithdrefn y Tribiwnlysoedd (Tribiwnlys yr Haen Gyntaf) (Y Siambr Iechyd, Addysg a Gofal Cymdeithasol) 2008 y bydd rhaid anfon hysbysiad o'r cais at y Tribiwnlys os bwriedir dwyn apêl.

(3) Caiff y Tribiwnlys, wrth benderfynu apêl, wneud unrhyw benderfyniad y gallai Bwrdd Iechyd Lleol ei wneud o dan y Rhan hon.

condition imposed under regulation 33; or

(iv) remove the person from the pharmaceutical list on grounds contained in regulation 35(1); or

(b) has reviewed a decision to impose conditions under regulation 39 (review of a decision to impose conditions) and has decided to take any of the actions in regulation 39(5); or

(c) has reviewed a decision to contingently remove the person from a pharmaceutical list by virtue of regulation 38 (review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act) and has—

(i) confirmed the contingent removal;

(ii) varied the conditions attached to the contingent removal or imposed different conditions; or

(iii) has removed the person from the pharmaceutical list,

may appeal that decision to the Tribunal.

(2) An appeal under paragraph (1) must be made in writing, setting out the grounds on which the appeal is made and must be submitted to the Tribunal within the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(3) The Tribunal, on determining an appeal, may make any decision that the Local Health Board could make under this Part.

RHAN 7

Taliadau i fferyllwyr GIG a chontractwyr cyfarpar GIG

Y Tariff Cyffuriau a chydabyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG

41.—(1) Mae'r Tariff Cyffuriau y cyfeirir ato yn adran 81(4) o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol ychwanegol) yn gyfuniad o'r canlynol—

(a) y penderfyniadau ar gydnabyddiaeth ariannol a wneir gan Weinidogion Cymru, tra'n gweithredu fel awdurdod penderfynu, o dan adran 88 o Ddeddf 2006 (cydnabyddiaeth ariannol i bersonau sy'n darparu gwasanaethau fferyllol); a

(b) unrhyw offerynnau eraill y mae'n ofynnol bod

PART 7

Payments to NHS pharmacists and NHS appliance contractors

The Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors

41.—(1) The Drug Tariff referred to in section 81(4) of the 2006 Act (arrangements for additional pharmaceutical services) is the aggregate of—

(a) the determinations of remuneration made by the Welsh Ministers, acting as a determining authority, under section 88 of the 2006 Act (remuneration for persons providing pharmaceutical services); and

(b) any other instruments that the Welsh Ministers

Gweinidogion Cymru, yn rhinwedd y Rheoliadau hyn neu Ddeddf 2006, yn eu cyhoeddi, neu y byddant yn eu cyhoeddi, ynghyd â'r penderfyniadau hynny,

yn y cyhoeddiad a elwir y Tariff Cyffuriau, a gyhoeddir gan Weinidogion Cymru ym mha bynnag fformat a ystyriant yn briodol.

(2) O ran penderfyniadau gan Weinidogion Cymru o dan adran 88 o Ddeddf 2006—

(a) caniateir eu gwneud drwy gyfeirio at raddfeydd, mynegeion neu fformiwla'u o unrhyw fath, ac os yw penderfyniad yn un sydd i'w wneud drwy gyfeirio at unrhyw raddfa, mynegai neu fformiwla o'r fath, caiff y penderfyniad ddarparu bod rhaid gwneud y cyfrifiad pris perthnasol drwy gyfeirio at y raddfa, mynegai neu fformiwla sydd—

(i) yn y ffurf sy'n gyfredol ar yr adeg y gwneir y penderfyniad, a

(ii) mewn unrhyw ffurf ddilynol a gaiff effaith ar ôl yr adeg honno; a

(b) cânt fod yn effeithiol o ran cydnabyddiaeth ariannol mewn perthynas â chyfnod sy'n cychwyn ar neu ar ôl y dyddiad a bennir yn y penderfyniad, a gaiff fod naill ai'n ddyddiad y penderfyniad neu'n ddyddiad cynharach neu ddiweddarach, ond ni chaiff fod yn ddyddiad cynharach ac eithrio pan nad yw'r penderfyniad, o'i gymryd yn ei gyfanrwydd, yn anffafriol i'r personau y mae'r penderfyniad yn ymwneud â'u cydnabyddiaeth ariannol.

(3) Os nad yw penderfyniad a gynhwysir yn y Tariff Cyffuriau yn pennu dyddiad fel y crybwyllir ym mharagraff (2)(b), bydd yn cael effaith o ran cydnabyddiaeth ariannol mewn perthynas â'r cyfnod sy'n cychwyn ar y dyddiad y cyhoeddir y newid yn y Tariff Cyffuriau yn unol â pharagraff (4).

(4) Rhaid i unrhyw ddiwygiadau i'r Tariff Cyffuriau, a wneir gan Weinidogion Cymru ar y cyfryw adegau a ystyriant yn briodol, gael eu cyhoeddi gan Weinidogion Cymru mewn fersiwn gydgrynoedig o'r Tariff Cyffuriau a fydd yn cynnwys y diwygiadau.

(5) Rhaid cynnal yr ymgynghoriad, a ymgymerir gan Weinidogion Cymru o dan adran 89(1) o Ddeddf 2006 (adran 88: atodol) cyn cynnwys neu cyn newid pris cyffur neu gyfarpar a fydd yn ffurfio rhan o gyfrifiad cydnabyddiaeth ariannol, drwy ymgynghori ynglŷn â'r broses ar gyfer penderfynu'r pris sydd i'w gynnwys neu ei newid, ac nid y pris arfaethedig ei hunan (onid yw'n amhosibl cynnal ymgynghoriad effeithiol mewn unrhyw ffordd arall).

(6) Rhaid i daliadau o dan y Tariff Cyffuriau gael eu gwneud—

(a) gan y Bwrdd Iechyd Lleol sy'n gyfrifol am wneud y taliad; a

are required by virtue of these Regulations or the 2006 Act to publish, or which they do publish, together with those determinations,

in the publication known as the Drug Tariff published by the Welsh Ministers in such format as they think fit.

(2) Determinations under section 88 of the 2006 Act by the Welsh Ministers—

(a) may be made by reference to scales, indices or formulae of any kind, and where a determination falls to be made by reference to any such scale, index or formula, the determination may provide that the relevant price calculation is to be made by reference to the scale, index or formula which is—

(i) in the form current at the time of the determination, and

(ii) in any subsequent form taking effect after that time; and

(b) may take effect in relation to remuneration in respect of a period beginning on or after the date specified in the determination, which may be the date of the determination or an earlier or later date, but it may be an earlier date only if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates.

(3) Where a determination included in the Drug Tariff does not specify a date as mentioned in paragraph (2)(b), it will have effect in relation to remuneration in respect of the period beginning on the date on which the change to the Drug Tariff is published in accordance with paragraph (4).

(4) Amendments that may be made to the Drug Tariff at such intervals as the Welsh Ministers think fit must be published by the Welsh Ministers in a consolidated version of the Drug Tariff that has the amendments included in it.

(5) The consultation that the Welsh Ministers undertake under section 89(1) of the 2006 Act (section 88: supplementary) prior to the inclusion of or a change to the price of a drug or appliance which is to form part of a calculation of remuneration must be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way).

(6) Payments under the Drug Tariff must be made—

(a) by the Local Health Board responsible for making the payment; and

- (b) yn unol â threfniadau ar gyfer hawlio a gwneud taliadau, sydd i'w pennu yn y Tariff Cyffuriau, ond yn ddarostyngedig, fel y bo'n briodol, i unrhyw dddyniad o gydnabyddiaeth ariannol fferylllydd GIG neu contractwr cyfarpar GIG y caniateir, neu y mae'n rhaid, ei wneud o dan y Rheoliadau hyn neu unrhyw Reoliadau eraill o dan Ddeddf 2006.

Byrddau Iechyd Lleol fel awdurdodau penderfynu

42.—(1) Caiff Gweinidogion Cymru ddatgan yn y Tariff Cyffuriau mai'r awdurdod penderfynu ar gyfer ffi, lwfans neu gydnabyddiaeth ariannol arall benodol fydd Bwrdd Iechyd Lleol y fferylllydd GIG neu contractwr cyfarpar GIG y mae'r gydnabyddiaeth ariannol yn berthynol iddo.

(2) Pan fo Bwrdd Iechyd Lleol wedi ei awdurdodi i fod yn awdurdod penderfynu, rhaid i'r Bwrdd Iechyd Lleol—

- (a) ymgynghori â'r Pwyllgor Fferyllol Lleol perthnasol cyn gwneud unrhyw benderfyniad;
- (b) cyhoeddi'r penderfyniad ym mha bynnag fodd a ystyria'n briodol ar gyfer ei ddwyn i sylw'r personau sy'n gynwysedig yn ei restrau fferyllol; ac
- (c) rhoi'r penderfyniad ar gael ar gyfer ei arolygu.

(3) Rhaid i benderfyniad a wneir gan Fwrdd Iechyd Lleol gynnwys y trefniadau ar gyfer hawlio a thalu'r gydnabyddiaeth ariannol ac—

- (a) rhaid i hawliadau gan fferyllwyr GIG a chontractwyr cyfarpar GIG gael eu gwneud yn unol â'r trefniadau; a
- (b) rhaid gwneud taliadau o'r gydnabyddiaeth ariannol yn unol â'r trefniadau yn ddarostyngedig, fel y bo'n briodol, i unrhyw dddyniad o'r gydnabyddiaeth ariannol y caniateir, neu y mae'n rhaid, ei wneud o dan y Rheoliadau hyn neu unrhyw Reoliadau eraill o dan Ddeddf 2006.

Gordaliadau

43.—(1) Os yw Bwrdd Iechyd Lleol o'r farn bod taliad wedi ei wneud i fferylllydd GIG neu contractwr cyfarpar GIG fel a grybwyllir yn rheoliad 41(6) neu 42(3) mewn amgylchiadau pan nad oedd y taliad yn ddyledus, rhaid i'r Bwrdd Iechyd Lleol dynnu sylw'r fferylllydd GIG neu'r contractwr cyfarpar GIG at y gordaliad ac—

- (a) os yw'r fferylllydd GIG neu'r contractwr cyfarpar GIG yn cydnabod bod gordaliad wedi ei wneud; neu
- (b) pan nad yw'r fferylllydd GIG neu'r contractwr cyfarpar GIG yn cydnabod bod gordaliad wedi ei wneud, ond y Bwrdd Iechyd Lleol neu, yn dilyn apel, Gweinidogion Cymru o dan reoliad 9(1)(c) o Reoliadau'r Gwasanaeth Iechyd

- (b) in accordance with arrangements for claiming and making payments which are to be set out in the Drug Tariff but subject, as appropriate, to any deduction that may or must be made from the remuneration of an NHS pharmacist or NHS appliance contractor under these Regulations or any other Regulations under the 2006 Act.

Local Health Boards as determining authorities

42.—(1) The Welsh Ministers may state in the Drug Tariff that the determining authority for a particular fee, allowance or other remuneration is to be the Local Health Board of the NHS pharmacist or NHS appliance contractor to whom the remuneration relates.

(2) Where a Local Health Board is authorised to be a determining authority, the Local Health Board must—

- (a) consult the relevant Local Pharmaceutical Committee before making any determination;
- (b) publish the determination in such manner as it thinks appropriate for bringing it to the attention of persons included in its pharmaceutical lists; and
- (c) make the determination available for inspection.

(3) A determination made by a Local Health Board must include the arrangements for claiming and paying the remuneration and—

- (a) claims by NHS pharmacists and NHS appliance contractors must be made in accordance with the arrangements; and
- (b) payments of remuneration must be made in accordance with the arrangements subject, as appropriate, to any deduction that may or must be made from the remuneration under these Regulations or any other Regulations under the 2006 Act.

Overpayments

43.—(1) Where a Local Health Board considers that a payment has been made to an NHS pharmacist or NHS appliance contractor as mentioned in regulation 41(6) or 42(3) in circumstances where it was not due, the Local Health Board must draw the overpayment to the attention of the NHS pharmacist or NHS appliance contractor and—

- (a) where the overpayment is admitted by him or her; or
- (b) where the NHS pharmacist or NHS appliance contractor does not admit there has been an overpayment but the Local Health Board or, on appeal, the Welsh Ministers under regulation 9(1)(c) of the National Health Service (Service

Gwladol (Pwyllgorau Gwasanaethu a'r Tribiwnlys) 1992, yn penderfynu bod gordaliad wedi ei wneud,

bydd y swm a ordalwyd yn adenilladwy, naill ai drwy ddidynnu o gydnabyddiaeth ariannol y fferyllydd GIG neu'r contractwr cyfarpar GIG neu rywfodd arall.

(2) Ni fydd adennill gordaliad o dan y rheoliad hwn yn lleihau dim ar effaith ymchwiliad i doriad honedig o'r telerau gwasanaethu.

Cynllun gwobrwyo

44.—(1) Bydd fferyllydd GIG y cyflwynir archeb iddo o dan baragraff 5 o Atodlen 4, neu contractwr cyfarpar GIG y cyflwynir archeb iddo o dan baragraff 4 o Atodlen 5, yn gymwys i hawlio taliad gan y Bwrdd Iechyd Lleol, yn unol â'r Tariff Cyffuriau—

- (a) os, yn unol â pharagraff 9 o Atodlen 4 neu baragraff 8 o Atodlen 5, gwrthododd y fferyllydd GIG neu'r contractwr cyfarpar GIG ddarparu'r cyffuriau neu'r meddyginiaethau neu'r cyfarpar rhestredig a archebwyd, ac os hysbysodd y Bwrdd Iechyd Lleol o'r weithred honno cyn gynted ag y bo'n ymarferol; neu
- (b) os cyflenwyd y cyffuriau neu'r cyfarpar rhestredig gan y fferyllydd GIG neu'r contractwr cyfarpar GIG, er bod rheswm ganddo ar y pryd, neu ei fod wedi cael rheswm yn ddiweddarach, dros gredu nad oedd yr archeb yn archeb ddilys ar gyfer y person a enwid ar y ffurflen bresgripsiwn neu ffurflen bresgripsiwn amlroddadwy, a'r fferyllydd GIG neu'r contractwr cyfarpar GIG wedi hysbysu'r Bwrdd Iechyd Lleol o'r gred honno cyn gynted ag y bo'n ymarferol,

ac yn y naill achos neu'r llall, y fferyllydd GIG neu'r contractwr cyfarpar GIG wedi anfon yr archeb y cyfeirir ati yn y paragraff hwn at y Bwrdd Iechyd Lleol a'r Bwrdd Iechyd Lleol wedi profi nad oedd yr archeb y cyfeirir ati yn y paragraff hwn yn archeb ddilys ar gyfer y person a enwid ar y ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy.

(2) Rhaid i'r Bwrdd Iechyd Lleol, mewn perthynas ag unrhyw hawliad o dan baragraff (1) wneud pa bynnag daliad sy'n ddyledus i'r fferyllydd GIG neu'r contractwr cyfarpar GIG, gan gyfrifo'r taliad yn y modd a bennir yn y Tariff Cyffuriau.

(3) Yn y paragraff hwn, mae "archeb" ("order") yn cynnwys archeb honedig

Taliadau i fferyllwyr GIG a chontractwyr cyfarpar GIG sydd wedi eu hatal dros dro

45.—(1) Rhaid i'r Bwrdd Iechyd Lleol wneud taliadau i unrhyw fferyllydd GIG neu contractwr

Committees and Tribunal) Regulations 1992, decides that there has been an overpayment,

the amount overpaid will be recoverable either by deduction from the remuneration of the NHS pharmacist or NHS appliance contractor or in some other manner.

(2) Recovery of an overpayment under this regulation is without prejudice to the investigation of an alleged breach of the terms of service.

Reward scheme

44.—(1) An NHS pharmacist who is presented with an order under paragraph 5 of Schedule 4 or an NHS appliance contractor who is presented with an order under paragraph 4 of Schedule 5 will be eligible to claim a payment from the Local Health Board, in accordance with the Drug Tariff, if—

- (a) in accordance with paragraph 9 of Schedule 4 or paragraph 8 of Schedule 5 the NHS pharmacist or the NHS appliance contractor refused to provide the drugs or medicines or listed appliances ordered and informed the Local Health Board of this action as soon as practicable; or
- (b) the NHS pharmacist or the NHS appliance contractor provided the drugs or listed appliances but had reason to believe at that time or subsequently came to have reason to believe that the order was not a genuine order for the person named on the prescription form or repeatable prescription form and informed the Local Health Board of this belief as soon as practicable,

and in either case the NHS pharmacist or the NHS appliance contractor has sent the order referred to in this paragraph to the Local Health Board and the Local Health Board has established that the order referred to in this paragraph was not a genuine order for the person named on the prescription form or repeatable prescription.

(2) The Local Health Board must in respect of any claim under paragraph (1) make such payment as is due to the NHS pharmacist or the NHS appliance contractor calculated in the manner specified in the Drug Tariff.

(3) In this paragraph "order" ("archeb") includes a purported order.

Payments to suspended NHS pharmacists and NHS appliance contractors

45.—(1) The Local Health Board must make payments to any NHS pharmacist or NHS appliance

cyfarpar GIG sydd wedi ei atal dros dro o restr fferyllol, yn unol â phenderfyniad Gweinidogion Cymru mewn perthynas â thaliadau o'r fath.

(2) Rhaid i Weinidogion Cymru wneud y penderfyniad yn unol â pharagraff (3), ar ôl ymgynghori â'r cyfryw sefydliadau a gydnabyddir ganddynt fel rhai sy'n cynrychioli fferyllwyr GIG a chontractwyr cyfarpar GIG y gwnaed trefniadau presennol gyda hwy ar gyfer darparu gwasanaethau fferyllol, a rhaid i Weinidogion Cymru gyhoeddi'r penderfyniad yn y Tariff Cyffuriau.

(3) Caiff Gweinidogion Cymru ddiwygio'r penderfyniad o bryd i'w gilydd ar ôl ymgynghori â'r sefydliadau y cyfeirir atynt ym mharagraff (2), a rhaid cyhoeddi unrhyw ddiwygiadau hefyd, ynghyd â'r Tariff Cyffuriau.

(4) Caiff penderfyniad Gweinidogion Cymru gynnwys darpariaeth na chaiff taliadau yn unol â'r penderfyniad fynd dros ben swm penodedig yn ystod unrhyw gyfnod penodedig.

contractor who is suspended from a pharmaceutical list, in accordance with the Welsh Ministers' determination in relation to such payments.

(2) The Welsh Ministers must make the determination in accordance with paragraph (3) after consultation with such organisations as they may recognise as representing NHS pharmacists and NHS appliance contractors with whom arrangements for the provision of pharmaceutical services exist, and must publish it in the Drug Tariff.

(3) The determination may be amended from time to time by the Welsh Ministers after consultation with the organisations referred to in paragraph (2), and any amendments must also be published with the Drug Tariff.

(4) The Welsh Ministers' determination may include provision that payments in accordance with the determination are not to exceed a specified amount in any specified period.

RHAN 8

Amrywiol

Bwrdd Iechyd Lleol cartref

46.—(1) Caiff ceisydd sy'n gorff corfforaethol ac y mae'n ofynnol iddo ddarparu'r wybodaeth a bennir yn Rhan 2 o Atodlen 1 wneud cais i Fwrdd Iechyd Lleol am i'r Bwrdd Iechyd Lleol hwnnw weithredu fel ei Fwrdd Iechyd Lleol cartref.

(2) Pan fo Bwrdd Iechyd Lleol wedi cytuno â chais a wnaed o dan baragraff (1), caiff ceisydd y mae'n ofynnol iddo ddarparu, fel rhan o gais, yr wybodaeth a bennir yn Rhan 2 o Atodlen 1, ddarparu'r wybodaeth honno i'w Fwrdd Iechyd Lleol cartref yn hytrach, a hysbysu'r Bwrdd Iechyd Lleol y gwneir y cais iddo fod yr wybodaeth honno eisoes ym meddiant y Bwrdd Iechyd Lleol cartref.

(3) Rhaid i'r Bwrdd Iechyd Lleol cartref drosglwyddo'r wybodaeth a gaiff gan geisydd o dan y rheoliad hwn ymlaen i unrhyw Fwrdd Iechyd Lleol y mae'r ceisydd yn gwneud cais iddo yn ddiweddarach, a rhaid iddo wneud hynny o fewn 30 diwrnod ar ôl cael cais am yr wybodaeth honno gan y Bwrdd Iechyd Lleol arall.

(4) Rhaid i'r ceisydd naill ai—

(a) cadarnhau wrth y Bwrdd Iechyd Lleol y gwneir y cais iddo fod yr wybodaeth yn gyfredol; neu

(b) diweddarau'r wybodaeth drwy ei hanfon at y Bwrdd Iechyd Lleol cartref.

PART 8

Miscellaneous

Home Local Health Board

46.—(1) An applicant which is a body corporate that is required to provide the information specified in Part 2 of Schedule 1 may make a request to a Local Health Board for that Local Health Board to act as its home Local Health Board.

(2) Where a Local Health Board has agreed to a request made under paragraph (1), an applicant required to provide as part of an application the information specified in Part 2 of Schedule 1 may instead provide that information to its home Local Health Board and inform the Local Health Board to which the application is made that the home Local Health Board already has the information.

(3) The home Local Health Board must pass the information it has received from an applicant under this regulation to any Local Health Board to which the applicant makes a subsequent application and must do so within 30 days of a request for that information from the other Local Health Board.

(4) The applicant must either—

(a) confirm to the Local Health Board to which the application is made that the information is up to date; or

(b) update the information by sending it to the home Local Health Board.

Cyhoeddi manylion

47.—(1) Rhaid i Fwrdd Iechyd Lleol gyhoeddi'r canlynol, ym mha bynnag ffurf y gwêl yn briodol, a rhoi copïau ohonynt ar gael yn ei swyddfeydd ar gyfer eu harchwilio—

- (a) ei restr fferyllol;
- (b) ei restr meddygon fferyllol;
- (c) map sy'n amlinellu ffiniau unrhyw ardaloedd rheoledig a lleoliadau neilltuedig sydd wedi eu penderfynu;
- (d) manylion am unrhyw benderfyniadau a wnaed gan y Bwrdd Iechyd Lleol o dan y Rheoliadau hyn yn ystod y tair blynedd blaenorol;
- (e) y telerau gwasanaethu ar gyfer fferyllwyr GIG yn Atodlen 4;
- (f) y telerau gwasanaethu ar gyfer contractwyr cyfarpar GIG yn Atodlen 5;
- (g) y telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanaethau fferyllol yn Atodlen 6; ac
- (h) y Tariff Cyffuriau.

(2) Caiff Bwrdd Iechyd Lleol—

- (a) rhoi pa bynnag rai o'r dogfennau y cyfeirir atynt ym mharagraff (1) ar gael i'w harchwilio ym mha bynnag fannau eraill yn yr ardal y sefydlwyd y Bwrdd ar ei chyfer, fel y bo'n ymddangos i'r Bwrdd yn gyfleus er gwybodaeth i bawb sydd â diddordeb; neu
- (b) cyhoeddi, mewn mannau o'r fath yn yr ardal y sefydlwyd y Bwrdd ar ei chyfer, hysbysiad o'r lleoedd a'r amseroedd y gellir gweld copïau o'r cyfryw dogfennau.

(3) Rhaid i Fwrdd Iechyd Lleol anfon copi o'i restrau fferyllol a'i restr meddygon fferyllol at Weinidogion Cymru, y Pwyllgor Meddygol Lleol, y Pwyllgor Fferyllol Lleol, a rhaid iddo, o fewn 14 diwrnod ar ôl unrhyw newid yn y rhestrau hynny, eu hysbysu o'r newidiadau hynny, mewn ysgrifen.

Arfer yr hawl i ddewis mewn achosion penodol

48. Caniateir gwneud cais i fferylllydd GIG neu contractwr cyfarpar GIG am wasanaethu fferyllol—

- (a) ar ran unrhyw blentyn gan y naill riant neu'r llall neu, yn absenoldeb y ddau riant, gan y gwarcheidwad neu berson arall sydd â gofal o'r plentyn;
- (b) ar ran unrhyw berson o dan 18 mlwydd oed sydd—
 - (i) yng ngofal awdurdod y'i traddodwyd i'w ofal o dan ddarpariaethau Deddf Plant 1989(1), gan berson a awdurdodwyd yn briodol gan yr awdurdod hwnnw, neu

(1) 1989 p.41.

Publication of particulars

47.—(1) A Local Health Board must publish in such manner as it sees fit and make available for inspection at its offices copies of—

- (a) its pharmaceutical list;
- (b) its dispensing doctor list;
- (c) a map delineating the boundaries of any controlled localities and reserved locations that have been determined;
- (d) details of any determinations made by the Local Health Board under these Regulations in the previous three years;
- (e) the terms of service for NHS pharmacists in Schedule 4;
- (f) the terms of service for NHS appliance contractors in Schedule 5;
- (g) the terms of service for doctors providing pharmaceutical services in Schedule 6; and
- (h) the Drug Tariff.

(2) A Local Health Board may—

- (a) make such of the documents referred to in paragraph (1) available for inspection at such other places in the area for which it is established as appear to it convenient for informing all persons interested; or
- (b) publish at such places in the area for which it is established a notice of the places and times at which copies of such documents may be seen.

(3) A Local Health Board must send a copy of its pharmaceutical lists and of its dispensing doctor list to the Welsh Ministers, the Local Medical Committee and the Local Pharmaceutical Committee, and must, within 14 days of any alteration to those lists, inform them in writing of those alterations.

Exercise of choice in certain cases

48. An application to an NHS pharmacist or an NHS appliance contractor for pharmaceutical services may be made—

- (a) on behalf of any child by either parent, or in the absence of both parents, the guardian or other person who has the care of the child;
- (b) on behalf of any person under 18 years of age who is—
 - (i) in the care of an authority to whose care he or she has been committed under the provisions of the Children Act 1989(1), by a person duly authorised by that authority, or

(1) 1989 c.41.

- (ii) yng ngofal sefydliad gwirfoddol, gan y sefydliad hwnnw neu berson a awdurdodwyd yn briodol gan y sefydliad;
- (c) ar ran unrhyw oedolyn nad oes ganddo'r gallu i wneud cais o'r fath neu i awdurdodi gwneud cais o'r fath ar ei ran, gan berthynas, neu brif ofalwr i'r person hwnnw; neu
- (d) ar ran unrhyw berson arall, gan unrhyw berson a awdurdodwyd yn briodol.

Darpariaethau trosiannol

49.—(1) Rhaid i unrhyw gais a wneir o dan Reoliadau 1992, sydd wedi ei gael gan Fwrdd Iechyd Lleol ar neu cyn 9 Mai 2013, gael ei benderfynu yn unol â darpariaethau Rheoliadau 1992 hyd at benderfynu'r cais hwnnw'n derfynol.

(2) Rhaid i unrhyw benderfyniad arfaethedig gan Fwrdd Iechyd Lleol o dan reoliad 9(2) o Reoliadau 1992 (penderfynu ar ardal reoledig), sydd wedi ei hysbysu yn unol â rheoliad 9(5) o'r Rheoliadau hynny ar neu cyn 9 Mai 2013, gael ei benderfynu yn unol â darpariaethau Rheoliadau 1992, hyd ei benderfynu'n derfynol.

(3) Rhaid i unrhyw apêl o dan Reoliadau 1992—

- (a) a ddaw i law Gweinidogion Cymru ar neu cyn 9 Mai 2013; neu
- (b) a wneir wedi i'r Rheoliadau hyn ddod i rym, mewn perthynas â chais a benderfynwyd yn unol â pharagraff (1), neu benderfyniad a wnaed o dan baragraff (2),

gael ei phenderfynu yn unol â darpariaethau Rheoliadau 1992.

(4) Os bydd hawl gan berson, cyn 10 Mai 2013 neu o ganlyniad i baragraff (1) neu (3), ar sail penderfyniad (boed yn benderfyniad gan Fwrdd Iechyd Lleol neu'n dilyn apêl)—

- (a) i gael ei gynnwys mewn rhestr fferyllol neu restr meddygon fferyllol, ond nad yw wedi ei gynnwys yn y rhestr honno; neu
- (b) i gael rhestru mangre mewn perthynas â'i gofnod mewn rhestr fferyllol neu restr meddygon fferyllol, ac nad yw'r fangre wedi ei rhestru mewn perthynas â'r person,

bydd y trefniadau ar gyfer rhestru'r person hwnnw neu'r fangre honno, a'r amgylchiadau pan â'r penderfyniad hwnnw'n ddi-rym, fel y'u pennir yn Rheoliadau 1992.

(5) Ar gyfer penderfyniad a wneir o dan baragraff (2), y weithdrefn y mae'n rhaid ei dilyn yw honno yn rheoliad 9(8) a (9) o Reoliadau 1992.

(6) Os rhoddwyd cydsyniad rhagarweiniol o dan reoliad 14 o Reoliadau 1992 (cydsyniad rhagarweiniol ar gyfer cynnwys person mewn rhestr fferyllol) (boed hynny yn unol â pharagraff (1) neu (3) ai peidio) ac nad

- (ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them;
- (c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer of that person; or
- (d) on behalf of any other person by any duly authorised person.

Transitional provisions

49.—(1) Any application under the 1992 Regulations that has been received by a Local Health Board on or before 9 May 2013 must be determined in accordance with the provisions of the 1992 Regulations until that application is finally determined.

(2) Any proposed determination by a Local Health Board under regulation 9(2) of the 1992 Regulations (determination of controlled locality) that has been notified in accordance with regulation 9(5) of those Regulations on or before 9 May 2013, must be determined in accordance with the provisions of the 1992 Regulations until finally determined.

(3) Any appeal under the 1992 Regulations that is—

- (a) received by the Welsh Ministers on or before 9 May 2013; or
- (b) made after the coming into force of these Regulations in respect of an application determined in accordance with paragraph (1) or a determination made under paragraph (2),

must be determined in accordance with the provisions of the 1992 Regulations.

(4) Where, before 10 May 2013 or as a consequence of paragraph (1) or (3) a person is entitled on the basis of a decision (whether by a Local Health Board or on appeal)—

- (a) to be included in a pharmaceutical list or a dispensing doctor list but has not been included in that list; or
- (b) to have listed in relation to their entry in a pharmaceutical list or dispensing doctor list premises that have not been listed in relation to them,

the arrangements for the listing of that person or those premises, and the circumstances in which that decision lapses, are as set out in the 1992 Regulations.

(5) In respect of a determination made under paragraph (2), the procedure that must be followed is that in regulation 9(8) and (9) of the 1992 Regulations.

(6) Where preliminary consent was granted under regulation 14 of the 1992 Regulations (preliminary consent to be included in a pharmaceutical list) (whether or not pursuant to paragraph (1) or (3)) and

oedd cais wedi ei wneud o dan reoliad 15 o Reoliadau 1992 (effaith cydsyniad rhagarweiniol) cyn y dyddiad y daeth y Rheoliadau hyn i rym, bydd rheoliad 12 (ceisiadau am gydsyniad rhagarweiniol ac effaith cydsyniad rhagarweiniol) yn gymwys, fel pe bai'r cydsyniad rhagarweiniol wedi ei roi o dan y rheoliad hwnnw.

(7) Pan fo paragraff (6) yn gymwys, mae rheoliad 14(5) o Reoliadau 1992 yn cymryd lle rheoliad 12(5).

(8) Os bydd penderfyniad o dan reoliad 9 o Reoliadau 1992 heb ei benderfynu'n derfynol cyn i'r Rheoliadau hyn ddod i rym ("penderfyniad yn yr arfaeth"), rhaid i Fwrdd Iechyd Lleol ohirio ystyried unrhyw gais a gyflwynir iddo o dan Rannau 4 neu 5 o'r Rheoliadau hyn os gallai penderfyniad sydd yn yr arfaeth effeithio ar y cais hwnnw, hyd nes bo'r penderfyniad sydd yn yr arfaeth wedi ei benderfynu'n derfynol.

(9) At ddibenion y rheoliad hwn, rhaid peidio â thrin cais neu benderfyniad fel pe bai wedi ei benderfynu'n derfynol cyn diwedd y cyfnod a ganiateir ar gyfer dwyn apêl yn erbyn y cais neu'r penderfyniad hwnnw, neu hyd nes penderfynir unrhyw apêl o'r fath, pa un bynnag yw'r diweddaraf.

Mân ddiwygiadau, diwygiadau canlyniadol a dirymiadau

50.—(1) Mae'r Rheoliadau a restrir yn Atodlen 7 wedi eu diwygio fel a bennir yn yr Atodlen.

(2) Mae'r Rheoliadau neu'r rhannau ohonynt a restrir yn Atodlen 8 wedi eu dirymu.

no application had been made under regulation 15 of the 1992 Regulations (effect of preliminary consent) before the date of the coming into force of these Regulations, regulation 12 (applications for preliminary consent and effect of preliminary consent) will apply as if the preliminary consent had been granted under that regulation.

(7) Where paragraph (6) applies, regulation 14(5) of the 1992 Regulations is substituted for regulation 12(5).

(8) If a determination under regulation 9 of the 1992 Regulations has not been finally determined before the coming into force of these Regulations ("an outstanding determination") a Local Health Board must defer consideration of any application submitted to it under Parts 4 or 5 of these Regulations if the application could be affected by an outstanding determination until such time as the outstanding determination is finally determined.

(9) For the purposes of this regulation, an application or a determination is not to be treated as finally determined until the end of the period for bringing an appeal against that application or determination or until the determination of any such appeal, whichever is later.

Minor and consequential amendments and revocations

50.—(1) The Regulations listed in Schedule 7 are amended as set out in the Schedule.

(2) The Regulations or parts of them listed in Schedule 8 are revoked.

Mark Drakeford

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol,
un o Weinidogion Cymru

17 Ebrill 2013

Minister for Health and Social Services, one of the
Welsh Ministers

17 April 2013

Patterson, Liz
05/26/2020 17:09:13

ATODLEN 1

Rheoliadau 8, 12, 17, 23, 26 a 27

Gwybodaeth sydd i'w chynnwys mewn ceisiadau am gael darparu gwasanaethau fferyllol

RHAN 1

Ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol

Gwybodaeth sy'n ofynnol gan bob ceisydd

Manylion am y cais

1. Enw'r Bwrdd Iechyd Lleol y gwneir y cais iddo.
2. Y math o gydsyniad y gwnaed cais amdano (llawn neu ragarweiniol).
3. Y math o gais (er enghraifft: cynnwys o'r newydd; adleoliad bach o fewn ardal Bwrdd Iechyd Lleol; adleoliad bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos; adleoli dros dro; newid perchnogaeth).

Manylion am y ceisydd

4. Enw a chyfeiriad y ceisydd.
5. Os yw'r ceisydd yn unigolyn neu'n bartneriaeth sy'n cynnal busnes fferyllfa fanwerthu, rhif cofrestru'r ceisydd neu rif cofrestru pob un o'r partneriaid yng nghofrestr y Cyngor Fferyllol Cyffredinol.
6. Os yw'r ceisydd yn gorff corfforaethol sy'n cynnal busnes fferyllfa fanwerthu, enw a rhif cofrestru uwch arolygydd y ceisydd yng nghofrestr y Cyngor Fferyllol Cyffredinol.

Manylion am y fangre a'r oriau agor

7. Cyfeiriad y fangre y mae'r ceisydd yn gwneud cais i ddarparu gwasanaethau fferyllol ohoni; neu leoliad y fangre y mae'r ceisydd yn bwriadu darparu gwasanaethau fferyllol ohoni os yw'r cais ar gyfer cydsyniad rhagarweiniol.
8. Pa un a yw'r fangre ym meddiant y ceisydd ar hyn o bryd, neu, er enghraifft, a yw'r fangre yn cael ei hadeiladu neu'n destun negodi.
9. Ar ba ddiwrnodau y bydd y fferyllfa ar agor ar gyfer darparu gwasanaethau fferyllol, a'r oriau agor ar y diwrnodau hynny.

Y gwasanaethau fferyllol sydd i'w darparu

10. Cadarnhad y bydd yr holl wasanaethau hanfodol yn cael eu darparu.

SCHEDULE 1

Regulations 8, 12, 17, 23, 26 and 27

Information to be included in applications to provide pharmaceutical services

PART 1

Application for inclusion in or for amendment to a pharmaceutical list

Information required from all applicants

Details of the application

1. Name of the Local Health Board to which the application is made.
2. Type of consent applied for (full or preliminary).
3. Type of application (for example: new inclusion; minor relocation within a Local Health Board's area; minor relocation between neighbouring Local Health Board areas; temporary relocation; change of ownership).

Details of the applicant

4. Name and address of applicant.
5. If the applicant is an individual or a partnership carrying on a retail pharmacy business, the applicant's or each partner's registration number in the General Pharmaceutical Council register.
6. If the applicant is a body corporate carrying on a retail pharmacy business, the name and registration number of applicant's superintendent in the General Pharmaceutical Council register.

Details of the premises and opening hours

7. The address of the premises from which the applicant applies to provide pharmaceutical services; or the location of the premises from which the applicant intends to provide pharmaceutical services if the application is for preliminary consent.
8. Whether the applicant is currently in possession of the premises or whether, for example, the premises are under construction or negotiation.
9. The days on which the pharmacy will be open for the provision of pharmaceutical services and the opening hours on those days.

Pharmaceutical services to be provided

10. Confirmation that all essential services will be provided.

11. Manylion am y gwasanaethau cyfeiriedig y mae'r ceisydd yn gwneud cais am gael eu darparu.

12. Os yw'r cais ar gyfer darparu gwasanaethau o ddisgrifiad gwahanol i'r rhai a ddarperir ar hyn o bryd o'r fangre restredig, manylion am y gwasanaethau hynny.

Gwybodaeth mewn perthynas â'r prawf angenrheidiol neu hwylus

13. Pan fo'r prawf angenrheidiol neu hwylus yn rheoliad 9 yn gymwys ar gyfer penderfynu cais, rhaid i'r ceisydd—

- (a) darparu disgrifiad ysgrifenedig o'r gymdogaeth arfaethedig;
- (b) darparu map sy'n dangos ffiniau'r gymdogaeth arfaethedig; ac
- (c) datgan y rhesymau pam y mae'r ceisydd o'r farn bod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau, yn y gymdogaeth, ddarpariaeth ddigonol, gan bersonau sydd wedi eu cynnwys mewn rhestr fferyllol o'r gwasanaethau a bennir yn y cais, neu rai o'r gwasanaethau hynny.

Gwybodaeth mewn perthynas â'r prawf niweidio

14. Pan fo'r prawf niweidio yn rheoliad 9 yn gymwys ar gyfer penderfynu cais, rhaid i'r ceisydd ddatgan y rhesymau pam y mae o'r farn na fydd caniatáu'r cais yn niweidio darpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau gweinyddu neu wasanaethau fferyllol yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn y cais.

Gwybodaeth mewn perthynas â cheisiadau sy'n ymwneud ag adleoliadau

15. Pan fo'r ceisydd yn gwneud cais adleoli (pa un ai o fewn ardal Bwrdd Iechyd Lleol o dan reoliad 13, rhwng ardaloedd Byrddau Iechyd Lleol cyfagos o dan reoliad 14, neu dros dro o dan reoliad 15), rhaid i'r ceisydd ddarparu manylion am yr adleoliad arfaethedig, gan gynnwys cyfeiriad mangre restredig bresennol y ceisydd.

16. Pan fo'r cais yn ymwneud ag adleoliad bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos o dan reoliad 14, rhaid i'r ceisydd ddatgan—

- (a) enw'r Bwrdd Iechyd Lleol y lleolir y fangre bresennol ynddo;
- (b) bod y ceisydd yn cydsynio â thynnu ei enw oddi ar y rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol y lleolir y fangre bresennol yn ei ardal, ac mewn perthynas â'r fangre restredig bresennol honno, gydag effaith o'r dyddiad y bydd y ddarpariaeth o wasanaethau fferyllol o'r fangre newydd yn cychwyn.

11. Details of directed services that the applicant applies to provide.

12. If the application is to provide services of a different description to those currently provided at the listed premises, details of those services.

Information relating to the necessary or expedient test

13. Where the necessary or expedient test in regulation 9 applies to the determination of an application the applicant must—

- (a) provide a written description of the proposed neighbourhood;
- (b) provide a map showing the boundaries of the proposed neighbourhood; and
- (c) state the reasons why the applicant considers granting the application is necessary or expedient to secure in the neighbourhood the adequate provision, by persons included in a pharmaceutical list, of the services or some of the services specified in the application.

Information relating to the prejudice test

14. Where the prejudice test in regulation 9 applies to the determination of an application, the applicant must state the reasons why he or she considers that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

Information relating to applications involving relocations

15. Where the applicant applies to relocate (whether within the Local Health Board's area under regulation 13, between neighbouring Local Health Board areas under regulation 14 or on a temporary basis under regulation 15) the applicant must provide details of the proposed relocation including the address of the applicant's existing listed premises.

16. Where the application involves a minor relocation between neighbouring Local Health Board areas under regulation 14 the applicant must state—

- (a) the name of the Local Health Board where the existing premises are located;
- (b) that the applicant consents to the removal of his or her name from the pharmaceutical list maintained by the Local Health Board in whose area the existing premises are located and in respect of those existing listed premises with effect from the date on which the provision of pharmaceutical services from the new premises will commence.

17. Rhaid i'r ceisydd ddarparu manylion fel a ganlyn—

- (a) pa un a yw lleoliad y fangre newydd yn llai hygyrch i raddau sylweddol, ar gyfer y cleifion sy'n gyfarwydd â chael mynediad i wasanaethau fferyllol yn y fangre bresennol;
- (b) pa un a ddarperir yr un gwasanaethau fferyllol yn y fangre newydd, ag a ddarperir yn y fangre restredig; ac
- (c) pa un a fydd y ddarpariaeth o wasanaethau fferyllol yn parhau'n ddi-dor, ynteu a fydd toriad, a'r rhesymau am unrhyw doriad.

18. Os yw'r cais yn gais am adleoliad dros dro, rhaid i'r ceisydd ddatgan yr amgylchiadau sy'n gwneud adleoli dros dro yn ofynnol.

Gwybodaeth mewn perthynas â cheisiadau sy'n ymwneud â newid perchnogaeth

19. Enw'r person sydd wedi ei gynnwys yn y rhestr fferyllol ac, ar hyn o bryd, yn darparu gwasanaethau fferyllol o'r fangre.

20. Rhaid i'r ceisydd ddarparu manylion fel a ganlyn—

- (a) pa un a barheir i ddarparu'r un gwasanaethau fferyllol o'r fangre; a
- (b) pa un a barheir i ddarparu'r gwasanaethau fferyllol yn ddi-dor, ynteu a fydd toriad, a'r rhesymau am unrhyw doriad.

Ymrwymiad y ceisydd

21. Rhaid i'r ceisydd roi ymrwymiad y bydd y ceisydd, os caniateir y cais, yn darparu'r gwasanaethau yn y fangre y caniateir y cais mewn perthynas â hi, yn unol â'r telerau gwasanaethu.

17. The applicant must provide details of whether—

- (a) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is significantly less accessible;
- (b) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises; and
- (c) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

18. If the application is for a temporary relocation, the applicant must state the circumstances that require a temporary relocation.

Information relating to applications involving a change of ownership

19. Name of the person included in the pharmaceutical list currently providing pharmaceutical services from the premises.

20. The applicant must provide details of whether—

- (a) the same pharmaceutical services will continue to be provided from the premises; and
- (b) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

Applicant's undertaking

21. The applicant must give an undertaking that if the application is granted the applicant will provide the services at the premises in respect of which the application is granted in accordance with the terms of service.

RHAN 2

Gwybodaeth ac ymrwymadau ar gyfer
ceisiadau am gynnwys person mewn rhestr
fferyllol

Manylion am y ceisydd

22.—(1) Rhaid i geisydd (ac eithrio ceisydd sy'n gorff corfforaethol) ddarparu'r wybodaeth ganlynol—

- (a) enw llawn;
- (b) rhyw;
- (c) dyddiad geni;
- (d) cyfeiriad a rhif teleffon;
- (e) datganiad bod y ceisydd yn fferylllydd

PART 2

Information and undertakings for
applications for inclusion in a pharmaceutical
list

Applicant's details

22.—(1) An applicant (other than an applicant which is a body corporate) must provide the following information—

- (a) full name;
- (b) gender;
- (c) date of birth;
- (d) address and telephone number;
- (e) a declaration that he or she is a registered

cofrestredig; ac

- (f) rhif cofrestru proffesiynol a'r dyddiad y'i cofrestrwyd gyntaf yn y gofrestr.

(2) Rhaid i geisydd sy'n gorff corfforaethol ddarparu'r wybodaeth ganlynol—

- (a) enw llawn;
- (b) rhif cofrestru cwmni;
- (c) swyddfa gofrestredig a rhif teleffon y swyddfa honno;
- (d) datganiad bod y ceisydd yn berson sy'n cynnal busnes fferyllfa fanwerthu yn gyfreithlon yn unol ag adran 69 o Ddeddf Meddyginiaethau 1968;
- (e) rhif cofrestru yn y Gofrestr o Fangreodd a gynhelir gan y Cyngor Fferylliaeth Cyffredinol;
- (f) manylion am unrhyw restr berthnasol y tynnwyd y ceisydd oddi arni, neu y'i tynnwyd yn ddigwyddiadol oddi arni, neu y gwrthodwyd ei dderbyn arni, neu y'i cynhwyswyd yn amodol ynddi ar sail addasrwydd, ynghyd ag esboniad o'r rhesymau am hynny.

Ymchwiliadau, achosion llys a chollfarnau

23. Rhaid i geisydd gyflenwi gwybodaeth ysgrifenedig ynghylch a yw'r ceisydd, neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd—

- (a) wedi ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) wedi ei rwymo yn dilyn collfarn droseddol yn y Deyrnas Unedig;
- (c) wedi derbyn rhybuddiad gan yr heddlu yn y Deyrnas Unedig;
- (d) mewn achos diannod yn yr Alban ynglŷn â throsedd, wedi bod yn destun gorchymyn i'w ryddhau'n ddiamod (heb fynd ymlaen at gollfarn);
- (e) wedi derbyn cynnig amodol o dan adran 302 o Ddeddf Gweithdrefn Droseddol (Yr Alban) 1995 (cosb benodedig: cynnig amodol gan y procuradur ffisgal) neu wedi cytuno i dalu cosb o dan adran 115A o Ddeddf Gweinyddu Nawdd Cymdeithasol 1992 (cosb fel dewis amgen yn lle erlyn);
- (f) wedi ei gollfarnu yn rhywle arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr, neu'n ddarostyngedig i gosb a fyddai'n cyfateb i rwymo neu rybuddiad;
- (g) ar hyn o bryd yn destun unrhyw achos a allai arwain at gollfarn o'r fath, ac nad hysbyswyd y Bwrdd Iechyd Lleol yn ei gylch eto;

pharmacist; and

- (f) professional registration number and date of first registration in the register.

(2) An applicant which is a body corporate must provide the following information—

- (a) full name;
- (b) company registration number;
- (c) registered office and telephone number relating to that office;
- (d) a declaration that it is a person who is or who will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968;
- (e) registration number in the Register of Premises maintained by the General Pharmaceutical Council;
- (f) details of any relevant list from which it has been removed or contingently removed, or to which it has been refused admission or in which it has been conditionally included, on fitness grounds, with an explanation as to why.

Investigations, proceedings and convictions

23. An applicant must supply in writing information as to whether he or she, or where the applicant is a body corporate, any of its directors or its superintendent—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been bound over following a criminal conviction in the United Kingdom;
- (c) has accepted a police caution in the United Kingdom;
- (d) has in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 (penalty as alternative to prosecution);
- (f) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales, or is subject to a penalty which would be the equivalent of being bound over or cautioned;
- (g) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board;

- (h) wedi bod yn destun unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall, gyda chanlyniad a oedd yn anffafriol;
- (i) ar hyn o bryd yn destun unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;
- (j) ar hyn o bryd, neu wedi bod gyda chanlyniad anffafriol, yn destun unrhyw ymchwiliad i'w ymddygiad proffesiynol mewn perthynas ag unrhyw gyflogaeth bresennol neu flaenorol;
- (k) yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, a allai arwain at ei dynnu oddi ar unrhyw restr berthnasol;
- (l) ar hyn o bryd, neu wedi bod gyda chanlyniad anffafriol, yn destun unrhyw ymchwiliad gan Awdurdod Gwasanaethau Busnes y GIG(1) mewn perthynas â thwyll;
- (m) wedi ei dynnu neu ei dynnu yn ddigwyddiadol oddi ar, neu ei gynnwys yn amodol ar, unrhyw restr berthnasol a gedwir gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, neu a yw wedi ei atal, ar hyn o bryd neu yn y gorffennol, oddi ar restr o'r fath ar sail addasrwydd ac os ydyw, y rhesymau am hynny ac enw'r Bwrdd Iechyd Lleol neu'r corff cyfatebol hwnnw; neu
- (n) ar hyn o bryd, neu wedi bod erioed, yn destun anghymhwysiad cenedlaethol,

ac os felly, rhaid i'r ceisydd roi manylion, gan gynnwys y dyddiadau yn fras, neu os cynhaliwyd neu os cynhelir unrhyw ymchwiliad neu achos cyfreithiol, natur yr ymchwiliad neu'r achos hwnnw ac unrhyw ganlyniad.

24. Os yw'r ceisydd, (ac os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd), neu os bu, yn ystod y chwe mis blaenorol, neu os oedd ar adeg y digwyddiadau cychwynnol, yn gyfarwyddwr neu'n uwcharolygydd corff corfforaethol, rhaid i'r ceisydd, yn ychwanegol, ddarparu gwybodaeth mewn ysgrifen i'r Bwrdd Iechyd Lleol ynghylch a yw'r corff corfforaethol—

- (a) wedi ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) wedi ei gollfarnu yn rhywle arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr;
- (c) ar hyn o bryd yn destun unrhyw achos a allai arwain at gollfarn o'r fath, ac nad hysbyswyd y Bwrdd Iechyd Lleol yn ei gylch eto;

- (h) has been subject to any investigation into his or her professional conduct by any licensing, regulatory or other body, where the outcome was adverse;
- (i) is currently subject to any investigation into his or her professional conduct by any licensing, regulatory or other body;
- (j) is or has been where the outcome was adverse, the subject of any investigation into his professional conduct in respect of any current or previous employment;
- (k) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to his removal from any relevant list;
- (l) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority(1) in relation to fraud;
- (m) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list kept by another Local Health Board or equivalent body, or has been or is currently suspended from such a list, on fitness grounds, and if so, why and the name of that Local Health Board or equivalent body; or
- (n) is, or ever has been, subject to a national disqualification,

and, if so, the applicant must give details including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings, and any outcome.

24. If the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is, has in the preceding six months been, or was at the time of the originating events, a director or superintendent of a body corporate, he or she must in addition supply information in writing to the Local Health Board as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board;

(1) Sefydlwyd gan Orchymyn Awdurdod Gwasanaethau Busnes y GIG (Awdurdod Gwasanaethau Busnes y GIG) (Sefydlu a Chyfansoddiad) 2005 (O.S. 2005/2414).

(1) Established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005 (S.I. 2005/2414).

- (d) wedi bod yn destun unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall, gyda chanlyniad a oedd yn anffafriol;
- (e) ar hyn o bryd yn destun unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;
- (f) yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, a allai arwain at ei dynnu oddi ar unrhyw restr berthnasol;
- (g) ar hyn o bryd, neu wedi bod gyda chanlyniad anffafriol, yn destun unrhyw ymchwiliad gan Awdurdod Gwasanaethau Busnes y GIG mewn perthynas â thwyll;
- (h) wedi ei dynnu neu ei dynnu yn ddigwyddiadol oddi ar, neu ei gynnwys yn amodol ar, unrhyw restr berthnasol neu a wrthodwyd ei gynnwys, neu a yw wedi ei atal, ar hyn o bryd neu yn y gorffennol, oddi ar restr o'r fath ar sail addasrwydd; neu
- (i) ar hyn o bryd, neu wedi bod erioed, yn destun anghymhwysiad cenedlaethol,

ac os felly, rhaid i'r ceisydd roi enw a chyfeiriad swyddfa gofrestredig y corff corfforaethol a manylion, gan gynnwys y dyddiadau yn fras, neu os cynhaliwyd neu os cynhelir unrhyw ymchwiliad neu achos cyfreithiol, natur yr ymchwiliad neu'r achos hwnnw, ac unrhyw ganlyniad.

Cymwysterau fferyllol, canolwyr etc.

25. Os yw'r ceisydd, (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) yn fferylllydd cofrestredig, rhaid i'r ceisydd gyflenwi manylion o'i gymwysterau fferyllol (gan gynnwys lle y'u cafwyd) a manylion cronolegol am ei brofiad proffesiynol (gan gynnwys dyddiadau cychwyn a gorffen pob penodiad), ynghyd ag esboniad o unrhyw fylchau rhwng y penodiadau a pham y'i diswyddwyd o unrhyw swydd.

26. Os yw'r ceisydd, (neu os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd) yn fferylllydd cofrestredig, rhaid i'r ceisydd gyflenwi enwau a chyfeiriadau dau ganolwr sy'n fodlon darparu geiradaon mewn perthynas â dwy swydd ddiweddar (caniateir cynnwys unrhyw swydd gyfredol) fel fferylllydd, a barhaodd am gyfnod o dri mis o leiaf heb doriad sylweddol, neu, os nad yw hynny'n bosibl, eglurhad llawn a chanolwyr amgen.

27. Os yw'r ceisydd yn gorff corfforaethol, rhaid cyflenwi enw a chyfeiriad pob cyfarwyddwr ac uwcharolygydd y corff corfforaethol.

28. Rhaid i'r ceisydd gyflenwi enw unrhyw Fwrdd

- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from any relevant list;
- (g) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority in relation to fraud;
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list, or has been or is currently suspended from such a list, on fitness grounds; or
- (i) is or ever has been, subject to a national disqualification,

and if so, the applicant must give the name and address of the registered office of the body corporate and details, including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings and any outcome.

Pharmaceutical qualifications, referees etc.

25. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply details of his or her pharmaceutical qualifications (including where obtained) and chronological details of his or her professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why he or she was dismissed from any post.

26. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply names and addresses of two referees who are willing to provide references in respect of two recent posts (which may include any current post) as a pharmacist which lasted at least three months without a significant break, or where this is not possible, a full explanation and alternative referees.

27. Where the applicant is a body corporate, the name and address of each director and superintendent of the body corporate must be supplied.

28. The applicant must supply the name of any Local

Iechyd Lleol (neu gorff cyfatebol) y cynhwysir y ceisydd ac, os yw'r ceisydd yn gorff corfforaethol, unrhyw gyfarwyddwr neu uwcharolygydd y ceisydd, yn ei restr fferyllol, a'r manylion am unrhyw geisiadau sydd yn yr arfaeth (gan gynnwys ceisiadau gohiriedig) am gynnwys ceisydd mewn unrhyw restr fferyllol Bwrdd Iechyd Lleol (neu gorff cyfatebol), neu am gydsyniad rhagarweiniol ar gyfer cynnwys ceisydd mewn unrhyw restr o'r fath, ynghyd ag enw'r Bwrdd Iechyd Lleol (neu'r corff) dan sylw.

29. Os yw'r ceisydd yn gyfarwyddwr neu'n uwcharolygydd corff corfforaethol sydd wedi ei gynnwys mewn unrhyw restr berthnasol, neu sydd â chais yn yr arfaeth (gan gynnwys cais gohiriedig) am gael ei gynnwys mewn unrhyw restr berthnasol, rhaid i'r ceisydd gyflenwi enw'r Bwrdd Iechyd Lleol neu'r corff cyfatebol dan sylw, ac enw a swyddfa gofrestredig unrhyw gorff corfforaethol o'r fath.

Ymrwymadau

30.—(1) Rhaid i'r ceisydd roi ymrwymiad ysgrifenedig i hysbysu'r Bwrdd Iechyd Lleol o fewn 7 diwrnod os digwydd unrhyw newidiadau perthnasol yn yr wybodaeth a ddarparwyd yn y cais—

- (a) hyd nes y cofnodir enw'r ceisydd yn y rhestr fferyllol;
- (b) hyd nes bo'r cyfnod wedi dod i ben, a bennir yn rheoliad 17(2) ar gyfer hysbysu'r Bwrdd Iechyd Lleol gan y ceisydd, y bydd y ceisydd yn cychwyn darparu'r gwasanaethau y gwnaed y cais mewn perthynas â hwy;
- (c) hyd nes bo'r ceisydd yn tynnu'r cais yn ôl; neu
- (d) yn achos ceisydd y rhoddwyd cydsyniad rhagarweiniol iddo o dan reoliad 12, hyd nes bo'r cyfnod pan fo'r cydsyniad rhagarweiniol yn cael effaith o dan reoliad 12(5) wedi dod i ben.

(2) Rhaid i'r ceisydd roi ymrwymiad ysgrifenedig y bydd yn hysbysu'r Bwrdd Iechyd Lleol os caiff ei gynnwys, neu os bydd yn gwneud cais am gael ei gynnwys mewn rhestr berthnasol.

RHAN 3

Hysbysiad o'r dyddiad cychwyn

Gwybodaeth sydd i'w darparu cyn cychwyn y ddarpariaeth o wasanaethau fferyllol

31. Rhaid i'r ceisydd ddarparu'r wybodaeth ganlynol—

- (a) enw'r ceisydd;
- (b) dyddiad caniatáu'r cais;

Health Board (or equivalent body) in whose pharmaceutical list the applicant, and where the applicant is a body corporate, any director or superintendent of the applicant, is included, and particulars of any outstanding applications (including deferred applications) for inclusion in, or preliminary consent to be included in, any pharmaceutical list of a Local Health Board (or equivalent body) with the name of the Local Health Board (or body) in question.

29. If the applicant is the director or superintendent of a body corporate that is included in any relevant list, or which has an outstanding application (including a deferred application) for inclusion in any relevant list, the applicant must supply the name of the Local Health Board or equivalent body in question, and the name and registered office of any such body corporate.

Undertakings

30.—(1) The applicant must give a written undertaking to notify the Local Health Board within 7 days of any material changes to the information provided in the application until—

- (a) his or her name is entered on the pharmaceutical list;
- (b) the period specified in regulation 17(2) for him or her to notify the Local Health Board that he or she will commence the provision of the services in respect of which the application was made has expired;
- (c) he or she withdraws the application; or
- (d) in the case of an applicant who has been granted preliminary consent under regulation 12, the period during which the preliminary consent has effect under regulation 12(5) has expired.

(2) The applicant must give a written undertaking to notify the Local Health Board if he or she is included or applies to be included in a relevant list.

PART 3

Notification of commencement date

Information to be provided prior to the commencement of the provision of pharmaceutical services

31. The applicant must provide the following information—

- (a) applicant's name;
- (b) date application granted;

- (c) y fangre a bennir yn y cais ac y darperir y gwasanaethau fferyllol ohoni;
- (d) cadarnhad bod y fangre wedi ei chofrestru gyda'r Cyngor Fferyllol Cyffredinol (gan gynnwys y rhif cyfeirnod);
- (e) manylion am y gwasanaethau sydd i'w darparu;
- (f) y dyddiad y bydd darparu gwasanaethau fferyllol yn cychwyn;
- (g) enw a rhif cofrestru'r fferylllydd cofrestredig sydd â chyfrifoldeb yn y fangre; ac
- (h) ymrwymiad y bydd y ceisydd, yn unol â'r cais a ganiatawyd gan y Bwrdd Iechyd Lleol, yn darparu'r gwasanaethau fferyllol o'r fangre yn unol â'r telerau gwasanaethu.

- (c) premises specified in the application from which the pharmaceutical services will be provided;
- (d) confirmation that premises are registered with the General Pharmaceutical Council (including reference number);
- (e) details of the services to be provided;
- (f) date on which the provision of pharmaceutical services will commence;
- (g) name and registration number of the registered pharmacist in charge at the premises; and
- (h) undertaking that the applicant will, in accordance with the application granted by the Local Health Board, provide the pharmaceutical services from the premises in accordance with the terms of service.

RHAN 4

Ceisiadau am gydsyniad amlinellol a chymeradwyaeth mangre

Manylion am y cais

32. Enw'r Bwrdd Iechyd Lleol y gwneir y cais iddo.

33. Y math o gais (cydsyniad amlinellol, cymeradwyaeth mangre neu'r ddau).

Manylion am y ceisydd

34. Enw a chyfeiriad y ceisydd.

35. Rhif cyfeirnod y Cyngor Meddygol Cyffredinol, y cynhwysir y ceisydd odano yn y Rhestr o Ymarferwyr Meddygol Cofrestredig a gynhelir gan y Cyngor Meddygol Cyffredinol.

Cais am gydsyniad amlinellol

36. Disgrifiad a map o'r ardal y mae'r ceisydd yn dymuno darparu gwasanaethau fferyllol ynddi.

37. Cyfeiriad unrhyw fferyllfa o fewn yr ardal a ddisgrifir ac a amlinellir o dan baragraff 36.

Cais am gymeradwyaeth mangre

38. Cyfeiriad y fangre practis y mae'r ceisydd yn gwneud cais i ddarparu gwasanaethau fferyllol ohoni, ac a yw'r fangre practis honno yn fangre restredig neu yn perthynas ag ardal wahanol.

39. Y pellter rhwng y fangre honno a'r fferyllfa agosaf (a chyfeiriad y fferyllfa honno).

40. Pa un o'r cais ar gyfer cymeradwyaeth

PART 4

Applications for outline consent and premises approval

Details of the application

32. Name of the Local Health Board to which the application is made.

33. Type of application (outline consent, premises approval or both).

Details of the applicant

34. Name and address of the applicant.

35. The General Medical Council reference number under which the applicant is included in the List of Registered Medical Practitioners maintained by the General Medical Council.

Application for outline consent

36. Description and map of the area within which the applicant wishes to provide pharmaceutical services.

37. Address of any pharmacy within the area described and delineated under paragraph 36.

Application for premises approval

38. The address of the practice premises from which the applicant applies to provide pharmaceutical services and whether those practice premises are listed premises in relation to a different area.

39. Distance between those premises and the nearest pharmacy (and the address of that pharmacy).

40. Whether the application is for premises approval,

mangre i fangre ychwanegol ynteu ar gyfer adleoli i fangre newydd (ac os yr olaf, y pellter o'r fangre newydd i'r fangre y mae gan y ceisydd gymeradwyaeth mangre mewn perthynas â hi ar hyn o bryd).

41. Pa un a yw'r cais yn codi oherwydd bod cyfuno practisiau naill ai wedi digwydd neu yn yr arfaeth, ac os felly, enwau'r meddygon neu'r contractwyr sy'n cymryd rhan yn y cyfuno.

42. Os oes cydsyniad amlinellol wedi ei roi eisoes, disgrifiad a map o'r ardal y rhoddwyd y cydsyniad mewn perthynas â hi.

43. Manylion am unrhyw fangre practis meddygol arall y rhoddwyd cymeradwyaeth mangre iddi, neu y gwnaed cais mewn perthynas â hi eisoes, nad yw'r Bwrdd Iechyd Lleol eto wedi ei benderfynu.

Y gwasanaethau fferyllol sydd i'w darparu

44. Y gwasanaethau fferyllol sydd i'w darparu a'r oriau agor a'r diwrnodau pan ddarperir y gwasanaethau hynny.

Y prawf niweidio

45. Y rhesymau pam y mae'r ceisydd o'r farn na fydd caniatáu'r cais yn niweidio darpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau gweinyddu neu wasanaethau fferyllol yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn y cais.

Angenrheidiol neu hwylus

46. Y rhesymau pam y mae'r ceisydd o'r farn bod caniatáu'r cais yn angenrheidiol neu'n hwylus er mwyn sicrhau darpariaeth ddigonol, gan bersonau a gynhwysir mewn rhestr, o'r gwasanaethau a bennir yn y cais, neu rai o'r gwasanaethau hynny, yn yr ardal y gwnaeth y ceisydd gais am gydsyniad amlinellol ynddi.

Ymrwymiad y ceisydd

47. Rhaid i'r ceisydd roi ymrwymiad, os caniateir y cais a phan fydd cydsyniad amlinellol a chymeradwyaeth mangre yn cael effaith, y bydd y ceisydd yn darparu'r gwasanaethau o'r fangre practis y caniateir y cais mewn perthynas â hi, yn unol â'r telerau gwasanaethu.

for additional premises or to relocate to new premises (and if the latter the distance from the new premises to the premises in respect of which the applicant currently has premises approval).

41. Whether the application arises because a practice amalgamation has taken place or will be taking place and, if so, the names of the doctors or contractors participating in the amalgamation.

42. If outline consent has already been granted a description and map of the area in respect of which consent has been granted.

43. Details of any other medical practice premises which have been granted premises approval or in respect of which an application has already been made but not yet determined by the Local Health Board.

Pharmaceutical services to be provided

44. The pharmaceutical services to be provided and the opening hours and days on which those services will be provided.

Prejudice test

45. The reasons why the applicant considers that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

Necessary or expedient

46. The reasons why the applicant considers it is necessary or expedient to grant the application in order to secure in the area in respect of which the applicant has applied for outline consent the adequate provision, by persons included in a list, of the services or some of the services specified in the application.

Applicant's undertaking

47. The applicant must given an undertaking that if the application is granted and outline consent and premises approval is in effect the applicant will provide the services from the practice premises in respect of which the application is granted in accordance with the terms of service.

Patterson, Liz
05/26/2020 17:09:13

ATODLEN 2

Rheoliadau 6, 8 a 24

Gweithdrefnau sydd i'w dilyn gan Fyrddau Iechyd Lleol wrth benderfynu ceisiadau o dan y Rheoliadau

RHAN 1

Materion rhagarweiniol

Egwyddorion cyffredinol

1.—(1) Ac eithrio i'r graddau y mae'r Rheoliadau hyn yn darparu i'r gwrthwyneb, caiff Bwrdd Iechyd Lleol benderfynu cais a gyflwynir iddo ym mha bynnag fodd yr ystyria'n briodol.

(2) Rhaid i Fwrdd Iechyd Lleol ddychwelyd cais a gyflwynir iddo os nad yw'r cais yn cynnwys yr holl wybodaeth y mae'n ofynnol i'r ceisydd ei darparu yn unol ag Atodlen 1.

(3) Caiff Bwrdd Iechyd Lleol, os yw o'r farn bod hynny'n briodol, ystyried dau neu ragor o geisiadau ar y cyd ac mewn perthynas â'i gilydd, ond os yw'r Bwrdd Iechyd Lleol yn bwriadu gwneud hynny rhaid iddo roi hysbysiad ysgrifenedig o'r bwriad hwnnw i'r canlynol—

- (a) pob ceisydd unigol; a
- (b) os yw'r cais yn un y mae'n rhaid rhoi hysbysiad ohono o dan baragraff 8, unrhyw berson arall y mae'n rhaid rhoi hysbysiad o'r cais hwnnw iddo.

(4) Pan fo Bwrdd Iechyd Lleol, yn unol ag is-baragraff (3), yn ystyried dau neu ragor o geisiadau y mae rheoliad 9(2) yn gymwys iddynt ar y cyd ac mewn perthynas â'i gilydd, caiff y Bwrdd Iechyd Lleol wrthod cais (er gwaethaf y ffaith y byddai, pe bai'n penderfynu'r cais fel cais unigol ar ei ben ei hunan, yn ei ganiatáu) os yw nifer y ceisiadau, neu'r amgylchiadau y gwneir y ceisiadau ynddynt yn peri y byddai caniatáu pob un, neu fwy nag un, ohonynt yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau fferyllol neu wasanaethau gweinyddu yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn y cais.

Yr amserlen ar gyfer penderfynu ceisiadau

2. Rhaid i Fwrdd Iechyd Lleol ymdrechu i benderfynu cais cyn gynted ag y bo'n ymarferol ar ôl ei gael.

SCHEDULE 2

Regulations 6, 8 and 24

Procedures to be followed by Local Health Boards to determine applications under the Regulations

PART 1

Preliminary matters

General principles

1.—(1) Except in so far as these Regulations provide to the contrary, a Local Health Board may determine an application submitted to it in such manner as it thinks fit.

(2) A Local Health Board must return an application submitted to it if the application does not contain all of the information that an applicant is required to provide in accordance with Schedule 1.

(3) A Local Health Board may if it thinks fit consider two or more applications together and in relation to each other but where it intends to do so it must give notice of that intention in writing to—

- (a) the respective applicants; and
- (b) where the application is one in respect of which notice must be given under paragraph 8, any other person that must be given notice of that application.

(4) Where in accordance with subparagraph (3) a Local Health Board considers two or more applications to which regulation 9(2) applies together and in relation to each other, it may refuse an application (notwithstanding the fact that it would if determining the application in isolation grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the application are situated.

Timetable for determining applications

2. A Local Health Board must endeavour to determine an application as soon as is practicable after its receipt.

Personau a waherddir rhag cymryd rhan mewn gwneud penderfyniadau ar geisiadau

3.—(1) Ni chaiff unrhyw berson gymryd rhan mewn penderfynu cais os yw—

- (a) yn berson sydd wedi ei gynnwys yn y rhestr fferyllol neu restr meddygon fferyllol a gynhelir gan y Bwrdd Iechyd Lleol neu'n gyflogai person o'r fath;
- (b) neu'n gyfranddaliwr, yn gyfarwyddwr neu'n ysgrifennydd cwmni sy'n cynnal busnes fferyllfa fanwerthu yn ardal y Bwrdd Iechyd Lleol;
- (c) yn ddarparwr gwasanaethau meddygol sylfaenol yn ardal y Bwrdd Iechyd Lleol;
- (d) yn contractwr GMDdA yn ardal y Bwrdd Iechyd Lleol, neu'n swyddog, ymddiriedolwr neu berson arall sy'n ymwneud â rheoli cwmni, cymdeithas neu sefydliad gwirfoddol neu gorff arall sy'n contractwr GMDdA, neu a gyflogir neu a gymerwyd ymlaen gan contractwr GMDdA o'r fath; neu
- (e) yn gyflogedig, neu wedi ei gymryd ymlaen, gan y Bwrdd Iechyd Lleol at y diben o ddarparu gwasanaethau meddygol sylfaenol o fewn practis GMBIL.

(2) Ni chaiff unrhyw berson arall gymryd rhan mewn penderfynu cais os byddai ei gyfranogiad, oherwydd buddiant neu gysylltiad sydd ganddo, neu oherwydd pwysau y gellid ei roi arno, yn peri amheuaeth resymol o bleidgarwch.

RHAN 2

Penderfynu ar ardaloedd rheoledig

Hysbysu ynghylch bwriad i wneud penderfyniad mewn perthynas ag ardaloedd rheoledig

4.—(1) Pan fo Bwrdd Iechyd Lleol, yn rhinwedd rheoliad 6(3) (ardaloedd sy'n ardaloedd rheoledig), yn penderfynu na all ystyried cais gan Bwyllgor Meddygol Lleol neu Bwyllgor Fferyllol Lleol, rhaid i'r Bwrdd Iechyd Lleol beidio â chymryd unrhyw gam mewn perthynas â'r cais hwnnw, ac eithrio hysbysu'r ceisydd o'r ffaith honno ac o hawl y ceisydd i apelio yn erbyn y penderfyniad hwnnw o dan reoliad 7 (apelau).

(2) Ym mhob achos arall, cyn gwneud penderfyniad o dan reoliad 6(2), rhaid i'r Bwrdd Iechyd Lleol roi hysbysiad ysgrifenedig o'i fwriad i wneud penderfyniad i'r canlynol—

- (a) y Pwyllgor Meddygol Lleol yn ei ardal;
- (b) y Pwyllgor Fferyllol Lleol yn ei ardal;
- (c) y Cyngor Iechyd Cymuned ar gyfer yr ardal; a

Persons prohibited from taking part in decision-making on applications

3.—(1) No person is to take part in determining an application if he or she—

- (a) is a person who is included in the pharmaceutical list or dispensing doctor list maintained by the Local Health Board, or is an employee of such a person;
- (b) is a shareholder, director or company secretary of a company which runs a retail pharmacy business in the area of the Local Health Board;
- (c) is a provider of primary medical services in the area of the Local Health Board;
- (d) is an APMS contractor in the area of the Local Health Board, or is an officer, trustee or other person concerned with the management of a company, society or voluntary organisation or other body which is an APMS contractor, or is employed or engaged by such an APMS contractor; or
- (e) is employed or engaged by the Local Health Board for the purposes of providing primary medical services within an LHBMS practice.

(2) No other person is to take part in determining an application if, because of an interest or an association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

PART 2

Determination of controlled localities

Notice of proposed determination in respect of controlled localities

4.—(1) If a Local Health Board decides that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 6(3) (areas that are controlled localities), the Local Health Board must take no action in relation to that application other than to notify the applicant of that fact and of its right of appeal against that decision under regulation 7 (appeals).

(2) In all other cases, before making a determination under regulation 6(2) a Local Health Board must give a written notice of proposed determination to—

- (a) the Local Medical Committee in its area;
- (b) the Local Pharmaceutical Committee in its area;
- (c) the Community Health Council for the area; and

- (d) unrhyw berson sydd wedi ei gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol ac unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot neu unrhyw ddarparwr gwasanaethau meddygol sylfaenol yn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer, y gallai'r penderfyniad effeithio arno ym marn y Bwrdd Iechyd Lleol.

(3) Rhaid i hysbysiad o fwriad i wneud penderfyniad roi gwybod i'r person a hysbysir fod hawl ganddo i gyflwyno sylwadau (neu, os hysbysir Pwyllgor Meddygol Lleol neu Bwyllgor Fferyllol Lleol a wnaeth gais am y penderfyniad, unrhyw sylwadau pellach) mewn ysgrifen ynglŷn â'r penderfyniad arfaethedig, o fewn 30 diwrnod o'r dyddiad yr anfonwyd yr hysbysiad ato.

Gohirio ystyried ceisiadau

5. Pan fo Bwrdd Iechyd Lleol wedi dyroddi hysbysiad o fwriad i wneud penderfyniad, rhaid i'r Bwrdd Iechyd Lleol ohirio'r ystyried unrhyw gais a gyflwynwyd o dan Ran 4 neu Ran 5 o'r Rheoliadau hyn ond nas penderfynwyd gan y Bwrdd, os yw'r cais yn un y gallai'r penderfyniad arfaethedig effeithio arno—

- (a) hyd nes bo'r Bwrdd wedi penderfynu a yw'r ardal yn ardal reoledig neu'n rhan o ardal reoledig ai peidio, a'r cyfnod a ganiateir ar gyfer dwyn apêl yn erbyn y penderfyniad hwnnw wedi dod i ben; neu
- (b) tan y dyddiad y penderfynir unrhyw apêl o'r fath.

Gosod amodau

6. Pan fo Bwrdd Iechyd Lleol yn penderfynu a yw unrhyw ardal benodol, o fewn yr ardal y sefydlwyd y Bwrdd ar ei chyfer, oherwydd ei chymeriad gwledig, yn ardal reoledig neu'n rhan o ardal reoledig ai peidio—

- (a) rhaid i'r Bwrdd Iechyd Lleol ystyried a yw'n debygol yr effeithir yn anffafriol ar y ddarpariaeth o—
 - (i) gwasanaethau meddygol sylfaenol gan ddarparwr gwasanaethau o'r fath (ac eithrio'r Bwrdd ei hunan),
 - (ii) gwasanaethau fferyllol gan fferyllydd GIG neu contractwr cyfarpar GIG,
 - (iii) gwasanaethau fferyllol lleol a ddarperir o dan gynllun peilot, neu
 - (iv) gwasanaethau fferyllol gan feddyg,

o ganlyniad i'r penderfyniad hwnnw; a

- (b) caiff y Bwrdd Iechyd Lleol, os yw o'r farn ei fod yn debygol yr effeithir yn anffafriol ar unrhyw un o'r gwasanaethau hynny, osod amodau i ohirio, am ba bynnag gyfnod yr

- (d) any person included in a pharmaceutical list maintained by the Local Health Board and any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established who, in the opinion of the Local Health Board, may be affected by the determination.

(3) A notice of proposed determination must inform the person notified of their right to make representations (or in the case of a Local Medical Committee or Local Pharmaceutical Committee being notified that applied for the determination any further representations) in writing on the proposed determination within 30 days of the date on which the notice was sent to them.

Deferral of applications

5. Where a Local Health Board has issued a notice of proposed determination it must defer consideration of any application submitted under Part 4 or Part 5 of these Regulations but not determined by it if the application could be affected by the proposed determination until—

- (a) it has determined whether or not the locality is or is part of a controlled locality and the period for bringing an appeal relating to that determination has ended; or
- (b) the date of the determination of any such appeal.

Imposition of conditions

6. Where a Local Health Board determines whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it—

- (a) must consider whether the provision of—
 - (i) primary medical services by a provider of such services (other than itself),
 - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
 - (iii) local pharmaceutical services provided under a pilot scheme, or
 - (iv) pharmaceutical services by a doctor,

is likely to be adversely affected as a consequence of that determination; and

- (b) may, where it is of the opinion that any of those services are likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of

ystyria'n briodol, wneud neu derfynu trefniadau o dan reoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon), neu ddarpariaeth gyfatebol o dan y Rheoliadau GMC ar gyfer darparu gwasanaethau fferyllol neu wasanaethau gweinyddu gan feddyg neu contractwr GMC i gleifion ar y rhestr cleifion berthnasol.

arrangements under regulation 20 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision under the GMS Regulations for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

Hysbysu ynghylch penderfyniadau a gweithredu yn dilyn penderfyniadau

7.—(1) Unwaith y bydd Bwrdd Iechyd Lleol wedi penderfynu'r cwestiwn pa un a yw unrhyw ardal benodol, o fewn yr ardal y sefydlwyd y Bwrdd ar ei chyfer, oherwydd ei chymeriad gwledig, yn ardal reoledig neu'n rhan o ardal reoledig ai peidio, rhaid i'r Bwrdd Iechyd Lleol—

- (a) cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad, roi hysbysiad ysgrifenedig i'r rhai a hysbyswyd o dan baragraff 4(2) i'w hysbysu o'r canlynol—
 - (i) y penderfyniad a'r rhesymau drosto,
 - (ii) unrhyw amodau a osodwyd gan y Bwrdd o dan baragraff 6, a
 - (iii) unrhyw hawliau i apelio o dan Atodlen 3; a
- (b) cyn gynted ag y bo'n ymarferol ar ôl y dyddiad perthnasol—
 - (i) amlinellu ffiniau'r ardal reoledig yn fanwl gywir ar fap, neu dynnu ymaith yr amlinelliad o ffin ardal sydd wedi peidio â bod yn ardal reoledig;
 - (ii) rhoi cyfnod rhesymol o rybudd i feddyg yr effeithir arno ynghylch unrhyw amodau sydd wedi eu gosod o dan baragraff 6 o ganlyniad i'r penderfyniad; a
 - (iii) mynd ymlaen i benderfynu unrhyw geisiadau sydd wedi eu gohirio o dan baragraff 5.

(2) At ddibenion y paragraff hwn, y "dyddiad perthnasol" ("*relevant date*") yw'r diweddaraf o'r canlynol—

- (a) y dyddiad y mae'r cyfnod ar gyfer dwyn apêl mewn perthynas â'r penderfyniad yn dod i ben; neu
- (b) dyddiad penderfynu unrhyw apêl o'r fath.

Notification of determinations and action following determinations

7.—(1) Once a Local Health Board has determined the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it must—

- (a) as soon as practicable after reaching a determination give notice in writing to those notified under paragraph 4(2) informing them of—
 - (i) the determination and the reasons for it,
 - (ii) any conditions that it has imposed under paragraph 6, and
 - (iii) any rights of appeal under Schedule 3; and
- (b) as soon as practicable after the relevant date—
 - (i) delineate precisely on a map the boundaries of the controlled locality or remove the delineated boundary of a locality that has ceased to be a controlled locality;
 - (ii) give a doctor that is affected reasonable notice of any conditions that have been imposed under paragraph 6 as a result of the determination; and
 - (iii) proceed to determine any applications that have been deferred under paragraph 5.

(2) For the purposes of this paragraph, the "relevant date" ("*dyddiad perthnasol*") is the later of—

- (a) the date on which the period for bringing an appeal relating to the determination ends; or
- (b) the date of the determination of any such appeal.

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RHAN 3

Ceisiadau am gynnwys personau mewn rhestrau fferyllol a rhestrau meddygon fferyllol, neu ddiwygio rhestrau o'r fath

Hysbysu ynghylch ceisiadau penodol

8.—(1) Mae'r paragraff hwn yn gymwys i geisiadau am—

- (a) cynnwys person mewn, neu ddiwygio—
 - (i) rhestr fferyllol a wnaed o dan Ran 4 o'r Rheoliadau hyn, ac eithrio ceisiadau o dan reoliad 16 (ceisiadau sy'n ymwneud â newid perchnogaeth); a
 - (ii) rhestr meddygon fferyllol a wnaed o dan Ran 5 o'r Rheoliadau hyn;
- (b) estyn y cyfnod perthnasol o dan reoliad 18; ac
- (c) penderfyniad pellach, pa un a yw mangre neu leoliad perthnasol mewn lleoliad neilltuedig o dan reoliad 11(2) ai peidio.

(2) Pan fo Bwrdd Iechyd Lleol wedi penderfynu na ellir ystyried cais sy'n dod o fewn—

- (a) is-baragraff (1)(a)(i) oherwydd rheoliad 10 (penderfynu ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol: effaith penderfyniadau cynharach); neu
- (b) is-baragraff (1)(a)(ii) oherwydd rheoliad 24(7),

rhaid i'r Bwrdd Iechyd Lleol beidio â chymryd unrhyw gam mewn perthynas â'r cais hwnnw, ac eithrio hysbysu'r ceisydd o'r ffaith honno ac o unrhyw hawl i apelio o dan Atodlen 3.

(3) Ym mhob achos arall, rhaid rhoi hysbysiad ysgrifenedig o'r cais yn unol â pharagraff 9.

(4) Caiff y rhai a hysbyswyd o'r cais, o fewn 30 o'r dyddiad yr anfonwyd yr hysbysiad atynt, gyflwyno sylwadau ysgrifenedig ar y cais i'r Bwrdd Iechyd Lleol y cyflwynwyd y cais iddo,.

Personau a chyrrff sydd i'w hysbysu

9.—(1) Y personau a'r cyrrff y mae'n rhaid i Fwrdd Iechyd Lleol eu hysbysu yw—

- (a) y Pwyllgor Fferyllol Lleol;
- (b) y Pwyllgor Meddygol Lleol;
- (c) unrhyw berson—
 - (i) sydd wedi ei gynnwys mewn rhestr fferyllol a gynhelir ganddo, neu
 - (ii) rhoddwyd iddo gydsyniad rhagarweiniol

PART 3

Applications for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

Notice of certain applications

8.—(1) This paragraph applies to applications for—

- (a) inclusion in or amendment to a—
 - (i) pharmaceutical list made under Part 4 of these Regulations, except for applications under regulation 16 (applications involving a change of ownership); and
 - (ii) dispensing doctor list made under Part 5 of these Regulations;
- (b) an extension of the relevant period under regulation 18; and
- (c) a further determination as to whether premises are or a relevant location is in a reserved location under regulation 11(2).

(2) Where a Local Health Board has determined that an application falling within—

- (a) sub-paragraph (1)(a)(i) cannot be considered because of regulation 10 (determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations); or
- (b) sub-paragraph (1)(a)(ii) cannot be considered because of regulation 24(7),

the Local Health Board must take no action in relation to that application other than to notify the applicant of that fact and of any right of appeal under Schedule 3.

(3) In all other cases, notice in writing of the application must be given in accordance with paragraph 9.

(4) Those notified of an application may within 30 days of the date on which the notification was sent to them, make representations on the application in writing to the Local Health Board to which the application was submitted.

Persons and bodies to be notified

9.—(1) The persons and bodies that must be notified by a Local Health Board are—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;
- (c) any person—
 - (i) included in a pharmaceutical list maintained by it, or
 - (ii) who has been granted preliminary consent

ar gyfer ei gynnwys mewn rhestr fferyllol,

y gallai caniatáu'r cais, ym marn y Bwrdd Iechyd Lleol, effeithio'n sylweddol ar ei fuddiannau;

- (d) unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot yn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer, y gallai caniatáu'r cais, ym marn y Bwrdd Iechyd Lleol, effeithio'n sylweddol ar ei fuddiannau;
- (e) unrhyw Gyngor Iechyd Cymuned sy'n gwasanaethu ardal y Bwrdd Iechyd Lleol;
- (f) unrhyw grŵp cleifion, grŵp defnyddwyr neu grŵp cymunedol yn ardal y Bwrdd Iechyd Lleol sydd â buddiant sylweddol, ym marn y Bwrdd, yn y ddarpariaeth o wasanaethau fferyllol yn yr ardal;
- (g) os yw'r fangre a bennir yn y cais mewn ardal reoledig, unrhyw berson (ac eithrio'r Bwrdd ei hunan) sy'n ddarparwr gwasanaethau meddygol sylfaenol o fewn ardal y Bwrdd Iechyd Lleol, neu sydd wedi ei gynnwys yn y rhestr meddygon fferyllol a gynhelir gan y Bwrdd Iechyd Lleol, ac y gallai caniatáu'r cais, ym marn y Bwrdd Iechyd Lleol, effeithio'n sylweddol ar ei fuddiannau;
- (h) unrhyw Fwrdd Iechyd Lleol neu gorff cyfatebol sydd ag unrhyw ran o'i ardal o fewn dau gilometr o'r fangre, neu o leoliad y fangre, a bennir yn y cais; ac
- (i) yn achos cais a wnaed o dan reoliad 14 (ceisiadau sy'n ymwneud ag adleoliad bach rhwng ardaloedd Byrddau Iechyd Lleol cyfagos) y Bwrdd Iechyd Lleol y mae'r ceisydd yn bwriadu adleoli o'i ardal.

(2) Rhaid i Fwrdd Iechyd Lleol a hysbysir o dan is-baragraff (1)(h)—

- (a) o fewn 14 diwrnod ar ôl cael yr hysbysiad, rhoi hysbysiad ysgrifenedig i'r personau a'r cyrff a bennir yn is-baragraff (1)(a) i (g) sydd o fewn, neu sy'n gwasanaethu, yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer; a
- (b) hysbysu'r Bwrdd Iechyd Lleol a ddarparodd yr hysbysiad o dan is-baragraff (1) ei fod wedi darparu'r hysbysiad sy'n ofynnol gan is-baragraff (2)(a).

(3) Caiiff corff cyfatebol a hysbysir o dan is-baragraff (1)(h) ofyn i'r Bwrdd Iechyd Lleol roi hysbysiad i'r personau hynny, yn yr ardal y sefydlwyd corff cyfatebol ar ei chyfer, y gallai caniatáu'r cais, ym marn y corff cyfatebol, effeithio'n sylweddol ar eu buddiannau, a rhaid i'r Bwrdd Iechyd Lleol gydymffurfio ag unrhyw ofyniad o'r fath.

for inclusion in a pharmaceutical list,

whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;

- (d) any provider of local pharmaceutical services under a pilot scheme in the area for which the Local Health Board is established whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;
- (e) any Community Health Council serving the area of the Local Health Board;
- (f) any patient group, consumer group or community group in the area of the Local Health Board that it considers has a significant interest in the provision of pharmaceutical services in the area;
- (g) where the premises specified in the application are in a controlled locality, any person (except itself) who is a provider of primary medical services within the Local Health Board's area or who is included in the dispensing doctor list maintained by the Local Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;
- (h) any Local Health Board or equivalent body any part of whose area is within two kilometres of the premises or the location of the premises specified in the application; and
- (i) in the case of an application made under regulation 14 (applications involving minor relocation between neighbouring Local Health Board areas), the Local Health Board from whose area the applicant wishes to relocate.

(2) A Local Health Board notified under sub-paragraph (1)(h) must—

- (a) within 14 days of receiving the notification give notice in writing to the persons and bodies specified in sub-paragraph (1)(a) to (g) that are within or that serve the area for which the Local Health Board is established; and
- (b) notify the Local Health Board that provided the notification under sub-paragraph (1) that it has provided the notification required by sub-paragraph (2)(a).

(3) An equivalent body notified under sub-paragraph (1)(h) may request the Local Health Board to give notification to such persons in the area for which the equivalent body is established whose interests might in the opinion of the equivalent body, be significantly affected if the application is granted and the Local Health Board must comply with any such request.

Cynnwys yr hysbysiadau

10. Rhaid i hysbysiad o gais o dan baragraff 8—

- (a) rhoi gwybod i'r person neu'r corff a hysbysir—
 - (i) am ei hawl i wneud sylwadau ar y cais o dan baragraff 8(4);
 - (ii) am yr amgylchiadau pan gaiff Bwrdd Iechyd Lleol ei gwneud yn ofynnol cynnal gwrandawriad llafar o dan baragraff 11; a
 - (iii) os yw'r Bwrdd Iechyd Lleol yn bwriadu ystyried y cais ar y cyd ac mewn perthynas ag unrhyw gais arall, am y bwriad hwnnw;
- (b) darparu copi iddo o'r cais a gyflwynwyd gan y ceisydd, i alluogi'r person neu'r corff a hysbysir i wneud sylwadau gwybodus ynglŷn ag a ddylid caniatáu'r cais ai peidio; ac
- (c) pan fo rheoliad 11(1) yn gymwys i gais o dan baragraff 8(1)(a), rhoi gwybod i'r person neu'r corff a hysbysir y bydd y Bwrdd Iechyd Lleol yn penderfynu pa un a yw'r fangre neu'r lleoliad perthnasol, a bennwyd yn y cais ac sydd mewn ardal reoledig, hefyd mewn lleoliad neilltuedig.

Gwrandawiadau llafar

11.—(1) Yn achos cais sy'n dod o fewn paragraff 8, caiff Bwrdd Iechyd Lleol ei gwneud yn ofynnol cynnal gwrandawriad llafar, os yw o'r farn bod angen clywed sylwadau llafar cyn penderfynu cais o'r fath.

(2) Os yw'r Bwrdd Iechyd Lleol yn penderfynu cynnal gwrandawriad llafar, rhaid iddo—

- (a) rhoi dim llai na 14 diwrnod o rybudd o amser a lleoliad y gwrandawriad i'r canlynol—
 - (i) y ceisydd; a
 - (ii) unrhyw berson sydd wedi gwneud sylwadau ar y cais o dan baragraff 8(4);
- (b) rhoi gwybod i'r ceisydd pwy y rhoddwyd hysbysiad iddynt o'r gwrandawriad; ac
- (c) rhoi gwybod i'r rhai a hysbysir y cânt roi sylwadau ar lafar yn y gwrandawriad, ynglŷn â'r cais.

(3) Caiff unrhyw berson a grybwyllir yn is-baragraff (2), sy'n dymuno rhoi sylwadau ar lafar yn y gwrandawriad, gael ei gynorthwyo i gyflwyno ei sylwadau gan berson arall a chael ei gynrychioli yn y gwrandawriad gan y person arall hwnnw, hyd yn oed pan na all y person a hysbysir o dan is-baragraff (2) fod yn bresennol ei hunan yn y gwrandawriad.

(4) Caiff y Bwrdd Iechyd Lleol benderfynu'r weithdrefn a ddilyniir yn y gwrandawriad.

Content of notifications

10. A notification of an application under paragraph 8 must—

- (a) inform the person or body notified—
 - (i) of their right to make representations on the application under paragraph 8(4);
 - (ii) of the circumstances in which the Local Health Board may require an oral hearing to be held under paragraph 11; and
 - (iii) if the Local Health Board intends to consider the application together with and in relation to any other application, of that intention;
- (b) provide a copy of the application submitted by the applicant to enable the person or body notified to make informed representations with regard to whether or not the application should be granted; and
- (c) where regulation 11(1) applies to an application under paragraph 8(1)(a) inform the person or body notified that the Local Health Board will be determining whether the premises or relevant location specified in the application that are in a controlled locality are also in a reserved location.

Oral hearings

11.—(1) In the case of an application falling within paragraph 8, a Local Health Board may require an oral hearing to be held if it considers it is necessary to hear oral representations before determining such an application.

(2) If the Local Health Board does decide to hold an oral hearing it must—

- (a) give not less than 14 days notice of the time and place of the hearing to—
 - (i) the applicant; and
 - (ii) any person who has made representations on the application under paragraph 8(4);
- (b) advise the applicant who has been given notice of the hearing; and
- (c) advise those notified that they may make oral representations relating to the application at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) A Local Health Board may determine the procedure to be followed at the oral hearing.

(5) Ni fydd y Bwrdd Iechyd Lleol wedi ei rwymo gan unrhyw argymhellion a fydd yn codi o wrandawriad llafar.

Gwybodaeth y mae'n rhaid i Fwrdd Iechyd Lleol roi sylw iddi

12. Wrth benderfynu cais sy'n dod o fewn paragraff 8 rhaid i Fwrdd Iechyd Lleol roi sylw, yn benodol, i'r canlynol—

- (a) unrhyw sylwadau a gaiff y Bwrdd Iechyd Lleol o dan baragraff 8(4);
- (b) unrhyw argymhellion sy'n codi o wrandawriad llafar, os cynhelir un o dan baragraff 11; ac
- (c) unrhyw wybodaeth arall sydd ar gael i'r Bwrdd Iechyd Lleol ac, ym marn y Bwrdd, yn berthnasol i'r ystyriaeth o'r cais.

Gosod amodau

13.—(1) Mae'r is-baragraff hwn yn gymwys pan fo Bwrdd Iechyd Lleol yn penderfynu caniatáu cais sy'n dod o fewn—

- (a) paragraff 8(1)(a)(i) pan fo'r fangre a bennir yn y cais mewn ardal reoledig; neu
- (b) paragraff 8(1)(a)(ii).

(2) Pan fo is-baragraff (1) yn gymwys, rhaid i Fwrdd Iechyd Lleol—

- (a) ystyried a yw'n debygol yr effeithir yn anffafriol ar y ddarpariaeth o—
 - (i) gwasanaethau meddygol sylfaenol gan ddarparwr gwasanaethau o'r fath (ac eithrio'r Bwrdd Iechyd Lleol ei hunan),
 - (ii) gwasanaethau fferyllol gan fferylllydd GIG neu gontractwr cyfarpar GIG,
 - (iii) gwasanaethau fferyllol lleol a ddarperir o dan gynllun peilot, neu
 - (iv) gwasanaethau fferyllol gan feddyg,

o ganlyniad i'w benderfyniad i ganiatáu'r cais; a

- (b) os yw o'r farn ei bod yn debygol yr effeithir yn anffafriol ar y ddarpariaeth o unrhyw un o'r gwasanaethau hynny, caiff osod amodau i ohirio, am ba bynnag gyfnod yr ystyria'n briodol, gwneud neu derfynu trefniadau o dan reoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon) neu ddarpariaeth gyfatebol gan feddyg neu gontractwr GMC o wasanaethau fferyllol neu wasanaethau gweinyddu i gleifion ar y rhestr berthnasol.

(5) A Local Health Board is not bound by any recommendations arising from an oral hearing.

Information to which a Local Health Board must have regard

12. In determining an application falling within paragraph 8 a Local Health Board must have regard, in particular, to—

- (a) any representations received by the Local Health Board under paragraph 8(4);
- (b) any recommendations arising from an oral hearing, if one is held under paragraph 11; and
- (c) any other information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application.

Imposition of conditions

13.—(1) This sub-paragraph applies where a Local Health Board decides to grant an application falling within—

- (a) paragraph 8(1)(a)(i) where the premises specified in the application are in a controlled locality; or
- (b) paragraph 8(1)(a)(ii).

(2) Where sub-paragraph (1) applies, a Local Health Board—

- (a) must consider whether the provision of—
 - (i) primary medical services by a provider of such services (other than itself),
 - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
 - (iii) local pharmaceutical services provided under a pilot scheme; or
 - (iv) pharmaceutical services by a doctor,

is likely to be adversely affected as a consequence of its decision to grant the application; and

- (b) may, where it is of the opinion that the provision of any of those services is likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant list.

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Hysbysu ynghylch penderfyniadau: ceisiadau am gynnwys person mewn rhestr fferyllol neu ddiwygio rhestr fferyllol

14.—(1) Rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad ar gais sy'n dod o fewn paragraff 8(1)(a)(i), roi hysbysiad ysgrifenedig o'i benderfyniad (gan gynnwys y cwestiwn o osod amodau o dan baragraff 13) ac o'r penderfyniad ynghylch lleoliad neilltuedig o dan reoliad 11(1)—

- (a) yn achos cais y mae paragraff 8(2)(a) yn gymwys iddo, i'r ceisydd;
- (b) yn achos pob cais arall sy'n dod o fewn paragraff 8(1)(a)(i)—
 - (i) i'r ceisydd, a
 - (ii) i unrhyw berson a gyflwynodd sylwadau ar y cais i'r Bwrdd Iechyd Lleol yn unol â pharagraff 8(4).

(2) Yn achos cais a benderfynir o dan reoliad 16 (ceisiadau sy'n ymwneud â newid perchnogaeth), rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad roi hysbysiad ysgrifenedig yn unol â pharagraff 9.

(3) Rhaid i hysbysiad o benderfyniad o dan y paragraff hwn gynnwys datganiad o'r rhesymau am y penderfyniad ac o unrhyw hawliau apelio.

Hysbysu ynghylch penderfyniadau: ceisiadau am gynnwys person mewn rhestr meddygon fferyllol neu ddiwygio rhestr meddygon fferyllol

15.—(1) Rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad ar gais sy'n dod o fewn paragraff 8(1)(a)(ii) roi hysbysiad ysgrifenedig o'i benderfyniad (gan gynnwys y cwestiwn o osod amodau o dan baragraff 13)—

- (a) yn achos cais y mae paragraff 8(2)(b) yn gymwys iddo, i'r ceisydd; a
- (b) yn achos pob cais arall sy'n dod o fewn paragraff 8(1)(a)(ii)—
 - (i) i'r ceisydd; a
 - (ii) i unrhyw berson sydd wedi cyflwyno sylwadau ar y cais i'r Bwrdd Iechyd Lleol yn unol â pharagraff 8(4).

(2) Rhaid i hysbysiad o benderfyniad o dan y paragraff hwn gynnwys datganiad o'r rhesymau am y penderfyniad ac o unrhyw hawliau apelio.

Hysbysu ynghylch penderfyniadau: ceisiadau o dan reoliad 18 am estyn y cyfnod perthnasol

16.—(1) Rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad ar gais sy'n dod o fewn paragraff 8(1)(b), roi hysbysiad ysgrifenedig o'i benderfyniad i—

- (a) y ceisydd, a

Notification of decisions: applications for inclusion in or amendment to pharmaceutical lists

14.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(i), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13 and the determination of reserved location under regulation 11(1))—

- (a) in the case of an application to which paragraph 8(2)(a) applies, to the applicant; and
- (b) in the case of all other applications falling within paragraph 8(1)(a)(i) to—
 - (i) the applicant, and
 - (ii) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) In the case of an application which is determined under regulation 16 (applications involving a change of ownership), a Local Health Board must as soon as practicable after reaching a decision give notice in writing in accordance with paragraph 9.

(3) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists

15.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(ii), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13)—

- (a) in the case of an application to which paragraph 8(2)(b) applies, to the applicant; and
- (b) in the case of all other applications falling within paragraph 8(1)(a)(ii) to—
 - (i) the applicant, and
 - (ii) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications under regulation 18 for extension of the relevant period

16.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(b), give notice in writing of its decision to—

- (a) the applicant, and

- (b) unrhyw berson a gyflwynodd sylwadau ar y cais i'r Bwrdd Iechyd Lleol yn unol â pharagraff 8(4).

(2) Rhaid i hysbysiad o benderfyniad o dan y paragraff hwn gynnwys datganiad o'r rhesymau am y penderfyniad ac o unrhyw hawliau apelio.

Hysbysu ynghylch penderfyniadau: ceisiadau o dan reoliad 11(2)

17.—(1) Rhaid i Fwrdd Iechyd Lleol, cyn gynted ag y bo'n ymarferol ar ôl cyrraedd penderfyniad ar gais sy'n dod o fewn paragraff 8(1)(c), roi hysbysiad ysgrifenedig o'i benderfyniad i—

- (a) y ceisydd, a
- (b) unrhyw berson a gyflwynodd sylwadau ar y cais i'r Bwrdd Iechyd Lleol yn unol â pharagraff 8(4).

(2) Rhaid i hysbysiad o benderfyniad o dan y paragraff hwn gynnwys datganiad o'r rhesymau am y penderfyniad ac o unrhyw hawliau apelio.

Gweithredu yn dilyn penderfyniad ynghylch lleoliadau neilltuedig

18.—(1) Ar ôl penderfynu cais sy'n dod o dan reoliad 11(2) neu wneud penderfyniad yn unol â rheoliad 11(1), cyn gynted ag y bo'n ymarferol ar ôl y dyddiad perthnasol rhaid i'r Bwrdd Iechyd Lleol amlinellu, yn fanwl gywir ar fap, ffiniau unrhyw leoliad neilltuedig a benderfynwyd ganddo, neu, yn ôl fel y digwydd, dynnu ymaith yr amlinelliad o ffin unrhyw leoliad sydd wedi peidio â bod yn lleoliad neilltuedig.

(2) At ddibenion y paragraff hwn, y "dyddiad perthnasol" ("*relevant date*") yw'r diweddaraf o'r canlynol—

- (a) y dyddiad y mae'r cyfnod ar gyfer dwyn apêl mewn perthynas â'r penderfyniad yn dod i ben; neu
- (b) dyddiad penderfynu unrhyw apêl o'r fath.

- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications under regulation 11(2)

17.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(c), give notice in writing of its decision to—

- (a) the applicant; and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Action following determination in respect of reserved locations

18.—(1) After determining an application falling under regulation 11(2) or making a determination in accordance with regulation 11(1), as soon as practicable after the relevant date the Local Health Board must delineate precisely on a map the boundaries of any reserved location that it has determined or remove the delineated boundary of a location that has ceased to be a reserved location, as the case may be.

(2) For the purposes of this paragraph, the "relevant date" ("*dyddiad perthnasol*") is the later of—

- (a) the date on which the period for bringing an appeal relating to the determination ends; or
- (b) the date of the determination of any such appeal.

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RHAN 1**PART 1**

Materion rhagarweiniol

Preliminary matters

Egwyddorion cyffredinol**General principles**

1. Ac eithrio i'r graddau y mae'r Rheoliadau hyn yn darparu i'r gwrthwyneb, caiff Gweinidogion Cymru benderfynu apêl a gyflwynir iddynt ym mha bynnag fodd yr ystyriant yn briodol, ac yn benodol, cânt—

1. Except in so far as these Regulations provide to the contrary, the Welsh Ministers may determine an appeal submitted to them in such manner as they think fit and may, in particular—

- (a) ystyried yr holl wybodaeth sydd ar gael iddynt ac, yn eu barn hwy, yn berthnasol i benderfynu'r apêl;
- (b) ystyried dwy neu ragor o apelau ar y cyd ac mewn perthynas â'i gilydd (ond nid oes rhwymedigaeth arnynt i wneud hynny pan fo'r Bwrdd Iechyd Lleol wedi penderfynu dau neu ragor o geisiadau ar y cyd ac mewn perthynas â'i gilydd), ond os ydynt yn bwriadu gwneud hynny, rhaid iddynt roi hysbysiad o'r bwriad hwnnw i bob apelydd ac i'r rhai a hysbysir ynghylch pob apêl yn unol â'r Atodlen hon;
- (c) pan fo Gweinidogion Cymru, yn unol ag is-baragraff (b), yn ystyried dwy neu ragor o apelau y mae rheoliad 9(2) yn gymwys iddynt ar y cyd ac mewn perthynas â'i gilydd, cânt wrthod apêl (er gwaethaf y ffaith y byddent, pe baent yn penderfynu'r apêl fel apêl unigol ar ei phen ei hunan, yn ei chaniatáu) os yw nifer yr apelau, neu'r amgylchiadau y'u gwneir ynddynt, yn peri y byddai caniatáu pob un, neu fwy nag un ohonynt, yn niweidio'r ddarpariaeth briodol o wasanaethau meddygol sylfaenol, gwasanaethau fferyllol neu wasanaethau gweinyddu yn yr ardal reoledig y lleolir ynddi'r fangre a bennir yn yr apêl;
- (d) dychwelyd apêl a gyflwynwyd iddynt at y Bwrdd Iechyd Lleol i'w ailbenderfynu, mewn achosion pan oedd yr wybodaeth y mae'n ofynnol i'r ceisydd ei darparu yn unol ag Atodlen 1 yn anghyflawn;
- (e) gwrthod apêl os ydynt o'r farn bod yr hysbysiad o apêl—
 - (i) yn annilys oherwydd nad yw'n cydymffurfio â gofynion yr Atodlen hon;
 - (ii) yn amddifad o unrhyw sail resymol dros apelio; neu
 - (iii) rywfodd arall yn flinderus neu'n wacsaw.

- (a) consider all information available to them which, in their opinion, is relevant to the determination of an appeal;
- (b) consider two or more appeals together and in relation to each other (but they are not obliged to do so where the Local Health Board has determined two or more applications together and in relation to each other) but where they intend to do so they must give notice of that intention to each appellant and those given notice of each appeal in accordance with this Schedule;
- (c) where in accordance with subparagraph (b) the Welsh Ministers consider two or more appeals to which regulation 9(2) applies together and in relation to each other, they may refuse an appeal (notwithstanding the fact that they would if determining the appeal in isolation grant it) where the number of appeals is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the appeal are situated.
- (d) remit an appeal submitted to them to a Local Health Board for re-determination in cases where the information that the applicant is required to provide in accordance with Schedule 1 was incomplete;
- (e) dismiss an appeal if they are of the opinion that the notice of appeal—
 - (i) is not valid because it does not comply with the requirements of this Schedule;
 - (ii) does not disclose any reasonable grounds of appeal; or
 - (iii) is otherwise vexatious or frivolous.

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Gwrandawiadau llafar

2.—(1) Caiff Gweinidogion Cymru ei gwneud yn ofynnol cynnal gwrandawriad llafar os ydynt o'r farn bod angen clywed sylwadau ar lafar cyn penderfynu apêl a gyflwynwyd iddynt.

(2) Os yw Gweinidogion Cymru yn penderfynu cynnal gwrandawriad llafar, rhaid iddynt—

- (a) penodi un neu ragor o bersonau i glywed yr apêl ac i adrodd wrthynt ar yr apêl;
- (b) rhoi dim llai na 14 diwrnod o rybudd o amser a lleoliad y gwrandawriad i'r apelydd ac i unrhyw berson yr anfonwyd copi o'r hysbysiad o apêl ato o dan baragraff 4 neu 7;
- (c) rhoi gwybod i'r apelydd i bwy y rhoddwyd hysbysiad o'r gwrandawriad; a
- (d) rhoi gwybod i'r rhai a hysbysir y cânt wneud sylwadau ar lafar ynglŷn â'r apêl yn y gwrandawriad.

(3) Caiff unrhyw berson a grybwyllir yn is-baragraff (2), sy'n dymuno rhoi sylwadau ar lafar yn y gwrandawriad, gael ei gynorthwyo i gyflwyno ei sylwadau gan berson arall a chael ei gynrychioli yn y gwrandawriad gan y person arall hwnnw, hyd yn oed pan na all y person a hysbysir o dan is-baragraff (2) fod yn bresennol ei hunan yn y gwrandawriad.

(4) Caiff y person neu'r personau a benodir gan Weinidogion Cymru i glywed yr apêl benderfynu'r weithdrefn a ddilynir yn y gwrandawriad.

(5) Ni fydd Gweinidogion Cymru wedi eu rhwymo gan unrhyw argymhellion a fydd yn codi o'r gwrandawriad llafar.

RHAN 2

Apelau yn erbyn penderfyniadau sy'n pennu ardaloedd rheoledig

Hawl i apelio i Weinidogion Cymru

3.—(1) Pan fo Bwrdd Iechyd Lleol wedi penderfynu, yn rhinwedd rheoliad 6(3) (ardaloedd sy'n ardaloedd rheoledig), na ellir ystyried cais gan Bwyllgor Meddygol Lleol neu Bwyllgor Fferyllol Lleol, caiff y ceisydd gyflwyno hysbysiad o apêl i Weinidogion Cymru yn erbyn y penderfyniad hwnnw.

(2) Pan fo Bwrdd Iechyd Lleol wedi penderfynu, o dan reoliad 6(2), a yw ardal benodol o fewn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer, oherwydd ei chymeriad gwledig, yn ardal reoledig neu rhan o ardal reoledig ai peidio, y personau sydd â hawl i gyflwyno hysbysiad o apêl i Weinidogion Cymru yn erbyn y penderfyniad hwnnw yw—

- (a) y Bwyllgor Meddygol Lleol;

Oral hearings

2.—(1) The Welsh Ministers may require an oral hearing to be held if they consider that it is necessary to hear oral representations before determining an appeal submitted to them.

(2) If the Welsh Ministers decide to hold an oral hearing they must—

- (a) appoint one or more persons to hear and to report to them on the appeal;
- (b) give not less than 14 days notice of the time and place of the hearing to the appellant and to any person sent a copy of the notice of appeal under paragraph 4 or 7;
- (c) advise the appellant who has been given notice of the hearing; and
- (d) advise those notified that they make oral representations relating to the appeal at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) The person or persons appointed by the Welsh Ministers to hear the appeal may determine the procedure to be followed at the hearing.

(5) The Welsh Ministers are not bound by any recommendations arising from an oral hearing.

PART 2

Appeals against decisions determining controlled localities

Right of appeal to the Welsh Ministers

3.—(1) Where a Local Health Board has decided that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 6(3) (areas that are controlled localities), the applicant may submit a notice of appeal against that decision to the Welsh Ministers.

(2) Where a Local Health Board has determined under regulation 6(2) whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality, the persons entitled to submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee;

- (b) y Pwyllgor Fferyllol Lleol; ac
- (c) unrhyw berson sydd wedi ei gynnwys mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol, unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot neu unrhyw ddarparwr gwasanaethau meddygol sylfaenol yn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer ac y rhoddwyd hysbysiad iddo o'r penderfyniad gan y Bwrdd Iechyd Lleol o dan baragraff 7(1) o Atodlen 2.

(3) Pan fo Bwrdd Iechyd Lleol wedi penderfynu y dylai neu na ddylai ohirio gwneud neu derfynu trefniadau, fel a grybwyllir ym mharagraff 6(b) o Atodlen 2, y rhai a gaiff gyflwyno hysbysiad o apêl i Weinidogion Cymru yn erbyn y penderfyniad hwnnw yw—

- (a) y Pwyllgor Meddygol Lleol;
- (b) y Pwyllgor Fferyllol Lleol; ac
- (c) unrhyw berson a gynhwysir mewn rhestr fferyllol a gynhelir gan y Bwrdd Iechyd Lleol, unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot neu unrhyw ddarparwr gwasanaethau meddygol sylfaenol, yn yr ardal y sefydlwyd y Bwrdd Iechyd Lleol ar ei chyfer ac y rhoddwyd hysbysiad o'r penderfyniad iddynt gan y Bwrdd Iechyd Lleol o dan baragraff 7(1) o Atodlen 2.

(4) Mae hysbysiad o apêl yn ddilys os—

- (a) cyflwynir yr hysbysiad gan berson sydd â hawl i apelio o dan is-baragraff (1), (2) neu (3);
- (b) anfonir yr hysbysiad at Weinidogion Cymru o fewn 30 diwrnod o'r dyddiad yr anfonodd y Bwrdd Iechyd Lleol yr hysbysiad o'r penderfyniad yr apelir yn ei erbyn at y person sy'n gwneud yr apêl; ac
- (c) bod yr hysbysiad yn cynnwys datganiad o seiliau'r apêl.

Hysbysu ynghylch apelau

4.—(1) Rhaid i Weinidogion Cymru, ar ôl cael hysbysiad o apêl a gyflwynwyd o dan baragraff 3(1) anfon copi o'r hysbysiad at y Bwrdd Iechyd Lleol.

(2) Rhaid i Weinidogion Cymru, ar ôl cael hysbysiad o apêl a gyflwynwyd o dan baragraff 3(2) neu 3(3) anfon copi o'r hysbysiad at—

- (a) y Bwrdd Iechyd Lleol; a
- (b) y personau hynny y rhoddodd y Bwrdd Iechyd Lleol hysbysiad o'i benderfyniad iddynt o dan baragraff 7(1) o Atodlen 2.

(3) Ar yr un pryd, rhaid i Weinidogion Cymru roi gwybod i'r rhai yr anfonwyd copi o'r hysbysiad o apêl atynt o dan is-baragraffau (1) i (3)—

- (a) y cânt gyflwyno sylwadau ysgrifenedig i Weinidogion Cymru ynglŷn â'r apêl, o fewn 30

- (b) the Local Pharmaceutical Committee; and
- (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 2.

(3) Where a Local Health Board has determined that it should or should not postpone the making or termination of arrangements, as mentioned in paragraph 6(b) of Schedule 2, those that may submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee;
- (b) the Local Pharmaceutical Committee; and
- (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 2.

(4) A notice of appeal is valid if—

- (a) it is submitted by a person with the right of appeal under sub-paragraph (1), (2) or (3);
- (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal; and
- (c) it contains a statement of the grounds of appeal.

Notification of appeals

4.—(1) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(1) send a copy of the notice to the Local Health Board.

(2) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(2) or 3(3) send a copy of the notice to—

- (a) the Local Health Board; and
- (b) those persons to whom the Local Health Board has given notice of its determination under paragraph 7(1) of Schedule 2.

(3) Those sent a copy of the notice of appeal under sub-paragraphs (1) to (3) must, at the same time, be informed by the Welsh Ministers—

- (a) that they may within 30 days of the date on which the notice of appeal was sent to them,

diwrnod o'r dyddiad yr anfonwyd yr hysbysiad o apêl atynt; a

- (b) am yr amgylchiadau pan gaiff Gweinidogion Cymru ei gwneud yn ofynnol cynnal gwrandawriad llafar.

Penderfynu mewn apelau

5.—(1) Rhaid i Weinidogion Cymru, ar ôl cyrraedd penderfyniad mewn apêl a gyflwynwyd o dan baragraff 3, roi hysbysiad ysgrifenedig o'u penderfyniad, ynghyd â'r rhesymau drosto, i'r personau yr anfonwyd copi o'r hysbysiad o apêl atynt o dan baragraff 4.

(2) O ran Gweinidogion Cymru—

- (a) rhaid iddynt, os ydynt yn caniatáu apêl yn erbyn penderfyniad gan Fwrdd Iechyd Lleol na ellid ystyried cais yn rhinwedd rheoliad 6(3), naill ai—
 - (i) penderfynu eu hunain y cwestiwn pa un a yw'r ardal benodol yn ardal reoledig neu'n rhan o ardal reoledig ai peidio, neu
 - (ii) dychwelyd y cwestiwn at y Bwrdd Iechyd Lleol ar gyfer ei benderfynu;
- (b) os oedd y Bwrdd Iechyd Lleol, wrth benderfynu'r cais, wedi ystyried gosod amodau o dan baragraff 6 o Atodlen 2, caiff Gweinidogion Cymru ystyried a ddylent, eu hunain, osod amodau;
- (c) os nad oedd y Bwrdd Iechyd Lleol, wrth benderfynu'r cais, wedi ystyried gosod amodau o dan baragraff 6 o Atodlen 2, caiff Gweinidogion Cymru naill ai—
 - (i) ystyried a ddylent, eu hunain, osod amodau; neu
 - (ii) dychwelyd y cwestiwn at y Bwrdd Iechyd Lleol ar gyfer ei benderfynu;
- (d) os oedd y Bwrdd Iechyd Lleol, wrth benderfynu'r cais, wedi ystyried y cwestiwn a ddylid gohirio gwneud neu ohirio terfynu trefniadau o dan reoliad 20 (neu ddarpariaeth gyfatebol o dan y Rheoliadau GMC) ar gyfer darparu gwasanaethau fferyllol neu wasanaethau gweinyddu i gleifion gan feddyg neu gontractwr GMC, caiff Gweinidogion Cymru eu hunain ohirio gwneud neu ohirio terfynu trefniadau o'r fath am ba bynnag gyfnod a ystyriant yn briodol; neu
- (e) os nad oedd y Bwrdd Iechyd Lleol wedi ystyried y cwestiwn a ddylid gohirio gwneud neu derfynu trefniadau o dan reoliad 20 (neu ddarpariaeth gyfatebol o dan y Rheoliadau GMC) ar gyfer darparu gwasanaethau fferyllol neu wasanaethau gweinyddu i gleifion gan feddyg neu gontractwr GMC, rhaid i Weinidogion Cymru ddychwelyd y cwestiwn at y Bwrdd Iechyd Lleol ar gyfer ei benderfynu.

make representations on the appeal in writing to the Welsh Ministers; and

- (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held.

Decision on appeals

5.—(1) The Welsh Ministers must after reaching a decision on an appeal submitted under paragraph 3 give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 4.

(2) The Welsh Ministers—

- (a) must, where they allow an appeal against a decision by a Local Health Board that an application cannot be considered by virtue of regulation 6(3), either—
 - (i) themselves determine the question of whether or not the particular locality is or is part of a controlled locality, or
 - (ii) remit the question to the Local Health Board for determination;
- (b) may, where the Local Health Board, on determining the application, considered the imposition of conditions under paragraph 6 of Schedule 2, themselves consider whether to impose conditions;
- (c) may, where the Local Health Board, on determining the application, has not considered the imposition of conditions under paragraph 6 of Schedule 2 either—
 - (i) themselves consider whether to impose conditions; or
 - (ii) remit the question to the Local Health Board for determination;
- (d) may, where the Local Health Board, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients, themselves postpone, for such period as they think fit, the making or termination of such arrangements; or
- (e) must, where the Local Health Board, did not consider the question whether to postpone the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients, remit the question to the Local Health Board for determination.

Apelau yn erbyn penderfyniadau ynglŷn â chynnwys personau mewn rhestrau fferyllol a rhestrau meddygon fferyllol neu ddiwygio rhestrau o'r fath

Appeals against decisions for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

Hawl i apelio i Weinidogion Cymru

6.—(1) Pan fo Bwrdd Iechyd Lleol, o dan baragraff 8(2) o Atodlen 2, wedi penderfynu peidio â gweithredu mewn perthynas â chais, caiff y ceisydd gyflwyno hysbysiad o apel i Weinidogion Cymru yn erbyn penderfyniad y Bwrdd Iechyd Lleol.

(2) Yn achos pob cais arall y mae paragraff 8 o Atodlen 2 yn gymwys iddo, y personau sydd â hawl i gyflwyno hysbysiad o apel i Weinidogion Cymru yn erbyn penderfyniad y Bwrdd Iechyd Lleol yw—

- (a) y ceisydd;
- (b) unrhyw rai o'r canlynol a gyflwynodd sylwadau ar y cais i'r Bwrdd Iechyd Lleol o dan baragraff 8(4) o Atodlen 2—
 - (i) unrhyw berson sydd wedi ei gynnwys mewn rhestr fferyllol,
 - (ii) unrhyw berson y rhoddwyd iddo gydsyniad rhagarweiniol ar gyfer ei gynnwys mewn rhestr fferyllol,
 - (iii) unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot, a
 - (iv) os yw'r fangre a bennir yn y cais mewn ardal reoledig, unrhyw berson sy'n ddarparwr gwasanaethau meddygol sylfaenol neu sydd wedi ei gynnwys yn y rhestr meddygon fferyllol.

(3) Yn achos cais a benderfynwyd o dan reoliad 16 (ceisiadau sy'n ymwneud â newid perchnogaeth), y personau sydd â hawl i gyflwyno hysbysiad o apel i Weinidogion Cymru yw—

- (a) y ceisydd; a
- (b) unrhyw rai o'r canlynol, y rhoddwyd iddynt hysbysiad, o dan baragraff 14(2) o Atodlen 2, o'r penderfyniad gan y Bwrdd Iechyd Lleol ar y cais—
 - (i) unrhyw berson sydd wedi ei gynnwys mewn rhestr fferyllol,
 - (ii) unrhyw berson y rhoddwyd iddo gydsyniad rhagarweiniol ar gyfer ei gynnwys mewn rhestr fferyllol,
 - (iii) unrhyw ddarparwr gwasanaethau fferyllol lleol o dan gynllun peilot, a
 - (iv) os yw'r fangre a bennir yn y cais mewn ardal reoledig, unrhyw berson sy'n ddarparwr gwasanaethau meddygol sylfaenol neu sydd wedi ei gynnwys yn y rhestr meddygon fferyllol.

Right of appeal to the Welsh Ministers

6.—(1) Where under paragraph 8(2) of Schedule 2 a Local Health Board has decided to take no action in relation to an application the applicant may submit a notice of appeal against the decision of the Local Health Board to the Welsh Ministers.

(2) In the case of all other applications to which paragraph 8 of Schedule 2 applies the persons entitled to submit a notice of appeal against the decision of the Local Health Board to the Welsh Ministers are—

- (a) the applicant;
- (b) any of the following who made representations on the application to the Local Health Board under paragraph 8(4) of Schedule 2—
 - (i) any person included in a pharmaceutical list,
 - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
 - (iii) any provider of local pharmaceutical services under a pilot scheme, and
 - (iv) where the premises specified in an application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.

(3) In the case of an application determined under regulation 16 (applications involving a change of ownership) the persons entitled to submit a notice of appeal to the Welsh Ministers are—

- (a) the applicant; and
- (b) any of the following who were, under paragraph 14(2) of Schedule 2, given notice of the Local Health Board's decision on the application—
 - (i) any person included in a pharmaceutical list,
 - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
 - (iii) any provider of local pharmaceutical services under a pilot scheme, and
 - (iv) where the premises specified in the application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.

(4) Mae hysbysiad o apêl yn ddilys os—

- (a) cyflwynir yr hysbysiad gan berson sydd â hawl i apelio o dan is-baragraffau (1), (2) neu (3);
- (b) anfonir yr hysbysiad at Weinidogion Cymru o fewn 30 diwrnod o'r dyddiad yr anfonodd y Bwrdd Iechyd Lleol yr hysbysiad o'r penderfyniad yr apelir yn ei erbyn at y person sy'n gwneud yr apêl; ac
- (c) bod yr hysbysiad yn cynnwys datganiad o seiliau'r apêl.

Hysbysu ynghylch apelau

7.—(1) Rhaid i Weinidogion Cymru, ar ôl cael hysbysiad o apêl a gyflwynwyd o dan baragraff 6(1) anfon copi o'r hysbysiad at y Bwrdd Iechyd Lleol.

(2) Rhaid i Weinidogion Cymru, ar ôl cael hysbysiad o apêl a gyflwynwyd o dan baragraff 6(2), anfon copi o'r hysbysiad at—

- (a) y ceisydd, os nad y ceisydd a gyflwynodd yr hysbysiad o apêl;
- (b) y Bwrdd Iechyd Lleol, ac
- (c) y rhai a hysbyswyd o'r cais ac a wnaeth sylwadau arno o dan baragraff 8(4) o Atodlen 2.

(3) Rhaid i Weinidogion Cymru, ar ôl cael hysbysiad o apêl a gyflwynwyd o dan baragraff 6(3) anfon copi o'r hysbysiad at—

- (a) y ceisydd, os nad y ceisydd a gyflwynodd yr hysbysiad o apêl;
- (b) y Bwrdd Iechyd Lleol, ac
- (c) y rhai y rhoddodd y Bwrdd Iechyd Lleol hysbysiad o'i benderfyniad iddynt o dan baragraff 14(2) o Atodlen 2.

(4) Ar yr un pryd, rhaid i Weinidogion Cymru roi gwybod i'r personau yr anfonwyd copi o'r hysbysiad o apêl atynt o dan y paragraff hwn—

- (a) y cânt, o fewn 30 diwrnod o'r dyddiad yr anfonwyd yr hysbysiad o apêl atynt, gyflwyno sylwadau ysgrifenedig i Weinidogion Cymru ynglŷn â'r apêl;
- (b) am yr amgylchiadau pan gaiff Gweinidogion Cymru ei gwneud yn ofynnol cynnal gwrandawriad llafar; ac
- (c) pan fo bwriad gan Weinidogion Cymru i ystyried dwy neu ragor o apelau ar y cyd ac mewn perthynas â'i gilydd, am y bwriad hwnnw.

Penderfynu mewn apelau

8.—(1) Rhaid i Weinidogion Cymru, wrth benderfynu apêl a wnaed o dan baragraff 6, naill ai—

- (a) caniatáu'r apêl; neu

(4) A notice of appeal is valid if—

- (a) it is submitted by a person with the right of appeal under sub-paragraphs (1), (2) or (3);
- (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal; and
- (c) it contains a statement of the grounds of appeal.

Notification of appeals

7.—(1) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 6(1) send a copy of the notice to the Local Health Board.

(2) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 6(2) send a copy of the notice to—

- (a) the applicant, if the applicant has not submitted the notice of appeal;
- (b) the Local Health Board, and
- (c) those notified of and who made representations on the application under paragraph 8(4) of Schedule 2.

(3) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 6(3) send a copy of the notice to—

- (a) the applicant, if the applicant has not submitted the notice of appeal;
- (b) the Local Health Board, and
- (c) those given notification of the Local Health Board's decision under paragraph 14(2) of Schedule 2.

(4) The persons to whom a copy of the notice of appeal is sent under this paragraph must, at the same time, be informed by the Welsh Ministers—

- (a) that they may within 30 days of the date on which the notice of appeal was sent to them, make representations on the appeal in writing to the Welsh Ministers;
- (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held; and
- (c) where the Welsh Ministers intend to consider two or more appeals together and in relation to each other, of that intention.

Decision on appeals

8.—(1) On determining an appeal made under paragraph 6, the Welsh Ministers must either—

- (a) allow the appeal; or

(b) cadarnhau penderfyniad y Bwrdd Iechyd Lleol.

(2) Pan fo Bwrdd Iechyd Lleol, o dan baragraff 8(2) o Atodlen 2, wedi penderfynu peidio â gweithredu mewn perthynas â chais, a Gweinidogion Cymru yn caniatáu apêl y ceisydd yn erbyn y penderfyniad hwnnw, rhaid i Weinidogion Cymru dychwelyd y cais yn ôl at y Bwrdd Iechyd Lleol ar gyfer ei benderfynu gan y Bwrdd Iechyd Lleol.

(3) Mewn achos pan fo'r fangre a bennir mewn cais, sydd yn destun apêl, mewn ardal reoledig—

(a) os oedd y Bwrdd Iechyd Lleol, wrth benderfynu'r cais, wedi ystyried a ddylid gosod amodau o dan baragraff 13 o Atodlen 2 neu reoliad 11(6)(b), caiff Gweinidogion Cymru eu hunain ystyried a ddylent osod amodau i ohirio gwneud neu derfynu trefniadau o'r fath, am ba bynnag gyfnod a ystyriant yn briodol; neu

(b) os nad oedd y Bwrdd Iechyd Lleol, wrth benderfynu'r cais, wedi ystyried a ddylid gosod amodau o dan baragraff 13 o Atodlen 2 neu reoliad 11(6)(b), rhaid i Weinidogion Cymru naill ai—

(i) ystyried a ddylent, eu hunain, osod amodau; neu

(ii) dychwelyd y cwestiwn yn ôl at y Bwrdd Iechyd Lleol ar gyfer ei benderfynu.

(4) Rhaid i Weinidogion Cymru, ar ôl cyrraedd penderfyniad mewn apêl, gan gynnwys gosod amodau o dan is-baragraff (3) roi hysbysiad ysgrifenedig o'u penderfyniad, ynghyd â'r rhesymau drosto, i'r personau hynny yr anfonwyd copi o'r hysbysiad o apêl atynt o dan baragraff 7.

Effaith penderfyniadau gan Weinidogion Cymru

9. At ddibenion y Rheoliadau hyn, mae penderfyniad Gweinidogion Cymru yn dod yn benderfyniad y Bwrdd Iechyd Lleol ar y mater (ond ni fydd apêl bellach i Weinidogion Cymru ar y penderfyniad hwnnw yn bosibl, oni chaiff penderfyniad Gweinidogion Cymru ei wrthdroi gan lys).

(b) confirm the decision of the Local Health Board.

(2) Where under paragraph 8(2) of Schedule 2 a Local Health Board has decided to take no action in relation to an application and the Welsh Ministers allow the applicant's appeal against that decision, the Welsh Ministers must remit the application back to the Local Health Board for the Local Health Board to determine.

(3) In the case where the premises specified in an application that is subject to appeal are in a controlled locality the Welsh Ministers—

(a) may, where the Local Health Board, on determining the application, considered whether to impose conditions under paragraph 13 of Schedule 2 or regulation 11(6)(b), themselves consider whether to impose conditions to postpone, for such period as they think fit, the making or termination of such arrangements; or

(b) must, where the Local Health Board on determining the application has not considered whether to impose conditions under paragraph 13 of Schedule 2 or regulation 11(6)(b) either—

(i) themselves consider whether to impose conditions; or

(ii) remit the question to the Local Health Board for determination.

(4) The Welsh Ministers must after reaching a decision on an appeal, including the imposition of conditions under sub-paragraph (3), give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 7.

Effect of decisions by the Welsh Ministers

9. For the purposes of these Regulations, the Welsh Ministers' decision becomes the Local Health Board's decision on the matter (but no further appeal to the Welsh Ministers on that decision is possible, unless the Welsh Ministers' decision is overruled by a court).

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Telerau gwasanaethu ar gyfer fferyllwyr GIG sy'n darparu gwasanaethau fferyllol yn benodol drwy ddarparu cyffuriau

Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provision of drugs

RHAN 1**PART 1****Cyffredinol****General****Dehongli**

1. Yn yr Atodlen hon, mae cyffuriau neu gyfarpar i'w hystyried wedi eu harchebu neu eu darparu yn unol â phresgripsiwn amlroddadwy, hyd yn oed os nad yw'r person sy'n dymuno cael y gwasanaethau fferyllol yn cyflwyno'r presgripsiwn hwnnw, cyhyd ag—

- (a) bod y presgripsiwn hwnnw gan y fferylllydd GIG yn ei feddiant; a
- (b) bod y person hwnnw'n cyflwyno swp-ddyroddiad cysylltiedig, neu fod gan y fferylllydd GIG swp-ddyroddiad cysylltiedig yn ei feddiant.

Ymgorffori darpariaethau

2. Mae unrhyw ddarpariaethau o'r canlynol sy'n effeithio ar hawliau a rhwymedigaethau fferyllwyr GIG sy'n darparu gwasanaethau fferyllol yn ffurfio rhan o'r telerau gwasanaethu—

- (a) y Rheoliadau;
- (b) y Tariff Cyffuriau i'r graddau y mae'n rhestru cyffuriau a chyfarpar at ddibenion adran 80 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol);
- (c) cymaint o Ran II o Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thribiwnlys) 1992 ag y sy'n ymwneud ag—
 - (i) ymchwiliadau a wneir gan y pwyllgor disgyblu fferyllol a'r cyd-bwyllgor disgyblu a chamau y caiff y Bwrdd Iechyd Lleol eu cymryd o ganlyniad i ymchwiliadau o'r fath, a
 - (ii) apelau i Weinidogion Cymru yn erbyn penderfyniadau'r Bwrdd Iechyd Lleol; a
- (d) cymaint o reoliad 29 o Reoliadau Cyngorau Iechyd Cymuned (Cyfansoddiad, Aelodaeth a Gweithdrefnau) (Cymru) 2010(1) (mynd i mewn i fangreoddd a'u harchwilio) ag y sy'n ymwneud â mynd i mewn i fangreoddd ac archwilio mangreoddd, y mae fferylllydd GIG naill ai'n berchen arnynt, neu'n eu rheoli neu'n darparu gwasanaethau fferyllol ynddynt.

Interpretation

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the NHS pharmacist has that prescription in his or her possession; and
- (b) that person presents, or the NHS pharmacist has in his or her possession, an associated batch issue.

Incorporation of provisions

2. Any provisions of the following affecting the rights and obligations of NHS pharmacists who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
 - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and,
 - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board; and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010(1) (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by the NHS pharmacist or where pharmaceutical services are provided by him or her.

(1) O.S. 2010/288 (Cy.37).

(1) S.I. 2010/288 (W.37).

RHAN 2

Gwasanaethau hanfodol

Gwasanaethau hanfodol

3. At ddibenion yr Atodlen hon, ystyr "gwasanaethau hanfodol" ("*essential services*") yw—

- (a) y gwasanaethau a ddisgrifir yn y Rhan hon; a
- (b) y gweithgareddau a ddisgrifir yn y Rhan hon sydd i'w cyflawni mewn cysylltiad â'r gwasanaethau hynny.

Gwasanaethau gweinyddu

4. Rhaid i fferyllydd GIG, i'r graddau y mae'n ofynnol gan baragraffau 5 i 9 ac yn y modd a ddisgrifir yn y paragraffau hynny, ddarparu cyffuriau a chyfarpar priodol a digonol i bersonau sy'n cyflwyno presgripsiwn am y cyffur neu'r cyfarpar hwnnw, wedi ei lofnodi gan ragnodydd yn unol â'r swyddogaethau yn y gwasanaeth iechyd yng Nghymru, Lloegr, yr Alban neu Ogledd Iwerddon.

Gweinyddu cyffuriau a chyfarpar

5.—(1) Yn ddarostyngedig i'r darpariaethau canlynol o'r Rhan hon, pan fo person yn cyflwyno ar ffurflen bresgripsiwn—

- (a) archeb am gyffuriau nad ydynt yn gyffuriau Atodlen, neu am gyfarpar nad ydyw'n gyfarpar argaeledd cyfyngedig, wedi ei lofnodi gan ragnodydd;
- (b) archeb am gyffur a bennir yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau (cyffuriau neu feddyginiaethau sydd i'w harchebu mewn amgylchiadau penodol yn unig), wedi ei lofnodi a'i harnodi ar ei hwyneb gyda'r cyfeirnod "SLS" gan ragnodydd; neu
- (c) archeb am gyfarpar argaeledd cyfyngedig, wedi ei lofnodi a'i harnodi ar ei hwyneb gyda'r cyfeirnod "SLS" gan ragnodydd,

rhaid i fferyllydd GIG, yn rhesymol brydlon ac yn unol ag unrhyw gyfarwyddiadau a roddir gan y rhagnodydd ar y ffurflen bresgripsiwn, ddarparu'r cyffuriau a archebir felly, a'r cyfryw rai o'r cyfarpar a archebir felly a gyflenwir gan y fferyllydd GIG yng nghwrs arferol ei fusnes.

(2) Yn ddarostyngedig i ddarpariaethau canlynol y Rhan hon, pan fo unrhyw berson—

- (a) yn cyflwyno presgripsiwn amlroddadwy anelectronig sy'n cynnwys—

PART 2

Essential Services

Essential services

3. For the purposes of this Schedule, "essential services" ("*gwasanaethau hanfodol*") means—

- (a) the services described in this Part; and
- (b) the activities described in this Part to be carried out in connection with those services.

Dispensing services

4. An NHS pharmacist must, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting a prescription for that drug or appliance signed by a prescriber in pursuance of their functions in the health service in Wales, England, Scotland or Northern Ireland.

Dispensing of drugs and appliances

5.—(1) Subject to the following provisions of this Part, where a person presents on a prescription form—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber;
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by, and endorsed on its face with the reference "SLS" by a prescriber; or
- (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a prescriber,

an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the prescriber in the prescription form, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her business.

(2) Subject to the following provisions of this Part, where any person—

- (a) presents a non-electronic repeatable prescription which contains—

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- (i) archeb am gyffuriau nad ydynt yn gyffuriau Atodlen, nac yn gyffuriau rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971(1), ac eithrio cyffur a bennir am y tro yn Atodlen 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001(2) (sy'n ymwneud â chyffuriau rheoledig a eithriwyd rhag gwaharddiadau penodol o dan y Rheoliadau), wedi ei llofnodi gan ragnodydd amlroddadwy,
- (ii) archeb am gyffur a bennir yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau, nad yw'n gyffur rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971, ac eithrio cyffur a bennir am y tro yn Atodlen 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001, wedi ei llofnodi a'i harnodi ar ei hwyneb gyda'r cyfeirnod "SLS" gan ragnodydd amlroddadwy,
- (iii) archeb am gyfarpar, nad ydynt yn gyfarpar argaeledd cyfyngedig, wedi ei llofnodi gan ragnodydd amlroddadwy, neu
- (iv) archeb am gyfarpar argaeledd cyfyngedig, wedi ei llofnodi a'i harnodi ar ei hwyneb gyda'r cyfeirnod "SLS" gan ragnodydd amlroddadwy,

a hefyd yn cyflwyno swp-ddyroddiad cysylltiedig; neu

- (b) yn gofyn am ddarparu cyffuriau neu gyfarpar yn unol â phresgripsiwn amlroddadwy electronig sy'n cynnwys archeb o fath a bennir ym mharagraff (a)(i) i (iv),

rhaid i fferyllydd GIG, yn rhesymol brydlon ac yn unol ag unrhyw gyfarwyddiadau a roddir gan y rhagnodydd amlroddadwy yn y presgripsiwn amlroddadwy, ddarparu'r cyffuriau a archebir felly, a'r cyfryw rai o'r gyfarpar a archebir felly a gyflenwir gan y fferyllydd GIG yng nghwrs arferol ei fusnes.

(3) At ddibenion y paragraff hwn, mae presgripsiwn amlroddadwy anelectronig am gyffuriau neu gyfarpar i'w ystyried wedi ei gyflwyno, hyd yn oed os nad yw'r person sy'n dymuno cael y cyffuriau neu gyfarpar yn cyflwyno'r presgripsiwn hwnnw, os yw—

- (a) y presgripsiwn hwnnw gan y fferyllydd GIG yn ei feddiant; a
- (b) y person hwnnw'n cyflwyno swp-ddyroddiad cysylltiedig, neu fod gan y fferyllydd GIG swp-ddyroddiad cysylltiedig yn ei feddiant.

- (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(1), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(2) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a repeatable prescriber,
- (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by and endorsed on its face with the reference "SLS" by a repeatable prescriber,
- (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
- (iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference "SLS" by a repeatable prescriber,

and also presents an associated batch issue; or

- (b) requests the provision of drugs or appliances in accordance with an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv),

an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the repeatable prescriber in the repeatable prescription, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances is to be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the NHS pharmacist has that prescription in his or her possession; and
- (b) that person presents, or the NHS pharmacist has in his or her possession, an associated batch issue.

(1) 1971 c.38. Gweler adran 2(1)(a) o'r Ddeddf honno sy'n diffinio "controlled drug" at ddibenion y Ddeddf honno.

(2) O.S. 2001/3998 (fel y'i diwygiwyd).

(1) 1971 c.38. See section 2(1)(a) of that Act which defines "controlled drug" for the purposes of that Act.

(2) S.I. 2001/3998 (as amended).

Cyflenwi ar frys heb bresgripsiwn

6.—(1) Mae'r paragraff yn gymwys pan fo rhagnodydd, mewn achos brys, yn gofyn i fferylllydd GIG ddarparu cyffur neu gyfarpar.

(2) Caiff y fferylllydd GIG ddarparu'r cyffur neu gyfarpar y gofynnir amdano cyn cael ffurflen bresgripsiwn na phresgripsiwn amlroddadwy mewn perthynas â'r cyffur neu gyfarpar hwnnw, ar yr amod—

- (a) yn achos cais am gyffur, nad yw'r cyffur—
 - (i) yn gyffur Atodlen, na
 - (ii) yn gyffur rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971, ac eithrio cyffur a bennir am y tro yn Atodlen 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001; a
- (b) yn achos cais am gyffur neu am gyfarpar, bod y rhagnodydd yn ymrwymo i—
 - (i) rhoi i'r fferylllydd GIG ffurflen bresgripsiwn anelectronig neu bresgripsiwn amlroddadwy anelectronig mewn perthynas â'r cyffur neu gyfarpar o fewn 72 awr ar ôl gwneud y cais, neu
 - (ii) rhoi i'r fferylllydd GIG ffurflen bresgripsiwn electronig neu ffurflen bresgripsiwn amlroddadwy electronig sy'n cydymffurfio â'r gwasanaeth TPE o fewn 72 awr ar ôl gwneud y cais.

Materion rhagarweiniol cyn darparu cyffuriau neu gyfarpar a archebwyd

7.—(1) Os gofynnir i'r fferylllydd GIG wneud hynny gan y person sy'n cyflwyno ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy neu'n gofyn am ddarparu cyffuriau neu gyfarpar yn unol â phresgripsiwn amlroddadwy—

- (a) rhaid i'r fferylllydd GIG roi amcangyfrif o'r amser pan fydd y cyffuriau neu'r cyfarpar yn barod; a
- (b) os na fyddant yn barod erbyn yr amser hwnnw, rhaid i'r fferylllydd GIG roi amcangyfrif diwygiedig o'r amser pan fyddant yn barod (ac felly ymlaen).

(2) Cyn darparu unrhyw gyffuriau neu gyfarpar yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—

- (a) rhaid i'r fferylllydd GIG ofyn i unrhyw berson, sy'n gwneud datganiad nad oes raid i'r person a enwir ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy dalu'r ffioedd a bennir yn rheoliad 3(1) o'r Rheoliadau Ffioedd (cyflenwi cyffuriau a chyfarpar gan fferyllwyr), yn rhinwedd naill ai—
 - (i) hawl i esemptiad o dan reoliad 8(1) (esemptiadau) o'r Rheoliadau Ffioedd, neu

Urgent supply without a prescription

6.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist to provide a drug or appliance.

(2) The NHS pharmacist may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—

- (a) in the case of a request for a drug, the drug is neither—
 - (i) a Scheduled drug, nor
 - (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001; and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
 - (i) give the NHS pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
 - (ii) give the NHS pharmacist an electronic prescription form or electronic repeatable prescription form complying with the ETP service within 72 hours of the request being made.

Preliminary matters before providing ordered drugs or appliances

7.—(1) If the person presenting the prescription form or repeatable prescription, or requesting the provision of drugs or appliances in accordance with a repeatable prescription, asks the NHS pharmacist to do so—

- (a) the NHS pharmacist must give an estimate of the time when the drugs or appliances will be ready; and
- (b) if they are not ready by then, the NHS pharmacist must give a revised estimate of the time when they will be ready (and so on).

(2) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription—

- (a) the NHS pharmacist must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
 - (i) entitlement to exemption under regulation 8(1) (exemptions) of the Charges Regulations, or

- (ii) hawl i beidio â thalu ffioedd o'r fath o dan reoliad 4 o'r Rheoliadau Peidio â Chodi Tâl (ffioedd GIG y gellir peidio â'u codi),

ddangos tystiolaeth foddhaol o'r cyfryw hawl, oni wneir y datganiad mewn perthynas â hawl i esemptiad o dan reoliad 8(1) o'r Rheoliadau Ffioedd neu mewn perthynas â hawl i beidio â thalu yn rhinwedd is-baragraffau (d) i (ng) o reoliad 4(2) o'r Rheoliadau Peidio â Chodi Tâl, a bod tystiolaeth o'r fath eisoes ar gael i'r fferylllydd GIG ar yr adeg y gwneir y datganiad; a

- (b) os na ddangosir tystiolaeth foddhaol i'r fferylllydd GIG, fel sy'n ofynnol gan baragraff (a), rhaid i'r fferylllydd GIG arnodi'r ffurflen y gwnaed y datganiad arni i'r perwyl hwnnw.

Darparu cyffuriau neu gyfarpar a archebwyd

8.—(1) Pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy i fferylllydd GIG, rhaid iddo beidio â darparu'r cyffuriau neu gyfarpar a archebir felly, ac eithrio—

- (a) pan fo'r ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy wedi eu llofnodi a'u harnodi yn briodol, fel a ddisgrifir ym mharagraff 5(1) neu (2); a
- (b) yn unol â'r archeb ac unrhyw gyfarwyddiadau a roddwyd gan y rhagnodydd ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy,

yn ddarostyngedig i unrhyw reoliadau sydd mewn grym o dan Ddeddf Pwysau a Mesurau 1985(1) a darpariaethau canlynol y Rhan hon.

(2) Rhaid i gyffuriau neu gyfarpar a archebir felly gael eu darparu naill ai gan fferylllydd cofrestredig neu o dan oruchwyliaeth uniongyrchol fferylllydd cofrestredig.

(3) Pan fo'r fferylllydd y cyfeirir ato yn is-baragraff (2) yn gyflogedig gan fferylllydd GIG, ni chaniateir i'r fferylllydd cofrestredig fod yn rhywun sydd—

- (a) wedi ei anghymhwyso rhag ei gynnwys mewn rhestr berthnasol; neu
- (b) wedi ei atal dros dro o Gofrestr y Cyngor Fferyllol Cyffredinol.

(4) Os yw'r archeb yn archeb am fath o gyfarpar y mae'n ofynnol ei fesur a'i ffitio (er enghraifft, gwasgrwym), rhaid i'r fferylllydd GIG wneud yr holl drefniadau angenrheidiol—

- (a) ar gyfer mesur y person a enwir ar y ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy ar gyfer y cyfarpar; a
- (b) ar gyfer ffitio'r cyfarpar.

- (ii) entitlement to remission of such charges under regulation 4 of the Remission of Charges Regulations (remissible NHS charges),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of sub-paragraphs (e) to (k) of regulation 4(2) of the Remission of Charges Regulations, and at the time of the declaration the NHS pharmacist already has such evidence available to him or her; and

- (b) if no satisfactory evidence, as required by paragraph (a), is produced to the NHS pharmacist, the NHS pharmacist must endorse the form on which the declaration is made to that effect.

Providing ordered drugs or appliances

8.—(1) Where an NHS pharmacist is presented with a prescription form or a repeatable prescription, the NHS pharmacist must only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and endorsed as described in paragraph 5(1) or (2); and
- (b) in accordance with the order and any directions given by the prescriber on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(1) and the following provisions of this Part.

(2) Drugs or appliances so ordered must be provided either by or under the direct supervision of a registered pharmacist.

(3) Where the pharmacist referred to in sub-paragraph (2) is employed by an NHS pharmacist, the registered pharmacist must not be someone—

- (a) who is disqualified from inclusion in a relevant list; or
- (b) who is suspended from the General Pharmaceutical Council Register.

(4) If the order is for an appliance of a type requiring measuring and fitting (for example a truss), the NHS pharmacist must make all necessary arrangements—

- (a) for measuring the person named on the prescription form or repeatable prescription for the appliance; and
- (b) for fitting the appliance.

(1) 1985 p.72.

(1) 1985 c.72.

(5) Os yw'r archeb yn archeb am gyffur neu gyfarpar sydd wedi ei gynnwys yn y Tariff Cyffuriau, Fformiwlari Cenedlaethol Prydain (gan gynnwys unrhyw Atodiad a gyhoeddwyd yn rhan o'r Fformiwlari hwnnw), Fformiwlari'r Ymarferydd Deintyddol, y Cyffuriadur Ewropeaidd neu Godecs Fferyllol Prydain, rhaid i'r cyffur neu gyfarpar a gyflenwir gydymffurfio â'r safon neu'r fformiwla a bennir yno.

(6) Os yw'r archeb—

- (a) yn archeb am gyffur; ond
- (b) nid yn archeb am gyffur rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971, ac eithrio cyffur a bennir am y tro yn Atodlenni 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001,

ac nad yw'r archeb yn rhagnodi ei faint, ei gryfder na'r dosau, caiff fferylllydd GIG ddarparu'r cyffur ym mha bynnag gryfder a dosau a ystyria'n briodol drwy arfer ei sgil, ei wybodaeth a'i ofal proffesiynol ac, yn ddarostyngedig i is-baragraff (7), ym mha bynnag faint a ystyrir yn briodol ganddo ar gyfer cwrs o driniaeth o ddim mwy na phum diwrnod.

(7) Os yw archeb y mae is-baragraff (6) yn gymwys iddi yn archeb ar gyfer—

- (a) sylwedd atal cenhedlu geneuol;
- (b) cyffur nad yw ar gael i'w gyflenwi fel rhan o wasanaethau fferyllol ac eithrio ar y cyd ag un neu ragor o gyffuriau eraill; neu
- (c) gwrthfotig ar ffurf hylif sydd i'w roi drwy'r genau, pan fo'n ofynnol, am resymau fferyllol mewn perthynas ag ef, ei ddarparu mewn pecyn heb ei agor,

nad yw ar gael i'w ddarparu fel rhan o wasanaethau fferyllol ac eithrio mewn pecynnau o'r fath lle mae'r maint lleiaf sydd ar gael yn cynnwys maint addas ar gyfer cwrs o driniaeth o fwy na 5 diwrnod, caiff y fferylllydd GIG ddarparu pecyn o'r maint lleiaf sydd ar gael.

(8) Pan fo unrhyw gyffur y mae'r paragraff hwn yn gymwys iddo (hynny yw, cyffur nad yw Deddf Camddefnyddio Cyffuriau 1971 yn gymwys iddo, onid yw'n gyffur a bennir am y tro yn Atodlenni 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001), a archebwyd gan ragnodydd ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, ar gael ar gyfer ei ddarparu gan fferylllydd GIG mewn pecyn mewn maint gwahanol i'r maint a archebwyd felly, a'r cyffur hwnnw—

- (a) yn ddi-haint;
- (b) yn eferw neu hygrosgopig;
- (c) yn gymysgedd hylifol i'w ychwanegu at ddŵr bath;
- (d) yn gymysgedd col-tar;
- (e) yn gymysgedd gludiog; neu

(5) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with the standard or formula specified therein.

(6) If the order—

- (a) is an order for a drug; but
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971 other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001,

and does not prescribe its quantity, strength or dosage, an NHS pharmacist may provide the drug in such strength and dosage as in the exercise of his or her professional skill, knowledge and care he or she considers to be appropriate and, subject to sub-paragraph (7), in such quantity as he or she considers to be appropriate for a course of treatment for a period not exceeding five days.

(7) Where an order to which sub-paragraph (6) applies is for—

- (a) an oral contraceptive substance;
- (b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or
- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, the NHS pharmacist may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by an NHS pharmacist in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile;
- (b) effervescent or hygroscopic;
- (c) a liquid preparation for addition to bath water;
- (d) a coal tar preparation;
- (e) a viscous preparation; or

- (f) wedi ei becynnu ar adeg ei weithgynhyrchu mewn pecyn calendr neu gynhwysydd arbennig,

rhaidd i'r fferyllydd GIG ddarparu'r cyffur yn y pecyn sydd o'r maint agosaf i'r maint a archebwyd felly.

(9) Yn y paragraff hwn, ystyr "cynhwysydd arbennig" ("*special container*") yw unrhyw gynhwysydd sydd â'r modd o roi'r cynnwys yn rhan integrol ohono, neu nad yw'n ymarferol ei ddefnyddio i weinyddu maint cywir o'r cynnwys.

(10) Pan fo rhagnodydd yn archebu cyffur mewn maint, neu luosydd o faint, sydd ar gael yn hwylus fel maint pecyn a weithgynhyrchir i ddeiliad awdurdodiad marchnata ar gyfer y cyffur, rhaid i'r fferyllydd GIG ddarparu'r cyffur mewn pecyn gwreiddiol (neu mewn pecynnau gwreiddiol) o'r maint hwnnw sydd wedi eu cydosod gan weithgynhyrchydd o'r cyffur ar gyfer y deiliad awdurdodiad marchnata hwnnw, oni bai—

- (a) nad yw'n bosibl i'r fferyllydd GIG gael pecyn (neu becynnau) o'r fath yn rhesymol brydlon yng nghwrs arferol busnes; neu
- (b) nad yw'n ymarferol i'r fferyllydd GIG ddarparu pecyn (neu becynnau) o'r fath wrth ymateb i'r archeb (er enghraifft oherwydd anghenion y claf neu'r dull o roi'r cyffur).

(11) Ac eithrio fel a ddarperir yn is-baragraff (12), rhaid i fferyllydd GIG beidio â darparu cyffur Atodlen wrth ymateb i archeb sy'n cyfeirio ato wrth ei enw, ei fformiwla neu ddisgrifiad arall ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy.

(12) Pan fo gan gyffur enw amherchnogol priodol a phan archebir ef ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, naill ai wrth yr enw hwnnw neu wrth ei fformiwla, caiff fferyllydd GIG ddarparu cyffur sydd â'r un fanyleb, hyd yn oed pan fo'r cyffur hwnnw'n gyffur Atodlen, ar yr amod pan fo cyffur Atodlen mewn pecyn sy'n cynnwys cyffur mewn mwy nag un cryfder, nad yw darparu felly yn golygu cyflenwi rhan yn unig o'r pecyn.

(13) Pan fo cyffur a archebir fel a bennir yn is-baragraff (12) yn gyfuniad o fwy nag un cyffur, nid yw'r is-baragraff hwnnw yn gymwys ac eithrio pan fo gan y cyfuniad enw amherchnogol priodol, pa un a oes gan y cyffuriau unigol yn y cyfuniad enwau o'r fath ai peidio.

(14) Rhaid i fferyllydd GIG ddarparu unrhyw gyffur y mae'n ofynnol iddo ei ddarparu o dan y paragraff mewn cynhwysydd addas.

Gwrthod darparu cyffuriau neu gyfarpar a archebir

9.—(1) Caiff fferyllydd GIG wrthod darparu cyffuriau neu gyfarpar a archebir ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—

- (f) packed at the time of its manufacture in a calendar pack or special container,

the NHS pharmacist must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) In this paragraph "special container" ("*cynhwysydd arbennig*") means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(10) Where a drug is ordered by a prescriber in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a marketing authorisation holder for the drug, the NHS pharmacist must provide the drug in an original pack (or in original packs) of that size which have been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

- (a) it is not possible for the NHS pharmacist to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or
- (b) it is not practicable for the NHS pharmacist to provide such a pack (or packs) in response to the order (for example because of patient needs or the method of administration of the drug).

(11) Except as provided in sub-paragraph (12), an NHS pharmacist must not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, an NHS pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph must apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) An NHS pharmacist must provide any drug which he or she is required to provide under this paragraph in a suitable container.

Refusal to provide drugs or appliances ordered

9.—(1) An NHS pharmacist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) os yw'r fferylllydd GIG yn credu, yn rhesymol, nad yw'r archeb yn archeb ddilys ar gyfer y person a enwir ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy (er enghraifft, oherwydd bod y fferylllydd GIG yn credu, yn rhesymol, fod y ffurflen wedi ei lladrata neu'i ffugio);
- (b) os yw'n ymddangos i'r fferylllydd GIG fod camgymeriad yn y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy neu'i swp-ddyroddiad cysylltiedig (gan gynnwys camgymeriad clinigol a wnaed gan y rhagnodydd) neu y byddai darparu'r cyffuriau neu'r cyfarpar, yn yr amgylchiadau, yn groes i farn glinigol y fferylllydd GIG;
- (c) os yw'r fferylllydd GIG neu bersonau eraill yn y fangre yn dioddef trais neu'n cael eu bygwth â thrais gan y person sy'n cyflwyno'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu gan unrhyw berson sydd gyda'r person hwnnw; neu
- (d) os yw'r person sy'n cyflwyno'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu unrhyw berson arall sydd gyda'r person hwnnw, yn cyflawni neu'n bygwth cyflawni trosedd.

(2) Rhaid i fferylllydd GIG wrthod darparu cyffur archebir ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy os yw'r archeb am feddyginiaeth a roddir ar bresgripsiwn yn unig, ac nad oedd hawl gan y rhagnodydd i'w rhagnodi.

(3) Rhaid i fferylllydd GIG wrthod darparu cyffuriau neu gyfarpar a archebir ar bresgripsiwn amlroddadwy—

- (a) os nad oes ganddo gofnod o'r presgripsiwn hwnnw;
- (b) os nad oes ganddo, yn achos presgripsiwn amlroddadwy anelectronig unrhyw swp-ddyroddiad cysylltiedig ac os na chyflwynir swp-ddyroddiad o'r fath iddo;
- (c) os nad yw wedi ei lofnodi gan ragnodydd amlroddadwy;
- (d) os byddai gwneud hynny yn anghyson ag unrhyw ysbeidiau a bennir yn y presgripsiwn;
- (e) os hwnnw fyddai'r tro cyntaf y darperid cyffur neu gyfarpar yn unol â'r presgripsiwn, ac os llofnodwyd y presgripsiwn fwy na chwe mis yn gynharach;
- (f) os aeth mwy na blwyddyn heibio er pan lofnodwyd y presgripsiwn amlroddadwy;
- (g) os yw'r dyddiad dod i ben ar y presgripsiwn amlroddadwy wedi mynd heibio; neu
- (h) os hysbyswyd y fferylllydd GIG, gan y rhagnodydd amlroddadwy, nad oes angen y presgripsiwn bellach.

(4) Pan fo claf yn gofyn am gyflenwi cyffuriau neu

- (a) the NHS pharmacist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because he or she reasonably believes the form has been stolen or forged);
- (b) it appears to the NHS pharmacist that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the NHS pharmacist's clinical judgement;
- (c) the NHS pharmacist or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription, or by any person accompanying that person; or
- (d) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) An NHS pharmacist must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) An NHS pharmacist must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) he or she has no record of that prescription;
- (b) he or she does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to him or her;
- (c) it is not signed by a repeatable prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously;
- (f) the repeatable prescription was signed more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) he or she has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or

gyfarpar a archebwyd ar bresgripsiwn amlroddadwy (ac eithrio'r tro cyntaf y mae'n gwneud cais o'r fath), rhaid i fferyllwydd GIG beidio â darparu cyffuriau a chyfarpar a archebir felly oni fydd wedi ei fodloni—

- (a) bod y claf yr ysgrifennwyd y presgripsiwn ar ei gyfer—
 - (i) yn cymryd neu'n defnyddio'r cyffur neu'r cyfarpar yn briodol, ac yn debygol o barhau i'w gymryd neu ei ddefnyddio felly, a
 - (ii) nad yw'n dioddef o unrhyw sgil effeithiau'r driniaeth, sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf;
- (b) nad yw trefn feddyginiaethol y claf yr ysgrifennwyd y presgripsiwn ar ei gyfer, neu'r modd y defnyddir y cyfarpar gan y claf hwnnw, wedi newid mewn ffordd sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf; ac
- (c) na ddigwyddodd unrhyw newidiadau yn iechyd y claf yr ysgrifennwyd y presgripsiwn ar ei gyfer, sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf.

Gweithgareddau pellach sydd i'w cyflawni mewn cysylltiad â gwasanaethau gwelyddu

10.—(1) Mewn cysylltiad â'r gwasanaethau a ddarperir o dan baragraff 4, rhaid i fferyllwydd GIG—

- (a) sicrhau y rhoddir cyngor priodol i gleifion ynghylch unrhyw gyffuriau neu gyfarpar a ddarperir iddynt—
 - (i) i'w galluogi i ddefnyddio'r cyffuriau neu'r cyfarpar yn briodol, a
 - (ii) bodloni anghenion rhesymol y claf am wybodaeth gyffredinol ynglŷn â'r cyffuriau neu gyfarpar;
- (b) darparu cyngor priodol i bersonau y mae'n darparu cyffuriau neu gyfarpar iddynt ynghylch—
 - (i) cadw'r cyffuriau neu'r cyfarpar yn ddiogel, a
 - (ii) dychwelyd unrhyw gyffuriau neu gyfarpar diangen i'r fferyllfa i'w dinistrio'n ddiogel;
- (c) wrth ddarparu cyffuriau i gleifion yn unol â phresgripsiwn amlroddadwy, darparu cyngor priodol, yn benodol, ar y pwysigrwydd o ofyn am yr eitemau hynny, yn unig, sydd arnynt eu hangen mewn gwirionedd;
- (d) wrth ddarparu cyfarpar i gleifion yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—
 - (i) darparu cyngor priodol, yn benodol, ar y pwysigrwydd o ofyn am yr eitemau hynny, yn unig, sydd arnynt eu hangen mewn gwirionedd, a

appliances ordered on a repeatable prescription (other than on the first occasion that he or she makes such a request), an NHS pharmacist must only provide the drugs and appliances so ordered if he or she is satisfied—

- (a) that the patient in respect of whom the prescription was written—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of, or manner of utilisation of the appliance by, the patient in respect of whom the prescription was written has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient in respect of whom the prescription was written which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

10.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist must—

- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
 - (i) to enable them to utilise the drugs or appliances appropriately, and
 - (ii) to meet the patient's reasonable needs for general information about the drugs or appliances;
- (b) provide appropriate advice to persons to whom they provide drugs or appliances on—
 - (i) the safe keeping of the drugs or appliances, and
 - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction;
- (c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;
- (d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

- (ii) at y dibenion hynny, rhoi sylw i'r manylion a gynhwysir yn y cofnodion a gynhelir o dan baragraff (f) mewn perthynas â darparu cyfarpar a'r patrwm presgripsiynu mewn cysylltiad â'r claf dan sylw;
- (e) darparu nodyn ysgrifenedig i'r claf o unrhyw gyffur neu gyfarpar sy'n ddyledus iddo, a rhoi gwybod i'r claf pan ddaw'r cyffur neu'r cyfarpar ar gael;
- (f) cadw a chynnal cofnodion—
 - (i) o'r cyffuriau a'r cyfarpar a ddarperir, pan yw'n angenrheidiol neu'n ddymunol gwneud hynny i hwyluso parhad gofal y claf;
 - (ii) mewn achosion priodol, o'r cyngor a roddir ac unrhyw ymyriadau neu atgyfeiriadau a wneir (yn enwedig ymyriadau o arwyddocâd clinigol mewn achosion sy'n ymwneud â phresgripsiynau amlroddadwy), a
 - (iii) o nodiadau a ddarperir o dan baragraff (e);
- (g) dilyn hyfforddiant priodol ynglŷn â phresgripsiynu amlroddadwy, gan roi sylw i unrhyw argymhellion ynglŷn ag hyfforddiant o'r fath a bennir yn y Tariff Cyffuriau;
- (h) os yw'r fferyllydd GIG yn cymryd meddiant o bresgripsiwn amlroddadwy neu swp-ddyroddiad cysylltiedig, storio'r presgripsiwn amlroddadwy neu'r swp-ddyroddiad cysylltiedig hwnnw yn ddiogel;
- (i) cynnal cofnodion o bresgripsiynau amlroddadwy mewn ffurf a fydd yn darparu trywydd archwilio eglur o'r cyflenwadau o dan y presgripsiwn amlroddadwy (gan gynnwys dyddiadau a'r meintiau a gyflenwir);
- (j) dinistrio unrhyw swp-ddyroddiadau dros ben mewn cysylltiad â chyffuriau neu gyfarpar—
 - (i) nad oes eu hangen, neu
 - (ii) y gwrthodwyd eu darparu i glaf yn unol â pharagraff 9;
- (k) sicrhau, pan wrthodir cyffuriau neu gyfarpar i berson yn unol â pharagraff 9(1)(b), (2), (3) neu (4), y cyfeirir y claf yn ôl at y rhagnodydd am gyngor pellach;
- (l) pan ddarperir cyffuriau neu gyfarpar i glaf o dan bresgripsiwn amlroddadwy, hysbysu'r rhagnodydd ynghylch unrhyw faterion o arwyddocâd clinigol sy'n codi mewn cysylltiad â'r presgripsiwn a chadw cofnod o'r hysbysiad hwnnw;
- (m) hysbysu'r rhagnodydd ynghylch unrhyw wrthodiad i ddarparu cyffuriau neu gyfarpar yn unol â pharagraff 9(4);
- (n) wrth ddarparu cyfarpar, darparu nodyn ysgrifenedig i'r claf, o enw, cyfeiriad a rhif telefon y fferyllydd GIG; ac

- (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
- (e) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when the drug or appliance becomes available;
- (f) keep and maintain records—
 - (i) of drugs and appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient;
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (in particular of clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under paragraph (e);
- (g) undertake appropriate training in respect of repeat prescribing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (h) if he or she takes possession of a repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (j) destroy any surplus batch issues relating to drugs or appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;
- (k) ensure that where a person is refused drugs or appliances pursuant to paragraph 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;
- (l) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;
- (m) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);
- (n) when providing appliances, provide a patient with a written note of the NHS pharmacist's name, address and telephone number; and

- (o) wrth ddarparu cyfarpar penodedig, cydymffurfio â'r gofynion ychwanegol a bennir ym mharagraff 11.

(2) Pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy mewn cysylltiad â gwasanaethau gweinyddu o dan baragraff 4, os na all fferylllydd GIG ddarparu cyfarpar, neu pan fo angen addasu cyfarpar stoma ac na all y fferylllydd GIG ddarparu'r addasiad, rhaid i'r fferylllydd GIG—

- (a) os yw'r claf yn cydsynio, atgyfeirio'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy at fferylllydd GIG arall neu at gontractwr cyfarpar GIG; neu
- (b) os nad yw'r claf yn cydsynio ag atgyfeirio, darparu i'r claf fanylion cyswllt dau, o leiaf, o bobl eraill sy'n fferyllwyr GIG neu'n gontractwyr cyfarpar GIG gyda'r gallu i ddarparu'r cyfarpar neu'r addasiad cyfarpar stoma (yn ôl fel y digwydd), os yw'r manylion hynny'n hysbys i'r fferylllydd GIG.

Gofynion ychwanegol mewn perthynas â chyfarpar penodedig

11.—(1) Mae'r paragraff hwn yn pennu'r gofynion ychwanegol y cyfeirir atynt ym mharagraff 10(1)(o) ynglŷn â darparu cyfarpar penodedig.

(2) Rhaid i fferylllydd GIG sy'n gweinyddu cyfarpar penodedig yng nghwrs arferol ei fusnes ddarparu gwasanaeth danfon i gartrefi mewn perthynas â'r cyfarpar hynny ac, yn rhan o'r gwasanaeth hwnnw—

- (a) rhaid i'r fferylllydd GIG gynnig danfon y cyfarpar penodedig i gartref y claf;
- (b) os yw'r claf yn derbyn y cynnig hwnnw, rhaid gwneud y danfoniad yn rhesymol brydlon ac ar yr adeg a gytunir gyda'r claf;
- (c) rhaid danfon y cyfarpar penodedig mewn pecyn nad yw'n arddangos unrhyw ysgrifen neu farciau eraill a allai ddynodi ei gynnwys; a
- (d) rhaid i'r modd y danfonir y pecyn ac unrhyw eitemau atodol sy'n ofynnol gan is-baragraff (3) beidio â chyfleu'r math o gyfarpar a ddanfonir.

(3) Mewn unrhyw achos pan ddarperir cyfarpar penodedig (drwy ei ddanfon i'r cartref neu fel arall), rhaid i'r fferylllydd GIG ddarparu cyflenwad rhesymol o eitemau atodol priodol (megis clytiau tafladwy a bagiau gwaredu) ac—

- (a) rhaid iddo sicrhau y caiff y claf, os yw'r claf yn dymuno, ymgynghori â pherson i gael cyngor clinigol arbenigol ynglŷn â'r cyfarpar; neu
- (b) os yw'r fferylllydd GIG o'r farn bod hynny'n briodol, rhaid iddo—
 - (i) cyfeirio'r claf at ragnodydd, neu
 - (ii) cynnig gwasanaeth i'r claf ar gyfer adolygu'r defnydd o'r cyfarpar.

- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, an NHS pharmacist is unable to provide an appliance, or stoma appliance customisation is required and the NHS pharmacist is unable to provide that, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

Additional requirements in relation to specified appliances

11.—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(o) relating to the provision of specified appliances.

(2) An NHS pharmacist who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS pharmacist must offer to deliver the specified appliance to the patient's home;
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS pharmacist must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or
- (b) if the NHS pharmacist believes it is appropriate to do so, must—
 - (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.

(4) Os na all y fferylllydd GIG ddarparu gwasanaeth ar gyfer adolygu'r defnydd o'r cyfarpar yn unol ag is-baragraff (3)(b)(ii), rhaid i'r fferylllydd GIG roi i'r claf fanylion cyswllt dau, o leiaf, o bobl eraill sy'n fferyllwyr GIG neu'n gcontractwyr cyfarpar GIG gyda'r gallu i drefnu ar gyfer darparu'r gwasanaeth hwnnw, os yw'r manylion hynny'n hysbys i'r fferylllydd GIG.

(5) Pan fo fferylllydd GIG yn darparu llinell gofal teleffon mewn perthynas â gweinyddu unrhyw gyfarpar penodedig, rhaid i'r fferylllydd GIG sicrhau, yn ystod cyfnodau y tu allan i oriau—

- (a) y bydd cyngor ar gael i gleifion drwy'r llinell gofal teleffon honno; neu
- (b) bod rhif teleffon Galw Iechyd Cymru, neu gyfeiriad gwefan Galw Iechyd Cymru(1), ar gael i gleifion drwy'r llinell gofal teleffon honno.

(6) At ddibenion y paragraff hwn—

ystyr "cyfnodau y tu allan i oriau" ("*out of hours periods*"), mewn perthynas â fferyllfa, yw'r cyfnodau y tu allan i'r cyfnodau pan fo'r fferylllydd GIG—

- (a) dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn y fferyllfa yn rhinwedd paragraff 22(1) neu 26(1); neu
- (b) yn darparu gwasanaethau fferyllol yn y fferyllfa yn unol â hysbysiad o dan baragraff 22(2);

ystyr "cyngor clinigol arbenigol" ("*expert clinical advice*"), mewn perthynas â chyfarpar penodedig yw cyngor a roddir gan berson sydd wedi ei hyfforddi'n briodol ac sydd â phrofiad perthnasol mewn cysylltiad â'r cyfarpar.

Gwasanaeth gwaredu mewn perthynas â chyffuriau diangen

12. Rhaid i fferylllydd GIG, i'r graddau y mae paragraff 13 yn ei gwneud yn ofynnol ac yn y modd a ddisgrifir yn y paragraff hwnnw, dderbyn a gwaredu cyffuriau diangen a gyflwynir iddo i'w gwaredu.

Gweithdrefn sylfaenol mewn perthynas â chyffuriau diangen

13.—(1) Yn ddarostyngedig i is-baragraff (2), os yw person yn cyflwyno i fferylllydd GIG, neu i unrhyw un o staff y fferylllydd GIG, unrhyw gyffuriau a ddarparwyd ar gyfer claf sydd—

- (a) ar aelwyd breifat; neu
- (b) mewn cartref gofal preswyl,

a'r cyffuriau wedi eu cadw yn un o'r mannau hynny, rhaid i'r fferylllydd GIG dderbyn y cyffuriau a'u gwaredu yn unol ag is-baragraff (3).

(1) Rhif teleffon Galw Iechyd Cymru yw 0845 46 47 a chyfeiriad ei wefan yw www.nhsdirect.wales.nhs.uk.

(4) If the NHS pharmacist is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the NHS pharmacist must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS pharmacist.

(5) Where an NHS pharmacist provides a telephone care line in respect of the dispensing of any specified appliance, the NHS pharmacist must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line; or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales(1), are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

"expert clinical advice" ("*cyngor clinigol arbenigol*"), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods" ("*cyfnodau y tu allan i oriau*"), in relation to a pharmacy, means the periods outside the periods during which the NHS pharmacist—

- (a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 22(1) or 26(1); or
- (b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 22(2).

Disposal service in respect of unwanted drugs

12. An NHS pharmacist must, to the extent paragraph 13 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs presented to him or her for disposal.

Basic procedure in respect of unwanted drugs

13.—(1) Subject to sub-paragraph (2), where a person presents to an NHS pharmacist or any of the NHS pharmacist's staff any drugs provided for a patient in, and which have been kept in—

- (a) a private household; or
- (b) a residential care home,

the NHS pharmacist must accept the drugs and dispose of them in accordance with sub-paragraph (3).

(1) NHS Direct Wales telephone number 0845 46 47, website address www.nhsdirect.wales.nhs.uk.

(2) Ni chaniateir ei gwneud yn ofynnol bod fferyllydd GIG yn derbyn unrhyw gyffuriau ar gyfer eu gwaredu oni fydd y Bwrdd Iechyd Lleol y mae'r fferyllydd GIG wedi ei gynnwys yn ei restr fferyllol, wedi gwneud trefniadau gyda'r fferyllydd GIG i gasglu a gwaredu cyffuriau o'r disgrifiad hwnnw.

(3) Ar ôl cael y cyffuriau, rhaid i'r fferyllydd GIG—

- (a) os gofynnir iddo wneud hynny gan y Bwrdd Iechyd Lleol, neu gan contractwr gwaredu gwastraff y defnyddir ei wasanaeth gan y Bwrdd Iechyd Lleol, wahanu'r cyffuriau solid neu ampylau, yr hylifau a'r aerosolau oddi wrth ei gilydd;
- (b) storio'r cyffuriau mewn cynwysyddion a ddarperir gan y Bwrdd Iechyd Lleol, neu gan contractwr gwaredu gwastraff y defnyddir ei wasanaeth gan y Bwrdd Iechyd Lleol at y diben o storio cyffuriau o'r disgrifiad hwnnw; ac
- (c) cydymffurfio ag unrhyw ofynion statudol eraill mewn perthynas â storio neu waredu cyffuriau o'r disgrifiad hwnnw (mae bodloni'r gofynion hynny, felly, yn wasanaeth hanfodol at ddibenion y Rheoliadau hyn),

a rhaid iddo gydweithredu ag unrhyw drefniadau addas sydd wedi eu sefydlu gan y Bwrdd Iechyd Lleol ar gyfer casglu'r cyffuriau yn rheolaidd o fangre'r fferyllydd GIG, gan neu ar ran y Bwrdd Iechyd Lleol.

Gweithgareddau pellach sydd i'w cyflawni mewn cysylltiad â gwaredu cyffuriau diangen

14. Mewn cysylltiad â'r gwasanaethau a ddarperir o dan baragraff 12, rhaid i fferyllydd GIG—

- (a) sicrhau bod y fferyllydd GIG ac unrhyw aelodau o'i staff yn ymwybodol o'r risgiau sy'n gysylltiedig â thrin cyffuriau gwastraff ac o'r gweithdrefnau cywir sydd i'w dilyn er mwyn lleihau'r risgiau hynny; a
- (b) sicrhau bod cyfarpar diogelu priodol, gan gynnwys menyg, oferôls a deunyddiau i drin â gollyngiadau, ar gael yn hwylus i'r fferyllydd GIG ac i unrhyw aelodau o'i staff, ac wrth law unrhyw fan lle cedwir cyffuriau gwastraff.

Hyrwyddo ffyrdd iach o fyw

15. Rhaid i fferyllydd GIG, i'r graddau y mae paragraffau 16 a 17 yn ei gwneud yn ofynnol, ac yn y modd a bennir yn y paragraffau hynny, hyrwyddo negeseuon iechyd cyhoeddus i aelodau o'r cyhoedd.

Ffurflydd mewn cysylltiad â phresgripsiwn

16.—(1) Pan fo person sy'n defnyddio fferyllfa—

- (a) yn cyflwyno ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy i fferyllydd GIG; ac

(2) An NHS pharmacist must not be required to accept any drugs for disposal unless the Local Health Board in whose pharmaceutical list the NHS pharmacist is included has made arrangements with the NHS pharmacist for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the NHS pharmacist must—

- (a) where required to do so by the Local Health Board or by a waste disposal contractor retained by the Local Health Board, separate solid drugs or ampoules, liquids and aerosols from each other;
- (b) store the drugs in containers provided by the Local Health Board, or by a waste disposal contractor retained by the Local Health Board for the purpose of storing drugs of that description; and
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and must co-operate with any suitable arrangements that the Local Health Board has in place for regular collection of the drugs from the NHS pharmacist's premises by or on behalf of the Local Health Board.

Further activities to be carried out in connection with the disposal of unwanted drugs

14. In connection with the services provided under paragraph 12, an NHS pharmacist must—

- (a) ensure that he or she and any of his or her staff, are aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks; and
- (b) ensure that he or she and any of his or her staff have readily available and close to any place where waste drugs are stored appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

Promotion of healthy lifestyles

15. An NHS pharmacist must, to the extent paragraphs 16 and 17 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

Prescription linked intervention

16.—(1) Where a person using a pharmacy—

- (a) presents a prescription form or repeatable prescription to an NHS pharmacist; and

- (b) os yw'n ymddangos i'r fferyllydd GIG fod y person hwnnw yn—
 - (i) dioddef o ddiabetes,
 - (ii) mewn perygl o ddioddef clefyd coronaidd y galon neu bwysedd gwaed uchel, neu
 - (iii) yn ysmygu neu'n pwysu gormod,

rhaid i'r fferyllydd GIG, fel y bo'n briodol, ddarparu cyngor i'r person hwnnw, gyda'r nod o ychwanegu at ei wybodaeth a'i ddealltwriaeth o'r materion iechyd sy'n berthnasol i amgylchiadau personol y person hwnnw.

(2) Caniateir ategu'r cyngor a roddir o dan is-baragraff (1), fel y bo'n briodol—

- (a) drwy ddarparu deunydd ysgrifenedig (er enghraifft, taflenni); a
- (b) drwy gyfeirio'r person at ffynonellau eraill o wybodaeth a chynghor.

(3) Rhaid i fferyllydd GIG, mewn achosion priodol, gadw a chynnal cofnod o'r cyngor a roddir yn unol â'r paragraff hwn, a rhaid i'r cofnod hwnnw fod mewn ffurf sy'n hwyluso—

- (a) cynnal archwiliad o'r ddarpariaeth o wasanaethau fferyllydd gan y fferyllydd GIG; a
- (b) gofal dilynol i'r person y rhoddwyd y cyngor iddo.

Ymgyrchoedd iechyd cyhoeddus

17. Rhaid i fferyllydd GIG, os gofynnir iddo gan y Bwrdd Iechyd Lleol y mae'r fferyllydd GIG wedi ei gynnwys yn ei restr fferyllydd, sicrhau—

- (a) bod y fferyllydd GIG ac unrhyw aelodau o'i staff yn cymryd rhan, yn y modd y gofynnir iddynt yn rhesymol gan y Bwrdd Iechyd Lleol, mewn hyd at chwe ymgyrch ym mhob blwyddyn galendr i hyrwyddo negeseuon iechyd cyhoeddus i ddefnyddwyr fferyllydd GIG; a
- (b) os gofynnir iddo wneud hynny gan y Bwrdd Iechyd Lleol, cofnodi'r nifer o bobl y ddarparwyd gwybodaeth iddynt fel rhan o un o'r ymgyrchoedd hynny.

Cyfeirio defnyddwyr

18. Rhaid i fferyllydd GIG, i'r graddau y mae paragraff 19 yn ei gwneud yn ofynnol, ac yn y modd a bennir yn y paragraff hwnnw, ddarparu gwybodaeth i ddefnyddwyr fferyllydd GIG ynghylch ddarparwyd iechyd a gofal cymdeithasol eraill a sefydliadau cymorth.

Amgylchiad o'r gwasanaeth mewn perthynas â chyfeirio defnyddwyr

19.—(1) Os yw'n ymddangos i fferyllydd GIG neu

- (b) it appears to the NHS pharmacist that the person—
 - (i) has diabetes,
 - (ii) is at risk of coronary heart disease or high blood pressure, or
 - (iii) smokes or is overweight,

the NHS pharmacist must, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets); and
- (b) by referring the person to other sources of information or advice.

(3) An NHS pharmacist must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist; and
- (b) follow-up care for the person who has been given the advice.

Public health campaigns

17. An NHS pharmacist must, at the request of the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, ensure that—

- (a) he or she and any of his or her staff participate, in the manner reasonably requested by the Local Health Board, in up to six campaigns in each calendar year to promote public health messages to users of the NHS pharmacist's pharmacy; and
- (b) where requested to do so by the Local Health Board, record the number of people that have been provided information as part of one of those campaigns.

Signposting

18. An NHS pharmacist must, to the extent paragraph 19 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

Service outline in respect of signposting

19.—(1) Where it appears to an NHS pharmacist or

aelod o'i staff, gan ystyried yr angen i leihau'r defnydd amhriodol o wasanaethau iechyd a gofal cymdeithasol a'r gwasanaethau cymorth, bod ar berson sy'n defnyddio fferyllydd GIG—

- (a) angen cyngor, triniaeth neu gymorth na all y fferyllydd GIG ei ddarparu neu ei ddarparu; ond
- (b) bod darparwr gwasanaethau iechyd a gofal cymdeithasol neu ddarparwr gwasanaethau cymorth arall, sy'n hysbys i'r fferyllydd GIG, yn debygol o allu darparu'r cyngor, y driniaeth neu'r cymorth hwnnw,

rhaid i'r fferyllydd GIG ddarparu manylion cyswllt y darparwr hwnnw i'r person hwnnw, ac mewn achosion priodol, rhaid iddo gyfeirio'r person hwnnw at y darparwr hwnnw.

(2) Os na all fferyllydd GIG, pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, ddarparu cyfarpar, neu addasu cyfarpar stoma, oherwydd nad yw darparu'r cyfarpar neu'r addasu yn dod o fewn maes busnes arferol y fferyllydd GIG, rhaid i'r fferyllydd GIG—

- (a) os yw'r claf yn cydsynio, atgyfeirio'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy at fferyllydd GIG arall neu at contractwr cyfarpar GIG; neu
- (b) os nad yw'r claf yn cydsynio ag atgyfeirio, darparu i'r claf fanylion cyswllt dau, o leiaf, o bobl eraill sy'n fferyllwyr GIG neu'n contractwyr cyfarpar GIG gyda'r gallu i ddarparu'r cyfarpar neu addasu'r cyfarpar stoma (yn ôl fel y digwydd), os yw'r manylion hynny'n hysbys i'r fferyllydd GIG.

(3) Pan fo'n briodol, caniateir defnyddio nodyn atgyfeirio ysgrifenedig i wneud atgyfeiriad o dan y paragraff hwn.

(4) Rhaid i fferyllydd GIG, mewn achosion priodol, gadw a chynnal cofnod o unrhyw wybodaeth a roddir, neu atgyfeiriad a weir, o dan y paragraff hwn, a rhaid i'r cofnod hwnnw fod mewn ffurf sy'n hwyluso—

- (a) cynnal archwiliad o'r ddarpariaeth o wasanaethau fferyllol gan y fferyllydd GIG; a
- (b) gofal dilynol i'r person y rhoddwyd yr wybodaeth iddo neu y gwnaed yr atgyfeiriad mewn perthynas ag ef.

Cymorth ar gyfer hunanofal

20. Rhaid i fferyllydd GIG, i'r graddau y mae paragraff 21 yn ei gwneud yn ofynnol, ac yn y modd a bennir yn y paragraff hwnnw, ddarparu cyngor a chymorth i bobl sy'n gofalu amdanynt eu hunain neu eu teuluoedd.

his or her staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the NHS pharmacist's pharmacy—

- (a) requires advice, treatment or support that the NHS pharmacist cannot provide; but
- (b) another provider, of which the NHS pharmacist is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

the NHS pharmacist must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, an NHS pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the NHS pharmacist's normal course of business, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Support for self-care

20. An NHS pharmacist must, to the extent paragraph 21 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

Amlinelliad o'r gwasanaeth mewn perthynas â chymorth ar gyfer hunanofal

21.—(1) Os yw'n ymddangos i fferylllydd GIG neu aelod o'i staff, gan ystyried yr angen i leihau'r defnydd amhriodol o wasanaethau iechyd a gofal cymdeithasol, y byddai person sy'n defnyddio fferyllfa'r fferylllydd GIG yn cael budd o gyngor gan y fferylllydd GIG i helpu'r person hwnnw i reoli cyflwr meddygol (gan gynnwys, yn achos gofalwr, cyngor i helpu'r gofalwr i gynorthwyo i reoli cyflwr meddygol person arall), rhaid i'r fferylllydd GIG ddarparu cyngor i'r person sy'n defnyddio'r fferyllfa ynglŷn â rheoli'r cyflwr meddygol gan gynnwys, fel y bo'n briodol, cyngor—

- (a) ar y dewis o driniaethau, gan gynnwys cyngor ar ddethol a defnyddio cyffuriau priodol nad ydynt yn gyffuriau a roddir ar bresgripsiwn yn unig; a
- (b) newidiadau yn ffordd o fyw y claf.

(2) Rhaid i fferylllydd GIG, mewn achosion priodol, gadw a chynnal cofnod o unrhyw gyngor a roddir o dan is-baragraff (1), a rhaid i'r cofnod hwnnw fod mewn ffurf sy'n hwyluso—

- (a) cynnal archwiliad o'r ddarpariaeth o wasanaethau fferyllol gan y fferylllydd GIG; a
- (b) gofal dilynol i'r person y rhoddwyd y cyngor iddo neu mewn perthynas ag ef.

RHAN 3

Oriau Agor Fferyllfa

Oriau agor fferyllfa: cyffredinol

22.—(1) Rhaid i fferylllydd GIG sicrhau y darperir gwasanaethau fferyllol ym mhob mangre y mae'r fferylllydd GIG wedi ymrwymo i ddarparu gwasanaethau fferyllol ohoni—

- (a) am ddim llai na 40 awr bob wythnos; neu
- (b) os yw'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo y caiff y fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fangre am lai na 40 awr yr wythnos ar yr amod bod y fferylllydd GIG yn darparu'r gwasanaethau hynny ar amseroedd penodol ac ar ddiwrnodau penodol, ar yr amseroedd ac ar y diwrnodau a bennwyd felly;
- (c) os yw'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo bod rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 40 awr yr wythnos ar amseroedd

Service outline in respect of support for self-care

21.—(1) Where it appears to an NHS pharmacist or his or her staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using the NHS pharmacist's pharmacy would benefit from advice from the NHS pharmacist to help the person manage a medical condition (including, in the case of a carer, to help the carer in assisting in the management of another person's medical condition), the NHS pharmacist must provide advice to the person using the pharmacy as regards managing the medical condition, including as appropriate advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and
- (b) on changes to the patient's lifestyle.

(2) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist; and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

Pharmacy Opening Hours

Pharmacy opening hours: general

22.—(1) An NHS pharmacist must ensure that pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services—

- (a) for not less than 40 hours each week; or
- (b) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that the NHS pharmacist provides those services at set times and on set days, at the times and on the days so set;
- (c) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week, at set times and

penodol ac ar ddiwrnodau penodol, ar yr amseroedd ac ar y diwrnodau a bennwyd felly; neu

- (d) os yw'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo bod rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 40 awr yr wythnos—
- (i) am y cyfanswm oriau bob wythnos sy'n ofynnol yn rhinwedd y cyfarwyddyd hwnnw, a
- (ii) o ran yr oriau ychwanegol y gwneir yn ofynnol bod y fferylllydd GIG yn darparu gwasanaethau fferyllol yn rhinwedd y cyfarwyddyd hwnnw, ar y diwrnodau ac ar yr amseroedd y mae'n ofynnol bod y fferylllydd GIG yn darparu gwasanaethau fferyllol yn ystod yr oriau ychwanegol hynny, fel a bennir yn y cyfarwyddyd hwnnw,

ond caiff Bwrdd Iechyd Lleol, mewn amgylchiadau priodol, gytuno i atal gwasanaethau dros dro am gyfnod penodedig, os yw wedi cael 3 mis o rybudd gan y fferylllydd GIG o'r bwriad i atal y gwasanaethau dros dro.

(2) Rhaid i fferylllydd GIG hysbysu'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol ynghylch oriau eraill y bydd y fangre yr ymrwymodd y fferylllydd GIG i ddarparu gwasanaethau fferyllol ohoni ar agor, sef oriau ychwanegol at yr oriau pan fo'r fferyllfa dan rwymedigaeth i agor yn rhinwedd is-baragraff (1) (ac y cyfeirir atynt fel "oriau agor atodol").

(3) Ym mhob un o'r mangreoedd y mae fferylllydd GIG wedi ymrwmo i ddarparu gwasanaethau fferyllol ohonynt, rhaid i'r fferylllydd GIG arddangos—

- (a) hysbysiad sy'n nodi'r amseroedd y bydd y fangre ar agor ar gyfer darparu cyffuriau a chyfarpar; a
- (b) ar yr adegau pan nad yw'r fangre ar agor, hysbysiad sy'n seiliedig ar wybodaeth a ddarperir gan y Bwrdd Iechyd Lleol ac yn ddarllenadwy o'r tu allan i'r fangre, sy'n nodi cyfeiriadau fferyllwyr GIG eraill a gynhwysir yn y rhestr fferyllol a'r amseroedd y gellir cael cyffuriau a chyfarpar o'r cyfeiriadau hynny.

(4) Rhaid i fferylllydd GIG, os gofynnir iddo, gyflwyno datganiad i'r Bwrdd Iechyd Lleol y mae'r fferylllydd GIG wedi ei gynnwys yn ei restr fferyllol, sy'n nodi—

- (a) yr amseroedd y darperir gwasanaethau fferyllol ym mhob un o'r mangreoedd yr ymrwymodd y fferylllydd GIG i ddarparu gwasanaethau fferyllol ohonynt (gan gynnwys

on set days, at the times and on the days so set; or

- (d) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week—
- (i) for the total number of hours each week required by virtue of that direction, and
- (ii) as regards the additional hours for which the NHS pharmacist is required to provide pharmaceutical services by virtue of that direction, at the days on which and the times at which the NHS pharmacist is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension from the NHS pharmacist.

(2) An NHS pharmacist must notify the Local Health Board in whose pharmaceutical list the NHS pharmacist is included of other hours during which the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to as "supplementary opening hours").

(3) At each of the premises from which an NHS pharmacist has undertaken to provide pharmaceutical services, the NHS pharmacist must exhibit—

- (a) a notice specifying the times at which the premises are open for the provision of drugs and appliances; and
- (b) at times when the premises are not open, a notice based on information provided by the Local Health Board, legible from outside the premises, specifying the addresses of other NHS pharmacists included in the pharmaceutical list and the times at which drugs and appliances may be obtained from those addresses.

(4) An NHS pharmacist must, on request, submit a return to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included setting out—

- (a) the times at which pharmaceutical services are provided at each of the premises from which he or she has undertaken to provide pharmaceutical services (including the times at

yr amseroedd y darperir gwasanaethau fferyllol pan nad yw'r fferylllydd GIG dan rwymedigaeth i wneud hynny yn rhinwedd is-baragraff (1)); a

- (b) y gwasanaethau fferyllol y mae'r fferylllydd GIG fel arfer yn eu darparu ym mhob un o'r mangreoddd hynny.

(5) Os yw fferylllydd GIG yn newid—

- (a) y diwrnodau neu'r amseroedd y bydd gwasanaethau fferyllol yn cael eu darparu o fangre yr ymrwymodd y fferylllydd GIG i ddarparu gwasanaethau fferyllol ohoni; neu
- (b) y gwasanaethau fferyllol y bydd y fferylllydd GIG fel arfer yn eu darparu yn y fangre honno,

rhaid i'r fferylllydd GIG gyflenwi, i'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol, ddatganiad sy'n rhoi gwybod i'r Bwrdd Iechyd Lleol am y newid.

(6) Pan fo fferylllydd GIG wedi cyflwyno datganiad o dan is-baragraff (4) neu (5) mewn perthynas ag unrhyw fangre, neu pan fo'r fferylllydd GIG wedi pennu, mewn cais o dan y Rheoliadau hyn am gael ei gynnwys yn y rhestr fferyllol, y diwrnodau a'r amseroedd y darperir gwasanaethau fferyllol yn y fangre y mae'r cais yn ymwneud â hi os caniateir y cais—

- (a) rhaid i'r fferylllydd GIG sicrhau y darperir gwasanaethau fferyllol yn y fangre y mae'r datganiad neu'r cais yn ymwneud â hi ar y diwrnodau ac ar yr amseroedd a bennir yn y datganiad neu'r cais (oni fydd y datganiad neu'r cais wedi ei ddisodli gan ddatganiad, neu ddatganiad pellach, o dan is-baragraff (5)); a
- (b) rhaid i'r fferylllydd GIG beidio â newid—
 - (i) y diwrnodau na'r amseroedd pan fo gwasanaethau fferyllol i'w darparu yn y fangre honno; neu
 - (ii) y gwasanaethau fferyllol y mae'r fferylllydd GIG i'w darparu fel arfer yn y fangre honno,

fel y'u pennir yn y datganiad neu'r cais hwnnw, am gyfnod o 3 mis o leiaf ar ôl y dyddiad y cafodd y Bwrdd Iechyd Lleol y datganiad neu'r cais hwnnw.

(7) Os rhwystrir fferylllydd GIG, gan salwch neu achos rhesymol arall, rhag cydymffurfio â'i rwymedigaethau o dan is-baragraff (1), rhaid iddo, os yw'n ymarferol, wneud trefniadau gydag un neu ragor o fferyllwyr GIG eraill sydd â'u mangreoddd wedi'u lleoli yn y gymdogaeth, ar gyfer darparu gwasanaethau fferyllol yn ystod y cyfnod hwnnw.

(8) Pan fo'r ddarpariaeth o wasanaethau fferyllol wedi ei hatal dros dro am reswm sydd y tu hwnt i reolaeth y fferylllydd GIG, ni fydd y fferylllydd GIG

which the NHS pharmacist is providing pharmaceutical services when he or she is not obliged to do so by virtue of sub-paragraph (1)); and

- (b) the pharmaceutical services which the NHS pharmacist ordinarily provides at each of those premises.

(5) Where an NHS pharmacist changes—

- (a) the days on which or the times at which pharmaceutical services are to be provided at premises from which the NHS pharmacist has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

the NHS pharmacist must supply the Local Health Board on whose pharmaceutical list the NHS pharmacist is included with a return informing it of the change.

(6) Where an NHS pharmacist has submitted a return under sub-paragraph (4) or (5) in respect of any premises, or where the NHS pharmacist has set out in an application under these Regulations for inclusion in the pharmaceutical list the days on which and the times at which pharmaceutical services will be provided at the premises to which the application relates if the application is granted—

- (a) the NHS pharmacist must ensure that pharmaceutical services are provided at the premises to which the return or application relates on the days and at the times set out in the return or application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (5)); and
- (b) the NHS pharmacist must not change—
 - (i) the days on which or the times at which pharmaceutical services are to be provided at those premises; or
 - (ii) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

as set out in that return or application, for a period of at least 3 months after that return or application was received by the Local Health Board.

(7) Where an NHS pharmacist is prevented by illness or other reasonable cause from complying with his or her obligations under sub-paragraph (1), he or she must, where practicable, make arrangements with one or more other NHS pharmacists whose premises are situated in the neighbourhood for the provision of pharmaceutical services during that time.

(8) Where there is a temporary suspension in the provision of pharmaceutical services for a reason beyond the control of the NHS pharmacist, the NHS

wedi torri paragraffau (1), (2) a (3) ar yr amod—

- (a) bod y fferylllydd GIG yn hysbysu'r Bwrdd Iechyd Lleol y cynhwysir y fferylllydd GIG yn ei restr fferyllol ynghylch yr ataliad hwnnw cyn gynted ag y bo'n ymarferol; a
- (b) bod y fferylllydd GIG yn gwneud pob ymdrech resymol i ailddechrau darparu gwasanaethau fferyllol cyn gynted ag y bo'n ymarferol.

(9) Nid yw gwaith a gynlluniwyd ymlaen llaw i ailwampio fferyllfa yn "achos rhesymol" at ddibenion is-baragraff (7) nac yn "rheswm sydd y tu hwnt i reolaeth y fferylllydd GIG" at ddibenion is-baragraff (8).

(10) At y dibenion o gyfrifo'r nifer o oriau y mae fferyllfa ar agor yn ystod wythnos sy'n cynnwys Dydd Nadolig, Dydd Gwener y Grogolith, Sul y Pasg neu wyl banc, rhaid ystyried bod y fferyllfa ar agor ar y diwrnod hwnnw yn ystod yr amseroedd y byddai wedi bod ar agor fel arfer ar y diwrnod hwnnw o'r wythnos.

(11) Yn y Rhan hon—

ystyr "cyfarwyddyd presennol" ("*existing direction*") yw cyfarwyddyd a wnaed yn unol â'r Rhan hon neu gyfarwyddyd a oedd yn bodoli ar y dyddiad y daeth y Rheoliadau hyn i rym; ac

yr "oriau ychwanegol" ("*additional hours*") pan wneir yn ofynnol bod fferylllydd GIG yn darparu gwasanaethau fferyllol yw'r oriau hynny pan na fyddai fferylllydd GIG yn darparu gwasanaethau fferyllol, pe bai'r fferylllydd GIG yn ddarostyngedig i'r amod a bennir yn is-baragraff (1)(a) ac nid yr amod a bennir yn is-baragraff (1)(d).

Materion i'w hystyried wrth ddyroddi cyfarwyddiadau mewn perthynas ag oriau agor fferyllfeydd

23.—(1) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd sy'n pennu amseroedd neu ddiwrnodau o dan y Rhan hon, rhaid iddo, wrth wneud hynny, geisio sicrhau bod yr oriau pan fydd mangre ar agor i ddarparu gwasanaethau fferyllol yn rhai sy'n sicrhau y darperir y gwasanaethau fferyllol ar y cyfryw ddiwrnodau ac amseroedd sy'n angenrheidiol er mwyn bodloni anghenion pobl y gymdogaeth, neu ddefnyddwyr tebygol eraill y fferyllfa, am wasanaethau fferyllol.

(2) Wrth ystyried y materion a grybwyllir yn is-baragraff (1), caiff y Bwrdd Iechyd Lleol roi sylw i unrhyw wasanaethau fferyllol a ddarperir yn y gymdogaeth honno mewn amgylchiadau pan nad oes rhwymedigaeth ar y fferylllydd GIG i ddarparu'r gwasanaethau hynny.

(3) Ni chaff y Bwrdd Iechyd Lleol gyfarwyddo y caiff fferylllydd GIG ddarparu gwasanaethau fferyllol

pharmacist will not be in breach of paragraphs (1), (2) and (3) provided that—

- (a) the NHS pharmacist notifies the Local Health Board on whose pharmaceutical list the NHS pharmacist is included of that suspension as soon as practicable; and
- (b) the NHS pharmacist uses all reasonable endeavours to resume provision of pharmaceutical services as soon as practicable.

(9) Planned refurbishment of a pharmacy is neither a "reasonable cause" for the purposes of sub-paragraph (7) nor a "reason beyond the control of the NHS pharmacist" for the purposes of sub-paragraph (8).

(10) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it must be deemed that the pharmacy was open on that day at the times at which it would ordinarily have been open on that day of the week.

(11) In this Part—

"additional hours" ("*oriau ychwanegol*") for which an NHS pharmacist is to be required to provide pharmaceutical services are those hours during which the NHS pharmacist would not be providing pharmaceutical services, were the NHS pharmacist subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d); and

"existing direction" ("*cyfarwyddyd presennol*") means one that has been made in accordance with this Part or one that was in existence on the date that these Regulations come into force.

Matters to be considered when issuing directions in respect of pharmacy opening hours

23.—(1) Where a Local Health Board issues a direction setting any times or days under this Part, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that the pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1) the Local Health Board may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the NHS pharmacist is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS pharmacist may provide pharmaceutical services

yn y fangre am lai na 40 awr yn ystod unrhyw wythnos, oni fodlonir y Bwrdd Iechyd Lleol fod y ddarpariaeth o wasanaethau fferyllol yn y gymdogaeth yn debygol o fod yn ddigonol i ddiwallu'r angen am wasanaethau o'r fath ar yr adegau pan na fydd y fferylllydd GIG yn darparu gwasanaethau fferyllol.

(4) Ni chaiff y Bwrdd Iechyd Lleol gyfarwyddo bod rhaid i fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 40 awr yn ystod unrhyw wythnos, oni fydd y Bwrdd Iechyd Lleol wedi ei fodloni y bydd y fferylllydd GIG yn cael cydnabyddiaeth ariannol resymol am yr oriau ychwanegol y gofynnir iddo ddarparu gwasanaethau fferyllol (a bydd unrhyw gydnabyddiaeth ariannol ychwanegol sy'n daladwy yn unol â phenderfyniad a wnaed o ganlyniad i reoliad 37 mewn perthynas â'r oriau hynny yn "gydnabyddiaeth ariannol resymol" at y dibenion hyn).

Penderfyniad a ysgogir gan y Bwrdd Iechyd Lleol ynghylch oriau agor fferyllfa

24.—(1) Os yw'n ymddangos i'r Bwrdd Iechyd Lleol sydd â'r fferylllydd GIG yn gynwysedig yn ei restr fferyllol, ar ôl ymgynghori â'r Pwyllgor Fferyllol Lleol neu ar ôl ystyried y mater ar gais y Pwyllgor hwnnw, nad yw, neu na fydd, yr amseroedd pan fo, neu pan fydd, fferyllfa ar agor i ddarparu gwasanaethau fferyllol bellach yn bodloni anghenion—

- (a) y bobl yn y gymdogaeth; neu
- (b) defnyddwyr tebygol eraill fferyllfa'r fferylllydd GIG,

am wasanaethau fferyllol, caiff y Bwrdd Iechyd Lleol asesu a ddylid dyroddi cyfarwyddyd i wneud yn ofynnol bod y fferylllydd GIG sy'n berchen y fferyllfa yn darparu gwasanaethau fferyllol yn y fferyllfa ar amseroedd penodedig ac ar ddiwrnodau penodedig (gan gynnwys, o bosibl, Dydd Nadolig, Dydd Gwener y Groglith, Sul y Pasg a gwyliau banc).

(2) Cyn cwblhau'r asesiad o dan is-baragraff (1) rhaid i'r Bwrdd Iechyd Lleol—

- (a) rhoi hysbysiad i'r fferylllydd GIG o unrhyw newidiadau arfaethedig yn yr amseroedd neu'r diwrnodau y mae'r fferyllfa i fod ar agor; a
- (b) caniatáu cyfnod o 30 diwrnod i'r fferylllydd GIG ar gyfer cyflwyno sylwadau ysgrifenedig i'r Bwrdd Iechyd Lleol ynglŷn â'r newidiadau arfaethedig.

(3) Ar ôl ystyried unrhyw sylwadau a wneir yn unol ag is-baragraff (2)(b), rhaid i'r Bwrdd Iechyd Lleol—

- (a) dyroddi cyfarwyddyd (a fydd yn disodli unrhyw gyfarwyddyd presennol) sy'n bodloni gofynion is-baragraffau (4) a (5);
- (b) cadarnhau unrhyw gyfarwyddyd presennol sy'n pennu ar ba ddiwrnodau ac amseroedd y mae'n rhaid i'r fferylllydd GIG ddarparu

at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in the neighbourhood is likely to be adequate to meet the need for such services at times when the NHS pharmacist is not providing pharmaceutical services.

(4) The Local Health Board may only direct that an NHS pharmacist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that the NHS pharmacist will receive reasonable remuneration in respect of the additional hours for which he or she is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as a consequence of regulation 37 in respect of those hours is "reasonable remuneration" for these purposes).

Determination of pharmacy opening hours instigated by the Local Health Board

24.—(1) Where it appears to the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the times at which a pharmacy is or will be open for the provision of pharmaceutical services will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of his or her pharmacy,

for pharmaceutical services, it may carry out an assessment as to whether to issue a direction requiring the NHS pharmacist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board must—

- (a) give notice to the NHS pharmacist of any proposed changes to the times at which or the days on which the pharmacy is to be open; and
- (b) allow the NHS pharmacist 30 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical

gwasanaethau fferyllol yn y fferyllfa, ar yr amod y byddai'r cyfarwyddyd presennol yn bodloni gofynion is-baragraffau (4) a (5) pe dyroddid ef o dan y paragraff hwn; neu

(c) naill ai—

- (i) dirymu (heb ei amnewid) unrhyw gyfarwyddyd presennol sy'n pennu ar ba amseroedd neu ddiwrnodau y mae'n rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fferyllfa, neu
- (ii) mewn achos pan nad oes cyfarwyddyd presennol, peidio â dyroddi unrhyw gyfarwyddyd,

ac mewn achos o'r fath, yn rhinwedd paragraff 22(1)(a), rhaid i'r fferyllfa fod ar agor am ddim llai na 40 o oriau bob wythnos.

(4) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd o dan is-baragraff (3), mewn perthynas â fferyllfa y mae'n ofynnol iddi fod ar agor—

- (a) am fwy na 40 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu—
 - (i) cyfanswm nifer yr oriau bob wythnos y bydd rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fferyllfa, a
 - (ii) ynglŷn â'r oriau ychwanegol y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol, ar ba ddiwrnodau ac ar ba amseroedd y bydd yn ofynnol i'r fferylllydd GIG ddarparu'r gwasanaethau hynny yn ystod yr oriau ychwanegol hynny,

ond rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, beidio â phennu ar ba ddiwrnodau neu ar ba amseroedd y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol yn ystod oriau nad ydynt yn oriau ychwanegol; neu

- (b) am lai na 40 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu ar ba ddiwrnodau ac amseroedd y mae gwasanaethau fferyllol i'w darparu yn y fferyllfa honno.

(5) Rhaid i'r Bwrdd Iechyd Lleol beidio â dyroddi cyfarwyddyd o dan is-baragraff (3) os ei effaith, yn syml, yw ei gwneud yn ofynnol bod fferyllfa ar agor am 40 awr bob wythnos ar ddiwrnodau penodedig ac amseroedd penodedig (hynny yw, rhaid i'r cyfarwyddyd gael yr effaith o wneud yn ofynnol bod y fferyllfa ar agor am naill ai mwy neu lai na 40 awr bob wythnos).

(6) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r fferylllydd GIG, mewn ysgrifen, o unrhyw gyfarwyddyd a dyroddir, neu unrhyw gam arall a gymerir, o dan is-baragraff (3), ac os yw'r Bwrdd Iechyd Lleol yn pennu diwrnodau newydd neu amseroedd newydd y mae'r fferylllydd GIG i ddarparu

services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph; or

(c) either—

- (i) revoke (without replacing it) any existing direction setting the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, or
- (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 22(1)(a), the pharmacy must be open for not less than 40 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS pharmacist must provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours; or

- (b) for less than 40 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(6) The Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services at the pharmacy, it must include with the notification a

gwasanaethau fferyllol yn y fferyllfa, rhaid i'r Bwrdd Iechyd Lleol gynnwys gyda'r hysbysiad ddatganiad ysgrifenedig o'r canlynol—

- (a) y rhesymau am y newid; a
- (b) hawl y fferylllydd GIG i apelio o dan is-baragraff (7).

(7) Caiff fferylllydd GIG, o fewn 30 diwrnod ar ôl cael hysbysiad o dan is-baragraff (6), apelio mewn ysgrifen i Weinidogion Cymru yn erbyn unrhyw gyfarwyddyd a roddwyd neu unrhyw gam arall a gymerwyd o dan is-baragraff (3), sy'n pennu diwrnodau newydd neu amseroedd newydd y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol.

(8) Caiff Gweinidogion Cymru, wrth benderfynu apêl, naill ai gadarnhau'r cam a gymerwyd gan y Bwrdd Iechyd Lleol neu gymryd unrhyw gam y gallai'r Bwrdd Iechyd Lleol fod wedi ei gymryd o dan is-baragraff (3).

(9) Rhaid i Weinidogion Cymru hysbysu'r fferylllydd GIG o'u penderfyniad mewn ysgrifen a rhaid iddynt, ym mhob achos, gynnwys gyda'r hysbysiad ddatganiad ysgrifenedig o'r rhesymau dros y penderfyniad.

(10) Os yw'r amseroedd neu'r diwrnodau y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol mewn fferyllfa wedi eu newid yn unol â'r paragraff hwn, rhaid i'r fferylllydd GIG gyflwyno'r newidiadau—

- (a) os nad yw'r fferylllydd GIG wedi apelio o dan is-baragraff (7), ddim hwyrach nag 8 wythnos ar ôl y dyddiad y mae'r fferylllydd GIG yn cael hysbysiad o dan is-baragraff (6); neu
- (b) os yw'r fferylllydd GIG wedi apelio o dan is-baragraff (7), ddim hwyrach nag 8 wythnos ar ôl y dyddiad y mae'r fferylllydd GIG yn cael hysbysiad o dan is-baragraff (9).

Penderfyniad a ysgogir gan y fferylllydd GIG ynghylch oriau agor fferyllfa

25.—(1) Caiff fferylllydd GIG wneud cais i Fwrdd Iechyd Lleol sydd â'r fferylllydd GIG yn gynwysedig yn ei restr fferyllol am i'r Bwrdd newid y diwrnodau neu'r amseroedd y mae'r fferylllydd GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn ei fferyllfa, mewn ffordd sy'n—

- (a) lleihau cyfanswm nifer yr oriau y mae'r fferylllydd GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol bob wythnos; neu
- (b) yn cadw cyfanswm nifer yr oriau yn ddigyfnewid.

(2) Pan fo fferylllydd GIG yn gwneud cais o dan is-baragraff (1), rhaid i'r fferylllydd GIG, yn rhan o'r cais hwnnw, ddarparu i'r Bwrdd Iechyd Lleol pa bynnag wybodaeth y gofynnir amdani yn rhesymol gan y Bwrdd Iechyd Lleol ynglŷn ag unrhyw newidiadau yn anghenion pobl y gymdogaeth, neu ddefnyddwyr

statement in writing of—

- (a) the reasons for the change; and
- (b) the NHS pharmacist's right of appeal under sub-paragraph (7).

(7) An NHS pharmacist may, within 30 days of receiving notification under sub-paragraph (6) appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the times at which or the days on which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if he or she has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives notification under sub-paragraph (6); or
- (b) if he or she has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives notification under sub-paragraph (9).

Determination of pharmacy opening hours instigated by the NHS pharmacist

25.—(1) An NHS pharmacist may apply to a Local Health Board on whose pharmaceutical list the NHS pharmacist is included for it to change the days on which or the times at which the NHS pharmacist is obliged to provide pharmaceutical services at the NHS pharmacist's pharmacy in a way that—

- (a) reduces the total number of hours for which the NHS pharmacist is obliged to provide pharmaceutical services each week; or
- (b) keeps the total number of hours the same.

(2) Where an NHS pharmacist makes an application under sub-paragraph (1), as part of that application the NHS pharmacist must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other

tebygol eraill y fferyllfa, am wasanaethau fferyllol sy'n berthnasol i'r cais.

(3) Rhaid i'r Bwrdd Iechyd Lleol benderfynu cais o dan is-baragraff (1) o fewn 60 diwrnod ar ôl cael y cais (ynghyd ag unrhyw wybodaeth y mae'n ofynnol i'r ceisydd ei darparu yn unol ag is-baragraff (2)).

(4) Wrth benderfynu'r cais, rhaid i'r Bwrdd Iechyd Lleol—

- (a) dyroddi cyfarwyddyd (a fydd yn disodli unrhyw gyfarwyddyd presennol) sy'n bodloni gofynion is-baragraffau (5) a (6) ac yn cael yr effaith naill ai o ganiatáu'r cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig;
- (b) cadarnhau unrhyw gyfarwyddyd presennol sy'n pennu ar ba ddiwrnodau ac amseroedd y mae'n rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fferyllfa, ar yr amod y byddai'r cyfarwyddyd presennol yn bodloni gofynion is-baragraffau (5) a (6); neu
- (c) naill ai—
 - (i) dirymu (heb ei amnewid) unrhyw gyfarwyddyd presennol sy'n pennu ar ba amseroedd neu ddiwrnodau y mae'n rhaid i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fferyllfa, pan fo hyn yn cael yr effaith naill ai o ganiatáu'r cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig, neu
 - (ii) mewn achos pan nad oes cyfarwyddyd presennol, peidio â dyroddi unrhyw gyfarwyddyd,

ac mewn achos o'r fath, yn rhinwedd paragraff 22(1)(a), rhaid i'r fferyllfa fod ar agor am ddim llai na 40 o oriau bob wythnos.

(5) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd o dan is-baragraff (4), mewn perthynas â fferyllfa y mae'n ofynnol iddi fod ar agor—

- (a) am fwy na 40 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu—
 - (i) cyfanswm nifer yr oriau bob wythnos y mae'n ofynnol i'r fferylllydd GIG ddarparu gwasanaethau fferyllol yn y fferyllfa, a
 - (ii) ynglŷn â'r oriau ychwanegol y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol, ar ba ddiwrnodau ac ar ba amseroedd y bydd yn ofynnol i'r fferylllydd GIG ddarparu'r gwasanaethau hynny yn ystod yr oriau ychwanegol hynny,

ond rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, beidio â phennu ar ba ddiwrnodau neu ar ba amseroedd y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol yn ystod oriau nad ydynt yn oriau ychwanegol; neu

likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (5) and (6); or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 22(1)(a), the pharmacy must be open for not less than 40 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS pharmacist is required to provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and the times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours; or

(b) am lai na 40 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu ar ba ddiwrnodau ac amseroedd y mae gwasanaethau fferyllol i'w darparu yn y fferyllfa honno.

(6) Rhaid i'r Bwrdd Iechyd Lleol beidio â dyroddi cyfarwyddyd o dan is-baragraff (4) os ei effaith, yn syml, yw ei gwneud yn ofynnol bod fferyllfa ar agor am 40 awr bob wythnos ar ddiwrnodau penodedig ac amseroedd penodedig (hynny yw, rhaid i'r cyfarwyddyd gael yr effaith o wneud yn ofynnol bod y fferyllfa ar agor am naill ai mwy neu lai na 40 awr bob wythnos).

(7) Pan fo'r Bwrdd Iechyd Lleol yn ystyried gweithredu o dan is-baragraff (4)(a) neu is-baragraff (4)(c)(i), rhaid iddo ymgynghori â'r Pwyllgor Fferyllol Lleol cyn penderfynu'r cais.

(8) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r fferylllydd GIG, mewn ysgrifen, o unrhyw gyfarwyddyd a ddyroddir, neu unrhyw gam arall a gymerir, o dan is-baragraff (4), ac os effaith hynny yw gwrthod cais a wnaed o dan y paragraff hwn, neu ei ganiatáu yn rhannol, rhaid i'r Bwrdd Iechyd Lleol anfon at y fferylllydd GIG ddatganiad ysgrifenedig sy'n nodi—

- (a) y rhesymau am y gwrthodiad neu, yn ôl fel y digwydd am ganiatáu y cais yn rhannol yn unig; a
- (b) hawl y fferylllydd GIG i apelio o dan is-baragraff (9).

(9) Caiff fferylllydd GIG, o fewn 30 diwrnod ar ôl cael hysbysiad yn unol ag is-baragraff (8), apelio mewn ysgrifen i Weinidogion Cymru yn erbyn unrhyw weithred o dan is-baragraff (4) sy'n cael yr effaith o wrthod cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig.

(10) Caiff Gweinidogion Cymru, wrth benderfynu apel, naill ai gadarnhau'r cam a gymerwyd gan y Bwrdd Iechyd Lleol neu gymryd unrhyw gam y gallai'r Bwrdd Iechyd Lleol fod wedi ei gymryd o dan is-baragraff (4).

(11) Rhaid i Weinidogion Cymru hysbysu'r fferylllydd GIG o'u penderfyniad mewn ysgrifen a rhaid iddynt, ym mhob achos, gynnwys gyda'r hysbysiad ddatganiad ysgrifenedig o'r rhesymau dros y penderfyniad.

(12) Os yw'r diwrnodau neu'r amseroedd y mae'r fferylllydd GIG i ddarparu gwasanaethau fferyllol mewn fferyllfa wedi eu newid yn unol â'r paragraff hwn, rhaid i'r fferylllydd GIG gyflwyno'r newidiadau—

- (a) os nad yw'r fferylllydd GIG wedi apelio o dan is-baragraff (9), ddim cynharach na 30 diwrnod ar ôl y dyddiad y mae'r fferylllydd GIG yn cael hysbysiad o dan is-baragraff (8); neu

(b) for less than 40 hours each week, it must set out in that direction the days on which and the times at which pharmaceutical services are to be provided at that pharmacy.

(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or sub-paragraph (4)(c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS pharmacist a statement in writing setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) the NHS pharmacist's right of appeal under sub-paragraph (9).

(9) An NHS pharmacist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if he or she has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives notification under sub-paragraph (8); or

- (b) os yw'r fferylllydd GIG wedi apelio o dan is-baragraff (9), ddim cynharach na 30 diwrnod ar ôl y dyddiad y mae'r fferylllydd GIG yn cael hysbysiad o dan is-baragraff (11).

Oriau agor dros dro a chyfnodau caeedig yn ystod argyfwng, sy'n galw am ddarparu gwasanaethau fferyllol yn hyblyg

26.—(1) Er gwaethaf darpariaethau'r Atodlen hon, yn ystod argyfwng pan yw'n ofynnol darparu gwasanaethau fferyllol mewn ffordd hyblyg, caiff y Bwrdd Iechyd Lleol y mae'r fferylllydd GIG yn gynwysedig yn ei restr fferyllol, os gwneir cais gan y fferylllydd GIG, ganiatáu i'r fferylllydd GIG newid dros dro y diwrnodau neu'r amseroedd pan fo'r fferylllydd GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn y fangre yr ymrwymodd i ddarparu gwasanaethau fferyllol ohoni, neu ganiatáu cau'r fangre honno dros dro—

- (a) os rhoddir 24 awr, o leiaf, o rybudd gan y fferylllydd GIG o'r newid neu'r cau; a
- (b) os yw'r rhesymau a roddir gan y fferylllydd GIG dros wneud y cais yn rhesymau digonol ym marn y Bwrdd Iechyd Lleol.

(2) Nid oes angen i'r Bwrdd Iechyd Lleol gymeradwyo'r cais ymlaen llaw cyn y newid neu'r cau, ac os nad yw'r Bwrdd yn cymeradwyo ymlaen llaw, ond yn penderfynu yn ddiweddarach nad yw rhesymau'r fferylllydd GIG, ym marn y Bwrdd, yn rhesymau digonol, yna rhaid i'r diwrnodau neu'r amseroedd y mae'r fferylllydd GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn y fangre ddychwelyd i'r hyn oeddent cyn eu disodli, o'r diwrnod ar ôl y dyddiad yr hysbysir y fferylllydd GIG o'r penderfyniad hwnnw.

RHAN 4

Llywodraethu Clinigol a Chwynion

Llywodraethu clinigol

27.—(1) Rhaid i fferylllydd GIG, mewn cysylltiad â'r holl wasanaethau a ddarperir ganddo, gyfranogi mewn system dderbyniol o lywodraethu clinigol, yn y modd y gofynnir iddo yn rhesymol gan y Bwrdd Iechyd Lleol y mae'r fferylllydd GIG wedi ei gynnwys yn ei restr fferyllol.

(2) Mae system o lywodraethu clinigol yn "derbyniol" os yw'n darparu ar gyfer—

- (a) cydymffurfiaeth â'r cydrannau llywodraethu clinigol a bennir yn is-baragraff (3), a
- (b) cyflwyno hunanasesiad blynyddol o'r gydymffurfiaeth (hyd at lefel gymeradwy) â'r

- (b) if he or she has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives notification under sub-paragraph (11).

Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

26.—(1) Notwithstanding the provisions of this Schedule, during an emergency requiring the flexible provision of pharmaceutical services, the Local Health Board in whose pharmaceutical list the NHS pharmacist is included may, on application from the NHS pharmacist, permit the NHS pharmacist a temporary change to the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS pharmacist gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by the NHS pharmacist for the request are, in the opinion of the Local Health Board, adequate reasons.

(2) The Local Health Board need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that the NHS pharmacist's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to the NHS pharmacist.

PART 4

Clinical Governance and Complaints

Clinical governance

27.—(1) An NHS pharmacist must, in connection with all the services that the NHS pharmacist provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in an acceptable system of clinical governance.

(2) A system of clinical governance is "acceptable" if it provides for—

- (a) compliance with the clinical governance components set out in sub-paragraph (3), and
- (b) submission of an annual self assessment of compliance (to an approved level) with those

cydrannau llywodraethu clinigol hynny, drwy gyfrwng trefniadau cyflwyno data cymeradwy sy'n caniatáu i'r Bwrdd Iechyd Lleol gael mynediad i'r asesiad hwnnw.

(3) Y cydrannau llywodraethu clinigol yw'r canlynol—

(a) rhaglen ar gyfer cynnwys y cleifion a'r cyhoedd, sy'n cynnwys—

- (i) gofyniad bod y fferylllydd GIG yn paratoi, mewn ffordd gymeradwy, taflen ymarfer mewn perthynas â fferyllfa'r fferylllydd GIG ac yn rhoi'r daflen ar gael mewn ffordd briodol,
- (ii) gofyniad bod y fferylllydd GIG yn rhoi cyhoeddusrwydd i'r gwasanaethau GIG sydd ar gael yn ei fferyllfa neu ohoni,
- (iii) gofyniad bod y fferylllydd GIG, wrth roi cyhoeddusrwydd i'r gwasanaethau GIG sydd ar gael yn ei fferyllfa neu ohoni (pa un a yw'r fferylllydd GIG yn paratoi ei ddeunyddiau cyhoeddusrwydd ei hunan, ynteu'n hysbysebu'r gwasanaethau mewn deunydd a gyhoeddir gan berson arall), yn gwneud hynny mewn ffordd sy'n dangos yn eglur mai fel rhan o'r gwasanaeth iechyd y cyllidir y gwasanaethau,
- (iv) gofyniad bod y fferylllydd GIG yn cynnal arolwg cymeradwy o foddhad y cleifion yn flynyddol, gan wneud hynny mewn ffordd a gymeradwyir, a chan gynnwys gofyniad i roi cyhoeddusrwydd i ganlyniadau'r arolwg ac i unrhyw gamau priodol y mae'r fferylllydd GIG yn bwriadu eu cymryd,
- (v) trefniadau ar gyfer monitro cyffuriau neu gyfarpar sy'n ddyledus i gleifion ond nad ydynt mewn stoc,
- (vi) system gwynion gymeradwy (sy'n bodloni gofynion y Rhan hon),
- (vii) gofyniad bod y fferylllydd GIG yn cydweithredu'n briodol gydag ymweliadau'r Cyngor Iechyd Cymuned Lleol ac yn cymryd camau priodol o ganlyniad i ymweliadau o'r fath,
- (viii) gofyniad bod y fferylllydd GIG yn cydweithredu'n briodol gydag unrhyw arolygiad neu adolygiad rhesymol y mae'r Bwrdd Iechyd Lleol neu unrhyw awdurdod statudol perthnasol yn dymuno'i gynnal, a
- (ix) trefniadau ar gyfer monitro cydymffurfiaeth â Deddf Cydraddoldeb 2010(1);

(b) rhaglen o archwiliadau clinigol (pum diwrnod, fel arfer), sy'n cynnwys o leiaf un archwiliad mewn fferyllfa ac un archwiliad amlddisgyblaethol a gytunir gyda'r Bwrdd Iechyd Lleol ym mhob blwyddyn ariannol;

clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.

(3) The clinical governance components comprise of the following—

(a) a patient and public involvement programme, which includes—

- (i) a requirement that the NHS pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of the NHS pharmacist's pharmacy,
- (ii) a requirement that the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist's pharmacy,
- (iii) a requirement that where the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist's pharmacy (whether the NHS pharmacist is producing their own publicity material or advertising services in material published by another person), the NHS pharmacist does so in a manner which makes clear that the services are funded as part of the health service,
- (iv) a requirement that the NHS pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS pharmacist intends to take,
- (v) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
- (vi) an approved complaints system (which meets the requirements of this Part),
- (vii) a requirement that the NHS pharmacist co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
- (viii) a requirement that the NHS pharmacist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
- (ix) monitoring arrangements for compliance with the Equality Act 2010(1);

(b) a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year;

- (c) rhaglen rheoli risg, sy'n cynnwys—
- (i) trefniadau i sicrhau bod yr holl stoc yn cael ei drafod mewn ffordd briodol,
 - (ii) trefniadau i sicrhau bod yr holl gyfarpar a ddefnyddir i ddarparu gwasanaethau fferyllol yn cael ei gynnal yn briodol,
 - (iii) system gymeradwy o adrodd am ddigwyddiadau, ynghyd â threfniadau ar gyfer dadansoddi ac ymateb i ddigwyddiadau critigol, sy'n cynnwys y canlynol—
 - (aa) cofnod o ddigwyddiadau diogelwch cleifion, a
 - (bb) cofnod o ddigwyddiadau croen dannedd,
 - (iv) trefniadau, sy'n cynnwys trefniadau cadw cofnodion, i ymdrin yn brydlon a phriodol â chyfathrebiadau ynglŷn â diogelwch cleifion oddi wrth Weinidogion Cymru, yr Asiantaeth Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd a Bwrdd Comisiynu'r Gwasanaeth Iechyd Gwladol,
 - (v) trefniadau gweithredu safonol priodol, gan gynnwys trefniadau gweithredu safonol mewn perthynas â phresgripsiynau amlroddadwy a darparu cyngor a chymorth i bobl sy'n gofalu amdanynt eu hunain neu eu teuluoedd,
 - (vi) trefniadau gwaredu gwastraff priodol (yn ychwanegol at yr hyn sy'n ofynnol o dan baragraffau 13 a 14) ar gyfer gwastraff clinigol a chyfrinachol,
 - (vii) arweinydd llywodraethu clinigol ym mhob fferyllfa unigol (sef naill ai person a benodir fel y cyfryw gan y fferylllydd GIG neu'r fferylllydd GIG ei hunan) sy'n wybodus ynglŷn â'r gweithdrefnau fferylliaeth yn y fferyllfa honno a'r gwasanaethau GIG eraill sydd ar gael yn ardal y fferyllfa honno,
 - (viii) gweithdrefnau priodol ar gyfer amddiffyn plant, a
 - (ix) trefniadau ar gyfer monitro cydymffurfiaeth â Deddf Iechyd a Diogelwch etc. 1974(1);
- (d) rhaglen effeithiolrwydd clinigol, sy'n cynnwys trefniadau i sicrhau y rhoddir cyngor priodol gan y fferylllydd GIG—

- (i) mewn perthynas â darparu cyffuriau yn unol â phresgripsiwn amlroddadwy,
- (ii) mewn perthynas â darparu cyfarpar yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu

- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
 - (aa) a patient safety incident log, and
 - (bb) a near-miss log,
 - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,
 - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (vi) appropriate waste disposal arrangements (in addition to those required under paragraphs 13 and 14) for clinical and confidential waste,
 - (vii) a clinical governance lead person for each pharmacy, appointed as such by the NHS pharmacist (or that is the NHS pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
 - (viii) appropriate child protection procedures, and
 - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(1);
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS pharmacist—
- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
 - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or

(1) 1974 p.37.

(1) 1974 c.37.

- (iii) i bobl sy'n gofalu amdanynt eu hunain neu eu teuluoedd,

a threfniadau i sicrhau bod y fferylllydd GIG, wrth roi cyngor i unrhyw glaf ar fater a grybwyllir ym mharagraff (d)(ii), yn rhoi sylw i'r manylion a gynhwysir yn y cofnodion a gynhelir o dan baragraff 10(1)(f) mewn perthynas â'r ddarpariaeth o gyfarpar a'r patrwm presgripsiynu ar gyfer y claf dan sylw;

- (e) rhaglen staffio a rheoli staff, sy'n cynnwys—

- (i) trefniadau i ddarparu hyfforddiant ymsefydlu priodol i aelodau o'r staff gan gynnwys unrhyw locwm,
- (ii) hyfforddiant priodol i'r holl staff ar gyfer pa bynnag rôl y gofynnir iddynt ei chyflawni,
- (iii) trefniadau i wirio cymwysterau a geir daon yr holl staff sy'n ymwneud â darparu gwasanaethau GIG,
- (iv) trefniadau ar gyfer canfod a chefnogi anghenion datblygu pob aelod o'r staff sy'n ymwneud â darparu gwasanaethau fel rhan o'r gwasanaeth iechyd, gan gynnwys datblygiad proffesiynol parhaus i fferyllwyr cofrestredig ac unrhyw achredu sydd ei angen mewn cysylltiad â darparu gwasanaethau cyfeiriedig,
- (v) trefniadau ar gyfer mynd i'r afael â pherfformiad gwael (ar y cyd â'r Bwrdd Iechyd Lleol fel y bo'n briodol), a
- (vi) trefniadau (y mae'n rhaid iddynt gynnwys polisi ysgrifenedig) i sicrhau, bod yr holl staff gan gynnwys unrhyw locwm sydd, o ganlyniad i'w cyflogaeth gyda'r fferylllydd GIG—
 - (aa) yn gwneud yr hyn sy'n ddatgeliad gwarchodedig o fewn yr ystyr a roddir i "protected disclosure" yn adran 43A o Ddeddf Hawliau Cyflogaeth 1996(1) (ystyr datgeliad gwarchodedig), yn cael arfer yr hawliau a roddir mewn perthynas â datgeliadau o'r fath gan y Ddeddf honno, a
 - (bb) yn darparu gwybodaeth yn ddidwyll ac nid er eu budd personol, i'r Cyngor Fferyllol Cyffredinol neu i Fwrdd Iechyd Lleol, sy'n cynnwys honiad difrifol ei natur, y credant yn

- (iii) to people caring for themselves or their families,

and arrangements for ensuring that the NHS pharmacist, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;

- (e) a staffing and staff management programme, which includes—

- (i) arrangements for appropriate induction training for staff, including any locum,
- (ii) appropriate training for all staff in respect of any role they are asked to perform,
- (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
- (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
- (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
- (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum, who, arising out of their employment with the NHS pharmacist—
 - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(1) (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and
 - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious

(1) 1996 p.18; mewnosodwyd adran 43A gan adran 1 o Ddeddf Datgelu i'r Lles y Cyhoedd 1998 (p.23). *Gweler* hefyd adran 43K(1)(c) o Ddeddf Hawliau Cyflogaeth 1996 sy'n ehangu ystyr "worker" ar gyfer y Rhan o'r Ddeddf honno sy'n ymdrin â datgeliadau gwarchodedig, er mwyn iddo gynnwys pob unigolyn sy'n darparu gwasanaethau fferyllol yn unol â threfniadau a wneir gan Fwrdd Iechyd Lleol o dan adran 80 o Ddeddf 2006.

(1) 1996 c.18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c.23). *See* also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of "worker" for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

rhysymol ei fod yn wir o ran ei sylwedd er nad yw datgeliad ohono yn ddatgeliad gwarchodedig o fewn yr ystyr a roddir i "protected disclosure" yn adran 43A, yn cael yr hawl i beidio â dioddef unrhyw anfantais neu ddioddef eu diswyddo o ganlyniad i'r weithred honno;

- (f) rhaglen lywodraethu gwybodaeth, sy'n darparu ar gyfer—
 - (i) cydymffurfio â gweithdrefnau cymeradwy ar gyfer rheoli a diogelu gwybodaeth, a
 - (ii) cyflwyno hunanasesiad blynyddol o'r gydymffurfiaeth (hyd at lefel gymeradwy) â'r gweithdrefnau hynny, drwy gyfrwng trefniadau cyflwyno data cymeradwy sy'n caniatáu i'r Bwrdd Iechyd Lleol gael mynediad i'r asesiad hwnnw; ac
- (g) rhaglen safonau mangre sy'n cynnwys—
 - (i) system ar gyfer cynnal glanweithdra yn y fferyllfa, sydd wedi ei chynllunio er mwyn sicrhau lleihau, mewn ffordd gymesur, y risg i bobl yn y fferyllfa o'u heintio drwy gael gofal iechyd, a
 - (ii) trefniadau ar gyfer gwahanu'n eglur rhwng y mannau mewn fferyllfa sy'n amgylchedd gofal iechyd priodol (lle mae cleifion yn cael gwasanaethau GIG) a'r mannau hynny nad ydynt yn amgylchedd gofal iechyd.

Safonau proffesiynol

28. Rhaid i fferylllydd GIG ddarparu gwasanaethau fferyllol, ac arfer unrhyw farn broffesiynol mewn cysylltiad â darparu'r gwasanaethau hynny, gan gydymffurfio â'r safonau a dderbynnir yn gyffredinol yn y proffesiwn fferyllol.

Cymhellion

29.—(1) Rhaid i fferylllydd GIG a'i staff beidio â rhoi, addo na chynnig, i unrhyw berson, unrhyw rodd neu wobr (boed ar ffurf cyfran o elw'r busnes, neu ddiidend ar yr elw hwnnw, neu ar ffurf disgownt neu ad-daliad, neu rywfodd arall) fel cymhelliad i'r person arall gyflwyno archeb am gyffuriau neu gyfarpar ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu'n gydnabyddiaeth am i'r person arall wneud hynny.

(2) Nid yw addo, cynnig neu ddarparu cymorth cydymffurfio neu wasanaeth danfon gartref yn "rhodd neu wobr" at ddibenion is-baragraff (1).

(3) Yn achos darparu cyfarpar, ni chaniateir i fferylllydd GIG nac unrhyw berson a gyflogir neu a gymerir ymlaen ganddo dderbyn na chael unrhyw rodd neu wobr mewn perthynas, yn unig, ag—

- (a) darparu manylion cyswllt fferyllwyr GIG neu

nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;

- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment; and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised, and
 - (ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

Professional standards

28. An NHS pharmacist must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements

29.—(1) An NHS pharmacist or his or her staff must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of the person presenting an order for drugs or appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a compliance aid or a home delivery service is not a "gift or reward" for the purposes of sub-paragraph (1).

(3) In the case of the provision of appliances, neither an NHS pharmacist nor any person employed or engaged by him or her must accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS

gontractwyr cyfarpar GIG amgen yn unol â pharagraff 10(2)(b), 11(4) neu 19(2)(b); neu

- (b) atgyfeirio ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy at fferyllydd GIG neu gontractwr cyfarpar GIG arall yn unol â pharagraff 10(2)(a) neu 19(2)(a) heb ddarparu unrhyw wasanaeth ychwanegol mewn cysylltiad â'r eitem ar y presgripsiwn hwnnw.

Dyletswydd i ddarparu gwybodaeth am faterion addasrwydd i ymarfer: Fferyllydd GIG sydd ar restrau fferyllo ar 10 Mai 2013

30. Rhaid i fferyllydd GIG ac, yn ddarostyngedig i baragraff 32, os yw'n gorff corfforaethol, pob cyfarwyddwr ac uwcharolygydd y fferyllydd GIG, sydd wedi ei gynnwys ar restr fferyllo a gynhelir gan Fwrdd Iechyd Lleol ar 10 Mai 2013, ddarparu i'r Bwrdd Iechyd Lleol, mewn ysgrifen ar neu cyn 9 Tachwedd 2013, yr wybodaeth am faterion addasrwydd a bennir ym mharagraff 31.

Dyletswydd i ddarparu gwybodaeth am faterion addasrwydd i ymarfer wrth iddynt godi

31.—(1) Yn ddarostyngedig i baragraff 32, rhaid i fferyllydd GIG, ac os yw'r fferyllydd GIG yn rhan o gorff corfforaethol, pob un o'i gyfarwyddwyr, hysbysu'r Bwrdd Iechyd Lleol mewn ysgrifen, o fewn 7 diwrnod ar ôl y digwyddiad, os yw'r fferyllydd GIG neu'r cyfarwyddwr—

- (a) yn cael ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) yn cael ei rwymo yn dilyn collfarn droseddol yn y Deyrnas Unedig;
- (c) yn derbyn rhybuddiad gan yr heddlu yn y Deyrnas Unedig;
- (d) mewn achos diannod yn yr Alban mewn perthynas â throsedd, wedi bod yn destun gorchymyn i'w ryddhau'n ddiamod (heb fynd ymlaen i'w gollfarnu);
- (e) wedi derbyn a chytuno i dalu naill ai dirwy procuradur ffisgal o dan adran 302 o Ddeddf Gweithdrefn Droseddol (Yr Alban) 1995(1) (cosb benodedig: cynnig amodol gan brocuradur ffisgal) neu gosb o dan adran 115A o Ddeddf Gweinyddu Nawdd Cymdeithasol 1992(2) (cosb fel dewis arall yn lle erlyn);
- (f) yn cael ei gollfarnu mewn man arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr;
- (g) yn cael ei gyhuddo o drosedd yn y Deyrnas Unedig, neu wedi ei gyhuddo mewn man arall

pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 11(4) or 19(2)(b); or

- (b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 10(2)(a) or 19(2)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness to practise matters: NHS pharmacists on pharmaceutical lists on 10 May 2013

30. An NHS pharmacist, and subject to paragraph 32 where it is a body corporate every director and superintendent of the NHS pharmacist, who is included in a pharmaceutical list maintained by a Local Health Board on 10 May 2013 must on or before 9 November 2013 provide in writing to the Local Health Board the information about fitness matters set out in paragraph 31.

Duty to provide information about fitness matters as they arise

31.—(1) Subject to paragraph 32, an NHS pharmacist, and where the NHS pharmacist is part of a body corporate each of its directors, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS pharmacist or a director—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is bound over following a criminal conviction in the United Kingdom;
- (c) accepts a police caution in the United Kingdom;
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him or her absolutely (without proceeding to conviction);
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(1) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(2) (penalty as alternative to prosecution);
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with

(1) 1995 p.46:13

(2) 1992 p.5.

(1) 1995 c.46.

(2) 1992 c.5.

o drosedd a fyddai wedi bod yn drosedd, pe bai wedi ei chyflawni yng Nghymru a Lloegr;

- (h) yn cael ei hysbysu am ganlyniad unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall, a bod canfyddiad yn ei erbyn;
- (i) yn mynd yn destun unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;
- (j) yn mynd yn destun ymchwiliad i'w ymddygiad proffesiynol mewn cysylltiad ag unrhyw gyflogaeth gyfredol neu flaenorol, neu'n cael ei hysbysu o ganlyniad unrhyw ymchwiliad o'r fath ac unrhyw ganfyddiad yn ei erbyn;
- (k) yn mynd yn destun unrhyw ymchwiliad gan Awdurdod Gwasanaethau Busnes y GIG mewn perthynas â thwyll;
- (l) yn mynd yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, a allai arwain at dynnu ymaith o restr berthnasol; neu
- (m) ar sail ei addasrwydd, yn cael ei dynnu ymaith, ei dynnu yn ddigwyddiadol, neu ei atal dros dro o restr berthnasol, neu os gwrthodir mynediad iddo i restr o'r fath, neu os caiff ei gynnwys yn amodol mewn rhestr o'r fath,

ac os felly, rhaid i'r fferylllydd GIG roi manylion am unrhyw ymchwiliad neu achos a gynhaliwyd neu sydd i'w gynnal, gan gynnwys natur yr ymchwiliad neu achos, ym mhle ac oddeutu pa bryd y cynhaliwyd neu y cynhelir yr ymchwiliad hwnnw neu'r achos hwnnw, ac unrhyw ganlyniad.

(2) Yn ddarostyngedig i baragraff 32, os yw person y mae paragraff (1) yn gymwys iddo yn gyfarwyddwr corff corfforaethol, neu os oedd yn gyfarwyddwr corff corfforaethol ar adeg y digwyddiadau cychwynnol, rhaid iddo, yn ychwanegol, hysbysu'r Bwrdd Iechyd Lleol o fewn 7 diwrnod os yw unrhyw gorff corfforaethol o'r fath—

- (a) yn cael ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) yn cael ei gollfarnu mewn man arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr;
- (c) yn cael ei gyhuddo o drosedd yn y Deyrnas Unedig, neu wedi ei gyhuddo mewn man arall o drosedd a fyddai wedi bod yn drosedd, pe bai wedi ei chyflawni yng Nghymru a Lloegr;
- (d) yn cael ei hysbysu gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall am ganlyniad unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol, a bod canfyddiad yn erbyn y corff corfforaethol;
- (e) yn mynd yn destun unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;

an offence which, if committed in England and Wales, would constitute a criminal offence;

- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into his or her professional conduct, and there is a finding against him or her;
- (i) becomes the subject of any investigation into his or her professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his or her professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him or her;
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud;
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness grounds,

and if so, the NHS pharmacist must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 32, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;

- (f) yn mynd yn destun unrhyw ymchwiliad mewn perthynas â thwyll neu wedi ei hysbysu o ganlyniad unrhyw ymchwiliad o'r fath, a'r canlyniad hwnnw yn ei erbyn;
- (g) yn mynd yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol neu gorff cyfatebol, a allai arwain at dynnu ymaith y corff corfforaethol o restr berthnasol; neu
- (h) ar sail ei addasrwydd, wedi ei dynnu ymaith, ei dynnu yn ddigwyddiadol, neu ei atal dros dro o restr berthnasol, neu os gwrthodwyd mynediad iddo i restr o'r fath, neu os yw wedi ei gynnwys yn amodol ar restr o'r fath,

ac os felly, rhaid i'r person hwnnw roi enw'r corff corfforaethol a chyfeiriad ei swyddfa gofrestredig a manylion am unrhyw ymchwiliad neu achos a gynhaliwyd neu sydd i'w gynnal, gan gynnwys natur yr ymchwiliad neu achos, ym mha le ac oddeutu pa bryd y cynhaliwyd neu y cynhelir yr ymchwiliad hwnnw neu'r achos hwnnw, ac unrhyw ganlyniad.

(3) Rhaid i berson y mae is-baragraff (1) neu (2) yn gymwys iddo gydsynio i'r Bwrdd Iechyd Lleol ofyn i unrhyw gyflogwr neu gyngyflogwr neu unrhyw gorff trwyddedu neu reoleiddio, yn y Deyrnas Unedig neu unrhyw le arall, am wybodaeth ynghylch ymchwiliad cyfredol neu ymchwiliad â chanlyniad anffafriol.

Bwrdd Iechyd Lleol cartref cyrff corfforaethol

32. Os yw fferylllydd GIG yn gorff corfforaethol sydd â'i swyddfa gofrestredig yng Nghymru a Lloegr, caniateir i'r wybodaeth sydd i'w darparu o dan baragraffau 30, 31 a 35(3) i (6) gael ei darparu yn hytrach i Fwrdd Iechyd Lleol cartref (fel y'i diffinnir yn rheoliad 46). Pan fo'r fferylllydd GIG yn darparu'r wybodaeth i'w Fwrdd Iechyd Lleol cartref, rhaid iddo hefyd ddarparu i'r Bwrdd Iechyd Lleol cartref fanylion o'r holl Fyrddau Iechyd Lleol eraill y cynhwysir y fferylllydd GIG yn eu rhestrau fferyllol.

Cwynion

33. Rhaid i fferylllydd GIG fod wedi sefydlu trefniadau sy'n cydymffurfio â gofynion Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011(1), ar gyfer trin ac ystyried unrhyw bryderon neu gwynion ynghylch mater sy'n gysylltiedig â'r ddarpariaeth o wasanaethau fferyllol gan y fferylllydd GIG.

- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Local Health Board of bodies corporate

32. Where an NHS pharmacist is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 30, 31 and 35(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 46). When the NHS pharmacist provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS pharmacist is included.

Complaints

33. An NHS pharmacist must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011(1), for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

Patterson, Liz
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(1) O.S. 2011/704 (Cy.108) a ddiwygiwyd gan O.S. 2011/1706 (Cy.192).

(1) S.I. 2011/704 (W.108) amended by S.I. 2011/1706 (W.192).

Telerau gwasanaethu eraill

Other terms of service

Gwasanaethau cyfeiriedig

34. Rhaid i fferylllydd GIG, y mae'r Bwrdd Iechyd Lleol sydd â'r fferylllydd GIG hwnnw ar ei restr fferyllol wedi gwneud trefniant gydag ef ar gyfer darparu unrhyw wasanaethau cyfeiriedig, gydymffurfio â thelerau ac amodau'r trefniant hwnnw.

Gwybodaeth sydd i'w chyflenwi

35.—(1) Rhaid i fferylllydd GIG roi hysbysiad o'r canlynol i'r Bwrdd Iechyd Lleol sydd â'r fferylllydd GIG hwnnw ar ei restr fferyllol, o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn)—

- (a) unrhyw ddigwyddiad sy'n ei gwneud yn ofynnol newid yr wybodaeth a gofnodwyd am y fferylllydd GIG yn y rhestr fferyllol, na roddodd y fferylllydd GIG hysbysiad ohono rywfodd arall yn unol â'r Rheoliadau hyn;
- (b) yn achos fferylllydd GIG sy'n unigolyn, unrhyw newid yn ei gyfeiriad preifat; ac
- (c) yn achos fferylllydd GIG sy'n gorff corfforaethol, unrhyw newid yng nghyfeiriad ei swyddfa gofrestredig.

(2) Rhaid i fferylllydd GIG, os gofynnir iddo, roi i'r Bwrdd Iechyd Lleol enw unrhyw fferylllydd GIG a gyflogir ganddo sy'n gyfrifol am weinyddu presgripsiwn penodol.

(3) Yn ddarostyngedig i is-baragraff (6), rhaid i fferylllydd GIG sy'n gorff corfforaethol roi hysbysiad ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn) o unrhyw newidiadau yn enwau a chyfeiriadau pob un o'i gyfarwyddwyr a'i uwcharolygydd.

(4) Yn ddarostyngedig i is-baragraff (6), os yw fferylllydd GIG sy'n gorff corfforaethol yn penodi cyfarwyddwr neu uwcharolygydd nas rhestrwyd yng nghais y fferylllydd GIG am ei gynnwys mewn rhestr fferyllol, rhaid i'r fferylllydd GIG roi hysbysiad ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn) o'r wybodaeth am addasrwydd y person hwnnw i ymarfer.

(5) Yn ddarostyngedig i is-baragraff (6), rhaid i fferylllydd GIG, neu gyfarwyddwr neu uwcharolygydd fferylllydd GIG sy'n gorff corfforaethol, hysbysu'r Bwrdd Iechyd Lleol—

- (a) os yw'r unigolyn hwnnw, neu'r corff corfforaethol y mae'n gyfarwyddwr neu'n uwcharolygydd ohono, yn gwneud cais am

Directed services

34. An NHS pharmacist with whom a Local Health Board on whose pharmaceutical list the NHS pharmacist is included makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

Information to be supplied

35.—(1) An NHS pharmacist must give notice to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about him or her in the pharmaceutical list which he or she has not otherwise notified in accordance with these Regulations;
- (b) in the case of an NHS pharmacist who is an individual, any change of his or her private address; and
- (c) in the case of an NHS pharmacist that is a body corporate, any change to the address of its registered office.

(2) An NHS pharmacist must give the Local Health Board, if it so requests, the name of any pharmacist employed by him or her who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS pharmacist that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors and superintendent.

(4) Subject to sub-paragraph (6), if an NHS pharmacist that is a body corporate appoints a director or superintendent that was not listed on the NHS pharmacist's application for inclusion in a pharmaceutical list, the NHS pharmacist must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS pharmacist or the director or superintendent of an NHS pharmacist that is a body corporate must inform the Local Health Board—

- (a) if he or she, or a body corporate of which he or she is a director or superintendent, applies to be included in any of another Local Health

gael ei gynnwys yn unrhyw un o restrau cyflawnwyr neu ddarparwyr GIG Bwrdd Iechyd Lleol arall ac o ganlyniad unrhyw gais o'r fath; a

- (b) os daw'r unigolyn hwnnw yn gyfarwyddwr neu'n uwcharolygydd corff corfforaethol sydd yn unrhyw un o restrau cyflawnwyr neu ddarparwyr GIG Bwrdd Iechyd Lleol arall, neu sy'n gwneud cais am ei gynnwys mewn rhestr o'r fath, ac o ganlyniad unrhyw gais o'r fath.

(6) Os yw'r fferylllydd GIG yn gorff corfforaethol sydd â'i swyddfa gofrestredig yng Nghymru, caiff ddarparu'r wybodaeth sydd i'w darparu o dan is-baragraffau (3) i (5) i'r Bwrdd Iechyd Lleol hwnnw, yn unig, y lleolir y swyddfa gofrestredig yn ei ardal, ar yr amod bod y fferylllydd GIG yn darparu i'r Bwrdd Iechyd Lleol hwnnw fanylion hefyd o'r holl Fyrddau Iechyd Lleol eraill y cynhwysir y fferylllydd GIG yn eu rhestrau fferyllol, ac mewn amgylchiadau o'r fath, rhaid i'r Bwrdd Iechyd Lleol hwnnw drosglwyddo'r wybodaeth ymlaen i unrhyw Fwrdd Iechyd Lleol arall—

- (a) y cynhwysir y fferylllydd GIG yn ei restr fferyllol; neu
- (b) y gwneir cais iddo gan y fferylllydd GIG am gael ei gynnwys yn ei restr fferyllol,

ac sy'n gofyn am yr wybodaeth.

(7) Yn y paragraff hwn, ystyr "rhestr cyflawnwyr neu ddarparwyr GIG" ("*NHS performers or providers list*") yw—

- (a) rhestr fferyllol; neu
- (b) rhestr a gynhelir o gyflawnwyr neu ddarparwyr cymeradwy gwasanaethau meddygol sylfaenol, deintyddol neu offthalmig.

Tynnu enwau yn ôl o restrau fferyllol

36. Os yw fferylllydd GIG yn bwriadu tynnu ei enw yn ôl o'r rhestr fferyllol, rhaid iddo hysbysu'r Bwrdd Iechyd Lleol o'i fwriad, dri mis o leiaf cyn y dyddiad hwnnw, oni fydd yn anymarferol iddo wneud hynny, ac os felly, rhaid iddo hysbysu'r Bwrdd Iechyd Lleol cyn gynted ag y bo'n ymarferol iddo wneud hynny.

Codi ffioedd am gyffuriau, ac ad-daliadau

37.—(1) Yn ddarostyngedig i reoliadau a wneir o dan adran 121 o Ddeddf 2006 (codi ffioedd am gyffuriau, meddyginiaethau neu gyfarpar, neu wasanaethau fferyllol) rhaid darparu'r holl gyffuriau, cynwysyddion a chyfarpar a ddarperir o dan y telerau gwasanaethu hyn yn ddi-dâl.

(2) Pan fo fferylllydd GIG, wrth ymateb i archeb am gyffuriau a lofnodwyd gan ragnodydd, yn cyflenwi

Board's NHS performers or providers lists, and of the outcome of any such application; and

- (b) if he or she becomes a director or superintendent of a body corporate which is in any of another Local Health Board's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS pharmacist is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS pharmacist also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS pharmacist is included; or
- (b) to whom the NHS pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

(7) In this paragraph, "NHS performers or providers list" ("*rhestr cyflawnwyr neu ddarparwyr GIG*") means—

- (a) a pharmaceutical list; or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

Withdrawal from pharmaceutical lists

36. Where an NHS pharmacist intends to withdraw from the pharmaceutical list, he or she must notify the Local Health Board of this at least three months in advance of that date, unless it is impracticable for him or her to do so in which case he or she must notify the Local Health Board as soon as it is practicable for him or her to do so.

Charges for drugs and refunds

37.—(1) Subject to regulations made under section 121 of the 2006 Act (charges for drugs, medicines or appliances, or pharmaceutical services) all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where an NHS pharmacist supplies a container in response to an order for drugs signed by a prescriber,

cynhwysydd, neu'n cyflenwi cynhwysydd ocsigen neu gyfarpar ocsigen, ac eithrio cyfarpar a bennir yn y Tariff Cyffuriau fel rhai nad ydynt yn ddychweladwy i'r fferyllydd GIG, bydd y cynhwysydd a'r cyfarpar yn parhau'n eiddo i'r fferyllydd GIG.

(3) Os yw unrhyw berson, sydd â hawl ganddo i ad-daliad o unrhyw ffi a dalwyd o dan y Rheoliadau Ffioedd, yn cyflwyno i fferyllydd GIG hawliad dilys am ad-daliad, rhaid i'r fferyllydd GIG wneud yr ad-daliad.

(4) At ddibenion is-baragraff (3), ni fydd hawliad am ad-daliad yn ddilys oni wneir yr hawliad yn briodol ar Ffurflen WP57 0405 o fewn tri mis o'r dyddiad y talwyd y ffi.

Arolygiadau a mynediad at wybodaeth

38.—(1) Rhaid i fferyllydd GIG ganiatáu i bersonau, a awdurdodwyd mewn ysgrifen gan y Bwrdd Iechyd Lleol sydd â'r fferyllydd GIG yn gynwysedig yn ei restr fferyllol, fynd i mewn i fferyllfa'r fferyllydd GIG ac i'w harchwilio ar unrhyw adeg resymol, at y dibenion canlynol—

- (a) canfod a yw'r fferyllydd GIG yn cydymffurfio â gofynion yr Atodlen hon ai peidio;
- (b) archwilio, monitro a dadansoddi—
 - (i) y ddarpariaeth a wneir gan y fferyllydd GIG ar gyfer gofal a thriniaeth i gleifion, a
 - (ii) y modd y mae'r fferyllydd GIG yn rheoli'r gwasanaethau fferyllol a ddarperir ganddo,

pan fo'r amodau yn is-baragraff (2) wedi eu bodloni.

(2) Yr amodau yw'r canlynol—

- (a) bod rhybudd rhesymol wedi ei roi o'r bwriad i fynd i mewn;
- (b) bod y Pwyllgor Fferyllol Lleol ar gyfer yr ardal y lleolir y fferyllfa ynddi wedi ei wahodd i fod yn bresennol yn yr arolygiad, os gofynnodd y fferyllydd GIG am hynny;
- (c) bod gan y person a awdurdodwyd mewn ysgrifen dystiolaeth ysgrifenedig o'i awdurdodiad yn ei feddiant, a bod y person hwnnw'n dangos y dystiolaeth honno os gofynnir iddo; a
- (d) na fydd y person a awdurdodwyd mewn ysgrifen yn mynd i mewn i unrhyw ran o'r fangre a ddefnyddir yn unig fel llety preswyl heb gydsyniad y preswylydd.

(3) Rhaid i fferyllydd GIG, ar gais y Bwrdd Iechyd Lleol neu berson a awdurdodwyd mewn ysgrifen a grybwyllir yn is-baragraff (1), ganiatáu i'r Bwrdd Iechyd Lleol neu berson a awdurdodir ganddo gael mynediad at unrhyw wybodaeth y gofynnir amdani yn

or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the NHS pharmacist, the container and equipment remains the property of the NHS pharmacist.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents an NHS pharmacist with a valid claim for repayment, the NHS pharmacist must make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if it is duly made on Form WP57 0405 within three months of the date on which the charge was paid.

Inspections and access to information

38.—(1) An NHS pharmacist must allow persons authorised in writing by the Local Health Board in whose pharmaceutical list the NHS pharmacist is included to enter and inspect the NHS pharmacist's pharmacy at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS pharmacist is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the NHS pharmacist for patient care and treatment, and
 - (ii) the management by the NHS pharmacist of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the pharmacy is situated has been invited to be present at the inspection, where this is requested by the NHS pharmacist;
- (c) the person authorised in writing carries written evidence of his or her authorisation, which he or she produces on request; and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS pharmacist must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow the Local Health Board or person authorised by it access to any information which the Local Health Board or person

rhesymol gan y Bwrdd Iechyd Lleol neu'r person hwnnw—

- (a) at y dibenion a grybwyllir yn is-baragraff (1); neu
- (b) yn achos y Bwrdd Iechyd Lleol, mewn cysylltiad â'i swyddogaethau sy'n ymwneud â gwasanaethau fferyllol.

reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

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Rheoliad 5

Regulation 5

Telerau gwasanaethu ar gyfer contractwyr cyfarpar GIG sy'n darparu gwasanaethau fferyllol drwy ddarparu cyfarpar yn unig

Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances

Ymgorffori darpariaethau

1. Mae unrhyw ddarpariaethau o'r canlynol sy'n effeithio ar hawliau a rhwymedigaethau contractwyr cyfarpar GIG sy'n darparu gwasanaethau fferyllol yn ffurfio rhan o'r telerau gwasanaethu—

- (a) y Rheoliadau;
- (b) y Tariff Cyffuriau i'r graddau y mae'n rhestru cyfarpar at ddibenion adran 80 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol);
- (c) cymaint o Ran II Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thriwlynlys) 1992 ag y sy'n ymwneud ag—
 - (i) ymchwiliadau a wneir gan y pwyllgor disgyblu fferyllol a'r cyd-bwyllgor disgyblu a chamau y caiff y Bwrdd Iechyd Lleol eu cymryd o ganlyniad i ymchwiliadau o'r fath, a
 - (ii) apelau i Weinidogion Cymru yn erbyn penderfyniadau'r Bwrdd Iechyd Lleol; a
- (d) cymaint o reoliad 29 o Reoliadau Cynghorau Iechyd Cymuned (Cyfansoddiad, Aelodaeth a Gweithdrefnau) (Cymru) 2010(1) (mynd i mewn i fangreodd a'u harchwilio) ag sy'n ymwneud â mynd i mewn i fangreodd sydd naill ai'n eiddo i gontractwr cyfarpar GIG neu dan ei reolaeth neu'n fangreodd lle mae contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol, ac archwilio mangreodd o'r fath.

Rhaniaid cyfrifoldebau rhwng unigolion a chyrrff corfforaethol

2.—(1) I'r graddau y mae'r Atodlen hon yn gosod ar gontractwr cyfarpar GIG ofyniad na ellid ei gyflawni gan neb ond person naturiol, neu a gyflawnid fel arfer gan berson naturiol—

- (a) os yw'r contractwr cyfarpar GIG yn fferylllydd cofrestredig—
 - (i) rhaid i'r fferylllydd cofrestredig hwnnw gydymffurfio â'r gofyniad hwnnw, neu
 - (ii) os yw'n cyflogi neu wedi cymryd ymlaen fferylllydd cofrestredig mewn cysylltiad â darparu gwasanaethau fferyllol, rhaid i'r fferylllydd cofrestredig hwnnw naill ai gydymffurfio â'r gofyniad hwnnw neu sicrhau cydymffurfiaeth â'r gofyniad hwnnw gan berson y mae'n ei gyflogi neu wedi ei gymryd ymlaen; a

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of NHS appliance contractors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
 - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and
 - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board; and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010(1) (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by the NHS appliance contractor or where pharmaceutical services are provided by him or her.

Division of responsibilities between individuals and corporate bodies

2.—(1) To the extent that this Schedule imposes a requirement on an NHS appliance contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the NHS appliance contractor is a registered pharmacist—
 - (i) that registered pharmacist must comply with that requirement, or
 - (ii) if he or she employs or engages a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by a person whom he or she employs or engages; and

(1) O.S. 2010/288 (Cy.37).

(1) S.I. 2010/288 (W.37).

- (b) os nad yw'r contractwr cyfarpar GIG yn berson naturiol, rhaid i'r contractwr cyfarpar GIG hwnnw sicrhau cydymffurfiaeth â'r gofyniad hwnnw gan berson y mae'n ei gyflogi neu wedi ei gymryd ymlaen,

a rhaid dehongli cyfeiriadau yn yr Atodlen hon at contractwr cyfarpar GIG yn unol â hynny.

(2) Pan fo'r Atodlen hon yn gosod gofyniad ar gyfarwyddwr corff corfforaethol sydd wedi ei gynnwys mewn rhestr fferyllol, rhaid ystyried toriad o'r gofyniad hwnnw yn doriad gan y corff corfforaethol o'i delerau gwasanaethu.

Gwasanaethau gweinyddu

3. Rhaid i gontractwr cyfarpar GIG, i'r graddau y mae'n ofynnol gan baragraffau 4 i 8 ac yn y modd a ddisgrifir yn y paragraffau hynny, ddarparu cyfarpar priodol a digonol i bersonau sy'n cyflwyno presgripsiynau am gyfarpar gan broffesiynolion gofal iechyd yn rhinwedd eu swyddogaethau.

Gweinyddu cyfarpar

4.—(1) Yn y paragraff hwn, mae "wedi ei llofnodi" ("*signed*") yn cynnwys llofnodi gyda llofnod electronig uwch y rhagnodydd.

(2) Yn ddarostyngedig i ddarpariaethau'r Atodlen hon, pan fo—

- (a) unrhyw berson yn cyflwyno ffurflen bresgripsiwn anelectronig sy'n cynnwys—
 - (i) archeb am gyfarpar, nad yw'n gyfarpar argaeledd cyfyngedig, wedi ei llofnodi gan ragnodydd, neu
 - (ii) archeb am gyfarpar argaeledd cyfyngedig wedi ei llofnodi gan ragnodydd ac yn cynnwys y cyfeirnod "SLS", "Selected List Scheme" neu "Drug Tariff"; neu
- (b) contractwr cyfarpar GIG yn cael presgripsiwn amlroddadwy electronig sy'n cydymffurfio â'r gwasanaeth TPE ac yn cynnwys archeb o fath a bennir ym mharagraff (a)(i) a (ii) ac—
 - (i) unrhyw berson yn gofyn am ddarparu cyfarpar yn unol â'r disgrifiad hwnnw, neu
 - (ii) y contractwr cyfarpar GIG wedi trefnu gyda'r claf yn flaenorol, y byddai'n gweinyddu'r presgripsiwn hwnnw pan ddeuai i law,

rhaid i'r contractwr cyfarpar GIG, yn rhesymol brydlon, ddarparu'r cyfryw rai o'r cyfarpar a archebir felly a gyflenwir gan y contractwr cyfarpar GIG yng nghwas arferol ei fusnes.

(3) At ddibenion y paragraff hwn, mae presgripsiwn amlroddadwy anelectronig am gyfarpar i'w ystyried

- (b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by a person whom it employs or engages,

and references in this Schedule to an NHS appliance contractor must be construed accordingly.

(2) Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, breach of that requirement must be deemed to be a breach by the body corporate of its terms of service.

Dispensing services

3. An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances by health care professionals in pursuance of their functions.

Dispensing of appliances

4.—(1) In this paragraph, "signed" ("*wedi ei llofnodi*") includes signature with a prescriber's advanced electronic signature.

(2) Subject to the provisions of this Schedule, where—

- (a) any person presents a non-electronic prescription form which contains—
 - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS", "Selected List Scheme" or "Drug Tariff"; or
- (b) an NHS appliance contractor receives an electronic repeatable prescription complying with the ETP service which contains an order of a kind specified in paragraph (a)(i) and (ii) and—
 - (i) any person requests the provision of an appliance in accordance with that prescription, or
 - (ii) the NHS appliance contractor has previously arranged with the patient that he or she will dispense that prescription on receipt,

an NHS appliance contractor must, with reasonable promptness, provide such of the appliances so ordered as he or she supplies in the normal course of business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for appliances is to

wedi ei gyflwyno, hyd yn oed os nad yw'r person sy'n dymuno cael y cyfarpar yn cyflwyno'r presgripsiwn hwnnw, os yw—

- (a) y presgripsiwn hwnnw gan y contractwr cyfarpar GIG yn ei feddiant; a
- (b) swp-ddyddiad cysylltiedig naill ai'n cael ei gyflwyno gan y person hwnnw, neu ym meddiant y contractwr cyfarpar GIG.

Cyflenwi ar frys heb bresgripsiwn

5.—(1) Mae'r paragraff hwn yn gymwys pan fo rhagnodydd, mewn achos brys, yn gofyn i contractwr cyfarpar GIG ddarparu cyfarpar.

(2) Caiff y contractwr cyfarpar GIG ddarparu'r cyfarpar y gofynnir amdano cyn cael ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy mewn perthynas â'r cyfarpar hwnnw, ar yr amod bod y rhagnodydd yn ymrwymo i—

- (a) rhoi i'r contractwr cyfarpar GIG ffurflen bresgripsiwn anelectronig neu bresgripsiwn amlroddadwy anelectronig mewn perthynas â'r cyfarpar o fewn 72 awr ar ôl gwneud y cais; neu
- (b) rhoi i'r contractwr cyfarpar GIG ffurflen bresgripsiwn electronig sy'n cydymffurfio â'r gwasanaeth TPE o fewn 72 awr ar ôl gwneud y cais.

Materion rhagarweiniol cyn darparu cyfarpar

6.—(1) Os yw'r person a bennir yn is-baragraff (2) yn gofyn i'r contractwr cyfarpar GIG wneud hynny—

- (a) rhaid i'r contractwr cyfarpar GIG roi amcangyfrif o'r amser pan fydd y cyfarpar yn barod; a
- (b) os na fydd y cyfarpar yn barod erbyn yr amser hwnnw, rhaid i'r contractwr cyfarpar GIG roi amcangyfrif diwygiedig o'r amser pan fydd yn barod.

(2) Person a bennir yn yr is-baragraff hwn yw person—

- (a) sy'n cyflwyno ffurflen bresgripsiwn anelectronig neu bresgripsiwn amlroddadwy anelectronig; neu
- (b) sy'n gofyn am ddarparu cyfarpar yn unol â ffurflen bresgripsiwn electronig neu bresgripsiwn amlroddadwy electronig.

(3) Cyn darparu cyfarpar yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—

- (a) rhaid i'r contractwr cyfarpar GIG ofyn i unrhyw berson, sy'n gwneud datganiad nad oes raid i'r person a enwir ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy dalu'r ffioedd a bennir yn rheoliad 3 o'r Rheoliadau Ffioedd (cyflenwi cyffuriau a

be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where—

- (a) the NHS appliance contractor has that prescription in his or her possession; and
- (b) that person presents, or the NHS appliance contractor has in his or her possession, an associated batch issue.

Urgent supply without a prescription

5.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor to provide an appliance.

(2) The NHS appliance contractor may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

- (a) give the NHS appliance contractor a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or
- (b) give the NHS appliance contractor an electronic prescription form complying with the ETP service within 72 hours of the request being made.

Preliminary matters before providing appliances

6.—(1) If the person specified in sub-paragraph (2) asks the NHS appliance contractor to do so—

- (a) the NHS appliance contractor must give an estimate of the time when the appliance will be ready; and
- (b) if it is not ready by then, the NHS appliance contractor must give a revised estimate of the time when it will be ready.

(2) A person specified in this sub-paragraph is a person—

- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or
- (b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription—

- (a) the NHS appliance contractor must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3 of the Charges Regulations (supply of drugs and appliances

chyfarpar gan fferyllwyr), yn rhinwedd naill ai—

- (i) hawl i esemptiad o dan reoliad 8 (esemptiadau) o'r Rheoliadau Ffioedd, neu
- (ii) hawl i beidio â thalu ffioedd o dan reoliad 5 o'r Rheoliadau Peidio â Chodi Tâl (hawl i beidio â thalu ffi o gwbl ac i gael taliad llawn),

ddangos tystiolaeth foddhaol o'r cyfryw hawl, oni wneir y datganiad mewn perthynas â hawl i esemptiad yn rhinwedd rheoliad 8 o'r Rheoliadau Ffioedd neu mewn perthynas â hawl i beidio â thalu yn rhinwedd rheoliad 5(1)(d) neu (2) o'r Rheoliadau Peidio â Chodi Tâl, pan fo tystiolaeth o'r fath eisoes ar gael i'r contractwr cyfarpar GIG ar yr adeg y gwneir y datganiad;

- (b) yn achos ffurflen bresgripsiwn anelectronig neu bresgripsiwn amlroddadwy anelectronig, os na ddangosir tystiolaeth foddhaol i'r contractwr cyfarpar GIG fel sy'n ofynnol gan baragraff (a), rhaid i'r contractwr cyfarpar GIG arnodi'r ffurflen y gwneir y datganiad arni, i'r perwyl hwnnw; ac
- (c) yn achos ffurflen bresgripsiwn electronig neu bresgripsiwn amlroddadwy electronig, rhaid i'r contractwr cyfarpar GIG gydymffurfio ag unrhyw ofynion gan y gwasanaeth TPE i ddarparu—
 - (i) cofnod o'r hawl o'r esemptiad neu'r hawl i beidio â thalu a hawliwyd, a pha un a ddangoswyd tystiolaeth foddhaol ai peidio, fel y cyfeirir ati ym mharagraff (a), a
 - (ii) mewn unrhyw achos pan fo ffi'n ddyledus, cadarnhad bod y ffi berthnasol wedi ei thalu.

Darparu cyfarpar

7.—(1) Pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy i contractwr cyfarpar GIG, rhaid i'r contractwr cyfarpar GIG beidio â darparu'r cyfarpar a archebir felly, ac eithrio—

- (a) pan fo'r ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy wedi eu llofnodi a'u cwblhau yn briodol, fel a ddisgrifir ym mharagraff 4; a
- (b) yn unol â'r archeb sydd ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy,

yn ddarostyngedig i unrhyw reoliadau sydd mewn grym o dan Ddeddf Pwysau a Mesurau 1985 a darpariaethau canlynol yr Atodlen hon.

(2) Os yw'r archeb yn archeb am fath o gyfarpar y mae'n ofynnol ei fesur a'i ffitio gan y contractwr cyfarpar GIG, rhaid i'r contractwr cyfarpar GIG wneud yr holl drefniadau angenrheidiol—

by chemists) by virtue of either—

- (i) entitlement to exemption under regulation 8 of the Charges Regulations (exemptions), or
- (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations and at the time of the declaration the NHS appliance contractor already has such evidence available to him or her;

- (b) if, in the case of a non-electronic prescription form or a non-electronic repeatable prescription no satisfactory evidence, as required by paragraph (a), is produced to the NHS appliance contractor, the NHS appliance contractor must endorse the form on which the declaration is made to that effect; and
- (c) in the case of an electronic prescription form or an electronic repeatable prescription, the NHS appliance contractor must comply with any requirements of the ETP service to provide—
 - (i) a record of the exemption from or remission of charges claimed and whether satisfactory evidence was produced, as referred to in paragraph (a), and
 - (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

Providing appliances

7.—(1) Where an NHS appliance contractor is presented with a prescription form or a repeatable prescription, the NHS appliance contractor must only provide the appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985 and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting by the NHS appliance contractor, the NHS appliance contractor must make all necessary arrangements for—

- (a) ar gyfer mesur y person a enwir ar y ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy ar gyfer y cyfarpar; a
- (b) ar gyfer ffitio'r cyfarpar.

(3) Os yw'r archeb yn archeb am gyfarpar sydd wedi ei gynnwys yn y Tariff Cyffuriau, Fformiwlari Cenedlaethol Prydain (gan gynnwys unrhyw Atodiad a gyhoeddwyd yn rhan o'r Fformiwlari hwnnw), Fformiwlari'r Ymarferydd Deintyddol, y Cyffuriadur Ewropeaidd neu Godecs Fferyllol Prydain, rhaid i'r cyfarpar a ddarperir gydymffurfio â'r safon neu'r fformiwlari a bennir yno.

Gwrthod darparu cyfarpar a archebir

8.—(1) Caiff contractwr cyfarpar GIG wrthod darparu cyfarpar a archebir ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—

- (a) os yw'r contractwr cyfarpar GIG yn credu, yn rhesymol, nad yw'r archeb yn archeb ddilys ar gyfer y person a enwir ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy;
- (b) os yw'n ymddangos i'r contractwr cyfarpar GIG fod camgymeriad yn y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy neu, yn achos presgripsiwn amlroddadwy anelectronig, yn ei swp-ddyroddiad cysylltiedig (gan gynnwys camgymeriad clinigol a wnaed gan y rhagnodydd) neu y byddai darparu'r cyfarpar, yn yr amgylchiadau, yn groes i farn glinigol y contractwr cyfarpar GIG;
- (c) os yw'r contractwr cyfarpar GIG neu bersonau eraill yn dioddef trais neu'n cael eu bygwth â thrais gan y person sy'n cyflwyno'r ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy neu'n gofyn am ddarparu cyfarpar yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu gan unrhyw berson sydd gyda'r person hwnnw; neu
- (d) os yw'r person sy'n cyflwyno'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy neu'n gofyn am ddarparu cyfarpar yn unol â ffurflen bresgripsiwn electronig neu bresgripsiwn amlroddadwy electronig neu unrhyw berson arall sydd gyda'r person hwnnw, yn cyflawni neu'n bygwth cyflawni trosedd.

(2) Rhaid i gontractwr cyfarpar GIG wrthod darparu cyfarpar a archebir ar bresgripsiwn amlroddadwy—

- (a) os nad oes gan y contractwr cyfarpar GIG gofnod o'r presgripsiwn hwnnw;
- (b) os nad oes gan y contractwr cyfarpar GIG, yn achos presgripsiwn amlroddadwy anelectronig, unrhyw swp-ddyroddiad cysylltiedig ac os na chyflwynir swp-ddyroddiad o'r fath i'r contractwr cyfarpar GIG;

- (a) measuring the person named on the prescription form or repeatable prescription for the appliance; and
- (b) fitting the appliance.

(3) If the order is for an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

Refusal to provide appliances ordered

8.—(1) An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) the NHS appliance contractor reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription;
- (b) it appears to the NHS appliance contractor that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to the clinical judgement of the NHS appliance contractor;
- (c) the NHS appliance contractor or other persons are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with a prescription form or repeatable prescription or by any person accompanying that person; or
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or electronic repeatable prescription or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) An NHS appliance contractor must refuse to provide appliances ordered on a repeatable prescription where—

- (a) he or she has no record of that prescription;
- (b) he or she does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to him or her;

- (c) os nad yw wedi ei lofnodi gan ragnodydd amlroddadwy;
- (d) os byddai gwneud hynny yn anghyson ag unrhyw ysbeidiau a bennir yn y presgripsiwn;
- (e) os hwnnw fyddai'r tro cyntaf y darperid cyfarpar yn unol â'r presgripsiwn, ac os llofnodwyd y presgripsiwn (yn electronig neu fel arall) fwy na chwe mis yn gynharach;
- (f) os llofnodwyd y presgripsiwn amlroddadwy (yn electronig neu fel arall) fwy na blwyddyn yn gynharach;
- (g) os yw'r dyddiad dod i ben ar y presgripsiwn amlroddadwy wedi mynd heibio; neu
- (h) os hysbyswyd y contractwr cyfarpar GIG, gan y ragnodydd amlroddadwy, nad oes angen y presgripsiwn bellach.

(3) Pan fo claf yn gofyn am gyflenwi cyfarpar a archebwyd ar bresgripsiwn amlroddadwy (ac eithrio'r tro cyntaf y gofynnir), rhaid i contractwr cyfarpar GIG beidio â darparu'r cyfarpar a archebir oni chaiff ei fodloni—

- (a) bod y claf y mae'r presgripsiwn ar ei gyfer—
 - (i) yn defnyddio'r cyfarpar yn briodol, ac yn debygol o barhau i'w ddefnyddio felly, a
 - (ii) nad yw'n dioddef o unrhyw sgil effeithiau'r driniaeth sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf;
- (b) nad yw'r modd y defnyddir y cyfarpar gan y claf y mae'r presgripsiwn ar ei gyfer wedi newid mewn ffordd sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf; ac
- (c) na ddigwyddodd unrhyw newidiadau yn iechyd y claf y mae'r presgripsiwn ar ei gyfer sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf.

Gweithgareddau pellach sydd i'w cyflawni mewn cysylltiad â darparu gwasanaethau gweinyddu

9.—(1) Mewn cysylltiad â'r gwasanaethau a ddarperir o dan baragraff 3, rhaid i contractwr cyfarpar GIG—

- (a) sicrhau y rhoddir cyngor priodol i gleifion ynghylch unrhyw gyfarpar a ddarperir iddynt—
 - (i) i'w galluogi i ddefnyddio'r cyfarpar yn briodol, a
 - (ii) bodloni anghenion rhesymol y cleifion am wybodaeth gyffredinol ynglŷn â'r cyfarpar;
- (b) darparu cyngor priodol i gleifion y mae'n cyflenwi cyfarpar iddynt ynglŷn â chadw'r cyfarpar yn ddiogel;
- (c) wrth ddarparu cyfarpar i glaf yn unol â ffurflen

- (c) it is not signed by a repeatable prescriber;
- (d) to do so would not be in accordance with any intervals specified in the prescription;
- (e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than six months previously;
- (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;
- (g) the expiry date on the repeatable prescription has passed; or
- (h) he or she has been informed by the repeatable prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), an NHS appliance contractor must only provide the appliance ordered if satisfied that—

- (a) the patient to whom the prescription relates—
 - (i) is using and is likely to continue to use the appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment;
- (b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

9.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor must—

- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
 - (i) to enable them to utilise the appliances appropriately, and
 - (ii) to meet the patients' reasonable needs for general information about the appliances;
- (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;
- (c) when providing appliances to a patient in

bresgripsiwn neu bresgripsiwn
amlroddadwy—

- (i) darparu cyngor priodol, yn benodol, ar y pwysigrwydd o ofyn am yr eitemau hynny, yn unig, sydd arno eu hangen mewn gwirionedd, a
- (ii) at y dibenion hynny, rhoi sylw i'r manylion a gynhwysir yn y cofnodion a gynhelir o dan baragraff (f) mewn perthynas â darparu cyfarpar a'r patrwm presgripsiynu mewn cysylltiad â'r claf dan sylw;
- (d) darparu i'r claf nodyn ysgrifenedig o unrhyw gyfarpar sy'n ddyledus iddo, a rhoi gwybod i'r claf pa bryd y disgwylir i'r cyfarpar fod ar gael;
- (e) darparu i'r claf nodyn ysgrifenedig o enw, cyfeiriad a rhif teleffon y contractwr cyfarpar GIG;
- (f) cadw a chynnal cofnodion—
 - (i) o'r cyfarpar a ddarparwyd, er mwyn hwyluso parhad gofal y claf,
 - (ii) mewn achosion priodol, o'r cyngor a roddir ac unrhyw ymyriadau neu atgyfeiriadau a wneir (gan gynnwys ymyriadau o arwyddocâd clinigol mewn achosion sy'n ymwneud â phresgripsiynau amlroddadwy), a
 - (iii) o nodiadau a ddarperir o dan baragraff (d);
- (g) dilyn hyfforddiant priodol ynglŷn ag amlweinyddu, gan roi sylw i unrhyw argymhellion ynglŷn ag hyfforddiant o'r fath a bennir yn y Tariff Cyffuriau;
- (h) os yw'r contractwr cyfarpar GIG yn cymryd meddiant o bresgripsiwn amlroddadwy anelectronig neu swp-ddyroddiad cysylltiedig, storio'r presgripsiwn amlroddadwy neu'r swp-ddyroddiad cysylltiedig hwnnw yn ddiogel;
- (i) os yw'r contractwr cyfarpar GIG yn darparu cyfarpar o dan bresgripsiwn electronig, darparu i'r claf, os yw'r claf yn gofyn amdano, gofnod ysgrifenedig o'r cyfarpar a archebwyd ar y presgripsiwn hwnnw, ac yn achos presgripsiwn amlroddadwy electronig, gofnod o'r nifer o droeon y caniateir ei weinyddu;
- (j) cynnal cofnodion o bresgripsiynau amlroddadwy mewn ffurf a fydd yn darparu trywydd archwilio eglur o'r cyflenwadau o dan y presgripsiwn amlroddadwy (gan gynnwys dyddiadau a'r meintiau a gyflenwir);
- (k) dinistrio unrhyw swp-ddyroddiadau dros ben mewn cysylltiad â chyfarpar—
 - (i) nad oes eu hangen, neu
 - (ii) y gwrthodwyd i glaf yn unol â pharagraff 8;
- (l) sicrhau, pan wrthodir cyfarpar i berson yn unol

accordance with a prescription form or repeatable prescription—

- (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
- (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
- (d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;
- (e) provide a patient with a written note of the NHS appliance contractor's name, address and telephone number;
- (f) keep and maintain records—
 - (i) of appliances provided, in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under paragraph (d);
- (g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;
- (h) if the NHS appliance contractor takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) if the NHS appliance contractor provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it may be dispensed;
- (j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);
- (k) destroy any surplus batch issues relating to appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused an appliance pursuant to paragraph 8;
- (l) ensure that where a person is refused

â pharagraff 8(1)(b), (2) neu (3), y cyfeirir y claf yn ôl at y rhagnodydd am gyngor pellach;

- (m) pan ddarperir cyfarpar i glaf o dan bresgripsiwn amlroddadwy, hysbysu'r rhagnodydd ynghylch unrhyw faterion o arwyddocâd clinigol sy'n codi mewn cysylltiad â'r presgripsiwn a chadw cofnod o'r hysbysiad hwnnw;
- (n) hysbysu'r rhagnodydd ynghylch unrhyw wrthodiad i ddarparu cyfarpar yn unol â pharagraff 8(3); ac
- (o) wrth ddarparu cyfarpar penodedig, cydymffurfio â'r gofynion ychwanegol a bennir ym mharagraff 10.

(2) Pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy mewn cysylltiad â gweinyddu cyfarpar o dan baragraff 4, os na all contractwr cyfarpar GIG ddarparu cyfarpar, neu os oes angen addasu cyfarpar stoma ac na all y contractwr cyfarpar GIG ddarparu'r addasiad hwnnw, rhaid i'r contractwr cyfarpar GIG—

- (a) os yw'r claf yn cydsynio, atgyfeirio'r ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy at gontractwr cyfarpar GIG arall neu at fferylllydd GIG; neu
- (b) os nad yw'r claf yn cydsynio ag atgyfeirio, darparu i'r claf fanylion cyswllt dau, o leiaf, o bobl sy'n fferyllwyr GIG neu'n gontractwyr cyfarpar GIG gyda'r gallu i ddarparu'r cyfarpar neu'r addasiad cyfarpar stoma (yn ôl fel y digwydd), os yw'r manylion hynny'n hysbys i'r contractwr cyfarpar GIG.

Gofynion ychwanegol mewn perthynas â chyfarpar penodedig

10.—(1) Mae'r paragraff hwn yn pennu'r gofynion ychwanegol y cyfeirir atynt ym mharagraff 9(1)(o) ynglŷn â darparu cyfarpar penodedig.

(2) Rhaid i gontractwr cyfarpar GIG sy'n gweinyddu cyfarpar penodedig yng nghwrs arferol ei fusnes ddarparu gwasanaeth danfon i gartrefi mewn perthynas â'r cyfarpar hwnnw ac, yn rhan o'r gwasanaeth hwnnw—

- (a) rhaid i'r contractwr cyfarpar GIG gynnig danfon y cyfarpar penodedig i gartref y claf;
- (b) os yw'r claf yn derbyn y cynnig hwnnw, rhaid gwneud y danfoniad yn rhesymol brydlon ac ar yr adeg a gytunir gyda'r claf;
- (c) rhaid danfon y cyfarpar penodedig mewn pecyn nad yw'n arddangos unrhyw ysgrifen neu farciau eraill a allai ddynodi ei gynnwys; a
- (d) rhaid i'r modd y danfonir y pecyn ac unrhyw eitemau atodol sy'n ofynnol gan is-baragraff

appliances pursuant to paragraph 8(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;

- (m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;
- (n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 8(3); and
- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 10.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, an NHS appliance contractor is unable to provide an appliance, or stoma appliance customisation is required and the NHS appliance contractor is unable to provide that, the NHS appliance contractor must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

Additional requirements in relation to specified appliances

10.—(1) This paragraph sets out the additional requirements referred to in paragraph 9(1)(o) relating to the provision of specified appliances.

(2) An NHS appliance contractor who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS appliance contractor must offer to deliver the specified appliance to the patient's home;
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and
- (d) the manner of delivery of the package and any supplementary items required by sub-

(3) beidio â chyfleu'r math o gyfarpar a ddanfonir.

(3) Mewn unrhyw achos pan ddarperir cyfarpar penodedig (drwy ei ddanfon i'r cartref neu fel arall), rhaid i'r contractwr cyfarpar GIG ddarparu cyflenwad rhesymol o eitemau atodol priodol (megis clytiau tafladwy a bagiau gwaredu) ac—

- (a) rhaid iddo sicrhau y caiff y claf, os yw'r claf yn dymuno, ymgynghori â pherson i gael cyngor clinigol arbenigol ynglŷn â'r cyfarpar; neu
- (b) os yw'r contractwr cyfarpar GIG o'r farn bod hynny'n briodol, rhaid iddo—
 - (i) cyfeirio'r claf at ragnodydd, neu
 - (ii) cynnig gwasanaeth i'r claf ar gyfer adolygu'r defnydd o'r cyfarpar.

(4) Os na all y contractwr cyfarpar GIG ddarparu gwasanaeth ar gyfer adolygu'r defnydd o'r cyfarpar yn unol ag is-baragraff (3)(b)(ii), rhaid i'r contractwr cyfarpar GIG roi i'r claf fanylion cyswllt dau, o leiaf, o bobl sy'n fferyllwyr GIG neu'n gontractwyr cyfarpar GIG gyda'r gallu i drefnu ar gyfer darparu'r gwasanaeth, os yw'r manylion hynny'n hysbys i'r contractwr cyfarpar GIG.

(5) Pan fo contractwr cyfarpar GIG yn darparu llinell gofal teleffon mewn perthynas â gweinyddu unrhyw gyfarpar penodedig, rhaid i'r contractwr cyfarpar GIG sicrhau, yn ystod cyfnodau y tu allan i oriau—

- (a) y bydd cyngor ar gael i gleifion drwy'r llinell gofal teleffon honno; neu
- (b) bod rhif teleffon Galw Iechyd Cymru, neu gyfeiriad gwefan Galw Iechyd Cymru, ar gael i gleifion drwy'r llinell gofal teleffon honno.

(6) At ddibenion y paragraff hwn—

ystyr "cyfnodau y tu allan i oriau" ("*out of hours periods*"), mewn perthynas â phob un o'r mangreoddd y mae contractwr cyfarpar GIG wedi ymrwymo i ddarparu gwasanaethau fferyllol ohonynt, yw'r cyfnodau y tu allan i'r cyfnodau pan fo'r contractwr cyfarpar GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn rhinwedd paragraff 12;

ystyr "cyngor clinigol arbenigol" ("*expert clinical advice*"), mewn perthynas â chyfarpar penodedig yw cyngor a roddir gan berson sydd wedi ei hyfforddi'n briodol ac sydd â phrofiad perthnasol mewn cysylltiad â'r cyfarpar.

Cyfeirio defnyddwyr

11.—(1) Os na all contractwr cyfarpar GIG, pan gyflwynir ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy ddarparu cyfarpar neu addasu cyfarpar stoma, oherwydd nad yw darparu'r cyfarpar neu addasu yng nghwrs busnes arferol y contractwr cyfarpar GIG,

paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS appliance contractor must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or
- (b) if the NHS appliance contractor believes it is appropriate to do so, must—
 - (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.

(4) If the NHS appliance contractor is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), he or she must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to him or her.

(5) Where an NHS appliance contractor provides a telephone care line in respect of the dispensing of any specified appliance, he or she must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line; or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph—

"expert clinical advice" ("*cyngor clinigol arbenigol*"), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods" ("*cyfnodau y tu allan i oriau*"), in relation to each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, means the periods outside the periods during which the NHS appliance contractor is obliged to provide pharmaceutical services by virtue of paragraph 12.

Signposting

11.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within his or her

rhaid iddo—

- (a) os yw'r claf yn cydsynio, atgyfeirio'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy at gontractwr cyfarpar GIG neu fferylllydd GIG arall; ac
- (b) os nad yw'r claf yn cydsynio ag atgyfeirio, darparu i'r claf fanylion cyswllt dau, o leiaf, o bobl sy'n fferyllwyr GIG neu'n gontractwyr cyfarpar GIG gyda'r gallu i ddarparu'r cyfarpar neu'r addasiad cyfarpar stoma (yn ôl fel y digwydd), os yw'r manylion hynny'n hysbys i'r contractwr cyfarpar GIG.

(2) Rhaid i gontractwr cyfarpar GIG, mewn achosion priodol, gadw a chynnal cofnod o unrhyw wybodaeth a roddir neu atgyfeiriad a wneir o dan is-baragraff (1), a rhaid i'r cofnod hwnnw fod mewn ffurf sy'n hwyluso—

- (a) cynnal archwiliad o'r ddarpariaeth o wasanaethau fferyllol gan y contractwr cyfarpar GIG; a
- (b) gofal dilynol i'r person y rhoddwyd yr wybodaeth iddo neu y gwnaed yr atgyfeiriad mewn perthynas ag ef.

Oriau agor: cyffredinol

12.—(1) Rhaid i gontractwr cyfarpar GIG sicrhau y darperir gwasanaethau fferyllol ym mhob mangre y mae'r contractwr cyfarpar GIG wedi ymrwymo i ddarparu gwasanaethau fferyllol ohoni—

- (a) am ddim llai na 30 awr bob wythnos;
- (b) os yw'r Bwrdd Iechyd Lleol y cynhwysir y contractwr cyfarpar GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo (naill ai o dan yr Atodlen hon neu Atodlen 2A i Reoliadau 1992) y caiff y contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre am lai na 30 awr yr wythnos ar yr amod y darperir y gwasanaethau hynny ar amseroedd penodol ac ar ddiwrnodau penodol, ar yr amseroedd ac ar y diwrnodau a bennwyd felly;
- (c) os yw'r Bwrdd Iechyd Lleol y cynhwysir y contractwr cyfarpar GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo (naill ai o dan yr Atodlen hon neu Ran 3 o Atodlen 1) fod rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 30 awr yr wythnos ac ar amseroedd penodol ac ar ddiwrnodau penodol, ar yr amseroedd ac ar y diwrnodau a bennwyd felly; neu
- (d) os yw'r Bwrdd Iechyd Lleol y cynhwysir y contractwr cyfarpar GIG yn ei restr fferyllol, neu Weinidogion Cymru yn dilyn apêl, wedi cyfarwyddo o dan yr Atodlen hon fod rhaid i'r

normal course of business, the NHS appliance contractor must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to him or her.

(2) The NHS appliance contractor must, in appropriate cases, keep and maintain a record of any information given or referral made under subparagraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS appliance contractor; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Opening hours: general

12.—(1) An NHS appliance contractor must ensure that pharmaceutical services are provided at each of the premises from which he or she has undertaken to provide pharmaceutical services—

- (a) for not less than 30 hours each week;
- (b) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 2A to the 1992 Regulations), that the NHS appliance contractor may provide pharmaceutical services at the premises for fewer than 30 hours per week, provided that those services are provided at set times and on set days, at the times and on the days so set;
- (c) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Part 3 of Schedule 1), that the NHS appliance contractor must provide pharmaceutical services at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set; or
- (d) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed under this Schedule

contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 30 awr bob wythnos—

- (i) am y cyfanswm oriau bob wythnos sy'n ofynnol yn rhinwedd y cyfarwyddyd hwnnw, a
- (ii) o ran yr oriau ychwanegol y gwneir yn ofynnol bod y contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol yn rhinwedd y cyfarwyddyd hwnnw, ar y diwrnodau ac ar yr amseroedd y mae'n ofynnol bod y contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol yn ystod yr oriau ychwanegol hynny, fel a bennir yn y cyfarwyddyd hwnnw,

ond caiff Bwrdd Iechyd Lleol, mewn amgylchiadau priodol, gytuno i atal gwasanaethau dros dro am gyfnod penodedig, os yw wedi cael 3 mis o rybudd o'r bwriad i atal y gwasanaeth dros dro.

(2) Ym mhob un o'r mangreoedd y mae contractwr cyfarpar GIG wedi ymrwymo i ddarparu gwasanaethau fferyllol ohonynt, rhaid i'r contractwr cyfarpar GIG arddangos hysbysiad sy'n pennu'r diwrnodau a'r amseroedd y bydd y fangre ar agor ar gyfer darparu cyfarpar.

(3) Rhaid i'r contractwr cyfarpar GIG, os gofynnir iddo, gyflwyno datganiad i'r Bwrdd Iechyd Lleol sy'n nodi—

- (a) y diwrnodau a'r amseroedd y darperir gwasanaethau fferyllol ym mhob un o'r mangreoedd yr ymrwymodd y contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol ohonynt (gan gynnwys yr amseroedd y darperir gwasanaethau fferyllol pan nad yw'r contractwr cyfarpar GIG dan rwymedigaeth i wneud hynny yn rhinwedd is-baragraff (1)); a
- (b) y gwasanaethau fferyllol y mae'r contractwr cyfarpar GIG fel arfer yn eu darparu ym mhob un o'r mangreoedd hynny.

(4) Os yw contractwr cyfarpar GIG yn newid—

- (a) y diwrnodau neu'r amseroedd y mae gwasanaethau fferyllol i'w darparu o fangre yr ymrwymodd y contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol ohoni; neu
- (b) y gwasanaethau fferyllol y mae contractwr cyfarpar GIG fel arfer i'w darparu yn y fangre honno,

rhaid i'r contractwr cyfarpar GIG gyflenwi datganiad i'r Bwrdd Iechyd Lleol, i roi gwybod iddo am y newid.

(5) Yn ddarostyngedig i is-baragraff (6), os rhwystrir contractwr cyfarpar GIG, gan salwch neu achos rhesymol arall, rhag cydymffurfio â'i rwymedigaethau o dan is-baragraff (1), rhaid i'r contractwr cyfarpar GIG, pan fo'n ymarferol, wneud trefniadau gydag un neu ragor o contractwyr cyfarpar GIG, fferyllwyr GIG

that the NHS appliance contractor must provide pharmaceutical services at the premises for more than 30 hours each week—

- (i) for the total number of hours each week required by virtue of that direction, and
- (ii) as regards the additional hours for which the NHS appliance contractor is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which the NHS appliance contractor is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

(2) At each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, an NHS appliance contractor must exhibit a notice specifying the days on which and times at which the premises are open for the provision of appliances.

(3) An NHS appliance contractor must, on request, submit a return to the Local Health Board setting out—

- (a) the days on which and times at which pharmaceutical services are provided at each of the premises from which the NHS appliance contractor has undertaken to provide pharmaceutical services (including times at which he or she is providing pharmaceutical services when he or she is not obliged to do so by virtue of sub-paragraph (1)); and
- (b) the pharmaceutical services which the NHS appliance contractor ordinarily provides at each of those premises.

(4) Where an NHS appliance contractor changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which he or she has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which he or she is ordinarily to provide at those premises,

the NHS appliance contractor must supply the Local Health Board with a return informing it of the change.

(5) Subject to sub-paragraph (6), where an NHS appliance contractor is prevented by illness or other reasonable cause from complying with its obligations under sub-paragraph (1) the NHS appliance contractor must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists

neu ddarparwyr gwasanaethau fferyllol lleol o dan gynllun peilot sydd â'u mangreoddd wedi'u lleoli yn y gymdogaeth, ar gyfer darparu gwasanaethau fferyllol neu wasanaethau fferyllol lleol yn ystod y cyfnod hwnnw.

(6) Ni chaiff contractwr cyfarpar GIG wneud trefniant gyda darparwr gwasanaethau fferyllol lleol o dan gynllun peilot o dan is-baragraff (5) ac eithrio pan fo'r darparwr hwnnw yn darparu gwasanaethau fferyllol lleol cyffelyb o ran disgrifiad a maint i'r gwasanaethau fferyllol a ddarperir fel arfer gan y contractwr cyfarpar GIG.

(7) Pan fo'r ddarpariaeth o wasanaethau fferyllol gan contractwr cyfarpar GIG wedi ei hatal dros dro am reswm sydd y tu hwnt i reolaeth y contractwr cyfarpar GIG, ni fydd y contractwr cyfarpar GIG wedi torri is-baragraffau (1) a (2), ar yr amod ei fod—

- (a) yn hysbysu'r Bwrdd Iechyd Lleol o'r ataliad hwnnw cyn gynted ag y bo'n ymarferol; a
- (b) yn gwneud pob ymdrech resymol i ailddechrau darparu gwasanaethau fferyllol cyn gynted ag y bo'n ymarferol.

(8) Nid yw gwaith a gynlluniwyd ymlaen llaw i ailwampio mangre yn "achos rhesymol" at ddibenion is-baragraff (5) nac yn "rheswm sydd y tu hwnt i reolaeth y contractwr cyfarpar GIG" at ddibenion is-baragraff (7).

(9) At y dibenion o gyfrifo'r nifer o oriau y mae mangre ar agor yn ystod wythnos sy'n cynnwys Dydd Nadolig, Dydd Gwener y Groglith, Sul y Pasg neu ŵyl banc, rhaid ystyried bod y fangre ar agor ar y diwrnod hwnnw yn ystod yr amseroedd y byddai wedi bod ar agor fel arfer ar y diwrnod hwnnw o'r wythnos.

(10) Yn yr Atodlen hon, yr "oriau ychwanegol" (*"additional hours"*) pan wneir yn ofynnol bod contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol yw'r oriau hynny pan na fyddai'r contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol, pe bai'r contractwr cyfarpar GIG yn ddarostyngedig i'r amod a bennir yn is-baragraff (1)(a) ac nid yr amod a bennir yn is-baragraff (1)(d).

(11) Er gwaethaf darpariaethau paragraffau 13 i 16, yn ystod argyfwng pan yw'n ofynnol darparu gwasanaethau fferyllol mewn ffordd hyblyg, caiff y Bwrdd Iechyd Lleol, os gwneir cais gan contractwr cyfarpar GIG, ganiatáu i'r contractwr cyfarpar GIG newid dros dro y diwrnodau neu'r amseroedd pan fo'r contractwr cyfarpar GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn y fangre yr ymrwymodd i ddarparu gwasanaethau fferyllol ohoni, neu ganiatáu i'r fangre honno dros dro—

- (a) os rhoddir 24 awr, o leiaf, o rybudd gan y contractwr cyfarpar GIG o'r newid neu'r cau; a
- (b) os yw'r rhesymau a roddir gan y contractwr cyfarpar GIG dros wneud y cais yn rhesymau

or providers of local pharmaceutical services under a pilot scheme whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) An NHS appliance contractor may make an arrangement with a provider of local pharmaceutical services under a pilot scheme under sub-paragraph (5) only where that provider provides local pharmaceutical services which are of a similar description, and a similar extent to, the pharmaceutical services which the NHS appliance contractor ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by an NHS appliance contractor for a reason beyond his or her control, the NHS appliance contractor will not be in breach of sub-paragraphs (1) and (2), provided that the NHS appliance contractor—

- (a) notifies the Local Health Board of that suspension as soon as practicable; and
- (b) uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(8) Planned refurbishment of premises is neither a "reasonable cause" for the purposes of sub-paragraph (5) nor a "reason beyond his or her control" for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(10) In this Schedule, the "additional hours" (*"oriau ychwanegol"*) for which an NHS appliance contractor is to be required to provide pharmaceutical services are those hours during which the NHS appliance contractor would not be providing pharmaceutical services, were the NHS appliance contractor subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d).

(11) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, a Local Health Board may, on application from an NHS appliance contractor, permit him or her a temporary change to the days on which or times at which he or she is obliged to provide pharmaceutical services at the premises from which he or she has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS appliance contractor gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by the NHS appliance contractor for the request are, in the opinion of

digonol ym marn y Bwrdd Iechyd Lleol.

(12) Nid oes angen i'r Bwrdd Iechyd Lleol gymeradwyo'r cais y cyfeirir ato yn is-baragraff (11) ymlaen llaw cyn y newid neu'r cau, ac os nad yw'r Bwrdd yn cymeradwyo ymlaen llaw, ond yn penderfynu yn ddiweddarach nad yw rhesymau'r contractwr cyfarpar GIG, ym marn y Bwrdd, yn rhesymau digonol, yna rhaid i'r diwrnodau neu'r amseroedd y mae'r contractwr cyfarpar GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn y fangre ddychwelyd i'r hyn oeddent cyn eu disodli, o'r diwrnod ar ôl y dyddiad yr hysbysir y contractwr cyfarpar GIG o'r penderfyniad hwnnw.

Materion i'w hystyried wrth ddyroddi cyfarwyddiadau mewn perthynas ag oriau agor

13.—(1) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd sy'n pennu unrhyw ddiwrnodau neu amseroedd o dan yr Atodlen hon, rhaid iddo, wrth wneud hynny, geisio sicrhau bod yr oriau pan fydd mangre ar agor i ddarparu gwasanaethau fferyllol yn rhai sy'n sicrhau y darperir y gwasanaethau fferyllol ar y cyfryw ddiwrnodau ac amseroedd sy'n angenrheidiol er mwyn bodloni anghenion pobl y gymdogaeth, neu ddefnyddwyr tebygol eraill y fangre, am wasanaethau fferyllol.

(2) Wrth ystyried y materion a grybwyllir yn is-baragraff (1)—

- (a) rhaid i'r Bwrdd Iechyd Lleol drin unrhyw wasanaethau fferyllol lleol a ddarperir yn y gymdogaeth honno ar y diwrnodau ac amseroedd dan sylw fel pe baent yn wasanaethau fferyllol a ddarperid felly; a
- (b) caiff y Bwrdd Iechyd Lleol roi sylw i unrhyw wasanaethau fferyllol a ddarperir yn y gymdogaeth honno mewn amgylchiadau pan nad oes rhwymedigaeth ar y person sy'n eu darparu i ddarparu'r gwasanaethau hynny.

(3) Ni chaiff y Bwrdd Iechyd Lleol roi cyfarwyddyd y caiff contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre am lai na 30 awr yn ystod unrhyw wythnos, oni fodlonir y Bwrdd Iechyd Lleol fod y trefniadau ar gyfer cyflenwi cyfarpar yn y gymdogaeth yn debygol o fod yn ddigonol i ddiwallu'r angen am wasanaethau o'r fath ar yr adegau pan na fydd y contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol.

(4) Ni chaiff y Bwrdd Iechyd Lleol roi cyfarwyddyd bod rhaid i contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre am fwy na 30 awr yn ystod unrhyw wythnos, oni fodlonir y Bwrdd Iechyd Lleol y bydd y contractwr cyfarpar GIG yn cael gydnabyddiaeth ariannol resymol am yr oriau ychwanegol y gofynnir iddo ddarparu gwasanaethau fferyllol (a bydd unrhyw gydnabyddiaeth ariannol ychwanegol sy'n daladwy o dan y Tariff Cyffuriau mewn perthynas â'r oriau hynny yn "gydnabyddiaeth ariannol resymol" at y dibenion hyn).

the Local Health Board, adequate reasons.

(12) The Local Health Board need not approve the request referred to in sub-paragraph (11), in advance of the change or closure, and if it does not do so but decides subsequently that the NHS appliance contractor's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to the NHS appliance contractor.

Matters to be considered when issuing directions in respect of opening hours

13.—(1) Where a Local Health Board issues a direction setting any days or times under this Schedule, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Local Health Board—

- (a) must treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided; and
- (b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the person providing the services is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS appliance contractor may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood are likely to be adequate to meet the need for such services at times when the NHS appliance contractor is not providing pharmaceutical services.

(4) A Local Health Board may only direct that an NHS appliance contractor must provide pharmaceutical services at premises for more than 30 hours in any week if a Local Health Board is satisfied that the NHS appliance contractor will receive reasonable remuneration in respect of the additional hours for which he or she is required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is "reasonable remuneration" for these purposes).

Penderfyniad ynghylch oriau agor a ysgogir gan y Bwrdd Iechyd Lleol

14.—(1) Os yw'n ymddangos i'r Bwrdd Iechyd Lleol, ar ôl ymgynghori â'r Pwyllgor Fferyllol Lleol neu ar ôl ystyried y mater ar gais y Pwyllgor hwnnw, nad yw, neu na fydd, y diwrnodau neu'r amseroedd pan fo, neu pan fydd mangre ar agor i ddarparu cyfarpar bellach yn bodloni anghenion—

- (a) y bobl yn y gymdogaeth; neu
- (b) defnyddwyr tebygol eraill mangre'r contractwr cyfarpar GIG,

ar gyfer cyflenwi cyfarpar, caiff y Bwrdd Iechyd Lleol asesu a ddylid dyroddi cyfarwyddyd sy'n ei gwneud yn ofynnol bod y contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol yn y fangre ar amseroedd penodedig ac ar ddiwrnodau penodedig (gan gynnwys, o bosibl, Dydd Nadolig, Dydd Gwener y Grogllith, Sul y Pasg a gwyliau banc).

(2) Cyn cwblhau'r asesiad o dan is-baragraff (1) rhaid i'r Bwrdd Iechyd Lleol—

- (a) rhoi hysbysiad i'r contractwr cyfarpar GIG o unrhyw newidiadau arfaethedig yn y diwrnodau neu'r amseroedd y mae'r fangre i fod ar agor; a
- (b) caniatáu cyfnod o 60 diwrnod i'r contractwr cyfarpar GIG ar gyfer cyflwyno sylwadau ysgrifenedig i'r Bwrdd Iechyd Lleol ynglŷn â'r newidiadau arfaethedig.

(3) Ar ôl ystyried unrhyw sylwadau a wneir yn unol ag is-baragraff (2)(b), rhaid i'r Bwrdd Iechyd Lleol—

- (a) dyroddi cyfarwyddyd (a fydd yn disodli unrhyw gyfarwyddyd presennol) sy'n bodloni gofynion is-baragraffau (4) a (5); neu
- (b) cadarnhau unrhyw gyfarwyddyd presennol mewn perthynas â pha ddiwrnodau ac amseroedd y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, ar yr amod y byddai'r cyfarwyddyd presennol, boed wedi ei ddyroddi o dan yr Atodlen hon neu Atodlen 2A i Reoliadau 1992, yn bodloni gofynion is-baragraffau (4) a (5) pe bai wedi ei ddyroddi o dan y paragraff hwn; neu
- (c) naill ai—
 - (i) dirymu (heb ei amnewid) unrhyw gyfarwyddyd presennol mewn perthynas â pha ddiwrnodau ac amseroedd y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, boed wedi ei ddyroddi o dan yr Atodlen hon neu Atodlen 2A i Reoliadau 1992, neu

- (ii) mewn achos pan nad oes cyfarwyddyd presennol, peidio â dyroddi unrhyw gyfarwyddyd,

Determination of opening hours instigated by the Local Health Board

14.—(1) Where it appears to the Local Health Board, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of the NHS appliance contractor's premises,

for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board must—

- (a) give notice to the NHS appliance contractor of any proposed changes to the days on which or times at which the premises are to be open; and
- (b) allow him or her 60 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5); or
- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 2A to the 1992 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph; or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 2A to the 1992 Regulations, or
 - (ii) in a case where there is no existing direction, issue no direction,

ac mewn achos o'r fath, yn rhinwedd paragraff 12(1)(a), rhaid i'r fangre fod ar agor am ddim llai na 30 o oriau bob wythnos.

(4) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd o dan is-baragraff (3), mewn perthynas â mangre y mae'n ofynnol iddi fod ar agor—

- (a) am fwy na 30 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu—
 - (i) cyfanswm nifer yr oriau bob wythnos y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, a
 - (ii) ynglŷn â'r oriau ychwanegol y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol, ar ba ddiwrnodau ac ar ba amseroedd y bydd yn ofynnol i'r contractwr cyfarpar GIG ddarparu'r gwasanaethau hynny yn ystod yr oriau ychwanegol hynny,

ond rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, beidio â phennu ar ba ddiwrnodau nac ar ba amseroedd y mae'r contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol yn ystod oriau nad ydynt yn oriau ychwanegol; neu

(b) am lai na 30 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu ar ba ddiwrnodau ac ar ba amseroedd y mae gwasanaethau fferyllol i'w darparu yn y fangre honno.

(5) Rhaid i'r Bwrdd Iechyd Lleol beidio â dyroddi cyfarwyddyd o dan is-baragraff (3) os ei effaith, yn syml, yw ei gwneud yn ofynnol bod mangre ar agor am 30 awr bob wythnos ar ddiwrnodau penodedig ac ar amseroedd penodedig (hynny yw, rhaid i'r cyfarwyddyd gael yr effaith o wneud yn ofynnol bod y fangre ar agor am naill ai mwy neu lai na 30 awr bob wythnos).

(6) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r contractwr cyfarpar GIG, mewn ysgrifen, o unrhyw gyfarwyddyd a ddyroddir, neu unrhyw gam arall a gymerir, o dan is-baragraff (3), ac os yw'r cyfarwyddyd yn pennu diwrnodau newydd neu amseroedd newydd y mae contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol yn y fangre, rhaid i'r Bwrdd Iechyd Lleol gynnwys gyda'r hysbysiad ddatganiad o'r canlynol—

- (a) y rhesymau am y newid; a
- (b) hawl y contractwr cyfarpar GIG i apelio o dan is-baragraff (7).

(7) Caiff contractwr cyfarpar GIG, o fewn 30 diwrnod ar ôl cael hysbysiad o dan is-baragraff (6), apelio mewn ysgrifen i Weinidogion Cymru yn erbyn unrhyw gyfarwyddyd a ddyroddwyd neu unrhyw gam arall a gymerwyd o dan is-baragraff (3), sy'n pennu diwrnodau newydd neu amseroedd newydd y mae contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol.

in which case, by virtue of paragraph 12(1)(a), the premises must be open for not less than 30 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which he or she is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours; or

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Local Health Board must notify the NHS appliance contractor in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises, it must include with the notification a statement of—

- (a) the reasons for the change; and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (7).

(7) An NHS appliance contractor may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services.

(8) Caiff Gweinidogion Cymru, wrth benderfynu apêl, naill ai gadarnhau'r cam a gymerwyd gan y Bwrdd Iechyd Lleol neu gymryd unrhyw gam y gallai'r Bwrdd Iechyd Lleol fod wedi ei gymryd o dan is-baragraff (3).

(9) Rhaid i Weinidogion Cymru hysbysu'r contractwr cyfarpar GIG o'u penderfyniad o dan is-baragraff (8) a rhaid iddynt, ym mhob achos, gynnwys gyda'r hysbysiad ddatganiad ysgrifenedig o'r rhesymau dros y penderfyniad.

(10) Os yw'r diwrnodau neu'r amseroedd y mae contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol yn y fangre wedi eu newid yn unol â'r paragraff hwn, rhaid i'r contractwr cyfarpar GIG gyflwyno'r newidiadau—

- (a) os nad yw'r contractwr cyfarpar GIG wedi apelio o dan is-baragraff (7), ddim hwyrach nag 8 wythnos ar ôl y dyddiad y mae'r contractwr cyfarpar GIG yn cael hysbysiad o dan is-baragraff (6); neu
- (b) os yw'r contractwr cyfarpar GIG wedi apelio o dan is-baragraff (7), ddim hwyrach nag 8 wythnos ar ôl y dyddiad y mae'r contractwr cyfarpar GIG yn cael hysbysiad o dan is-baragraff (9).

Penderfyniad ynghylch oriau agor a ysgogir gan y contractwr cyfarpar GIG

15.—(1) Caiff contractwr cyfarpar GIG wneud cais i Fwrdd Iechyd Lleol mewn ysgrifen, gan roi 90 diwrnod o rybudd, am i'r Bwrdd newid y diwrnodau neu'r amseroedd y mae'r contractwr cyfarpar GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol yn ei fangre, mewn ffordd sy'n—

- (a) lleihau cyfanswm nifer yr oriau y mae'r contractwr cyfarpar GIG dan rwymedigaeth i ddarparu gwasanaethau fferyllol bob wythnos; neu
- (b) yn cadw cyfanswm nifer yr oriau hynny yn ddigyfnewid.

(2) Pan fo contractwr cyfarpar GIG yn gwneud cais o dan is-baragraff (1), rhaid i'r contractwr cyfarpar GIG, yn rhan o'r cais hwnnw, ddarparu i'r Bwrdd Iechyd Lleol pa bynnag wybodaeth y gofynnir amdani yn rhesymol gan y Bwrdd Iechyd Lleol ynghylch unrhyw newidiadau yn anghenion pobl y gymdogaeth, neu ddefnyddwyr tebygol eraill y fangre, am wasanaethau fferyllol sy'n berthnasol i'r cais.

(3) Rhaid i'r Bwrdd Iechyd Lleol benderfynu cais o dan is-baragraff (1) o fewn 60 diwrnod ar ôl cael y cais (gan gynnwys unrhyw wybodaeth sy'n ofynnol gan y contractwr yn unol ag is-baragraff (2)).

(4) Wrth benderfynu'r cais, rhaid i'r Bwrdd Iechyd Lleol—

- (a) dyroddi cyfarwyddyd (a fydd yn disodli

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS appliance contractor of a determination under sub-paragraph (8) and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which an NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if he or she has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives his or her notification under sub-paragraph (6); or
- (b) if he or she has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives his or her notification under sub-paragraph (9).

Determination of opening hours instigated by the NHS appliance contractor

15.—(1) An NHS appliance contractor may apply to a Local Health Board in writing with 90 days' notice for it to change the days on which or times at which he or she is obliged to provide pharmaceutical services at his or her premises, in a way that—

- (a) reduces the total number of hours for which the NHS appliance contractor is obliged to provide pharmaceutical services each week; or
- (b) keeps that total number of hours the same.

(2) Where an NHS appliance contractor makes an application under sub-paragraph (1), as part of that application he or she must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any

unrhyw gyfarwyddyd presennol) sy'n bodloni gofynion is-baragraffau (5) a (6) ac yn cael yr effaith naill ai o ganiatáu'r cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig;

- (b) cadarnhau unrhyw gyfarwyddyd presennol mewn perthynas â pha ddiwrnodau ac amseroedd y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, ar yr amod y byddai'r cyfarwyddyd presennol, boed wedi ei ddyroddi o dan yr Atodlen hon neu o dan Reoliadau 1992, yn bodloni gofynion is-baragraffau (5) a (6); neu
- (c) naill ai—
 - (i) dirymu (heb ei amnewid) unrhyw gyfarwyddyd presennol mewn perthynas â pha ddiwrnodau ac amseroedd y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, boed y cyfarwyddyd wedi ei ddyroddi o dan yr Atodlen hon neu o dan Reoliadau 1992, pan fo hyn yn cael yr effaith naill ai o ganiatáu'r cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig, neu
 - (ii) mewn achos pan nad oes cyfarwyddyd presennol, peidio â dyroddi unrhyw gyfarwyddyd,

ac mewn achos o'r fath, yn rhinwedd paragraff 12(1)(a), rhaid i'r fangre fod ar agor am ddim llai na 30 o oriau bob wythnos.

(5) Pan fo Bwrdd Iechyd Lleol yn dyroddi cyfarwyddyd o dan is-baragraff (4), mewn perthynas â mangre y mae'n ofynnol iddi fod ar agor—

- (a) am fwy na 30 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu—
 - (i) cyfanswm nifer yr oriau bob wythnos y mae'n rhaid i'r contractwr cyfarpar GIG ddarparu gwasanaethau fferyllol yn y fangre, a
 - (ii) ynglŷn â'r oriau ychwanegol y mae'r contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol, ar ba ddiwrnodau ac ar ba amseroedd y mae'n ofynnol i'r contractwr cyfarpar GIG ddarparu'r gwasanaethau hynny yn ystod yr oriau ychwanegol hynny,

ond rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, beidio â phennu ar ba ddiwrnodau ac ar ba amseroedd y mae'r contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol yn ystod oriau nad ydynt yn oriau ychwanegol; neu

- (b) am lai na 30 awr bob wythnos, rhaid i'r Bwrdd Iechyd Lleol, yn y cyfarwyddyd hwnnw, bennu ar ba ddiwrnodau ac amseroedd y mae gwasanaethau fferyllol i'w darparu yn y fangre honno.

existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;

- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or the 1992 Regulations, would meet the requirements of sub-paragraphs (5) and (6); or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or the 1992 Regulations, where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 12(1)(a), the premises must be open for not less than 30 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which he or she is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours; or

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) Rhaid i'r Bwrdd Iechyd Lleol beidio â dyroddi cyfarwyddyd o dan is-baragraff (4) os ei effaith, yn syml, yw ei gwneud yn ofynnol bod mangre ar agor am 30 awr bob wythnos ar ddiwrnodau penodedig ac ar amseroedd penodedig (hynny yw, rhaid i'r cyfarwyddyd gael yr effaith o wneud yn ofynnol bod y fangre ar agor am naill ai mwy neu lai na 30 awr bob wythnos).

(7) Pan fo'r Bwrdd Iechyd Lleol yn ystyried gweithredu o dan is-baragraff (4)(a) neu (c)(i), rhaid iddo ymgynghori â'r Pwyllgor Fferyllol Lleol cyn penderfynu'r cais.

(8) Rhaid i'r Bwrdd Iechyd Lleol hysbysu'r contractwr cyfarpar GIG o unrhyw gyfarwyddyd a ddyroddir, neu unrhyw gam arall a gymerir, o dan is-baragraff (4), ac os effaith hynny yw gwrthod cais a wnaed o dan y paragraff hwn, neu ei ganiatáu yn rhannol, rhaid i'r Bwrdd Iechyd Lleol anfon datganiad at y contractwr cyfarpar GIG, sy'n nodi—

- (a) y rhesymau am y gwrthodiad neu, yn ôl fel y digwydd, am ganiatáu y cais yn rhannol yn unig; a
- (b) hawl y contractwr cyfarpar GIG i apelio o dan is-baragraff (9).

(9) Caiff contractwr cyfarpar GIG, o fewn 30 diwrnod ar ôl cael hysbysiad yn unol ag is-baragraff (8), apelio i Weinidogion Cymru yn erbyn unrhyw weithred o dan is-baragraff (4) sy'n cael yr effaith o wrthod cais o dan y paragraff hwn neu ei ganiatáu yn rhannol yn unig.

(10) Caiff Gweinidogion Cymru, wrth benderfynu apêl, naill ai gadarnhau'r cam a gymerwyd gan y Bwrdd Iechyd Lleol neu gymryd unrhyw gam y gallai'r Bwrdd Iechyd Lleol fod wedi ei gymryd o dan is-baragraff (4).

(11) Rhaid i Weinidogion Cymru hysbysu'r contractwr cyfarpar GIG o'u penderfyniad mewn ysgrifen a rhaid iddynt, ym mhob achos, gynnwys gyda'r hysbysiad ddatganiad ysgrifenedig o'r rhesymau dros y penderfyniad.

(12) Os yw'r diwrnodau neu'r amseroedd y mae'r contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol yn y fangre wedi eu newid yn unol â'r paragraff hwn, rhaid i'r contractwr cyfarpar GIG gyflwyno'r newidiadau—

- (a) os nad yw'r contractwr cyfarpar GIG wedi apelio o dan is-baragraff (9), ddim cynharach nag 30 diwrnod ar ôl y dyddiad y mae'r contractwr cyfarpar GIG yn cael hysbysiad o dan is-baragraff (4); neu
- (b) os yw'r contractwr cyfarpar GIG wedi apelio o dan is-baragraff (9), ddim cynharach nag 30 diwrnod ar ôl y dyddiad y mae'r contractwr cyfarpar GIG yn cael hysbysiad o dan is-baragraff (11).

(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the NHS appliance contractor of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS appliance contractor a statement setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (9).

(9) An NHS appliance contractor may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the NHS appliance contractor in writing of its determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if he or she has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives a notification under sub-paragraph (4); or
- (b) if he or she has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives his or her notification under sub-paragraph (11).

Llywodraethu clinigol

16.—(1) Rhaid i contractwr cyfarpar GIG, mewn cysylltiad â'r holl wasanaethau a ddarperir ganddo, gyfranogi mewn system dderbyniol o lywodraethu clinigol, yn y modd y gofynnir iddo yn rhesymol gan y Bwrdd Iechyd Lleol y mae'r contractwr cyfarpar GIG wedi ei gynnwys ar ei restr fferyllol.

(2) Mae system o lywodraethu clinigol yn "dderbyniol" os yw'n darparu ar gyfer—

- (a) cydymffurfiaeth â'r cydrannau llywodraethu clinigol a bennir yn is-baragraff (3), a
- (b) cyflwyno hunanasesiad blynyddol o'r gydymffurfiaeth (hyd at lefel gymeradwy) â'r cydrannau llywodraethu clinigol hynny, drwy gyfrwng trefniadau cyflwyno data cymeradwy sy'n caniatáu i'r Bwrdd Iechyd Lleol gael mynediad i'r asesiad hwnnw.

(3) Y cydrannau llywodraethu clinigol yw'r canlynol—

- (a) rhaglen ar gyfer cynnwys y cleifion a'r cyhoedd, sy'n cynnwys—
 - (i) gofyniad bod y contractwr cyfarpar GIG yn paratoi, mewn ffordd gymeradwy, ac yn rhoi ar gael, mewn ffordd briodol, taflen ymarfer mewn perthynas â phob mangre y mae'r contractwr cyfarpar GIG yn darparu gwasanaethau fferyllol ohoni,
 - (ii) gofyniad bod y contractwr cyfarpar GIG yn rhoi cyhoeddusrwydd i'r gwasanaethau GIG sydd ar gael yn, neu o'r, fangre y mae'r contractwr cyfarpar GIG yn darparu gwasanaethau ohoni,
 - (iii) gofyniad bod y contractwr cyfarpar GIG, wrth roi cyhoeddusrwydd i'r gwasanaethau GIG sydd ar gael yn, neu o'r, fangre y mae'r contractwr cyfarpar GIG yn darparu gwasanaethau ohoni (pa un a yw'r contractwr cyfarpar GIG yn paratoi ei ddeunyddiau cyhoeddusrwydd ei hunan, ynteu'n hysbysebu'r gwasanaethau mewn deunydd a gyhoeddir gan berson arall), yn gwneud hynny mewn ffordd sy'n dangos yn eglur mai fel rhan o'r gwasanaeth iechyd y cyllidir y gwasanaethau,
 - (iv) gofyniad bod y contractwr cyfarpar GIG yn cynnal arolwg cymeradwy o foddhad y cleifion yn flynyddol, gan wneud hynny mewn ffordd a gymeradwyir, a chan gynnwys gofyniad i roi cyhoeddusrwydd i ganlyniadau'r arolwg ac i unrhyw gamau priodol y mae'r contractwr cyfarpar GIG yn bwriadu eu cymryd,
 - (v) trefniadau ar gyfer monitro cyfarpar sy'n ddyledus i gleifion ond nad ydynt mewn stoc,
 - (vi) system gwynion gymeradwy (sy'n bodloni

Clinical governance

16.—(1) An NHS appliance contractor must, in connection with all the services that he or she provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list he or she is included, in an acceptable system of clinical governance.

(2) A system of clinical governance is "acceptable" if it provides for—

- (a) compliance with the clinical governance components set out in sub-paragraph (3), and
- (b) submission of an annual self assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.

(3) The clinical governance components comprise of the following—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the NHS appliance contractor should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of each of the premises from which he or she provides pharmaceutical services,
 - (ii) a requirement that the NHS appliance contractor publicises the NHS services that are available at or from the premises from which the NHS appliance contractor provides services,
 - (iii) a requirement that where the NHS appliance contractor publicises the NHS services that are available at or from premises from which the NHS appliance contractor provides services (whether he or she is producing his or her own publicity material or advertising services in material published by another person), the NHS appliance contractor does so in a manner which makes clear that the services are funded as part of the health service,
 - (iv) a requirement that the NHS appliance contractor should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS appliance contractor intends to take,
 - (v) monitoring arrangements for appliances owed to patients but which are out of stock,
 - (vi) an approved complaints system (which

gofynion y Rhan hon),

- (vii) gofyniad bod y contractwr cyfarpar GIG yn cydweithredu'n briodol gydag ymweliadau'r Cyngor Iechyd Cymuned lleol ac yn cymryd camau priodol o ganlyniad i ymweliadau o'r fath,
- (viii) gofyniad bod y contractwr cyfarpar GIG yn cydweithredu'n briodol gydag unrhyw arolygiad neu adolygiad rhesymol y mae'r Bwrdd Iechyd Lleol neu unrhyw awdurdod statudol perthnasol yn dymuno'i gynnal, a
- (ix) trefniadau ar gyfer monitro cydymffurfiaeth â Deddf Cydraddoldeb 2010(1);
- (b) rhaglen o archwiliadau clinigol (pum diwrnod, fel arfer), sy'n cynnwys o leiaf un archwiliad mewn mangre ac un archwiliad amlddisgyblaethol a gytunir gyda'r Bwrdd Iechyd Lleol ym mhob blwyddyn ariannol;
- (c) rhaglen rheoli risg, sy'n cynnwys—
 - (i) trefniadau i sicrhau bod yr holl stoc yn cael ei drafod mewn ffordd briodol,
 - (ii) trefniadau i sicrhau bod yr holl gyfarpar a ddefnyddir i ddarparu gwasanaethau fferyllol yn cael ei gynnal yn briodol,
 - (iii) system gymeradwy o adrodd am ddigwyddiadau, ynghyd â threfniadau ar gyfer dadansoddi ac ymateb i ddigwyddiadau critigol, sy'n cynnwys y canlynol—
 - (aa) cofnod o ddigwyddiadau diogelwch cleifion, a
 - (bb) cofnod o ddigwyddiadau 'croen dannedd',
 - (iv) trefniadau, sy'n cynnwys trefniadau cadw cofnodion, i ymdrin yn briodol ac yn brydlon â chyfathrebiadau ynglŷn â diogelwch cleifion oddi wrth Weinidogion Cymru, yr Asiantaeth Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd a Bwrdd Comisiynu'r Gwasanaeth Iechyd Gwladol,
 - (v) trefniadau gweithredu safonol priodol, gan gynnwys trefniadau gweithredu safonol mewn perthynas â phresgripsiynau amlroddadwy a darparu cyngor a chymorth i bobl sy'n gofalu amdanynt eu hunain neu eu teuluoedd,
 - (vi) trefniadau gwaredu priodol ar gyfer gwastraff clinigol a chyfrinachol,
 - (vii) arweinydd llywodraethu clinigol ar gyfer pob mangre y mae'r contractwr cyfarpar GIG yn darparu gwasanaethau ohoni, sy'n wybodus ynglŷn â'r naill a'r llall o

meets the requirements of this Part),

- (vii) a requirement that the NHS appliance contractor co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
- (viii) a requirement that the NHS appliance contractor co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
- (ix) monitoring arrangements for compliance with the Equality Act 2010(1);
- (b) a clinical audit programme (normally of five days), which includes at least one premises-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year;
- (c) a risk management programme, which includes—
 - (i) arrangements for ensuring that all stock is handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
 - (aa) a patient safety incident log, and
 - (bb) a near-miss log,
 - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,
 - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (vi) appropriate waste disposal arrangements for clinical and confidential waste,
 - (vii) a clinical governance lead person for each of the premises from which the NHS appliance contractor provides services, who is knowledgeable about both the

(1) 2010 p.15.

(1) 2010 c.15.

weithdrefnau'r contractwr cyfarpar GIG a'r gwasanaethau GIG eraill sydd ar gael yn yr ardal,

- (viii) gweithdrefnau priodol ar gyfer amddiffyn plant, a
- (ix) trefniadau ar gyfer monitro cydymffurfiaeth â Deddf Iechyd a Diogelwch etc. 1974(1);
- (d) rhaglen effeithiolrwydd clinigol, sy'n cynnwys trefniadau i sicrhau y rhoddir cyngor priodol gan y contractwr cyfarpar GIG—
 - (i) mewn perthynas â darparu cyfarpar yn unol â ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu
 - (ii) i bobl sy'n gofalu amdanynt eu hunain neu eu teuluoedd,

a threfniadau i sicrhau bod y contractwr cyfarpar GIG, wrth roi cyngor i unrhyw glaf ar fater a grybwyllir ym mharagraff (d)(i), yn rhoi sylw i'r manylion a gynhwysir yn y cofnodion a gynhelir o dan baragraff 9(1)(f) mewn perthynas â'r ddarpariaeth o gyfarpar a'r patrwm presgripsiynu ar gyfer y claf dan sylw;

- (e) rhaglen staffio a rheoli staff, sy'n cynnwys—
 - (i) trefniadau i ddarparu hyfforddiant ymsefydlu priodol i aelodau o'r staff gan gynnwys unrhyw locwm,
 - (ii) hyfforddiant priodol i'r holl staff ar gyfer pa bynnag rôl y gofynnir iddynt ei chyflawni,
 - (iii) trefniadau i wirio cymwysterau a geir daon yr holl staff sy'n ymwneud â darparu gwasanaethau GIG,
 - (iv) trefniadau ar gyfer canfod a chefnogi anghenion datblygu pob aelod o'r staff sy'n ymwneud â darparu gwasanaethau yn rhan o'r gwasanaeth iechyd, gan gynnwys datblygiad proffesiynol parhaus i fferyllwyr cofrestredig ac unrhyw achredu sydd ei angen mewn cysylltiad â darparu gwasanaethau cyfeiriedig,
 - (v) trefniadau ar gyfer mynd i'r afael â pherfformiad gwael (ar y cyd â'r Bwrdd Iechyd Lleol fel y bo'n briodol), a
 - (vi) trefniadau (y mae'n rhaid iddynt gynnwys polisi ysgrifenedig) i sicrhau bod yr holl staff gan gynnwys unrhyw locwm sydd, o ganlyniad i'w cyflogaeth gyda'r contractwr cyfarpar GIG—

procedures of the NHS appliance contractor and the other NHS services that are available in the locality,

- (viii) appropriate child protection procedures, and
- (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(1);
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS appliance contractor—
 - (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (ii) to people caring for themselves or their families,

and arrangements for ensuring that the NHS appliance contractor, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 9(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;

- (e) a staffing and staff management programme, which includes—
 - (i) arrangements for appropriate induction training for staff, including any locum,
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
 - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
 - (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum who, arising out of their employment with the NHS appliance contractor—

- (aa) yn gwneud yr hyn sy'n ddatgeliad gwarchodedig o fewn yr ystyr a roddir i "protected disclosure" yn adran 43A o Ddeddf Hawliau Cyflogaeth 1996(1) (ystyr datgeliad gwarchodedig), yn cael yr hawliau a roddir mewn perthynas â datgeliadau o'r fath gan y Ddeddf honno, a
- (bb) yn darparu gwybodaeth yn ddidwyll ac nid er eu budd personol, i'r Cyngor Fferyllol Cyffredinol neu i Fwrdd Iechyd Lleol, sy'n cynnwys honiad difrifol ei natur, y credant yn rhesymol ei fod yn wir o ran ei sylwedd er nad yw datgeliad ohono yn ddatgeliad gwarchodedig o fewn yr ystyr a roddir i "protected disclosure" yn adran 43A, yn cael yr hawl i beidio â dioddef unrhyw anfantais neu ddioddef eu diswyddo o ganlyniad i'r weithred honno;
- (f) rhaglen lywodraethu gwybodaeth, sy'n darparu ar gyfer—
 - (i) cydymffurfio â gweithdrefnau cymeradwy ar gyfer rheoli a diogelu gwybodaeth, a
 - (ii) cyflwyno hunanasesiad blynyddol o'r gydymffurfiaeth (hyd at lefel gymeradwy) â'r gweithdrefnau hynny, drwy gyfrwng trefniadau cyflwyno data cymeradwy sy'n caniatáu i'r Bwrdd Iechyd Lleol gael mynediad i'r asesiad hwnnw; ac
- (g) rhaglen safonau mangre sy'n cynnwys—
 - (i) system ar gyfer cynnal glanweithdra yn y fangre y mae'r contractwr cyfarpar GIG yn darparu gwasanaethau ohoni, sydd wedi ei chynllunio er mwyn sicrhau lleihau, mewn ffordd gymesur, y risg i bobl yn y fangre o'u heintio drwy gael gofal iechyd, a
 - (ii) trefniadau ar gyfer gwahanu'n eglur rhwng y mannau hynny yn y fangre sy'n amgylchedd gofal iechyd priodol (lle mae cleifion yn cael gwasanaethau GIG) a'r mannau hynny nad ydynt yn amgylchedd gofal iechyd.

Safonau proffesiynol

17. Rhaid i gontractwr cyfarpar GIG ddarparu gwasanaethau fferyllol, ac arfer unrhyw farn broffesiynol mewn cysylltiad â darparu'r gwasanaethau hynny, mewn cydymffurfiaeth â'r safonau a dderbynnir yn gyffredinol yn y proffesiwn fferyllol.

(1) 1996 c.18; mewnosodwyd adran 43A gan adran 1 o Ddeddf Datgelu er Lles y Cyhoedd 1998 (p.23). *Gweler* hefyd adran 43K(1)(c) o Ddeddf Hawliau Cyflogaeth 1996 sy'n ehangu ystyr "worker" ar gyfer y Rhan o'r Ddeddf honno sy'n ymdrin â datgeliadau gwarchodedig, er mwyn iddo gynnwys pob unigolyn sy'n darparu gwasanaethau fferyllol yn unol â threfniadau a wneir gan Fwrdd Iechyd Lleol o dan adran 80 o Ddeddf 2006.

- (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(1) (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and
- (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;
- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment; and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the premises from which the NHS appliance contractor provides services which is designed to ensure, in a proportionate manner, that the risk to people at the premises of healthcare acquired infection is minimised, and
 - (ii) arrangements for there to be a clear separation between the areas of the premises which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

Professional Standards

17. An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

(1) 1996 c.18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c.23). *See* also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of "worker" for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

Cymhellion

18.—(1) Rhaid i gcontractwr cyfarpar GIG ac unrhyw berson a gyflogir, neu a gymerwyd ymlaen, gan gcontractwr cyfarpar GIG, beidio â rhoi, addo na chynnig, i unrhyw berson, unrhyw rodd neu wobr (boed ar ffurf cyfran o elw'r busnes, neu ddifidend ar yr elw hwnnw, neu ar ffurf disgownt neu ad-daliad, neu rywffodd arall) fel cymhelliad neu gydnabyddiaeth i'r person arall gyflwyno archeb am gyfarpar ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy.

(2) Nid yw addo, cynnig neu ddarparu gwasanaeth danfon gartref yn "rhodd neu wobr" at ddibenion is-baragraff (1).

(3) Ni chaiff contractwr cyfarpar GIG, nac unrhyw berson a gyflogir neu a gymerwyd ymlaen gan gcontractwr cyfarpar GIG, dderbyn na chael unrhyw rodd neu wobr mewn perthynas, yn unig, ag—

- (a) darparu manylion cyswllt fferyllwyr GIG neu gcontractwyr cyfarpar GIG amgen yn unol â pharagraff 9(2)(b), 10(4) neu 11(1)(b); neu
- (b) atgyfeirio ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy at gcontractwr cyfarpar GIG neu fferylllydd GIG arall yn unol â pharagraff 9(2)(a) neu 11(1)(a) heb ddarparu unrhyw wasanaeth ychwanegol mewn cysylltiad â'r eitem ar y presgripsiwn hwnnw.

Dyletswydd i ddarparu gwybodaeth am faterion addasrwydd i ymarfer wrth i'r materion godi

19.—(1) Yn ddarostyngedig i baragraff 20, rhaid i gcontractwr cyfarpar GIG, ac os yw'r contractwr cyfarpar GIG yn gorff corfforaethol, pob cyfarwyddwr y corff corfforaethol, hysbysu'r Bwrdd Iechyd Lleol mewn ysgrifen, o fewn 7 diwrnod ar ôl y digwyddiad, os yw'r contractwr cyfarpar GIG neu gyfarwyddwr—

- (a) yn cael ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) yn cael ei rwymo yn dilyn collfarn droseddol yn y Deyrnas Unedig;
- (c) yn derbyn rhybuddiad gan yr heddlu yn y Deyrnas Unedig;
- (d) mewn achos diannod yn yr Alban mewn perthynas â throsedd, wedi bod yn destun gorchymyn i'w ryddhau'n ddiamod (heb fynd ymlaen i'w gollfarnu);
- (e) wedi derbyn a chytuno i dalu naill ai dirwy procuradur ffisgal o dan adran 302 o Ddeddf Gweithdrefn Droseddol (Yr Alban) 1995(1) (cosb benodedig: cynnig amodol gan brocuradur ffisgal) neu gosb o dan adran 115A o Ddeddf Gweinyddu Nawdd Cymdeithasol 1992(2) (cosb fel dewis arall yn lle erlyn);

(1) 1995 p.46.¹³

(2) 1992 p.5.

Inducements

18.—(1) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor must give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his or her presenting an order for appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a home delivery service is not a "gift or reward" for the purposes of subparagraph (1).

(3) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor may accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 9(2)(b), 10(4) or 11(1)(b); or
- (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 9(2)(a) or 11(1)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness to practise matters as they arise

19.—(1) Subject to paragraph 20, an NHS appliance contractor, and where the NHS appliance contractor is a body corporate every director of the body corporate, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS appliance contractor or a director—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is bound over following a criminal conviction in the United Kingdom;
- (c) accepts a police caution in the United Kingdom;
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him or her absolutely (without proceeding to conviction);
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(1) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(2) (penalty as alternative to prosecution);

(1) 1995 c.46.

(2) 1992 c.5.

- (f) yn cael ei gollfarnu mewn man arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr;
- (g) yn cael ei gyhuddo o drosedd yn y Deyrnas Unedig, neu wedi ei gyhuddo mewn man arall o drosedd a fyddai wedi bod yn drosedd, pe bai wedi ei chyflawni yng Nghymru a Lloegr;
- (h) yn cael ei hysbysu am ganlyniad unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall, a bod canfyddiad yn ei erbyn;
- (i) yn mynd yn destun unrhyw ymchwiliad i'w ymddygiad proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;
- (j) yn mynd yn destun ymchwiliad i'w ymddygiad proffesiynol mewn cysylltiad ag unrhyw gyflogaeth gyfredol neu flaenorol, neu'n cael ei hysbysu o ganlyniad unrhyw ymchwiliad o'r fath ac unrhyw ganfyddiad yn ei erbyn;
- (k) yn mynd yn destun unrhyw ymchwiliad gan Awdurdod Gwasanaethau Busnes y GIG mewn perthynas â thwyll;
- (l) yn mynd yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, a allai arwain at dynnu ymaith o restr berthnasol; neu
- (m) ar sail ei addasrwydd i ymarfer, yn cael ei dynnu ymaith, ei dynnu yn ddigwyddiadol, neu ei atal dros dro o restr berthnasol, neu os gwrthodir mynediad iddo i restr o'r fath, neu os caiff ei gynnwys yn amodol mewn rhestr o'r fath,

ac os felly, rhaid i'r contractwr cyfarpar GIG roi manylion am unrhyw ymchwiliad neu achos a gynhaliwyd neu sydd i'w gynnal, gan gynnwys natur yr ymchwiliad neu achos, ym mha le ac oddeutu pa bryd y cynhaliwyd neu y cynhelir yr ymchwiliad hwnnw neu'r achos hwnnw, ac unrhyw ganlyniad.

(2) Yn ddarostyngedig i baragraff 20, os yw person y mae paragraff (1) yn gymwys iddo yn gyfarwyddwr corff corfforaethol, neu os oedd yn gyfarwyddwr corff corfforaethol ar adeg y digwyddiadau cychwynnol, rhaid iddo, yn ychwanegol, hysbysu'r Bwrdd Iechyd Lleol o fewn 7 diwrnod os yw unrhyw gorff corfforaethol o'r fath—

- (a) yn cael ei gollfarnu am unrhyw drosedd yn y Deyrnas Unedig;
- (b) yn cael ei gollfarnu mewn man arall am drosedd, neu'r hyn a fyddai'n drosedd pe bai wedi ei gyflawni yng Nghymru a Lloegr;
- (c) yn cael ei gyhuddo o drosedd yn y Deyrnas Unedig, neu wedi ei gyhuddo mewn man arall o drosedd a fyddai wedi bod yn drosedd, pe bai wedi ei chyflawni yng Nghymru a Lloegr;
- (d) yn cael ei hysbysu gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall am

- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into his or her professional conduct, and there is a finding against him or her;
- (i) becomes the subject of any investigation into his or her professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his or her professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him or her;
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud;
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness to practise grounds,

and if so, the NHS appliance contractor must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 20, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into

ganlyniad unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol, a bod canfyddiad yn erbyn y corff corfforaethol;

- (e) yn mynd yn destun unrhyw ymchwiliad i'w ddarpariaeth o wasanaethau proffesiynol gan unrhyw gorff trwyddedu, corff rheoleiddio neu gorff arall;
- (f) yn mynd yn destun unrhyw ymchwiliad mewn perthynas â thwyll neu wedi ei hysbysu o ganlyniad unrhyw ymchwiliad o'r fath, a'r canlyniad hwnnw yn ei erbyn;
- (g) yn mynd yn destun unrhyw ymchwiliad gan Fwrdd Iechyd Lleol arall neu gorff cyfatebol, a allai arwain at dynnu ymaith y corff corfforaethol o restr berthnasol; neu
- (h) ar sail ei addasrwydd i ymarfer, wedi ei dynnu ymaith, ei dynnu yn ddigwyddiadol, neu ei atal dros dro o restr berthnasol, neu os gwrthodwyd mynediad iddo i restr o'r fath, neu os yw wedi ei gynnwys yn amodol mewn rhestr o'r fath,

ac os felly, rhaid i'r person hwnnw roi enw'r corff corfforaethol a chyfeiriad ei swyddfa gofrestredig a manylion am unrhyw ymchwiliad neu achos a gynhaliwyd neu sydd i'w gynnal, gan gynnwys natur yr ymchwiliad neu achos, ym mha le ac oddeutu pa bryd y cynhaliwyd neu y cynhelir yr ymchwiliad hwnnw neu'r achos hwnnw, ac unrhyw ganlyniad.

(3) Rhaid i berson y mae is-baragraff (1) neu (2) yn gymwys iddo gydsynio i'r Bwrdd Iechyd Lleol ofyn i unrhyw gyflogwr neu gyngyflogwr neu unrhyw gorff trwyddedu neu reoleiddio, yn y Deyrnas Unedig neu unrhyw le arall, am wybodaeth ynghylch ymchwiliad cyfredol neu ymchwiliad â chanlyniad anffafriol.

Bwrdd Iechyd Lleol cartref cyrff corfforaethol

20. Os yw contractwr cyfarpar GIG yn gorff corfforaethol sydd â'i swyddfa gofrestredig yng Nghymru a Lloegr, caiff ddarparu'r wybodaeth, sydd i'w darparu o dan baragraffau 19 a 23(3) i (6), yn hytrach i Fwrdd Iechyd Lleol cartref (fel y'i diffinnir yn rheoliad 46). Pan fo'r contractwr cyfarpar GIG yn darparu'r wybodaeth i'w Fwrdd Iechyd Lleol cartref, rhaid iddo ddarparu, i'r Bwrdd Iechyd Lleol cartref, fanylion hefyd o'r holl Fyrddau Iechyd Lleol eraill y cynhwysir y contractwr cyfarpar GIG yn eu rhestrau fferyllol.

Cwynion

21. Rhaid i gcontractwr cyfarpar GIG fod wedi sefydlu trefniadau sy'n cydymffurfio â gofynion Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011, ar gyfer trin ac ystyried unrhyw bryderon neu gwynion ynghylch mater sy'n gysylltiedig â'r ddarpariaeth o wasanaethau fferyllol gan y contractwr cyfarpar GIG.

its provision of professional services, and there is a finding against the body corporate;

- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness to practise grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Local Health Board of bodies corporate

20. Where an NHS appliance contractor is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 19 and 23(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 46). When the NHS appliance contractor provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS appliance contractor is included.

Complaints

21. An NHS appliance contractor must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

Gwasanaethau cyfeiriedig

22. Rhaid i gcontractwr cyfarpar GIG, y mae'r Bwrdd Iechyd Lleol wedi gwneud trefniant gydag ef ar gyfer darparu unrhyw wasanaethau cyfeiriedig, gydymffurfio â thelerau ac amodau'r trefniant hwnnw.

Gwybodaeth sydd i'w chyflenwi

23.—(1) Rhaid i gcontractwr cyfarpar GIG roi i'r Bwrdd Iechyd Lleol sydd â'r contractwr cyfarpar GIG hwnnw ar ei restr fferyllol hysbysiad ysgrifenedig o'r canlynol, o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn)—

- (a) unrhyw ddigwyddiad sy'n ei gwneud yn ofynnol newid yr wybodaeth a gofnodwyd am y contractwr cyfarpar GIG yn y rhestr fferyllol, nad oedd y contractwr cyfarpar GIG wedi hysbysu'r Bwrdd Iechyd Lleol ohono rywfodd arall yn unol â'r Rheoliadau hyn;
- (b) yn achos contractwr cyfarpar GIG sy'n unigolyn, unrhyw newid yn ei gyfeiriad preifat; ac
- (c) yn achos contractwr cyfarpar GIG sy'n gorff corfforaethol, unrhyw newid yng nghyfeiriad ei swyddfa gofrestredig.

(2) Rhaid i gcontractwr cyfarpar GIG, os gofynnir iddo, roi i'r Bwrdd Iechyd Lleol enw unrhyw fferylllydd cofrestredig a gyflogir ganddo sy'n gyfrifol am weinyddu presgripsiwn penodol.

(3) Yn ddarostyngedig i is-baragraff (6), rhaid i gcontractwr cyfarpar GIG sy'n gorff corfforaethol roi hysbysiad ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn) o unrhyw newidiadau yn enwau a chyfeiriadau ei gyfarwyddwyr.

(4) Yn ddarostyngedig i is-baragraff (6), os yw contractwr cyfarpar GIG sy'n gorff corfforaethol yn penodi cyfarwyddwr neu uwcharolygydd nas rhestrwyd yng nghais y contractwr cyfarpar GIG am ei gynnwys mewn rhestr fferyllol, rhaid i'r contractwr cyfarpar GIG roi hysbysiad ysgrifenedig i'r Bwrdd Iechyd Lleol o fewn 28 diwrnod (neu os nad yw hynny'n ymarferol, cyn gynted ag y bo'n ymarferol wedyn) o'r wybodaeth am addasrwydd y person hwnnw i ymarfer.

(5) Yn ddarostyngedig i is-baragraff (6), rhaid i gcontractwr cyfarpar GIG, neu gyfarwyddwr neu uwcharolygydd contractwr cyfarpar GIG sy'n gorff corfforaethol, hysbysu'r Bwrdd Iechyd Lleol—

- (a) os yw'r unigolyn hwnnw, neu'r corff corfforaethol y mae'n gyfarwyddwr neu'n uwcharolygydd ohono, yn gwneud cais am gael ei gynnwys mewn unrhyw un o restrau cyflawnwyr neu ddarparwyr GIG Bwrdd Iechyd Lleol arall, ac o ganlyniad unrhyw gais o'r fath; a

Directed Services

22. An NHS appliance contractor with whom a Local Health Board makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

Information to be supplied

23.—(1) An NHS appliance contractor must give written notice to the Local Health Board on whose pharmaceutical list he or she is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about the NHS appliance contractor in the pharmaceutical list which the NHS appliance contractor has not otherwise notified to the Local Health Board in accordance with these Regulations;
- (b) in the case of an NHS appliance contractor who is an individual, any change of his or her private address; and
- (c) in the case of an NHS appliance contractor that is a body corporate, any change to the address of its registered office.

(2) An NHS appliance contractor must give the Local Health Board, if it so requests, the name of any registered pharmacist employed by the NHS appliance contractor who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS appliance contractor that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impractical, as soon as practicable thereafter) of any changes to the names and addresses of its directors.

(4) Subject to sub-paragraph (6), if an NHS appliance contractor that is a body corporate appoints a director or superintendent that was not listed on the NHS appliance contractor's application for inclusion in a pharmaceutical list, the NHS appliance contractor must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS appliance contractor or the director or superintendent of an NHS appliance contractor that is a body corporate must inform the Local Health Board—

- (a) if he or she, or a body corporate of which he or she is a director or superintendent, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application; and

- (b) os daw'r unigolyn hwnnw yn gyfarwyddwr neu'n uwcharolygydd corff corfforaethol sydd ar unrhyw un o restrau cyflawnwyr neu ddarparwyr GIG Bwrdd Iechyd Lleol arall, neu sy'n gwneud cais am ei gynnwys mewn rhestr o'r fath, ac o ganlyniad unrhyw gais o'r fath.

(6) Os yw'r contractwr cyfarpar GIG yn gorff corfforaethol sydd â'i swyddfa gofrestredig yng Nghymru, caiff ddarparu'r wybodaeth sydd i'w darparu o dan is-baragraffau (3) i (5) i'r Bwrdd Iechyd Lleol hwnnw, yn unig, y lleolir y swyddfa gofrestredig yn ei ardal, ar yr amod bod y contractwr cyfarpar GIG yn darparu i'r Bwrdd Iechyd Lleol hwnnw fanylion hefyd o'r holl Fyrddau Iechyd Lleol eraill y cynhwysir y contractwr cyfarpar GIG yn eu rhestrau fferyllol, ac mewn amgylchiadau o'r fath, rhaid i'r Bwrdd Iechyd Lleol hwnnw drosglwyddo'r wybodaeth ymlaen i unrhyw Fwrdd Iechyd Lleol arall—

- (a) y cynhwysir y contractwr cyfarpar GIG yn ei restr fferyllol; neu
- (b) y gwneir cais iddo gan y contractwr cyfarpar GIG am gael ei gynnwys yn ei restr fferyllol, ac sy'n gofyn am yr wybodaeth.

(7) Yn y paragraff hwn, ystyr "rhestr cyflawnwyr neu ddarparwyr GIG" ("*NHS performers or providers list*") yw—

- (a) rhestr fferyllol; neu
- (b) rhestr a gynhelir o gyflawnwyr neu ddarparwyr gwasanaethau meddygol sylfaenol, deintyddol neu offthalmig.

Tynnu enwau yn ôl o restrau fferyllol

24. Os yw contractwr cyfarpar GIG yn bwriadu tynnu ei enw yn ôl o'r rhestr fferyllol mewn perthynas â mangre benodol, rhaid iddo hysbysu'r Bwrdd Iechyd Lleol o'i fwriad, dri mis o leiaf cyn y dyddiad hwnnw, onid yw'n anymarferol i'r contractwr cyfarpar GIG wneud hynny, ac os felly, rhaid i'r contractwr cyfarpar GIG hysbysu'r Bwrdd Iechyd Lleol cyn gynted ag y bo'n ymarferol gwneud hynny.

Codi ffioedd am gyfarpar

25. Yn ddarostyngedig i reoliadau a wneir o dan adran 121 o Ddeddf 2006, rhaid darparu'r holl gyfarpar a ddarperir o dan y telerau gwasanaethu hyn yn ddi-dâl.

Arolygiadau a mynediad at wybodaeth

26.—(1) Rhaid i gontractwr cyfarpar GIG ganiatáu i bersonau, a awdurdodwyd mewn ysgrifen gan y Bwrdd Iechyd Lleol fynd i mewn i unrhyw fangre a ddefnyddir gan y contractwr cyfarpar GIG i ddarparu gwasanaethau fferyllol ac i'w harchwilio, ar unrhyw adeg resymol, at y dibenion canlynol—

- (a) canfod a yw'r contractwr cyfarpar GIG yn

- (b) if he or she becomes a director or superintendent of a body corporate which is on any of another Local Health Board's NHS performers or providers list, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS appliance contractor is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS appliance contractor also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS appliance contractor is included; or
- (b) to whom the NHS appliance contractor makes an application to be included in its pharmaceutical list, that requests it.

(7) In this paragraph, "NHS performers or providers list" ("*rhestr cyflawnwyr neu ddarparwyr GIG*") means—

- (a) a pharmaceutical list; or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

Withdrawal from pharmaceutical lists

24. Where an NHS appliance contractor intends to withdraw from the pharmaceutical list in respect of particular premises, the NHS appliance contractor must notify the Local Health Board of this at least three months in advance of that date unless it is impracticable for the NHS appliance contractor to do so in which case the NHS appliance contractor must notify the Local Health Board as soon as it is practicable to do so.

Charges for appliances

25. Subject to regulations made under section 121 of the 2006 Act, all appliances provided under these terms of service must be provided free of charge.

Inspections and access to information

26.—(1) An NHS appliance contractor must allow persons authorised in writing by the Local Health Board to enter and inspect any premises he or she uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS appliance

cydymffurfio â gofynion yr Atodlen hon ai peidio;

(b) archwilio, monitro a dadansoddi—

- (i) y ddarpariaeth a wneir gan y contractwr cyfarpar GIG wrth ddarparu gwasanaethau fferyllol, o ran gofal a thriniaeth i gleifion gan gynnwys unrhyw drefniant a wneir gyda pherson ynglŷn â darparu cyfarpar, a
- (ii) y modd y mae'r contractwr cyfarpar GIG yn rheoli'r gwasanaethau fferyllol a ddarperir ganddo,

pan fo'r amodau yn is-baragraff (2) wedi eu bodloni.

(2) Yr amodau yw'r canlynol—

- (a) bod rhybudd rhesymol wedi ei roi o'r bwriad i fynd i mewn;
- (b) bod y Pwyllgor Fferyllol Lleol ar gyfer yr ardal y lleolir y fangre ynddi wedi ei wahodd i fod yn bresennol yn yr arolygiad, os gofynnodd y contractwr cyfarpar GIG am hynny;
- (c) bod gan y person a awdurdodwyd mewn ysgrifen dystiolaeth ysgrifenedig o'i awdurdodiad yn ei feddiant, a bod y person hwnnw'n dangos y dystiolaeth honno os gofynnir iddo; a
- (d) na fydd y person a awdurdodwyd mewn ysgrifen yn mynd i mewn i unrhyw ran o'r fangre a ddefnyddir fel llety preswyl yn unig, heb gydsyniad y preswylydd.

(3) Rhaid i gontractwr cyfarpar GIG, ar gais y Bwrdd Iechyd Lleol neu berson a awdurdodwyd mewn ysgrifen fel a grybwyllir yn is-baragraff (1), ganiatáu i'r Bwrdd neu'r person hwnnw gael mynediad at unrhyw wybodaeth y gofynnant amdani yn rhesymol—

- (a) at y dibenion a grybwyllir yn is-baragraff (1); neu
- (b) yn achos y Bwrdd Iechyd Lleol, mewn cysylltiad â'i swyddogaethau sy'n ymwneud â gwasanaethau fferyllol.

contractor is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

- (i) the provision made by the NHS appliance contractor, in the course of providing pharmaceutical services, for patient care and treatment including any arrangement made with a person in respect of provision of appliances, and
- (ii) the management by the NHS appliance contractor of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the NHS appliance contractor;
- (c) the person authorised in writing carries written evidence of his or her authorisation, which he or she produces on request; and
- (d) he or she does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS appliance contractor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him or her access to any information which it or he or she reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

Patterson, Liz
05/26/2020 17:09:13

Telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanaethau fferyllol

Terms of service for doctors providing pharmaceutical services

Dehongli

1. Yn yr Atodlen hon, rhaid ystyried bod cyffuriau neu gyfarpar wedi eu harchebu neu eu darparu yn unol â phresgripsiwn amlroddadwy, hyd yn oed os nad yw'r person sy'n dymuno cael y gwasanaethau fferyllol yn cyflwyno'r presgripsiwn hwnnw, cyhyd ag—

- (a) bod y presgripsiwn hwnnw gan y meddyg yn ei feddiant; a
- (b) bod y person hwnnw'n cyflwyno swp-ddyroddiad cysylltiedig, neu fod gan y meddyg swp-ddyroddiad cysylltiedig yn ei feddiant.

Ymgorffori darpariaethau

2. Mae unrhyw ddarpariaethau o'r canlynol sy'n effeithio ar hawliau a rhwymedigaethau meddygon sy'n darparu gwasanaethau fferyllol yn ffurfio rhan o'r telerau gwasanaethu—

- (a) y Rheoliadau;
- (b) y Tariff Cyffuriau i'r graddau y mae'n rhestru cyffuriau a chyfarpar ar ddibenion adran 80 o Ddeddf 2006 (trefniadau ar gyfer gwasanaethau fferyllol);
- (c) cymaint o Ran II o Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thribiwnlys) 1992 ag y sy'n ymwneud ag—
 - (i) ymchwiliadau a wneir gan y pwyllgor disgyblu fferyllol a'r cyd-bwyllgor disgyblu a chamau y caiff y Bwrdd Iechyd Lleol eu cymryd o ganlyniad i ymchwiliadau o'r fath, a
 - (ii) apelau i Weinidogion Cymru yn erbyn penderfyniadau'r Bwrdd Iechyd Lleol; a
- (d) cymaint o reoliad 29 o Reoliadau Cyngorau Iechyd Cymuned (Cyfansoddiad, Aelodaeth a Gweithdrefnau) (Cymru) 2010(1) (mynd i mewn i fangreoedd a'u harchwilio) ag sy'n ymwneud â mynd i mewn i fangreoedd sydd naill ai'n eiddo i'r meddyg fferyllol neu'n fangreoedd lle y darperir gwasanaethau fferyllol ganddo, ac archwilio mangreoedd o'r fath

Personau a awdurdodir yn briodol i weinyddu ar ran meddygon fferyllol

3. Pan fo'r Atodlen hon yn gosod gofyniad ar feddyg fferyllol mewn perthynas â gweithgaredd y mae'r meddyg hwnnw wedi awdurdodi person arall i

Interpretation

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the doctor has that prescription in his or her possession; and
- (b) that person presents, or the doctor has in his or her possession, an associated batch issue.

Incorporation of provisions

2. Any provisions of the following affecting the rights and obligations of doctors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
 - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and,
 - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board; and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010(1) (entry and inspection of premises) as relate to the entry and inspection of premises either owned by the dispensing doctor or where pharmaceutical services are provided by him or her.

Persons duly authorised to dispense on behalf of dispensing doctors

3. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which he or she has duly authorised another person to undertake, if

(1) O.S. 2010/288 (Cy.37).

(1) S.I. 2010/288 (W.37).

ymgymryd ag ef, os yw'r person arall hwnnw'n ymgymryd â'r gweithgaredd hwnnw yn lle'r meddyg fferyllol—

- (a) rhaid i'r person arall hwnnw gydymffurfio â'r gofyniad hwnnw; a
- (b) rhaid i'r meddyg fferyllol hwnnw sicrhau cydymffurfiaeth â'r gofyniad gan y person arall hwnnw,

ac mae cyfeiriadau at feddyg fferyllol yn yr Atodlen hon i'w dehongli'n unol â hynny.

Gweinyddu cyffuriau a chyfarpar a archebwyd gan ragnodydd arall

4.—(1) Yn ddarostyngedig i ddarpariaethau canlynol yr Atodlen hon, pan fo unrhyw berson yn cyflwyno i feddyg fferyllol ffurflen bresgripsiwn sy'n cynnwys—

- (a) archeb am gyffuriau, nad ydynt yn gyffuriau Atodlen, neu am gyfarpar, nad ydynt yn gyfarpar argaeledd cyfyngedig, a lofnodwyd gan ragnodydd ac eithrio'r meddyg fferyllol;
- (b) archeb am gyffur a bennir yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau (cyffuriau neu feddyginiaethau sydd i'w harchebu mewn amgylchiadau penodol yn unig), a lofnodwyd gan ragnodydd ac eithrio'r meddyg fferyllol ac yn cynnwys y cyfeirnod "SLS"; neu
- (c) archeb am gyfarpar argaeledd cyfyngedig, a lofnodwyd gan ragnodydd ac eithrio'r meddyg fferyllol ac yn cynnwys y cyfeirnod "SLS",

a'r meddyg fferyllol wedi ei awdurdodi neu dan ofyniad yn rhinwedd rheoliad 20 (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon) o'r Rheoliadau hyn i ddarparu'r cyffuriau neu'r cyfarpar a archebwyd felly, rhaid i'r meddyg fferyllol, yn rhesymol brydlon, ddarparu'r cyffuriau a archebwyd felly a'r cyfryw rai o'r cyfarpar a archebwyd felly a gyflenwir gan y meddyg fferyllol yng nghwrs arferol ei bractis neu ei fusnes.

(2) Yn ddarostyngedig i ddarpariaethau canlynol yr Atodlen hon, pan fo—

- (a) unrhyw berson yn cyflwyno i feddyg fferyllol bresgripsiwn amlroddadwy anelectronig sy'n cynnwys—
 - (i) archeb am gyffuriau nad ydynt yn gyffuriau Atodlen, nac yn gyffuriau rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971, ac eithrio cyffur a bennir am y tro yn Atodlen 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001 (sy'n ymwneud â chyffuriau rheoledig a eithriwyd rhag gwaharddiadau penodol o dan y Rheoliadau), wedi ei lofnodi gan ragnodydd ac eithrio'r meddyg fferyllol, sy'n ragnodydd amlroddadwy;

that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement; and
- (b) that dispensing doctor must secure compliance with that requirement by that other person,

and references in this Schedule to a dispensing doctor are to be construed accordingly.

Dispensing of drugs and appliances ordered by another prescriber

4.—(1) Subject to the following provisions of this Schedule, where any person presents to a dispensing doctor a prescription form which contains—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor;
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by a prescriber other than the dispensing doctor, and including the reference "SLS"; or
- (c) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor and including the reference "SLS",

and the dispensing doctor is authorised or required by virtue of regulation 20 (arrangements for the provision of pharmaceutical services by doctors) of these Regulations to provide the drugs or appliances so ordered, he or she must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(2) Subject to the following provisions of this Schedule, where—

- (a) any person presents to a dispensing doctor a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber other than the dispensing doctor who is a repeatable prescriber;

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- (ii) archeb am gyffur a bennir yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau, nad yw'n gyffur rheoledig yn yr ystyr a roddir i "controlled drug" yn Neddf Camddefnyddio Cyffuriau 1971, ac eithrio cyffur a bennir am y tro yn Atodlen 4 neu 5 i Reoliadau Camddefnyddio Cyffuriau 2001, wedi ei llofnodi gan ragnodydd ac eithrio'r meddyg fferyllol sy'n rhagnodydd amlroddadwy, ac yn cynnwys y cyfeirnod "SLS";
- (iii) archeb am gyfarpar, nad ydynt yn gyfarpar argaeledd cyfyngedig, wedi ei llofnodi gan ragnodydd ac eithrio'r meddyg fferyllol sy'n rhagnodydd amlroddadwy; neu
- (iv) archeb am gyfarpar argaeledd cyfyngedig a lofnodwyd gan ragnodydd ac eithrio'r meddyg fferyllol sy'n rhagnodydd amlroddadwy, ac yn cynnwys y cyfeirnod "SLS",

a hefyd yn cyflwyno swp-ddyroddiad cysylltiedig; neu

- (b) y meddyg fferyllol yn cael presgripsiwn amlroddadwy electronig sy'n cynnwys archeb o fath a bennir ym mharagraff (a)(i) i (iv), ac—
 - (i) unrhyw berson yn gofyn am ddarparu cyffuriau neu gyfarpar yn unol â'r presgripsiwn amlroddadwy hwnnw, neu
 - (ii) y meddyg fferyllol wedi trefnu gyda'r claf yn flaenorol, y byddai'n gweinyddu'r presgripsiwn amlroddadwy hwnnw pan ddeuai i law,

a'r meddyg fferyllol wedi ei awdurdodi neu dan ofyniad yn rhinwedd rheoliad 20 i ddarparu'r cyffuriau neu'r cyfarpar a archebwyd felly, rhaid i'r meddyg fferyllol, yn rhesymol brydlon, ddarparu'r cyffuriau a archebwyd felly a'r cyfryw rai o'r cyfarpar a archebwyd felly a gyflenwir gan y meddyg fferyllol yng nghwrs arferol ei bractis neu ei fusnes.

(3) At ddibenion y paragraff hwn, mae presgripsiwn amlroddadwy anelectronig am gyffuriau neu gyfarpar i'w ystyried wedi ei gyflwyno, hyd yn oed os nad yw'r person sy'n dymuno cael y cyffuriau neu gyfarpar yn cyflwyno'r presgripsiwn hwnnw, os yw—

- (a) y presgripsiwn hwnnw gan y meddyg fferyllol yn ei feddiant; a
- (b) swp-ddyroddiad cysylltiedig naill ai'n cael ei gyflwyno gan y person hwnnw, neu ym meddiant y meddyg fferyllol.

(4) Rhaid i'r cyffuriau a'r cyfarpar rhestredig a ddarperir o dan y paragraff hwn gael eu darparu mewn cynhwysyddion addas.

- (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference "SLS";
- (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber; or
- (iv) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference "SLS",

and also presents an associated batch issue; or

- (b) the dispensing doctor receives an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
 - (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
 - (ii) the dispensing doctor has previously arranged with the patient that he or she will dispense that repeatable prescription on receipt,

and the dispensing doctor is authorised or required by regulation 20 to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances will be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the dispensing doctor has that prescription in his or her possession; and
- (b) that person presents, or the dispensing doctor has in his or her possession, an associated batch issue.

(4) Drugs and listed appliances provided under this paragraph must be provided in a suitable container.

Gweinyddu cyffuriau a chyfarpar a archebir gan y meddyg fferyllol

5. Mewn amgylchiadau pan nad yw paragraff 4 yn gymwys, ac yn ddarostyngedig i ddarpariaethau canlynol yr Atodlen hon, pan fo meddyg fferyllol wedi ei awdurdodi neu dan ofyniad yn rhinwedd Rhan 5 o'r Rheoliadau hyn i ddarparu cyffuriau neu gyfarpar i berson, rhaid i'r meddyg fferyllol—

- (a) cofnodi archeb am ddarparu unrhyw gyffuriau neu gyfarpar sydd eu hangen ar gyfer trin y claf ar ffurflen bresgripsiwn a gwblheir yn unol â chontract GMC sy'n rhoi effaith i baragraff 39 o Atodlen 6 i'r Rheoliadau GMC (telerau contract eraill: rhagnodi);
- (b) darparu'r cyffuriau neu'r cyfarpar hynny mewn cynhwysydd addas;
- (c) peidio â darparu i'r claf unrhyw gyffur a bennir yn Atodlen 2 i'r Rheoliadau Rhagnodi Cyffuriau ac eithrio pan fo'r amodau ym mharagraff 42(2) o Atodlen 6 i'r Rheoliadau GMC (cyfyngiadau ar ragnodi gan ymarferwyr meddygol) wedi eu bodloni; a
- (d) peidio â darparu i'r claf unrhyw gyfarpar argaeledd cyfyngedig ac eithrio ar gyfer claf sy'n berson, neu at ddiben, a bennir yn y Tariff Cyffuriau.

Materion rhagarweiniol cyn darparu cyffuriau neu gyfarpar a archebwyd

6. Cyn darparu cyffuriau neu gyfarpar rhestredig a gofnodwyd ar ffurflen bresgripsiwn yn unol â pharagraff 4, neu yn yr amgylchiadau a bennir ym mharagraff 7—

- (a) rhaid i'r meddyg fferyllol ofyn i unrhyw berson, sy'n gwneud datganiad nad oes raid i'r claf dalu'r ffioedd a bennir yn rheoliad 4(1) o'r Rheoliadau Ffioedd (cyflenwi cyffuriau a chyfarpar gan feddygon), yn rhinwedd naill ai—
 - (i) hawl i esemptiad o dan reoliad 8(1) (esemptiadau) o'r Rheoliadau Ffioedd, neu
 - (ii) hawl i beidio â thalu ffi o dan reoliad 5 o'r Rheoliadau Peidio â Chodi Tâl (hawl i beidio â thalu ffi o gwbl ac i gael taliad llawn),

ddangos tystiolaeth foddhaol o'r cyfryw hawl, oni wneir y datganiad mewn perthynas â hawl i esemptiad yn rhinwedd rheoliad 8 o'r Rheoliadau Ffioedd neu mewn perthynas â hawl i beidio â thalu yn rhinwedd rheoliad 5(1)(d) neu 5(2)(d) neu (dd) o'r Rheoliadau Peidio â Chodi Tâl, pan fo tystiolaeth o'r fath eisoes ar gael i'r meddyg fferyllol ar yr adeg y gwneir y datganiad; a

- (b) os na ddangosir tystiolaeth foddhaol i'r

Dispensing of drugs and appliances ordered by the dispensing doctor

5. In circumstances where paragraph 4 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of Part 5 of these Regulations to provide drugs or appliances to a person, the dispensing doctor must—

- (a) record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with a GMS contract which gives effect to paragraph 39 of Schedule 6 to the GMS Regulations (other contract terms: prescribing);
- (b) provide those drugs or appliances in a suitable container;
- (c) provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations (restrictions on prescribing by medical practitioners) are satisfied; and
- (d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

6. Before providing drugs or listed appliances recorded on a prescription form in accordance with paragraph 4, or in the circumstances set out in paragraph 7—

- (a) the dispensing doctor must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations (supply of drugs and appliances by doctors) by virtue of either—
 - (i) entitlement to an exemption under regulation 8(1) of the Charges Regulations (exemptions), or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of remission by virtue of regulation 5(1)(e) or 5(2)(e) or (f) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor already has such evidence available to him or her; and

- (b) if no satisfactory evidence, as required by sub-

meddyg fferyllol fel sy'n ofynnol gan is-baragraff (a), rhaid i'r meddyg fferyllol arnodi'r ffurflen y gwnaed y datganiad arni i'r perwyl hwnnw.

Darparu cyffuriau Atodlen

7.—(1) Yn ddarostyngedig i is-baragraff (2), rhaid i feddyg fferyllol beidio â darparu unrhyw gyffur Atodlen ar gyfer claf, ac eithrio, pan fo'r meddyg fferyllol neu ragnodydd annibynnol wedi archebu cyffur sydd ganddo enw amherchnogol priodol, naill ai wrth yr enw hwnnw neu wrth ei fformiwla, caiff meddyg fferyllol ddarparu cyffur sydd â'r un fanyleb, hyd yn oed os yw'r cyffur hwnnw yn gyffur Atodlen (ond, yn achos cyffur sy'n gyfuniad o fwy nag un cyffur, ni chaniateir gwneud hynny ac eithrio pan fo gan y cyfuniad enw amherchnogol priodol).

(2) Nid oes dim yn yr Atodlen hon sy'n atal meddyg fferyllol rhag darparu cyffur Atodlen neu gyfarpar argaeledd cyfyngedig ar gyfer claf, rywfodd heblaw o dan y gwasanaethau fferyllol.

Gwrthod darparu cyffuriau neu gyfarpar a archebir

8.—(1) Caiff meddyg fferyllol wrthod darparu cyffuriau neu gyfarpar a archebir ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy—

- (a) os yw'r meddyg fferyllol yn credu, yn rhesymol, nad yw'r archeb yn archeb ddilys ar gyfer y person a enwir ar y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy (er enghraifft, oherwydd bod y meddyg fferyllol yn credu, yn rhesymol, fod y ffurflen wedi ei lladrata neu'i ffugio); neu
- (b) os yw'n ymddangos i'r meddyg fferyllol fod camgymeriad yn y ffurflen bresgripsiwn neu'r presgripsiwn amlroddadwy neu'i swp-ddyroddiad cysylltiedig (gan gynnwys camgymeriad clinigol a wnaed gan y rhagnodydd) neu y byddai darparu'r cyffuriau neu'r cyfarpar, yn yr amgylchiadau, yn groes i farn glinigol y meddyg fferyllol.

(2) Caiff meddyg fferyllol wrthod darparu cyffuriau neu gyfarpar a archebir ar ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu y byddai'r meddyg fferyllol, fel arall, wedi ei awdurdodi neu dan ofyniad i'w darparu yn rhinwedd rheoliad 20—

- (a) os yw'r meddyg fferyllol neu bersonau eraill yn y fangre yn dioddef trais neu'n cael eu bygwth â thrais gan y person sy'n cyflwyno'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu gan unrhyw berson sydd gyda'r person hwnnw; neu
- (b) os yw'r person sy'n cyflwyno'r ffurflen bresgripsiwn neu bresgripsiwn amlroddadwy, neu unrhyw berson arall sydd gyda'r person hwnnw, yn cyflawni neu'n bygwth cyflawni trosedd.

paragraph (a) is produced to the dispensing doctor, the dispensing doctor must endorse the form on which the declaration is made to that effect.

Provision of Scheduled drugs

7.—(1) Subject to sub-paragraph (2), a dispensing doctor must not provide for a patient any Scheduled drug, except that, where the dispensing doctor or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, he or she may provide a drug which has the same specification notwithstanding that it is a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this Schedule prevents a dispensing doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

8.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example, because the dispensing doctor reasonably believes that it has been stolen or forged); or
- (b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber), or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which he or she is otherwise authorised or required to provide by virtue of regulation 20, where—

- (a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription or repeatable prescription, or by any person accompanying that person; or
- (b) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) Rhaid i feddyg fferyllol wrthod darparu cyffuriau neu gyfarpar a archebir ar bresgripsiwn amlroddadwy—

- (a) os nad oes gan y meddyg fferyllol gofnod o'r presgripsiwn hwnnw;
- (b) os nad yw'r presgripsiwn wedi ei lofnodi gan ragnodydd amlroddadwy;
- (c) os byddai gwneud hynny yn anghyson ag unrhyw ysbeidiau a bennir yn y presgripsiwn;
- (d) os hwnnw fyddai'r tro cyntaf y darperid cyffur neu gyfarpar yn unol â'r presgripsiwn, ac os llofnodwyd y presgripsiwn fwy na chwe mis yn gynharach;
- (e) os aeth mwy na blwyddyn heibio er pan lofnodwyd y presgripsiwn amlroddadwy;
- (f) os yw'r dyddiad dod i ben ar y presgripsiwn amlroddadwy wedi mynd heibio; neu
- (g) os hysbyswyd y meddyg fferyllol, gan y rhagnodydd amlroddadwy, nad oes angen y presgripsiwn bellach.

(4) Pan fo claf yn gofyn am gyflenwi cyffuriau neu gyfarpar a archebwyd ar bresgripsiwn amlroddadwy (ac eithrio'r tro cyntaf y mae'r claf yn gwneud cais o'r fath), rhaid i feddyg fferyllol beidio â darparu cyffuriau neu gyfarpar a archebir felly oni fydd wedi ei fodloni—

- (a) bod y claf y mae'r presgripsiwn ar ei gyfer—
 - (i) yn cymryd neu'n defnyddio'r cyffur neu'r cyfarpar yn briodol, ac yn debygol o barhau i'w gymryd neu ei ddefnyddio felly, a
 - (ii) nad yw'n dioddef o unrhyw sgil effeithiau'r driniaeth sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf;
- (b) nad yw trefn feddyginiaethol y claf y mae'r presgripsiwn ar ei gyfer, wedi newid mewn ffordd sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf; ac
- (c) na ddigwyddodd unrhyw newidiadau yn iechyd y claf mae'r presgripsiwn ar ei gyfer sy'n dynodi bod angen, neu y byddai'n fuddiol, adolygu triniaeth y claf.

Ffioedd a chodi tâl

9.—(1) Mae'r telerau mewn contract GMC sy'n rhoi effaith i reoliad 24 (ffioedd a chodi tâl) o'r Rheoliadau GMC ac Atodlen 5 i'r Rheoliadau hynny yn gymwys mewn perthynas â darparu unrhyw gyffuriau neu gyfarpar gan feddyg fferyllol fel y maent yn gymwys mewn perthynas â phresgripsiynau am gyffuriau a chyfarpar.

(2) Os yw meddyg fferyllol yn darparu cyffur neu gyfarpar o dan wasanaethau fferyllol neu'n darparu

(3) A dispensing doctor must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the dispensing doctor has no record of that prescription;
- (b) it is not signed by a repeatable prescriber;
- (c) to do so would not be in accordance with any intervals specified in the prescription;
- (d) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously;
- (e) if the repeatable prescription was signed more than one year previously;
- (f) the expiry date on the repeatable prescription has passed; or
- (g) where the dispensing doctor has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where the patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), a dispensing doctor may only provide the drugs or appliances ordered if he or she is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way that indicates the need or desirability of reviewing the patient's treatment; and
- (c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Fees and charges

9.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to, the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in relation to prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services or provides

unrhyw wasanaeth ychwanegol mewn cysylltiad â gweinyddu cyffuriau a chyfarpar o'r fath—

- (a) yn unol â'r Atodlen hon neu gytundeb â'r Bwrdd Iechyd Lleol; a
- (b) pe bai'r cyffur, y cyfarpar neu'r gwasanaeth ychwanegol wedi ei ddarparu gan contractwr sy'n darparu gwasanaethau gweinyddu o dan contract GMC byddai hawl gan y contractwr, yn rhinwedd cyfarwyddiadau a roddwyd gan Weinidogion Cymru o dan adran 45 o Ddeddf 2006 (contractau GMC: taliadau), i gael taliad—
 - (i) mewn perthynas â'r cyffur neu gyfarpar; neu
 - (ii) mewn perthynas â darparu'r gwasanaeth ychwanegol,

bydd y Bwrdd Iechyd Lleol yn credydu'r meddyg fferyllol â'r taliad.

Cwynion a phryderon

10.—(1) Os yw meddyg fferyllol—

- (a) yn contractwr GMC, neu wedi ei gymryd ymlaen neu'n gyflogedig gan contractwr GMC, y weithdrefn gwynion a sefydlwyd yn unol â thelerau contract GMC sy'n rhoi effaith i baragraffau 89A a 90 o Atodlen 6 i'r Rheoliadau GMC (pryderon a chwynion);
- (b) yn contractwr GMDdA, neu wedi ei gymryd ymlaen neu'n gyflogedig gan contractwr GMDdA, y weithdrefn gwynion a sefydlwyd gan y contractwr GMDdA perthnasol i ymdrin â chwynion mewn perthynas â darparu gwasanaethau meddygol sylfaenol;
- (c) wedi ei gyflogi neu'i gymryd ymlaen gan Fwrdd Iechyd Lleol at y diben o ddarparu gwasanaethau o fewn practis GMBILl, y weithdrefn gwynion a sefydlwyd gan y practis GMBILl hwnnw i ymdrin â chwynion mewn perthynas â darparu gwasanaethau meddygol sylfaenol,

sy'n gymwys mewn perthynas ag unrhyw fater a gysylltir yn rhesymol â darparu gwasanaethau fferyllol, fel y mae'n gymwys mewn perthynas â gwasanaethau a ddarperir o dan y contract neu'r cytundeb hwnnw, neu o fewn y practis hwnnw.

(2) Gan hynny, mae contract GMC sy'n rhoi effaith i baragraff 95 o Atodlen 6 i'r Rheoliadau GMC (cydweithredu gydag ymchwiliadau) yn gymwys hefyd mewn perthynas â chwynion neu bryderon a hysbysir ynghylch materion o'r fath.

Arolygiadau a mynediad at wybodaeth

11.—(1) Rhaid i feddyg fferyllol ganiatáu i bersonau a awdurdodwyd gan y Bwrdd Iechyd Lleol fynd i mewn i unrhyw fangre a ddefnyddir gan y meddyg

any additional service associated with the dispensing of such drugs and appliances—

- (a) in accordance with this Schedule or an agreement with the Local Health Board; and
- (b) had the drug, appliance or additional service been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled by, by virtue of directions given by the Welsh Ministers under section 45 of the 2006 Act (GMS contracts: payments), to a payment—
 - (i) in respect of the drug or appliance; or
 - (ii) in respect of the additional service provision,

the Local Health Board will credit the dispensing doctor with the payment.

Complaints and concerns

10.—(1) Where a dispensing doctor—

- (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraphs 89A and 90 of Schedule 6 to the GMS Regulations (concerns and complaints);
- (b) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;
- (c) is employed or engaged by a Local Health Board for the purposes of providing services within an LHBMS practice, the complaints procedure established by that LHBMS practice to deal with complaints in relation to the provision of primary medical services,

applies in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, a GMS contract which gives effect to paragraph 95 of Schedule 6 to the GMS Regulations (co-operation with investigations) also applies in relation to complaints or concerns notified about such matters.

Inspections and access to information

11.—(1) A dispensing doctor must allow persons authorised by the Local Health Board to enter and inspect any premises that he or she uses for the

fferyllol i ddarparu gwasanaethau fferyllol ac i'w harchwilio, ar unrhyw adeg resymol, at y dibenion canlynol—

- (a) canfod a yw'r meddyg fferyllol yn cydymffurfio â gofynion yr Atodlen hon ai peidio;
- (b) archwilio, monitro a dadansoddi—
 - (i) y ddarpariaeth a wneir gan y meddyg fferyllol wrth ddarparu gwasanaethau fferyllol, o ran gofal a thriniaeth i gleifion gan gynnwys unrhyw drefniant a wneir gyda pherson ynglŷn â darparu cyfarpar, a
 - (ii) y modd y mae'r meddyg fferyllol yn rheoli'r gwasanaethau fferyllol a ddarperir ganddo,

pan fo'r amodau yn is-baragraff (2) wedi eu bodloni.

(2) Yr amodau yw'r canlynol—

- (a) bod rhybudd rhesymol wedi ei roi o'r bwriad i fynd i mewn;
- (b) bod y Pwyllgor Fferyllol Lleol ar gyfer yr ardal y lleolir y fangre ynddi wedi ei wahodd i fod yn bresennol yn yr arolygiad, os gofynnodd y meddyg fferyllol am hynny;
- (c) bod gan y person a awdurdodwyd mewn ysgrifen dystiolaeth ysgrifenedig o'i awdurdodiad yn ei feddiant, a rhaid iddo ddangos y dystiolaeth honno os gofynnir iddo; a
- (d) na fydd y person a awdurdodwyd mewn ysgrifen yn mynd i mewn i unrhyw ran o'r fangre a ddefnyddir fel llety preswyl yn unig, heb gydsyniad y preswylydd.

(3) Rhaid i feddyg fferyllol, ar gais y Bwrdd Iechyd Lleol neu berson a awdurdodwyd mewn ysgrifen fel a grybwyllir yn is-baragraff (1), ganiatáu i'r Bwrdd neu'r person hwnnw gael mynediad at unrhyw wybodaeth y gofynnant amdani yn rhesymol—

- (a) at y dibenion a grybwyllir yn is-baragraff (1); neu
- (b) yn achos y Bwrdd Iechyd Lleol, mewn cysylltiad â'i swyddogaethau sy'n ymwneud â gwasanaethau fferyllol.

provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and
 - (ii) the management by the dispensing doctor of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Medical Committee for the area in which the premises are situated has been invited to be present at the inspection, where this is requested by the dispensing doctor;
- (c) the person authorised in writing carries written evidence of his or her authorisation, which must be produced on request; and
- (d) he or she does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or that person access to any information which it or that person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

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Rheoliad 50

Regulation 50

Mân ddiwygiadau a diwygiadau canlyniadol

Minor and consequential amendments

**Rheoliadau'r Gwasanaeth Iechyd Gwladol
(Pwyllgorau Gwasanaeth a Thribiwnlys) 1992**

1. Yn rheoliad 2 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Pwyllgorau Gwasanaeth a Thribiwnlys) 1992(1) (dehongli)—

- (a) ym mharagraff (1), yn y diffiniad o "chemist", ar ôl y geiriau "has the same meaning as" mewnosoder, "NHS appliance contractor and NHS pharmacist";
- (b) ym mharagraff (1), yn y diffiniad o "Pharmaceutical Regulations", yn lle'r geiriau "National Health Service (Pharmaceutical Services) Regulations 1992" rhodder "National Health Service (Pharmaceutical Services) (Wales) Regulations 2013"; ac
- (c) ym mharagraff (4)(c)(2), yn lle'r geiriau "paragraphs 10A and 10B of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992" rhodder "paragraph 33 of Schedule 4 to, or paragraph 21 of Schedule 5 to, the Pharmaceutical Regulations".

**Rheoliadau'r Gwasanaeth Iechyd Gwladol
(Symiau Dangosol) 1997**

2. Yn rheoliad 1(2) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Symiau Dangosol) 1997 (enwi, cychwyn a dehongli)(3), yn y diffiniad o "Drug Tariff" yn lle'r geiriau "regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations)" rhodder "regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013".

**Rheoliadau'r Gwasanaeth Iechyd Gwladol
(Taliadau gan Awdurdodau Lleol i Awdurdodau Iechyd) (Swyddogaethau Rhagnodedig) (Cymru) 2001**

3. Yn rheoliad 2(2) (swyddogaethau rhagnodedig yr Awdurdodau Iechyd yng Nghymru) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Taliadau gan Awdurdodau Lleol i Awdurdodau Iechyd) (Swyddogaethau Rhagnodedig) (Cymru) 2001(4), yn ym mharagraff (ch), rhodder—

- (1) O.S. 1992/664.
- (2) Mewnosodwyd paragraff (4) gan O.S. 1996/703.
- (3) O.S. 1997/980 fel y'i diwygiwyd gan O.S. 2007/1112 (Cy.117).
- (4) O.S. 2001/1543 (Cy.108), a ddiwygiwyd gan O.S. 2007/1112 (Cy.117).

The National Health Service (Service Committees and Tribunal) Regulations 1992

1. In regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(1) (interpretation)—

- (a) in paragraph (1), in the definition of "chemist", after the words "has the same meaning as" insert, "NHS appliance contractor and NHS pharmacist";
- (b) in paragraph (1), in the definition of "Pharmaceutical Regulations", for the words "National Health Service (Pharmaceutical Services) Regulations 1992" substitute "National Health Service (Pharmaceutical Services) (Wales) Regulations 2013"; and
- (c) in paragraph (4)(c)(2), for the words "paragraphs 10A and 10B of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992" substitute "paragraph 33 of Schedule 4 to, or paragraph 21 of Schedule 5 to, the Pharmaceutical Regulations".

The National Health Service (Indicative Amounts) Regulations 1997

2. In regulation 1(2) of the National Health Service (Indicative Amounts) Regulations 1997 (citation, commencement and interpretation)(3), in the definition of "Drug Tariff", for the words "regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations)", substitute "regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013".

The National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001

3. In regulation 2(2) (prescribed functions of Health Authorities in Wales) of the National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001(4), for sub-paragraph (d) substitute—

- (1) S.I. 1992/664.
- (2) Paragraph (4) was inserted by S.I. 1996/703.
- (3) S.I. 1997/980, as amended by S.I. 2007/1112 (W.117).
- (4) S.I. 2001/1543 (W.108), amended by S.I. 2007/1112 (W.117).

"(ch) darparu cyfarpar nad yw wedi'i restru yn Rhan IX o'r Tariff Cyffuriau a gyhoeddir yn unol â rheoliad 41 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Cymru) 2013 (y Tariff Cyffuriau a chydabyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG)"

**Rheoliadau'r Gwasanaeth Iechyd Gwladol
(Contractau Gwasanaethau Meddygol Cyffredinol)
(Cymru) 2004**

4.—(1) Mae Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004(1) wedi eu diwygio yn unol â'r paragraff hwn.

(2) Yn rheoliad 2(1) (dehongli)—

- (a) yn y diffiniad o "Drug Tariff", yn lle "regulation 18" rhodder "regulation 41"; ac
- (b) yn y diffiniad o "Pharmaceutical Regulations", yn lle "National Health Service (Pharmaceutical Services) Regulations 1992" rhodder "National Health Service (Pharmaceutical Services) (Wales) Regulations 2013".

(3) Yn Atodlen 6 (telerau contractol eraill)—

- (a) ym mharagraff 47 (darparu gwasanaethau gweinyddu)—
 - (i) yn is-baragraffau (4)(b) a (9)(a), yn y ddau achos, yn lle "regulation 12(15) or 13(13)(b) of" rhodder "paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or paragraph 8(3) of Schedule 3 to", a
 - (ii) yn is-baragraff (9)(b)(ii), yn lle "regulation 9(10) of" rhodder "Part 2 of Schedule 3 to" ac yn lle "(determination of whether an area is a controlled locality)" rhodder "(appeals against decisions determining controlled localities)";
- (b) ym mharagraff 48 (cydsyniad i weinyddu)—
 - (i) yn is-baragraff (2)—
 - (aa) yn lle "regulations 12 and 13 of" rhodder "regulation 24 of and Part 3 of Schedule 2 to", a
 - (bb) yn lle "regulation 21" rhodder "regulation 24",
 - (ii) yn is-baragraff (4), yn lle "regulation 12(16)" rhodder "regulation 24(9)",
 - (iii) yn lle is-baragraff (5) rhodder—

"(5) Regulation 24 of the Pharmaceutical Regulations will apply as if modified as follows: in paragraph (1) for "to provide pharmaceutical services to patients under regulation 20(1)(b) or (c)

"(d) the provision of appliances which are not listed in Part IX of the Drug Tariff which is published in accordance with regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)".

The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

4.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(1) are amended in accordance with this paragraph.

(2) In regulation 2(1) (interpretation)—

- (a) in the definition of "Drug Tariff", for "regulation 18" substitute "regulation 41"; and
- (b) in the definition of "Pharmaceutical Regulations", for "National Health Service (Pharmaceutical Services) Regulations 1992" substitute "National Health Service (Pharmaceutical Services) (Wales) Regulations 2013".

(3) In Schedule 6 (other contractual terms)—

- (a) in paragraph 47 (provision of dispensing services)—
 - (i) in sub-paragraphs (4)(b) and (9)(a), in each case for "regulation 12(15) or 13(13)(b) of" substitute "paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or paragraph 8(3) of Schedule 3 to", and
 - (ii) in sub-paragraph (9)(b)(ii), for "regulation 9(10) of" substitute "Part 2 of Schedule 3 to" and for "(determination of whether an area is a controlled locality)" substitute "(appeals against decisions determining controlled localities)";
- (b) in paragraph 48 (consent to dispense)—
 - (i) in sub-paragraph (2)—
 - (aa) for "regulations 12 and 13 of" substitute "regulation 24 of and Part 3 of Schedule 2 to", and
 - (bb) for "regulation 21" substitute "regulation 24",
 - (ii) in sub-paragraph (4), for "regulation 12(16)" substitute "regulation 24(9)",
 - (iii) for sub-paragraph (5) substitute—

"(5) Regulation 24 of the Pharmaceutical Regulations will apply as if modified as follows: in paragraph (1) for "to provide pharmaceutical services to patients under regulation 20(1)(b) or (c)

(1) O.S. 2004/478 (Cy.48).

(1) S.I. 2004/478 (W.48).

(arrangements for the provision of pharmaceutical services by doctors)" there were substituted a reference to the provision of dispensing services to patients under paragraph 47."

(iv) yn lle is-baragraff (6) rhodder—

"(6) Part 3 of Schedule 2 will apply as if modified as follows: in paragraph 8(1)(a) (ii) for "dispensing doctor list made under Part 5 of these Regulations" there were substituted a reference to an application under sub-paragraph (1) of this paragraph."

(c) Yn lle paragraff 49(8)(1) (telerau sy'n ymwneud â darparu gwasanaethau gweinyddu) rhodder—

"(8) A contractor providing dispensing services must comply with paragraph 6 of Schedule 6 to the Pharmaceutical Regulations, as if modified as follows—

(a) for "paragraph 4", substitute "paragraph 49(4) of Schedule 6 to the GMS Regulations";

(b) for "dispensing doctor" in sub-paragraph (a) and (b), substitute "the contractor providing dispensing services."

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007

5. Yn rheoliad 2(1) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007(2), yn y diffiniad o "Tariff Cyffuriau", yn lle "rheoliad 18(e) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (darpariaethau yn ymwneud â phenderfyniadau)" rhodder "rheoliad 41 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Cymru) 2013 (y Tariff Cyffuriau a chydabyddiaeth ariannol i fferyllwyr GIG a chontractwyr cyfarpar GIG)".

Rheoliadau Codi Tâl am Fagiau Siopa Untro (Cymru) 2010

6. Ym mharagraff 1(3) o Atodlen 1 i Reoliadau Codi Tâl am Fagiau Siopa Untro (Cymru) 2010(3), yn y diffiniad o "nyrs sy'n rhagnodi'n annibynnol", yn lle "Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992" rhodder "Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Cymru) 2013".

(arrangements for the provision of pharmaceutical services by doctors)" there were substituted a reference to the provision of dispensing services to patients under paragraph 47."

(iv) for sub-paragraph (6) substitute—

"(6) Part 3 of Schedule 2 will apply as if modified as follows: in paragraph 8(1)(a) (ii) for "dispensing doctor list made under Part 5 of these Regulations" there were substituted a reference to an application under sub-paragraph (1) of this paragraph."

(c) For paragraph 49(8)(1) (terms relating to the provision of dispensing services) substitute—

"(8) A contractor providing dispensing services must comply with paragraph 6 of Schedule 6 to the Pharmaceutical Regulations, as if modified as follows—

(a) for "paragraph 4", substitute "paragraph 49(4) of Schedule 6 to the GMS Regulations";

(b) for "dispensing doctor" in sub-paragraph (a) and (b), substitute "the contractor providing dispensing services."

The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

5. In regulation 2(1) of the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(2), in the definition of "Drug Tariff" for "regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations)" substitute "regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)".

The Single Use Carrier Bags Charge (Wales) Regulations 2010

6. In paragraph 1(3) of Schedule 1 to the Single Use Carrier Bags Charge (Wales) Regulations 2010(3), in the definition of "independent nurse prescriber" for "National Health Service (Pharmaceutical Services) Regulations 1992" substitute "National Health Service (Pharmaceutical Services) (Wales) Regulations 2013".

(1) Amnewidiwyd is-baragraff 8 gan O.S. 2006/358 (Cy.46).

(2) O.S. 2007/121 (Cy.11). Amnewidiwyd y diffiniad o "Drug Tariff" gan O.S. 2007/1112 (Cy. 117).

(3) O.S. 2010/2880 (Cy.238).

(1) Sub-paragraph 8 was substituted by S.I. 2006/358 (W.46).

(2) S.I. 2007/121 (W.11). The definition of "Drug Tariff" was substituted by S.I. 2007/1112 (W.117).

(3) S.I. 2010/2880 (W.238).

Dirymiadau

1. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(1).
2. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1993(2).
3. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol a Ffioedd am Gyffuriau a Chyfarpar) 1994(3).
4. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1995(4).
5. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1996(5).
6. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1998(6).
7. Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1999(7).
8. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) a (Gwasanaethau Meddygol Cyffredinol) (Diwygio) (Cymru) 2002(8).
9. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) a (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2003(9).
10. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2003(10).
11. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau ynghylch Rhagnodi gan Nyrsys Atodol ac Annibynnol) (Cymru) 2003(11).
12. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Rhif 2) (Cymru) 2003(12).

Revocations

1. The National Health Service (Pharmaceutical Services) Regulations 1992(1).
2. The National Health Service (Pharmaceutical Services) Amendment Regulations 1993(2).
3. The National Health Service (Pharmaceutical Services and Charges for Drugs and Appliances) Amendment Regulations 1994(3).
4. The National Health Service (Pharmaceutical Services) Amendment Regulations 1995(4).
5. The National Health Service (Pharmaceutical Services) Amendment Regulations 1996(5).
6. The National Health Service (Pharmaceutical Services) Amendment Regulations 1998(6).
7. The National Health Service (Pharmaceutical Services) Amendment Regulations 1999(7).
8. The National Health Service (Pharmaceutical Services) and (General Medical Services) (Amendment) (Wales) Regulations 2002(8).
9. The National Health Service (General Medical Services) and (Pharmaceutical Services) (Amendment) (Wales) Regulations 2003(9).
10. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2003(10).
11. The National Health Service (Amendments concerning Supplementary and Independent Nurse Prescribing) (Wales) Regulations 2003(11).
12. The National Health Service (Pharmaceutical Services) (Amendment) (No.2) (Wales) Regulations 2003(12).

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- (1) O.S. 1992/662.
 (2) O.S. 1993/2451.
 (3) O.S. 1994/2402.
 (4) O.S. 1995/644.
 (5) O.S. 1996/698.
 (6) O.S. 1998/681.
 (7) O.S. 1999/696.
 (8) O.S. 2002/3189 (Cy.305).
 (9) O.S. 2003/139 (Cy.11).
 (10) O.S. 2003/783 (Cy.94).
 (11) O.S. 2003/2624 (Cy.252).
 (12) O.S. 2003/3236 (Cy.316).

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- (1) S.I. 1992/662.
 (2) S.I. 1993/2451.
 (3) S.I. 1994/2402.
 (4) S.I. 1995/644.
 (5) S.I. 1996/698.
 (6) S.I. 1998/681.
 (7) S.I. 1999/696.
 (8) S.I. 2002/3189 (W.305).
 (9) S.I. 2003/139 (W.11).
 (10) S.I. 2003/783 (W.94).
 (11) S.I. 2003/2624 (W.252).
 (12) S.I. 2003/3236 (W.316).

13. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol etc) (Presgripsiynau Amlroddadwy) (Diwygio) (Cymru) 2004(1).

14. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2004(2).

15. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2005(3).

16. Paragraff 6 o Atodlen 1 i Orchymyn Darpariaethau Trosiannol a Chanlyniadol Gwasanaethau Deintyddol Cyffredinol a Gwasanaethau Deintyddol Personol (Cymru) 2006(4).

17. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2006(5).

18. Paragraff 1 o Atodlen 2 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007(6).

19. Rheoliad 3 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau Amrywiol Ynghylch Nyrsys Sy'n Rhagnodi'n Annibynnol, Rhagnodwyr Atodol, Nyrsys-ragnodwyr Annibynnol a Fferyllwyr-ragnodwyr Annibynnol) (Cymru) 2007(7).

20. Rheoliadau 3, 4, 5, 6, 7 ac 8 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Taliadau i bersonau sy'n darparu Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2007(8).

21. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2009(9).

22. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2010(10).

23. Rheoliad 2 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau Amrywiol ynghylch Rhagnodi Annibynnol) (Cymru) 2010(11).

24. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) (Rhif 2) 2010(12).

13. The National Health Service (Pharmaceutical Services etc) (Repeatable Prescriptions) (Amendment) (Wales) Regulations 2004(1).

14. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2004(2).

15. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2005(3).

16. Paragraph 6 of Schedule 1 to the General Dental Services and Personal Dental Services Transitional and Consequential Provisions (Wales) Order 2006(4).

17. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2006(5).

18. Paragraph 1 of Schedule 2 to the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(6).

19. Regulation 3 of the National Health Service (Miscellaneous Amendments Concerning Independent Nurse Prescribers, Supplementary Prescribers, Nurse Independent Prescribers and Pharmacist Independent Prescribers) (Wales) Regulations 2007(7).

20. Regulations 3, 4, 5, 6, 7 and 8 of the National Health Service (Pharmaceutical Services) (Remuneration for Persons providing Pharmaceutical Services) (Amendment) (Wales) Regulations 2007(8).

21. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2009(9).

22. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010(10).

23. Regulation 2 of the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010(11).

24. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) (No.2) Regulations 2010(12).

(1) O.S. 2004/1018 (Cy.115).

(2) O.S. 2004/1021 (Cy.118).

(3) O.S. 2005/1013 (Cy.67).

(4) O.S. 2006/946 (Cy.95).

(5) O.S. 2006/2985 (Cy.275).

(6) O.S. 2007/121 (Cy.11).

(7) O.S. 2007/205 (Cy.19).

(8) O.S. 2007/1112 (Cy.117).

(9) O.S. 2009/1491 (Cy.144).

(10) O.S. 2010/868 (Cy.90).

(11) O.S. 2010/1647 (Cy.155).

(12) O.S. 2010/1648 (Cy.156).

(1) S.I. 2004/1018 (W.115).

(2) S.I. 2004/1021 (W.118).

(3) S.I. 2005/1013 (W.67).

(4) S.I. 2006/946 (W.95).

(5) S.I. 2006/2985 (W.275).

(6) S.I. 2007/121 (W.11).

(7) S.I. 2007/205 (W.19).

(8) S.I. 2007/1112 (W.117).

(9) S.I. 2009/1491 (W.144).


(10) S.I. 2010/868 (W.90).

(11) S.I. 2010/1647 (W.155).

(12) S.I. 2010/1648 (W.156).

25. Paragraff 2 o Atodlen 2 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011**(1)**.

26. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2011**(2)**.

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25. Paragraph 2 of Schedule 2 to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011**(1)**.

26. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011**(2)**.

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(1) O.S. 2011/704 (Cy.108).

(2) O.S. 2011/2907 (Cy.311).

(1) S.I. 2011/704 (W.108).

(2) S.I. 2011/2907 (W.311).

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ON

Powys THB Finance Department

Resource Planning & Financial Management 2020/21

Board Agenda Item 2.9

FY 2020/21

Date Meeting: 27th May 2020

Patterson, Liz
05/26/2020 17:09:13



Subject:	RESOURCE PLAN & FINANCIAL MANAGEMENT 2020/2021
Approved & Presented by:	Pete Hopgood, Interim Director of Finance
Prepared by:	Sam Moss, Assistant Director of Finance
Other Committees and meetings considered at:	Board

PURPOSE:
<ul style="list-style-type: none"> The summary IMTP Financial Plan was presented to Strategy & Planning Committee 16th January and Board on 29th January. These papers outlined the general principles around the IMTP Financial Plan and assumptions underpinning the plan. The purpose of this paper on the Resource Plan and Financial Management for 2020/21: <ul style="list-style-type: none"> ➤ is to expand on the key assumption, savings and risks within the IMTP ➤ to summarise the IMTP and the Resource Plan for 2020/21 ➤ methodology for allocation of the 2020/21 budget
RECOMMENDATION:
<p>It is recommended that the Board:</p> <ul style="list-style-type: none"> NOTE the methodology and key assumptions underpinning the resource plan / IMTP NOTE the risks faced by the Health board linked to these NOTE the WG allocation for 2020/21 NOTE and DISCUSS the allocation of the NEW savings target for 2020/21

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):		
Strategic Objectives:	• Focus on Wellbeing	✗
	• Provide Early Help and Support	✗
	• Tackle the Big Four	✗
	• Enable Joined up Care	✗
	• Develop Workforce Futures	✗
	• Promote Innovative Environments	✗
	• Put Digital First	✗
	• Transforming in Partnership	✓
Health and Care Standards:	• Staying Healthy	✗
	• Safe Care	✗
	• Effective Care	✗
	• Dignified Care	✗
	• Timely Care	✗
	• Individual Care	✗
	• Staff and Resources	✓
	• Governance, Leadership & Accountability	✗

Approval/Ratification/Decision	Discussion	Information
	✓	

NOTE: All the information presented in this document was established before the Covid-19 pandemic and so the resource plan, allocation letter, financial plan in IMTP are based on the original submission and do not reflect any of the financial implications as a consequence of Covid-19.

2020-2023 IMTP for Powys tHB

Establishing and delivering a balanced 3 year financial plan for the period 2020 to 2023 is a major challenge for the board, executives, senior management and staff. The three year financial plan contained within the 2020-2023 IMTP was developed using the latest assumption regarding the health board's funding from Welsh Government, the likely cost pressures facing the organisation and an aspirational target for 2020/21 savings, which was detailed in the paper presented to the Strategy & Planning Committee on the 16th January 2020.

Reminder of General Principles underpinning IMTP

- **Starting position** for the plan is based on forecast 2019/20 outturn of breakeven using the detailed information at Mth 8. So what is the risk?
 - In using the 2019/20 outturn budget holders will be expected to maintain the current level of expenditure trends – so if an area is underspending in 2019/20 there is an expectation that will continue in 2020/21.
 - Movement from these expenditure trends (overall) in 2020/21 will impact on the Health Boards ability to deliver a balanced position at 31st March 2021.
 - This will include unmet savings targets from previous financial years, which have not been met on a recurrent basis.
 - Final outturn for 2019/20 may change from the Mth 8 position used, especially as some areas such as commissioning have deteriorated since Mth 8
- **Underlying Deficit** - the Health Board has delivered financial balance for the last 4-5 years, often using non-recurrent opportunities, as detailed in the 2019/20 Financial Performance Reports. As these non-recurrent opportunities happen each year it has been agreed that the 'concept' of an underlying deficit is removed assuming non-recurrent benefits continue year on year. So what is the risk?
 - If the non-recurrent opportunities do not materialise e.g. the current pay position increases above anticipated growth, or the level of non-recurrent investment from WG which provides some slippage is different in 2020/21 then the Health Board will not be able to deliver a balance position at 31st March 2021.
- **Savings Target 2020/21** – the original plan presented to Performance & Resources Committee on 16th December had a provisional target of £3.9m. The recognised pressures linked to WHSSC, EASC and WRP increased this by £1.7m. The total savings requirement for 2020/21 = £5.6m. So what is the risk?
 - Powys tHB does not have a track record of being able to deliver this level of savings. In 2019/20 it is anticipated to deliver £3.4m and some of the £3.4m is non-recurrent.

Further Modelling Assumptions Within the IMTP

- Revenue Resource Limit uplift of 1% for inflation and 1% for growth Welsh LTAs
- Direct increased cost of new Pay Awards to be funded in full including all Employer Pension Contribution changes over the 3 years of the plan
- Indirect cost of the new pay awards (through Commissioned Services) to be funded
- English Provider HRG4+ and CQuin Costs to be funded in full
- No material impact from IFRS 16
- No impact from any potential equalisation of the Welsh Government Resource Allocation model in either of the 3 years of the plan

Table 1: Finance Plan Summary 2020-2023

Financial Plan Summary – by Category of Spend	2020/21 £M	2021/22 £M	2022/23 £M
Revenue Resource Limit	-321.881	-325.460	-330.404
Other Income	-5.760	-5.783	-5.807
Total Income	-327.641	-331.243	-336.211
Primary Care – (excluding drugs)	43.920	43.920	44.183
Primary Care – drugs & appliances	27.333	28.252	29.156
Provided Services – pay	74.808	74.531	74.522
Provided Services – non pay	16.510	15.505	15.450
Secondary Care – drugs	0.981	0.973	0.964
Healthcare Services – other NHS bodies	135.940	139.310	142.613
Continuing Care and FNC	14.159	14.643	15.120
Other Private & Voluntary Sector	2.630	2.692	2.753
Joint Financing & Other	6.707	6.737	6.768
Depreciation etc.	3.507	3.507	3.507
Other Financial Charges	1.126	1.126	1.126
General Reserves	0.000	0.000	0.000
Total Costs	327.620	331.196	336.164
Net Residual Risk	-0.021	-0.047	-0.048

Table 2: Incremental Movement of Finance Plan

Financial Plan Summary	2020/21 £M	2021/22 £M	2022/23 £M
b/f Financial Deficit / (Surplus)	0.000	-0.021	-0.047
Revenue Resource Limit	-8.133	-4.853	-4.944
New Year Cost Pressures	13.749	8.537	9.006
Savings Plans	-5.638	-3.710	-4.062
Net Residual Risk	-0.021	-0.047	-0.048

Summary IMTP Financial Plan:

The financial plan is balanced over the three year period showing a small underspend. This contains the expectation that in-year savings will be achieved to deliver this balanced position and thereby are already incorporated in the financial position shown. Furthermore the recurrent non-recurrent opportunities that have been used to support the in year financial position continue each year over the 3 years of the plan. This is an extremely challenging financial strategy that relies upon efficiency in service delivery, effective financial and budgetary discipline, containment of Commissioned Services growth and robust delivery of service and savings plans.

The major assumptions and notes regarding income for 2020/21 are as follows:

- No uplift for Primary Care (pending finalisation of current national negotiations) as assumed any changes to the contracts will be funded in full
- Funding for Service Increment for Training (SIFT), Postgraduate Medical and Dental Education Research and Development and Public Health Laboratory Services (PHLS) allocated separately
- Allocations for accelerated depreciation, depreciation for donated assets, impairments and approved capital charge funding with confirmed strategic support will be issued as direct funding where applicable
- No funding assumed for RTT or Winter Plans unless pressures arise in year.

In addition to the baseline allocation, a number of assumptions have been included in the level of Revenue Resource Limit to be received in 2020/21, a summary is shown below:

Table 3: Movement of allocation totals from 2019/20-2020/21

Powys tHb Allocation Cash Letter	HCHS (Discretionary) £m	Ring Fenced (MH) £m	Ring Fenced (Other) £m	Directed £m	GMS £m	Pharmacy £m	Dental £m	Total £m
As per 2019/20 Cash Letter	208.669	27.770	18.620	4.108	33.162	4.753	5.904	302.986
Consolidation of 19-20 Funding	0.341	0.600	0.000	0.000	0.292	0.058	0.316	1.607
Transfer between funding Streams	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
New Top Slicing	-0.138	0.000	0.019	0.000	0.000	0.000	0.000	-0.119
Additional 20-21 Funding	10.022	0.594	0.000	0.000	0.000	0.000	0.000	10.616
As per 2020/21 Cash Letter	218.894	28.964	18.639	4.108	33.454	4.811	6.220	315.090

Table 4: Revenue Resource Limit Summary & Additional Anticipated Funding

Area	Financial Plan £m
2020/21 Baseline – as per WG	315.090
Anticipated Allocations:	
➤ Pay Award (indirect) – English Commissioners	0.606
➤ Other Anticipated Allocations	6.185
Total	321.881

Table 5: Revenue Resource Limit Summary & Additional Anticipated Funding

Area	Financial Plan £m
Discretionary uplift 2%	4.170
Additional Cluster Funding	0.417
Mental Health allocation uplift	0.594
In Year Changes Tariff/CQUIN	3.369
A4C/DDBR/ESP Pay Uplifts	1.493
Other	0.573
Total	10.616

Table 6: Adjustments for New Growth and Recurrent Impact Known Pressures in 2020/21 #

Area	£
New Datix Module	36,450
WHC 2019 026 - Nationally Standardised Adult Inpatient Assessment	29,893
Commissioning Pay Award & DDRB	516,931
NEPTS Removal FRP	317,557
OOH & 111	525,000
Pay Adjustments	91,003
Commissioning inc WHSSC/EASC/CQUIN	1,947,696
WRP	577,000
Cluster Funding	417,000
Service Changes	89,007
Mental Health Services	308,544
Total	4,856,081

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Note – this list excludes inflation, underlying pressures from 2019/20 and growth in existing budgets e.g. prescribing

What Has Offset the Health Boards Underlying Deficit

Historically the Underlying Deficit and the Unmet Savings Target brought Forward have been met by offsetting this pressures with non-recurrent benefits. These benefits have been reported in the Board Papers for the last 6 months.

The benefits which have been used to offset the underlying deficit include:

- **Operational Underspends and changes in provisions** = across multiple areas of the Health Board there have been non-recurrent operational underspends every year. In order to maintain a balanced position these underspend need to continue and so the actual spend of the Health Board change increase in 2020/21.
- **Slippage Funding Opportunities** = each year the Health Board receives additional allocations from Welsh Government above the initial funding detailed on page 5, due to the timing of the funding being released or the difficulty in recruiting to posts to support these investment the Health Board has benefited from this non-recurrent funding. Changes in the level of this funding may impact on the ability of the Health Board to deliver a balance plan

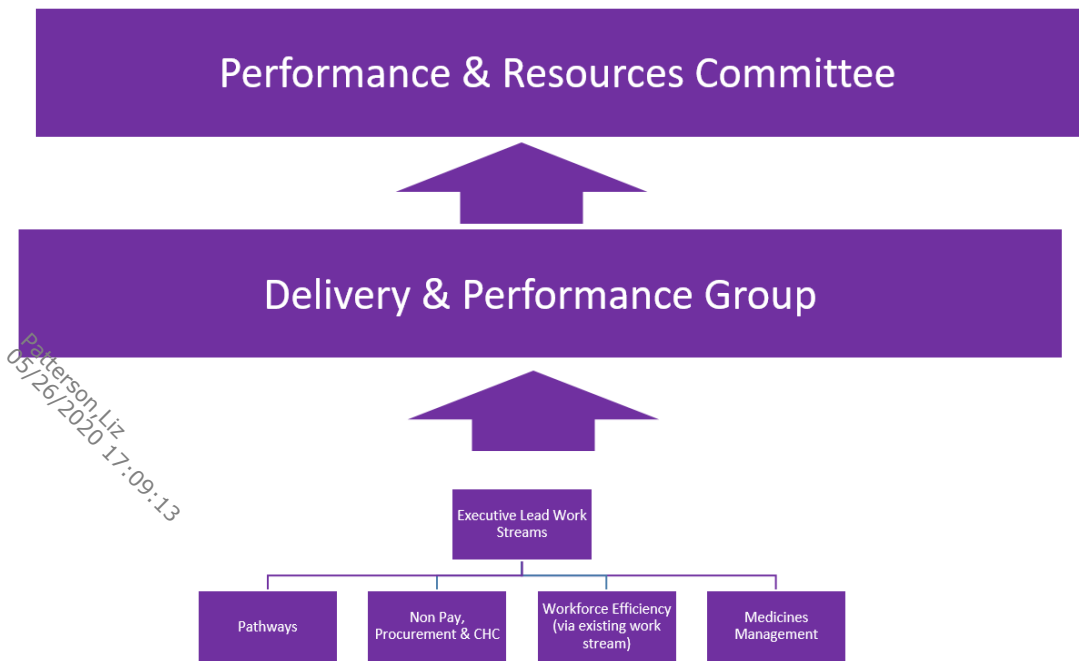
Unmet Savings Targets = the Health Board has not delivered the savings requirements on a recurrent basis each year and so any target not met recurrently are automatically rolled in to the next financial year to deliver. As we head into 2020/21 there remains unmet savings from previous financial years in the plan. In previous financial years these have been mitigated by all the opportunities detailed in the 2 points above. Should these opportunities cease then the brought forward unmet savings targets will become apparent in the position.

What Are the Savings Targets in the Financial Plan

- As outlined on page 6 the Health Board has unmet savings targets brought forward from previous years, which as outlined has been offset with opportunities elsewhere within the financial position
- In addition to this the Health Board agreed that to achieve a balanced IMTP in 202/21 it would set a NEW year target of **£5.6m**.

How Should Target Be Allocated?

- Historically the Health Board has opted to allocate the new year savings target across all cost centres where relevant.
 - What does this mean? So certain areas of the Health Board cannot have a savings target. One area that would not attract a savings target is GMS as the Health Board has to comply with the national contract and so cannot expect service managers to make saving in these areas.
 - Therefore with the exception of certain areas all other cost centres would be allocated a savings targets. The value will vary depending on the size of the opening budget.
- For 2020/21 the Health Board has adopted for a different approach to the allocation and management of savings. The target of £5.6m will be allocated to the 4 Executive Lead Work streams to deliver, although the delivery of savings will be taken from relevant budgets across the Health Board. Each Workstream will report on progress, action and delivery to Delivery and Performance Group and then to the Performance and Resources Committee.



Summary Executive Work Streams




Note: For purpose of uploading the 2020/21 budget into the ledger the full £5.6m is currently held on one cost centre in the ledger and will be allocated to the relevant Executive Lead Work Stream Cost Centres once they become operational.

Letters of Accountability

In line with FCP 26 within a month of the IMTP being approved a letter of accountability will be issued to all Principle Budget Holders. The proposed format of the letter is provided below, which will be updated to include the final budgets allocated. This will be completed once confirmation of the IMTP is received and the agreed model for allocating the savings target is set by the Health Board. However in the interim the preparatory work has commenced to ensure the letters are issued as quickly as possible.

Vivienne Hargwood, Cadeirdd / Chair
Ffôn / Phone: 01874 615971
E-bost / Email: Vivienne.Hargwood@wales.nhs.uk

Carol Shillabeer, Y Prif Weithredwr /
Chief Executive
Ffôn / Phone: 01874 615980
E-bost / Email: carol.shillabeer2@wales.nhs.uk



Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

Date:

Dear

DELEGATION OF BUDGETS FOR THE FINANCIAL YEAR 2020/21

You will be aware that the Health Board has a statutory obligation to perform its functions within available financial resources. In line with the Board's Budgetary Control Financial Control Procedure, I am formally writing to you to confirm the revenue budget delegated to you for the 2020/21 financial year – this is set out in Table 1.

The delegated revenue budget is in accordance with the Health Board approved IMTP 2020-2023 and as per the Resource Plan paper agreed by the Delivery and Performance Group on x and taken to Board on x.

Achieving your budget responsibilities is one of your key performance objectives and will be reviewed as part of your Performance Appraisal and Development Review (PADR).


Table 1: Delegated Annual Revenue Budget 2020/21 financial year

TO BE INSERTED

[This letter provides formal authorisation for you to incur expenditure during the financial year, up to the annual budget, to perform the functions necessary to deliver the Health Board's priorities and objectives. It also clarifies your accountability to deliver services within the budget and not to overspend.


You should manage your budgets in line with the Health Board's Budgetary Control Financial Control Procedure which is available on the intranet and sets out, in detail, budget holder's responsibilities and actions that should take place, if budget overspends arise.

Both Corffordd (Die)
Neuadd Brycheiniog, Ffordd Cambrian,
Aberhonddu, Powys LD3 7HR
Ffôn: 01874 711981

 CYFLOGWYR YSTYRIAOL
MINDFUL EMPLOYER

Corporate Hub (South)
Neuadd Brycheiniog, Cambrian Way,
Brecon, Powys LD3 7HR
Tel: 01874 711981

Rydym yn croeso iau gŵbaleddu Gymraeg
Bwrdd Iechyd Addysgu Powys yn enw gŵbaleddu Bwrdd Iechyd Lloed
Addysgu Powys

 CYMRU
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CYMRU

Welsh welcome correspondence in Welsh
Powys Teaching Health Board is the operational name of
Powys Teaching Local Health Board

APPENDIX 1

Acceptance of delegated budget for the 2020/21 financial year

To Chief Executive

I am signing to confirm acceptance of the budget delegated to me, for the purposes outlined, in your letter dated xxxxx. I can also confirm that I have read and understood the Health Board's Standing Orders (SOs), Standing Financial Instructions (SFIs) and financial control procedures and policies.

Name.....

Post.....

Signature.....

Date.....

This letter should be read in conjunction with the Health Board's Standing Orders (SO), Standing Financial Instructions (SFI) and financial policies and procedures – specifically, the Financial Control Procedure on Budgetary Control.

Budgetary Management
The formal delegation of the budget should be cascaded through all tiers of line management responsible for budget management, with budgetary performance reviews undertaken and appropriate actions taken. It is important that all budget holders have read and understood the SFIs and financial control procedures and are competent to manage a budget. Therefore all budget holders are required to confirm this as part of accepting their budget responsibilities.

Financial Advice and Information
Your lead Management Accountant will be able to provide financial advice and routine budgetary and financial management information to support you and your delegated budget holders in all financial management responsibilities.

As part of supporting budget holders to competently manage their budgets, the Health Board requires all budget holders to successfully complete an on-line budget training programme. It is designed to improve budget holders' financial management, knowledge and skills.

Please confirm your acceptance of the delegated budget by signing and returning Appendix 1 to me by xxxxx. You may wish to accompany your acceptance with a statement of any risks associated with your delegated budget.

Please note that relevant budgets will be adjusted accordingly in line with any Structure and Responsibility changes.

Yours sincerely,

Carol Shillabeer
Chief Executive Officer

Note: The interim C-19 FCP outlines that the timescales referred to in FCP 26 and detailed above are currently on hold during the C-19 pandemic, but will be issued a some future point to be determined.

BOARD MEETING		Date of Meeting: 27 May 2020
Subject :	CORPORATE RISK REGISTER – May 2020	
Approved and Presented by:	Rani Mallison, Board Secretary	
Prepared by:	Caroline Evans, Head of Risk & Assurance	
Other Committees and meetings considered at:	The Executive Committee has reviewed the Corporate Risk Register and recommends to the Board the proposed amendments set out in this paper.	

PURPOSE:

The purpose of this paper is to provide the Board with the May 2020 version of the Corporate Risk Register review and ratification.

RECOMMENDATION(S):

It is recommended that:

- the Board **REVIEWS** the May 2020 version of the Corporate Risk Register, ensuring that it is a complete and a true reflection of the health board's current high-level risks; and
- **APPROVES** the proposed amendments set out within this paper to those risks already recorded within the Corporate Risk Register.

Approval/Ratification/Decision	Discussion	Information
✓	✓	x

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

The Board approved its Risk Management Framework in September 2019, which sets out the components that provide the foundation and organisational arrangements for supporting risk management processes across the organisation. The Risk Management Framework includes the Board's Risk Appetite Statement, approved in July 2019.

COVID-19 was declared a pandemic by the World Health Organisation on 11 March 2020, and this has subsequently led to NHS organisations, including Powys Teaching Health Board, needing to focus on preparations and plans for dealing with an expected surge in demand of patients requiring interventions. The nature and scale of the response will depend on the course of the disease. The situation is changing constantly and will require an agile response.

The Board's approach to risk management will therefore need to be balanced and proportionate to ensure effective risk management arrangements, whilst ensuring capacity is made available to plan and respond to COVID-19. The approach to releasing capacity and determining priorities (COVID and 'business as usual' related) during this period will need to be determined by an assessment of risk.

The Corporate Risk Register provides a summary of the significant risks to the delivery of the health board's strategic objectives. This paper provides the Board with an updated version of the Corporate Risk Register, at May 2020. Executive Directors have reviewed and updated respective areas since the Board's last meeting in March 2020.

BACKGROUND AND ASSESSMENT:

Management of Strategic Risks during COVID-19

Strategic risks are those risks that represent a threat to achieving the health board's strategic objectives or its continued existence.

Strategic risks are recorded in the Board's Corporate Risk Register (CRR), which provides an organisational-wide summary of significant risks facing the Board. The criteria for a risk to be included in the Corporate Risk register is:

- The risk must represent an issue that has the potential to hinder achievement of one or more of the health board's strategic objectives;
- The risk cannot be addressed at directorate level;
- Further control measures are needed to reduce or eliminate the risk;
- A considerable input of resource is needed to treat the risk (finance, people, time, etc.).

The Corporate Risk Register (CRR) is considered by the Executive Committee and is considered by the Board at each of its meetings. This arrangement will continue during the COVID-19 pandemic.

The Executive Committee has reviewed the existing CRR in light of the emerging COVID-19 pandemic to:

- Consider whether any existing risks may need to be updated to reflect the impact of COVID-19 on them which may reduce/increase the risk score in terms of likelihood and/or impact;
- Consider whether there are new risks emerging from the impact of COVID-19 on the achievement of the board's strategic objectives;
- Assess and make recommendations to the Board regarding those risks where appetite and tolerance may need adjusting to recognise the impact of COVID-19 on the organisation.

Proposed Changes to the Corporate Risk Register

The Board is asked to consider these changes for approval: -

Corporate Risk	Change to Rating	Recommended Change
CRR 001 There is a risk that: Some commissioned services are not sustainable or safe, and do not meet national targets	Risk Rating increased from 16 ([L]4x[I]4) to 20 ([L]5x[I]4)	It is proposed that the likelihood of this risk occurring be increased from 'Likely' to 'Almost Certain'
CRR 002 There is a risk that: The health board does not meet its statutory	No change proposed to risk description or rating	

duty to achieve a breakeven position		
CRR 004 There is a risk that: ICT systems are not robust or stable enough to support safe, effective and up to date care	No change proposed to risk description or rating	
CRR 005 There is a risk that: The care provided in some areas is compromised due to the health board's estate being non-compliant and not fit for purpose	No change proposed to risk description or rating	
CRR 006 There is a risk that: The health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctors	Amended Description	There is a risk that: the health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctors (GPs)
CRR 007 There is a risk that: Effective governance arrangements are not embedded across all parts of the health board	No change proposed to risk description or rating	
CRR 008 There is a risk that: Fragmented and unsustainable service models as a result of population changing need and service reconfiguration of neighbouring NHS bodies	Risk Rating increased from 12 ([L]3x[I]4) to 16 ([L]4x[I]4)	It is proposed that the likelihood of this risk occurring be increased from 'Possible' to 'Likely'
CRR 009 There is a risk that:	Risk De-escalated to	It is proposed that this risk is de-escalated to Directorate level

There is a Service Failure of Out of Hours GMS Care	Directorate Risk Register	
CRR 010 There is a risk that: Resources (financial and other) are not fully aligned to the health board's priorities	Risk Rating decreased from 16 ([L]4x[I]4) to 12 ([L]3x[I]4)	It is proposed that the likelihood of this risk occurring be decreased from 'Likely' to 'Possible'
CRR 012 There is a risk that: The health board does not comply to the Welsh Language standards, as outlined in the compliance notice	No change proposed to risk description or rating	
CRR 013 There is a risk that: Services provided are fragile, not sustainable, and impact on PTHB ability to achieve National Outcome Framework measures	No change proposed to risk description or rating	
CRR 014 There is a risk that: Potential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19)	Amended Description	There is a risk that: Potential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19)

The full Corporate Risk Register is attached at **Appendix A**. It should be noted that any updates to the supporting information in the Corporate Risk Register is included in red text for ease of reference.

Management of COVID-19 Specific Risks

In light of the COVID-19 pandemic, the Chief Executive Officer established a command and control structure under Business Continuity Planning arrangements, led by a Strategic (Gold) Group. Gold Group is responsible for determining the coordinated strategy and policy for the overall management of the health board's response to COVID-19, to protect the reputation of the

organisation and ensure the delivery of effective, efficient and safe care for the population of Powys.

In assessing the health board's ability to respond to COVID-19, Gold Group has identified the key risks which require mitigation and monitoring and a COVID-19 Risk Register developed. Risks contained within the COVID-19 Risk Register relate solely to the health board's arrangements for responding to COVID-19 and does not include the COVID-19 related risks relevant to the achievement of the Board's strategic objectives (recorded through the Corporate Risk Register) or those risks related to service delivery (recorded through Directorate Risk Registers).

The COVID-19 Risk Register is reviewed regularly by Strategic (Gold) Group and is reported to the Board via the Report "Review of Phase 1" at agenda item 2.1.

NEXT STEPS:

The Corporate Risk Register will continue to be reviewed by Executive Committee, to ensure it illustrates a true reflection of the strategic risks that represent a threat to achieving the health board's strategic objectives, or its continued existence.

Executive Directors will review and update Directorate Risk Registers, to ensure there is a robust process for escalation of risks to the Corporate Risk Register.

The COVID-19 Risk Register will continue to be reviewed regularly by Strategic (Gold) Group, to ensure it illustrates a true reflection of the strategic risks that represent a threat to the health board's arrangements for responding to COVID-19.

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Powys Teaching
Health Board

Corporate Risk Register May 2020

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CORPORATE RISK HEAT MAP: May 2020

There is a risk that...

Impact	Catastrophic	5					
	Major	4		<ul style="list-style-type: none">There is a Service Failure of Out of Hours GMS Care	<ul style="list-style-type: none">The health board does not meet its statutory duty to achieve a breakeven positionICT systems are not robust or stable enough to support safe, effective and up to date careThe health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctorsEffective governance arrangements are not embedded across all parts of the health boardResources (financial and other) are not fully aligned to the health board’s priorities	<ul style="list-style-type: none">The care provided in some areas is compromised due to the health board’s estate being non-compliant and not fit for purposeFragmented and unsustainable service models as a result of population changing need and service reconfiguration of neighbouring NHS bodiesPotential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19)	<ul style="list-style-type: none">Some commissioned services are not sustainable or safe, and do not meet national targets
	Moderate	3				<ul style="list-style-type: none">The health board does not comply to the Welsh Language standards, as outlined in the compliance noticeServices provided are fragile, not sustainable, and impact on PTHB ability to achieve National Outcome Framework measures	
	Minor	2					
	Negligible	1					
			1	2	3	4	5
		Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain

CORPORATE RISK DASHBOARD – May 2020

Risk Lead	Risk ID	Main Risk Type	Risk Description There is a risk that:	SCORE (Likelihood x Impact)	Trend	Board Risk Appetite	Risk Target	At Target ✓/✗	Lead Board Committee	Risk Impacts on
DPP	CRR 001	Quality & Safety of Services	Some commissioned services are not sustainable or safe, and do not meet national targets	5 x 4 = 20	➔	Low	6	✗	Performance and Resources	Organisational Priorities underpinning WBO 1 to 4
DFIIT	CRR 002	Finance	The health board does not meet its statutory duty to achieve a breakeven position	3 x 4 = 12	➔	Moderate	8	✗	Performance and Resources	Organisational Priorities underpinning WBO 8.2
DFIIT	CRR 004	Quality & Safety of Services	ICT systems are not robust or stable enough to support safe, effective and up to date care	3 x 4 = 12	➔	Low	6	✗	Performance and Resources	Organisational Priorities underpinning WBO 1 to 4, 7.1, 7.2 & 7.3
DPP	CRR 005	Quality & Safety of Services	The care provided in some areas is compromised due to the health board's estate being non-compliant and not fit for purpose	4 x 4 = 16	➔	Low	4	✗	Performance and Resources	Organisational Priorities Underpinning WBO 1 to 4
DWODSS	CRR 006	Quality & Safety of Services	The health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctors	3 x 4 = 12	➔	Low	6	✗	Performance and Resources	Organisational Priorities Underpinning WBO 1 to 8
BS	CRR 007	Regulation & Compliance	Effective governance arrangements are not embedded across all parts of the health board	3 x 4 = 12	➔	Low	6	✗	Audit, Risk and Assurance	Organisational Priorities Underpinning WBO 1 to 4

DPP	CRR 008	Innovation & Strategic Change	Fragmented and unsustainable service models as a result of population changing need and service reconfiguration of neighbouring NHS bodies	4 x 4 = 16	➔	High	12	✓	Strategy and Planning	Organisational Priorities WBO 1 to 4
DPCMH	CRR 009	Quality & Safety of Services	There is a Service Failure of Out of Hours GMS Care	2 x 4 = 8	➔	Low	4	*	Performance and Resources	Organisational Priorities Underpinning WBO 1 to 3
CEO	CRR 010	Finance / Resources	Resources (financial and other) are not fully aligned to the health board's priorities	3 x 4 = 12	↓	Low	8	*	Performance and Resources	Organisational Priorities underpinning WBO 1 to 8
DTHS	CRR 012	Regulation & Compliance	The health board does not comply to the Welsh Language standards, as outlined in the compliance notice	4 x 3 = 12	➔	Low	6	*	Performance and Resources	Organisational Priorities Underpinning WBO 1 to 8
DPCMH	CRR 013	Quality & Safety of Services	Services provided are fragile, not sustainable, and impact on PTHB ability to achieve National Outcome Framework measures	4 x 3 = 12	➔	Low	6	*	Performance and Resources	Organisational Priorities underpinning WBO 4 – specifically 4.3

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DPH	CRR 014	Quality & Safety of Services	Potential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19)	4 x 4 = 16	➔	Low	12	*	Executive	Organisational Priorities Underpinning WBO 1 to 8
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KEY:

LIKELIHOOD	IMPACT				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Almost Certain 5	5	10	15	20	25
Likely 4	4	8	12	16	20
Possible 3	3	6	9	12	15
Unlikely 2	2	4	6	8	10
Rare 1	1	2	3	4	5

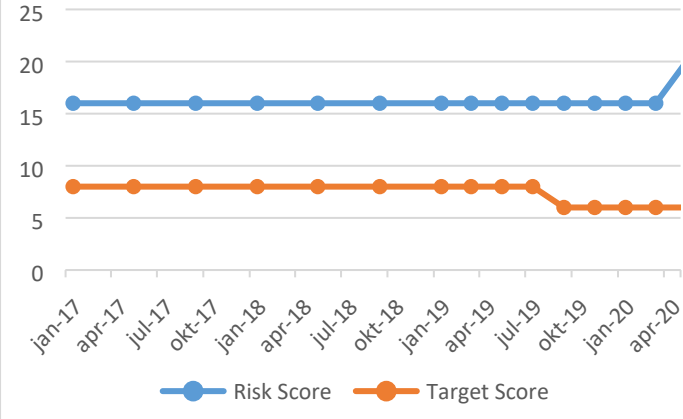
Very Low	1-3	Low	4-8	Moderate	9-12	High	15-25
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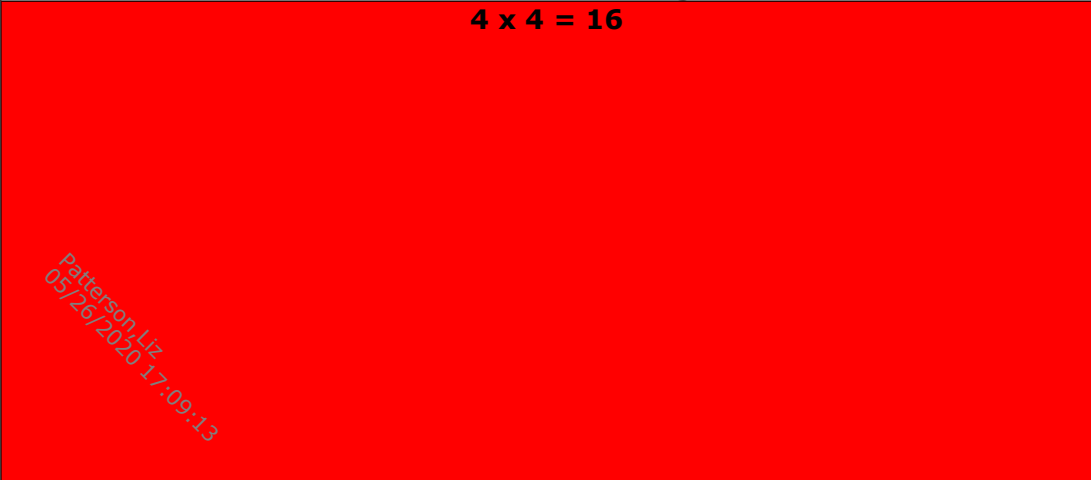
Executive Lead:	
CEO	Chief Executive
DPCMH	Director of Primary, Community Mental Health Services
DN	Director of Nursing
DFIIT	Director of Finance, Information and IT
MD	Medical Director
DPH	Director of Public Health
DWODSS	Director of Workforce & OD and Support Services
DTHS	Director of Therapies & Health Sciences
DPP	Director of Planning & Performance
BS	Board Secretary

RISK APPETITE		
Category	Appetite for Risk	
Quality & Safety of Services	Low	Risk Score 1-6
Regulation & Compliance	Low	Risk Score 1-6
Reputation & Public Confidence	Moderate	Risk Score 8-10
Finance	Moderate	Risk Score 8-10
Innovation & Strategic Change	High	Risk Score 12-15

Trend	
↑	risk score increased
→	risk score remains static
↓	risk score reduced

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CRR 001 Risk that: Some commissioned services are not sustainable or safe, and do not meet national targets		Lead Director: Director of Planning & Performance Lead Board Committee: Performance and Resources Committee and Experience, Quality and Safety Committee (for experience, quality and safety of commissioned services)																																														
Risk Impacts on: Organisational Priorities underpinning WBO 1 to 4		Date last reviewed: May 2020																																														
Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 5 x 4 = 20 Target: 2 x 3 = 6	 <table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>Jan-17</td><td>16</td><td>8</td></tr><tr><td>Apr-17</td><td>16</td><td>8</td></tr><tr><td>Jul-17</td><td>16</td><td>8</td></tr><tr><td>Okt-17</td><td>16</td><td>8</td></tr><tr><td>Jan-18</td><td>16</td><td>8</td></tr><tr><td>Apr-18</td><td>16</td><td>8</td></tr><tr><td>Jul-18</td><td>16</td><td>8</td></tr><tr><td>Okt-18</td><td>16</td><td>8</td></tr><tr><td>Jan-19</td><td>16</td><td>8</td></tr><tr><td>Apr-19</td><td>16</td><td>8</td></tr><tr><td>Jul-19</td><td>16</td><td>8</td></tr><tr><td>Okt-19</td><td>16</td><td>6</td></tr><tr><td>Jan-20</td><td>16</td><td>6</td></tr><tr><td>Apr-20</td><td>20</td><td>6</td></tr></tbody></table>	Date	Risk Score	Target Score	Jan-17	16	8	Apr-17	16	8	Jul-17	16	8	Okt-17	16	8	Jan-18	16	8	Apr-18	16	8	Jul-18	16	8	Okt-18	16	8	Jan-19	16	8	Apr-19	16	8	Jul-19	16	8	Okt-19	16	6	Jan-20	16	6	Apr-20	20	6	Rationale for current score: PTHB is a predominantly commissioning organisation that must have the capacity, capability and governance processes to commission safely, effectively and compliantly across the whole system. There are four key areas of risk : i) <i>PTHB processes not identifying and addressing risks for Powys residents across the whole system</i> ii) <i>PTHB does not have the right capacity, capability and processes for whole system commissioning</i> iii) <i>Lack of clarity about pathways for Powys patients leading to significant harm (especially in the Midlands); and expenditure will not be in line with budget.</i> iv) <i>Non-compliance with statutory requirements in relation to joint commissioning with the local authority (including Section 33)</i> PTHB’s commissioning arrangements are amongst the most complex in the UK. As a highly rural area, with no DGH, 90% of Admitted Patient Care is commissioned from 15 main other NHS organisations across England and Wales. PTHB also commissions primary care; continuing health care; in partnership with the local authority; and participates in all Wales arrangements including for tertiary services.	
Date	Risk Score	Target Score																																														
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Date added to the risk register January 2017																																																
Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">Implementation of the Strategic Commissioning Framework (for whole system commissioning)Embedding the Commissioning Assurance Framework (CAF) escalation processExecutive Committee Strategic Commissioning and Change Group (including consideration of fragile services)Regular review at Delivery and Performance MeetingsScrutiny by Performance and Resources CommitteeScrutiny by Experience, Quality and Safety CommitteeInternal AuditsContract Quality and Performance Review Meetings for the 15 NHS Providers and key private sector providers		Mitigating actions (What more should we do?) <table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Embed whole system commissioning through the implementation of the Strategic Commissioning Framework</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Embed and ensure implementation of the Commissioning Assurance Framework</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Implement commissioning intentions for 2020-21</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Robustly manage the performance of all providers of planned care services for the people of Powys through the Commissioning Assurance Framework</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr></tbody></table>		Action	Lead	Deadline	Embed whole system commissioning through the implementation of the Strategic Commissioning Framework	DPP	In line with Annual Plan for 2020-21	Embed and ensure implementation of the Commissioning Assurance Framework	DPP	In line with Annual Plan for 2020-21	Implement commissioning intentions for 2020-21	DPP	In line with Annual Plan for 2020-21	Robustly manage the performance of all providers of planned care services for the people of Powys through the Commissioning Assurance Framework	DPP	In line with Annual Plan for 2020-21																														
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<ul style="list-style-type: none"> Individual Patient Funding Request Panel and Policy WHSCC Joint Committee and Management Group WHSSC ICP agreed within PTHB IMTP Emergency Ambulances Services Committee Shared Services Framework Agreements Section 33 Agreements Responsible Commissioner Regulations for Vulnerable Children Placed away from Home Specific Organisational Delivery Objectives set out in health board's Annual Plan for 2019-20 Participation in the Cross-Border Network Between England and Wales (Statement of Values and Principles between England and Wales) Commissioning Intentions set out in IMTP NHS LTA and SLA Overview submitted to the Executive Committee (and approval process) Executive Committee approved LTA and SLA narrative (updated each year) CEO signed LTAs and SLAs for healthcare CAF developed for General Dental Services CAF developed for General Medical Services Recruitment of Public Health Consultant to help strengthen commissioning intelligence Prior approval policy in place EEA policy and arrangements in place INNU policy out to consultation Recruitment of a pooled fund manager for Section 33 Residential Care 	Programme of work to strengthen effective processes to develop and manage condition specific and service plans	DPP	In line with Annual Plan for 2020-21
	Strengthening of commissioning intelligence in line with IMTP	DPP	In line with Annual Plan for 2020-21
	Review Patient flows and activity into specialised services to ensure safe and appropriate pathways	DPP	In line with IMTP/ICP
	Strengthen the organisation's capacity, capability and governance processes for commissioning – including interface with specialised services	DPP	In line with IMTP/ICP
	As a member of the Powys Regional Partnership Board, support delivery of the Powys Area Plan which includes commissioning appropriate, effective and efficient accommodation options for older people, individual children and looked after children	DPP	In line with Annual Plan for 2020-21
	Through the Joint Partnership Board, continue to develop opportunities for pooling Third Sector commissioning	DPP	In line with Annual Plan for 2020-21
	Strengthen the whole system approach to the Big 4	DPP	In line with IMTP
Current Risk Rating		Additional Comments	
4 x 4 = 16 		During the COVID period the usual commissioning arrangements are not in place, nor the actions set out in the Annual Plan. Health Boards and NHS Trusts providing services for Powys patients have made immediate service changes in response to directions from respective governments in England and Wales. The Commissioning Assurance Framework had to be suspended as it is not possible to score the domains at present: for example, routine services and performance monitoring have been suspended and finance has moved to block arrangements. Neighbouring English providers have moved into whole system Silver and Gold command arrangements. Mitigating actions in place include: participation in the Silver and Gold arrangements for neighbouring English regions; monitoring Q&S and maternity information; a weekly DGH log of pathway changes; shared modelling assumptions with NHS partners;	

participation in the Welsh Government Essential Services work – with weekly reporting introduced; an Exec Led DGH and Specialised Services Workstream; fast-tracking of elements of the Big 4 work to strengthen local resilience; Exec led meetings with the Ambulance Service; and continued work with the Welsh Health Specialised Services Committee; and planning for the next phase. (There is now a separate Exec lead Oversight Group in relation to care settings).

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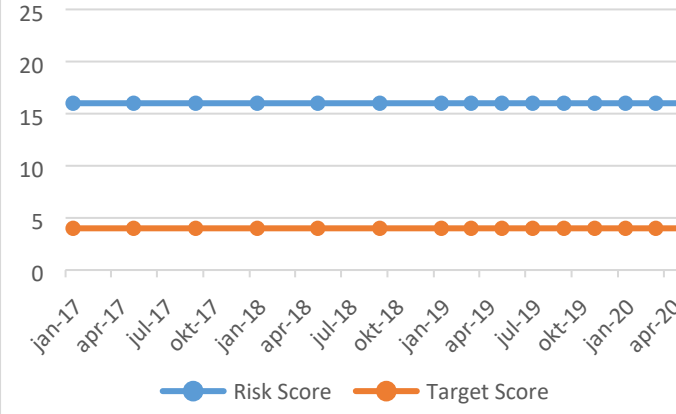
CRR 002 Risk that: the health board does not meet its statutory duty to achieve a breakeven position		Lead Director: Director of Finance, Information and IT Lead Board Committee: Performance and Resources Committee																																		
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Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">IMTP Financial Plan approvedMonthly meetings on monitoring of progress of deliveryFinancial Control Procedures and Standing Orders and Standing Financial InstructionsBudgetary Control FrameworkContracting FrameworkSavings PlansFinancial Recovery Plan Workshops (for 2020/21)Risks and Opportunities – focus and action to maximise opportunities and minimise / mitigate risks.		Mitigating actions (What more should we do?) <table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Strengthening of the capability and sustainability of the Finance Team</td><td>DFIIT</td><td>In Progress new Deputy Director of Finance in post</td></tr><tr><td>Discussions with Welsh Government re baseline budget now resolved</td><td>DFIIT</td><td>Complete</td></tr><tr><td>Increase focus on longer term efficiency and sustainability and balance with in year delivery as needed for plan</td><td>DFIIT</td><td>In Progress</td></tr></tbody></table>			Action	Lead	Deadline	Strengthening of the capability and sustainability of the Finance Team	DFIIT	In Progress new Deputy Director of Finance in post	Discussions with Welsh Government re baseline budget now resolved	DFIIT	Complete	Increase focus on longer term efficiency and sustainability and balance with in year delivery as needed for plan	DFIIT	In Progress																				
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Current Risk Rating 3 x 4 = 12		Additional Comments																																		

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CRR 004 Risk that: ICT systems are not robust or stable enough to support safe, effective and up to date care Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 4, 7.1, 7.2 & 7.3		Director Lead: Director of Finance, Information and IT Assuring Committee: Performance and Resources Committee Date last reviewed: May 2020																																		
<div><div>Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 3 x 4 = 12 Target: 2 x 3 = 6</div><div>Date added to the risk register January 2017</div></div> <div><table><caption>Risk Rating History</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>des-17</td><td>16</td><td>6</td></tr><tr><td>mar-18</td><td>16</td><td>6</td></tr><tr><td>jun-18</td><td>16</td><td>6</td></tr><tr><td>sep-18</td><td>16</td><td>6</td></tr><tr><td>des-18</td><td>16</td><td>6</td></tr><tr><td>mar-19</td><td>16</td><td>6</td></tr><tr><td>jun-19</td><td>16</td><td>6</td></tr><tr><td>sep-19</td><td>12</td><td>6</td></tr><tr><td>des-19</td><td>12</td><td>6</td></tr><tr><td>mar-20</td><td>12</td><td>6</td></tr></tbody></table></div>	Date	Risk Score	Target Score	des-17	16	6	mar-18	16	6	jun-18	16	6	sep-18	16	6	des-18	16	6	mar-19	16	6	jun-19	16	6	sep-19	12	6	des-19	12	6	mar-20	12	6	Rationale for current score: The risk rating remains high and will do until we are able to <ol style="list-style-type: none">1. Upgrade data center to remove high level risks (e.g. power, air-conditioning, wide area network, physical security) OR2. Invest in alternative data centre capability to address high risks (Such capability could be provisioned via "Cloud", third party data centre, shared data centre or our own new data center) AND3. Ensure appropriate and capable hot disaster recovery solution (Ability to provide services from alternative safe location should primary location is unavailable. Such capability would all services to be provided with minimal disruption to users) All alternatives and mitigation will require investment. Options are presently being re-reviewed for development of a business case.		
Date	Risk Score	Target Score																																		
des-17	16	6																																		
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Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">▪ Joint ICT Strategy with Powys County Council▪ Establishment of an ICT Programme Board and relevant Project Boards▪ Establishment of a specific Data Centre Programme▪ Engagement and input in to the National Implementation Board▪ Disaster Recovery arrangements in place▪ System Performance Measures in place▪ Specific Well-being Objective 7 – Digital First-<i>Digital Infrastructure and Intelligence</i> set as an Organisational Priority in the health board's Annual Plan for 2020-21.▪ Enhanced systems implemented in response to COVID-19.		Mitigating actions (What more should we do?) <table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Increase flexibility for accessing information and systems (anytime/anywhere/any device) including improved connectivity e.g. mobile coverage, broadband, Wi-Fi and modern, agile ready systems with integration by design.</td><td>DFIIT</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Improve information storage, server hosting, security and disaster recovery, back up and archiving capabilities</td><td>DFIIT</td><td>In line with Annual Plan for 2020-21</td></tr></tbody></table>			Action	Lead	Deadline	Increase flexibility for accessing information and systems (anytime/anywhere/any device) including improved connectivity e.g. mobile coverage, broadband, Wi-Fi and modern, agile ready systems with integration by design.	DFIIT	In line with Annual Plan for 2020-21	Improve information storage, server hosting, security and disaster recovery, back up and archiving capabilities	DFIIT	In line with Annual Plan for 2020-21																							
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Current Risk Rating 3 x 4 = 12		Additional Comments For Local infrastructure IT has continued to improve its Business																																		

	<p>continuity and disaster recovery process and procedures. Including system patching to protect from Cyber-attacks.</p> <p>IT is exploring the re-location of its data centre to further reduce the risk of outages and its reliance on the Bronllys site. This work is being looked at in conjunction with the Council who have the same risk.</p> <p>A business case is under development for this data centre work. To bring disaster recovery and backup capability to a secure and robust level will require investment in such capability.</p>
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CRR 005 Risk that: the care provided in some areas is compromised due to the health board's estate being non-compliant and not fit for purpose		Director Lead: Director of Planning & Performance Assuring Committee: Performance and Resources Committee																																														
Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 4		Date last reviewed: May 2020																																														
<div><div>Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 4 x 4 = 16 Target: 1 x 4 = 4</div><div>Date added to the risk register January 2017</div></div>	 <table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>Jan-17</td><td>16</td><td>4</td></tr><tr><td>Apr-17</td><td>16</td><td>4</td></tr><tr><td>Jul-17</td><td>16</td><td>4</td></tr><tr><td>Okt-17</td><td>16</td><td>4</td></tr><tr><td>Jan-18</td><td>16</td><td>4</td></tr><tr><td>Apr-18</td><td>16</td><td>4</td></tr><tr><td>Jul-18</td><td>16</td><td>4</td></tr><tr><td>Okt-18</td><td>16</td><td>4</td></tr><tr><td>Jan-19</td><td>16</td><td>4</td></tr><tr><td>Apr-19</td><td>16</td><td>4</td></tr><tr><td>Jul-19</td><td>16</td><td>4</td></tr><tr><td>Okt-19</td><td>16</td><td>4</td></tr><tr><td>Jan-20</td><td>16</td><td>4</td></tr><tr><td>Apr-20</td><td>16</td><td>4</td></tr></tbody></table>	Date	Risk Score	Target Score	Jan-17	16	4	Apr-17	16	4	Jul-17	16	4	Okt-17	16	4	Jan-18	16	4	Apr-18	16	4	Jul-18	16	4	Okt-18	16	4	Jan-19	16	4	Apr-19	16	4	Jul-19	16	4	Okt-19	16	4	Jan-20	16	4	Apr-20	16	4	Rationale for current score: Estates Compliance; 42% of the estate infrastructure was built pre-1948 and only 2% of the estate post-2005. Significant investment and risk-based programmes of work over several years across the compliance disciplines (fire, water hygiene, electric, medical gases, ventilation, etc.) will be required. Capital; the health board has not had the resource or infrastructure in place in recent times to deliver a significant capital programme and this places pressures on systems, capital resource and the wider organisation to fully support major project activity. Furthermore, Discretionary Capital acts as the safety net for overspend on capital projects for the health boards and with a very limited discretionary allowance in PTHB, this is a significant financial risk. Failure to secure funds could impact business continuity in terms of healthcare services. Environment & Sustainability; Welsh Government declared a Climate Crisis in April 2019 requiring escalated activity with ambitious targets in terms of decarbonisation of public sector by 2030 and zero waste to landfill by 2050.	
Date	Risk Score	Target Score																																														
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Apr-20	16	4																																														
Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)																																														
ESTATES <ul style="list-style-type: none">Specialist sub-groups for each compliance disciplineRisk based improvement plans introducedSpecialist leads identifiedEstates Compliance Group and Capital Control Group establishedMedical Gases Committee; Fire Safety Group; Water Safety Group; Health & Safety Committee in placeCapital Programme developed for compliance and approvedCapital and Estates set as a specific Organisational Priority (OP 22) in the health board's Annual Plan for 2019-20 with related Organisational Delivery ObjectivesAddress (on an ongoing basis) maintenance and compliance issuesAddress maintenance and compliance improvements to ensure patient environment is safe, appropriate and in line with standards. CAPITAL		Action	Lead	Deadline																																												
		Implement the Capital Programme and develop the long term capital programme	DPP	In line with Annual Plan for 2020-21																																												
		Continue to seek WG funding	DPP	In line with Annual Plan for 2020-21																																												
		Develop capacity and efficiency of the Estates and Capital function	DPP	In line with Annual Plan for 2020-21																																												
		Review current structure of capital and estates department	DPP	March 2020																																												

<ul style="list-style-type: none"> Capital Procedures for project activity Routine oversight / meetings with NWSSP Procurement Specialist advice and support from NWSSP Specialist Estates Services Audit reviews by NWSSP Audit and Assurance Close liaison with Welsh Government, Capital Function Reporting routinely to P&R Committee Capital Programme developed and approved Detailed Strategic, Outline and Full Business Cases defining risk Capital and Estates set as a specific Organisational Priority (OP 22) in the health board's Annual Plan for 2018-19 with related Organisational Delivery Objectives <p>ENVIRONMENT</p> <ul style="list-style-type: none"> ISO 14001 accreditation with ongoing external audit to retain accreditation Environment & Sustainability Group NWSSP Specialist Estates Services (Environment) support and oversight Welsh Government support and advice 			
Current Risk Rating	Additional Comments		
<p>4 x 4 = 16</p> <p>Patterson, Liz 05/26/2020 17:09:13</p>	<p>COVID-19 has introduced risk pressures in respect of the health board's estate and the ability of the Estates team to manage and prioritise risk mitigation in a number of ways:</p> <p>ESTATES – significant pressures to rapidly introduce bulk oxygen tanks (VIE) into 3 main hospitals will step up the risk around management of specialist enhanced oxygen systems. NWSSP SES ventilation lead in conjunction with Infection Prevention & Control, Microbiologist and H&S have highlighted the need, particularly related to COVID-19, to ensure ward areas have 6 air changes per hour and 12 air changes where aerosol generating practices take place; the only hospital (part) with mechanical ventilation is Brecon and a cost for introducing across our hospitals would be in the order of £0.5 to £1.0M+, with time and access constraints to do the work.</p> <p>Social distancing requests for space planning moves for teams and enhanced measures, such as screens and signs, are expanding rapidly and will benefit from central guidance but carries a HSE risk if not compliant. Work group stood up to review quality and adequacy of staff change and shower facilities for COVID activity and to support surge activity. Estates compliance - team focus on statutory compliance along with COVID works, with non-statutory / routine activity stood down, however, prolongation of the current lockdown may see further risks & pressures emerge. CAPITAL stand down of capital activity will put Discretionary Capital programme and Major Capital Schemes at risk and stand-up of activity overlapping with COVID will create further risk to timelines &</p>		

cost. **ENVIRONMENT & SUSTAINABILITY** accreditation audits for ISO 14001 continues and prolonged delay in engagement to work towards WG targets for carbon reduction, etc. will affect target attainability. **FIRE** – enhanced risks around oxygen enrichment of wards areas and changes in use and staffing of space at short notice. **PROPERTY** short notice search and lease timelines give rise to potential risk around legal and commercial agreements which are not fully developed (e.g. storage units, testing centres, community surge).

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CRR 006 Risk that: the health board is unable to attract, recruit and retain staff to some medical and clinical roles, principally registered nurses and doctors (GPs) Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 8		Director Lead: Director of Workforce & OD and Support Services Assuring Committee: Performance & Resources Committee Date last reviewed: May 2020																																			
Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 3 x 4 = 12 Target: 2 x 3 = 6	<table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>des-17</td><td>16</td><td>4</td></tr><tr><td>mar-18</td><td>16</td><td>4</td></tr><tr><td>jun-18</td><td>16</td><td>4</td></tr><tr><td>sep-18</td><td>16</td><td>4</td></tr><tr><td>des-18</td><td>16</td><td>4</td></tr><tr><td>mar-19</td><td>16</td><td>4</td></tr><tr><td>jun-19</td><td>16</td><td>4</td></tr><tr><td>sep-19</td><td>12</td><td>6</td></tr><tr><td>des-19</td><td>12</td><td>6</td></tr><tr><td>mar-20</td><td>12</td><td>6</td></tr></tbody></table>		Date	Risk Score	Target Score	des-17	16	4	mar-18	16	4	jun-18	16	4	sep-18	16	4	des-18	16	4	mar-19	16	4	jun-19	16	4	sep-19	12	6	des-19	12	6	mar-20	12	6	Rationale for current score: The health board continues to have difficulties recruiting and retaining certain posts and areas of the health board. It is recognised that for some professions the workforce is ageing and so there is a need to have clear succession and recruitment plans in place. The Nursing and Midwifery Workforce continues to provide challenges in relation to recruitment. On average, the health board since January 2018 have had 91 WTE nursing vacancies, including healthcare support workers. The temporary staffing unit are continuing to provide support to meet this demand. As a health board, there has been a 2.53% increase in the staff employed over the past 12 months (Dec 17 – Dec 18).	
Date	Risk Score	Target Score																																			
des-17	16	4																																			
mar-18	16	4																																			
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sep-19	12	6																																			
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mar-20	12	6																																			
Date added to the risk register January 2017	Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)																																		
	<ul style="list-style-type: none">Work continues to embed the centralised temporary staffing unit for all staffing groups.A Recruitment and Retention delivery plan has been developed via the Strategic Recruitment and Retention group. The Group is monitoring and implementing the programme of work, and escalate any issues in relation to the plan via the Executive Team and the Performance & Resources Committee.Weekly reports on temporary staffing are produced and shared with Community Service Managers and reviewed mid-week to ensure optimum cover options are explored.Developmental roles have been explored due to a difficulty in recruiting to a band 6 ear care role. Discussions are taking place and we are looking to adopt this approach within occupational therapy and other areas where appropriate. A review meeting of the band 6 ear care post is planned for October where we will scope out the strengths and weaknesses of this approach. Initial discussions were held around a post in OT but hasn't been explored any further as yet.The health board has been involved in a Mid Wales collaborative to develop a rural health recruitment campaign. The recruitment campaign includes a film of a day in the life experience from birth (PTHB) to emergency care		Action	Lead	Deadline																																
			Develop a strong, distinctive employment offer that captures the uniqueness of Powys Teaching Health Board.	DWODSS	In line with Annual Plan for 2020-21																																
			Work with the All Wales team on the implementation of the benefits portal page and ensure that this provides the opportunity to capture any local initiatives that are in place.	DWODSS	In line with Annual Plan for 2020-21																																
			The health board is currently developing a proposal for approval to consider a pilot Health Care Support Worker development in order to support unqualified to qualified approach (NVQ level 2 training).	DWODSS	TBD																																
			The health board has been chosen as a pilot area for the new 'Nurse Cadet Scheme'.	DWODSS	TBD																																

<p>(H DUHB) and finally palliative care (BCUHB) and aims to raise awareness of nursing careers within Mid Wales in the hope of attracting nurses from outside of the country. This campaign is now in place – we are yet to receive any expressions of interest.</p> <ul style="list-style-type: none"> ▪ Workforce & OD has created and solidified links with external organisations including Careers Wales, Armed Forces and Powys JobCentre plus to support the health board in promoting opportunities to work within the health board. 6 monthly meetings are now scheduled with the JobCentre and careers Wales. ▪ The Resourcing Team holds quarterly recruitment events and open days to secure stable levels of staffing on the bank and support substantive recruitment. ▪ The health board is using a hard-to-fill (enhanced) rate for shifts that are difficult to cover (Registered Nurses only). ▪ Workforce Quality and Efficiency Group established, which uses the Insight System to monitor performance against rosters, bank and agency usage. ▪ Ensure that recruitment timescales are minimised and that issues of delay are appropriately and proactively managed to ensure recruitment performance indicators are consistent with national targets. ▪ To maximise the ability to cover short term ad-hoc staffing requirements through bank workers Temporary Staffing Unit aims to reduce agency worker reliance. ▪ A review of the internal operating and processes for Job Evaluation has been undertaken to ensure that appropriate systems are in place which are timely and responsive to need whilst maintaining governance and integrity. ▪ We continue to develop potential alternative staffing models where appropriate. ▪ Establishments have been reviewed in inpatient areas to assess skill mix and staffing requirements, the aim to review staffing numbers and skill mix against bed numbers and patient needs, reflecting the All Wales Staffing Act 25a. The Interim District Nursing Principles continue to embed into the Community Teams. ▪ Work is progressing to look at developing creative and redesigning roles to meet the changing health needs of the local population, to include development of band 4 roles to encourage opportunities for growing and retaining our own staff within the Powys area. ▪ Band 4 Assistant Practitioner roles are being introduced into community teams as part of the Neighbourhood Nursing pilot. Also due to be 'tested' within Inpatient Areas as a test of change. These posts are now going through the recruitment process for Neighbourhood Nursing, with one post also out to advert for the inpatient ward in Llanidloes. 	<p>Recruitment guidance and a recruitment managers training package developed which supports managers in understanding the end to end recruitment process.</p>	<p>DWODSS</p>	<p>In line with Annual Plan for 2020-21</p>
<p>Current Risk Rating</p>	<p>Additional Comments</p>		

$3 \times 4 = 12$	
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CRR 007 Risk that: effective governance arrangements are not embedded across all parts of the health board Risk Impacts on: Organisational Priorities underpinning Enabling Well-being Objectives 1 to 4		Director Lead: Board Secretary Assuring Committee: Audit, Risk and Assurance, and Respective Committees Date last reviewed: May 2020																																		
Risk Rating (likelihood x impact): Initial: 3 x 4 = 12 Current: 3 x 4 = 12 Target: 2 x 3 = 6 Date added to the risk register January 2017	<table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>des-17</td><td>12</td><td>6</td></tr><tr><td>mar-18</td><td>12</td><td>6</td></tr><tr><td>jun-18</td><td>12</td><td>6</td></tr><tr><td>sep-18</td><td>12</td><td>6</td></tr><tr><td>des-18</td><td>12</td><td>6</td></tr><tr><td>mar-19</td><td>12</td><td>6</td></tr><tr><td>jun-19</td><td>12</td><td>6</td></tr><tr><td>sep-19</td><td>8</td><td>6</td></tr><tr><td>des-19</td><td>12</td><td>6</td></tr><tr><td>mar-20</td><td>12</td><td>6</td></tr></tbody></table>	Date	Risk Score	Target Score	des-17	12	6	mar-18	12	6	jun-18	12	6	sep-18	12	6	des-18	12	6	mar-19	12	6	jun-19	12	6	sep-19	8	6	des-19	12	6	mar-20	12	6	Rationale for current score: Wales Audit Office's Structured Assessment report for 2019 outlined that the health board is generally well led and has a comprehensive plan to continue to strengthen its governance arrangements. An internal audit of risk management arrangements identified gaps in relation to the embedding of the Risk Management Framework. Internal Audit issued a 'limited assurance' rated review on Freedom Of Information and a 'no assurance' rated review for records management. These reviews make a number of recommendations with regards to the need for improvement in compliance and governance areas.	
Date	Risk Score	Target Score																																		
des-17	12	6																																		
mar-18	12	6																																		
jun-18	12	6																																		
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sep-19	8	6																																		
des-19	12	6																																		
mar-20	12	6																																		
Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">Standing OrdersStanding Financial InstructionsBoard agreed Committee structureRisk Management FrameworkAssurance Framework – Board agreed principles and approachPolicies related to – gifts and hospitality, legal fees, use of Common Seal, Concerns etc.Internal audit arrangements in place and focused on risk areasAnnual Governance Programme has been agreed by the BoardSelf-assessment against ICO 12-steps undertakenElectronic Information Asset Register developed, piloted and populated with pilot services assetsMandatory IG e-learning training updated to reflect GDPRSchedule of WASPI ISPs and other agreements e.g. DDAs in place and process for developing new ISPs existsGDPR requirements reflected in existing fair processing notice for staffUpdated Intranet and Internet GDPR pages with fair processing / privacy notices (patients and staff)Data Protection Officer in place		Mitigating actions (What more should we do?) <table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Deliver the Annual Governance Programme 2020/21</td><td>BS</td><td>In line with Annual Plan for 2020/21</td></tr><tr><td>Develop and implement an Improvement Plan for Information Governance</td><td>BS</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Deliver the Records Management Improvement Plan</td><td>BS</td><td>In line with Annual Plan for 2020/21</td></tr><tr><td>Ensure the effective implementation of the COVID-19 Governance Framework</td><td>BS</td><td>Ongoing</td></tr></tbody></table>		Action	Lead	Deadline	Deliver the Annual Governance Programme 2020/21	BS	In line with Annual Plan for 2020/21	Develop and implement an Improvement Plan for Information Governance	BS	In line with Annual Plan for 2019-20	Deliver the Records Management Improvement Plan	BS	In line with Annual Plan for 2020/21	Ensure the effective implementation of the COVID-19 Governance Framework	BS	Ongoing																		
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Current Risk Rating		Additional Comments																																		

3 x 4 = 12

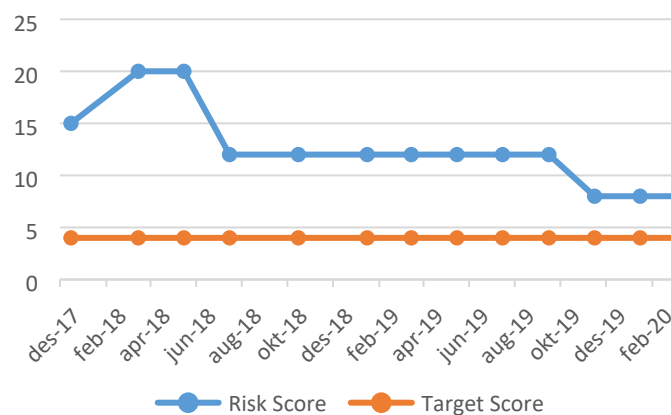
In light of COVID-19, the Board will be required to take a greater level of assurance from the organisation in the absence of some of its committees meeting (Performance & Resources Committee and Strategy & Planning Committee). In addition, the Board will be unable to rely on its audit programmes for assurance during this period given the temporary suspension of the internal audit programme and delays in the external audit programme commencing. Whilst these matters should not impact upon the controls in place to mitigate risk CRR007, the Board will need to place greater reliance on its 1st and 2nd line of defence (assurances) to satisfy itself that the controls are working effectively.

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CRR 008		Director Lead: Director of Planning & Performance																																		
Risk that: fragmented and unsustainable service models as a result of population changing need and service reconfiguration of neighbouring NHS bodies		Assuring Committee: Strategy and Planning Committee																																		
Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 4		Date last reviewed: May 2020																																		
Risk Rating (likelihood x impact): Initial: 3 x 3 = 9 Current: 4 x 4 = 16 Target: 3 x 4 = 12	 <table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>des-17</td><td>9</td><td>4</td></tr><tr><td>mar-18</td><td>9</td><td>4</td></tr><tr><td>jun-18</td><td>12</td><td>4</td></tr><tr><td>sep-18</td><td>12</td><td>4</td></tr><tr><td>des-18</td><td>12</td><td>4</td></tr><tr><td>mar-19</td><td>12</td><td>4</td></tr><tr><td>jun-19</td><td>12</td><td>4</td></tr><tr><td>sep-19</td><td>12</td><td>4</td></tr><tr><td>des-19</td><td>12</td><td>12</td></tr><tr><td>mar-20</td><td>12</td><td>12</td></tr></tbody></table>	Date	Risk Score	Target Score	des-17	9	4	mar-18	9	4	jun-18	12	4	sep-18	12	4	des-18	12	4	mar-19	12	4	jun-19	12	4	sep-19	12	4	des-19	12	12	mar-20	12	12	Rationale for current score: As a result of the Covid Planning / Implementation across NHS Wales and NHS England currently, strategic change programmes have been paused or significantly changed. Programme management arrangements externally and internally have been paused. The usual stocktake and pipeline processes to manage strategic change have been ceased temporarily and there is no reporting to Strategic Planning and Commissioning Group, and Board. All current planning and programme management capacity in PTHB has been redeployed to Covid Planning.	
Date	Risk Score	Target Score																																		
des-17	9	4																																		
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Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)																																		
A number of critical controls remain in place however the majority have been paused as a result of the COVID-19 Planning / Implementation across NHS Wales and NHS England. Critical controls remaining in place: <ul style="list-style-type: none">- DPP Briefings with CHC- Chief Executive and Directors of Planning meetings- Also reference the Corporate Risk entry for Commissioning as there is liaison with external providers to understand their individual plans Controls that will be resumed when it is safe and appropriate to deploy capacity back into strategic change planning, from COVID-19 planning: - <ul style="list-style-type: none">■ Implementation of the long term Health and Care Strategy for Powys through the IMTP, Annual Plan and Directorate Planning process.■ Compliance with Wellbeing of Future Generations Act and Social Services and Well-being Act.		<table><thead><tr><th>Action – on hold in Q1</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Provide robust management of and response to the Future Fit Programme in Shrewsbury and Telford Hospital NHS Trust</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Continuous monitoring of impact as Hywel Dda UHB’s Transforming Clinical Services Programme is implemented</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Provide robust management of engagement and response to the Hereford and Worcestershire Sustainability and Transformation Plan and Stroke programme</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Provide robust management of engagement and response to the Clinical Futures programme in Aneurin Bevan UHB.</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Robustly manage the response and engagement with external service change</td><td>DPP</td><td>In line with Annual Plan for 2020-21</td></tr></tbody></table>		Action – on hold in Q1	Lead	Deadline	Provide robust management of and response to the Future Fit Programme in Shrewsbury and Telford Hospital NHS Trust	DPP	In line with Annual Plan for 2020-21	Continuous monitoring of impact as Hywel Dda UHB’s Transforming Clinical Services Programme is implemented	DPP	In line with Annual Plan for 2020-21	Provide robust management of engagement and response to the Hereford and Worcestershire Sustainability and Transformation Plan and Stroke programme	DPP	In line with Annual Plan for 2020-21	Provide robust management of engagement and response to the Clinical Futures programme in Aneurin Bevan UHB.	DPP	In line with Annual Plan for 2020-21	Robustly manage the response and engagement with external service change	DPP	In line with Annual Plan for 2020-21															
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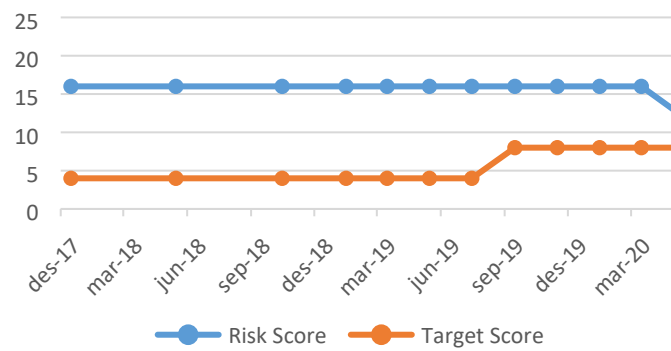
<ul style="list-style-type: none"> Specific Organisational Well-being Objective – WBO8 – Transforming in Partnership. Development of a Model of Care for Powys with Rural Regional Centre and Community Wellbeing Hubs; including taking forward the North Powys/Newtown proposals into a business case process. Strategic Change Stocktake process in place and regular updates providing a monitoring tool as part of the reporting cycle for Performance and Resources Committee and PTHB Board. Strategic Change Steering Group in place with a role to monitor external change and assess the impact clinically, operationally, and strategically of live consultations and engagement. Impact Assessment process in place for detailed analysis of live strategic change programmes. Powys Consultation Plans and weekly situation reports developed for each live consultation to ensure PTHB responses take into account the impact on Powys residents. Regular engagement and updates provided to CHC Services Planning Committee and Full Committee on live consultations. Executive Committee Strategic Planning and Commissioning meetings being held regularly. Establishment of Project Board to manage impact of the changes in pathways and services in relation to the Grange development. Participation in external Programme mechanisms as appropriate for key live programmes either as watching brief/ receipt of information or as programme participant in the case of NHS Future Fit. 	<p>programmes and developments as they arise during the year.</p> <p>As a member of the Mid Wales Joint Committee for Health and Care support delivery of the agreed Action Plan.</p>	DPP	In line with Annual Plan for 2020-21
Current Risk Rating	Additional Comments		
3 x 4 = 12			

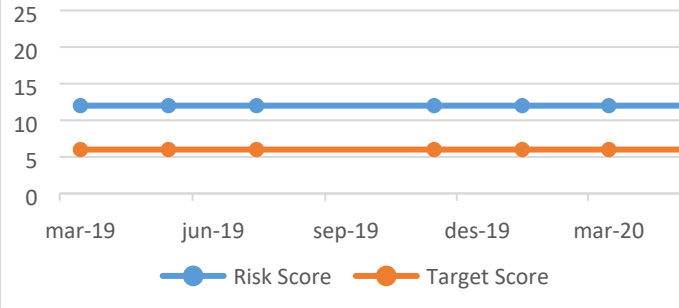
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CRR 009 Risk that: there is a service failure of Out of Hours GMS Care		Director Lead: Director Primary, Community and Mental Health Services Assuring Committee: Performance and Resources Committee Date last reviewed: May 2020																																														
Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 3																																																
Risk Rating (likelihood x impact): Initial: 3 x 3 = 9 Current: 2 x 4 = 8 Target: 1 x 4 = 4 Date added to the risk register July 2017	 <table><caption>Risk Score and Target Score Data</caption><thead><tr><th>Date</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>des-17</td><td>15</td><td>4</td></tr><tr><td>feb-18</td><td>20</td><td>4</td></tr><tr><td>apr-18</td><td>20</td><td>4</td></tr><tr><td>jun-18</td><td>12</td><td>4</td></tr><tr><td>aug-18</td><td>12</td><td>4</td></tr><tr><td>okt-18</td><td>12</td><td>4</td></tr><tr><td>des-18</td><td>12</td><td>4</td></tr><tr><td>feb-19</td><td>12</td><td>4</td></tr><tr><td>apr-19</td><td>12</td><td>4</td></tr><tr><td>jun-19</td><td>12</td><td>4</td></tr><tr><td>aug-19</td><td>12</td><td>4</td></tr><tr><td>okt-19</td><td>8</td><td>4</td></tr><tr><td>des-19</td><td>8</td><td>4</td></tr><tr><td>feb-20</td><td>8</td><td>4</td></tr></tbody></table>	Date	Risk Score	Target Score	des-17	15	4	feb-18	20	4	apr-18	20	4	jun-18	12	4	aug-18	12	4	okt-18	12	4	des-18	12	4	feb-19	12	4	apr-19	12	4	jun-19	12	4	aug-19	12	4	okt-19	8	4	des-19	8	4	feb-20	8	4	Rationale for current score: During 2017-18 issues arose in relation to the financial sustainability of the health boards Out of Hours provider. The CCGs in England went out to tender for services which PTHB provider won thus providing some financial security to the external organisation. The current PTHB contract with the OOH provider expires 31 March 2020. A procurement process under VEAT will now take place to award a contract into 2022 for this service, in line with Board discussions in September 2019. Lack of combined reporting between 111 & Shropdoc; therefore unable to report on all of the OOH framework standards.	
Date	Risk Score	Target Score																																														
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Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)																																														
<ul style="list-style-type: none">Shropdoc have a contract with CCGs into 2022/23 financial year.Successful implementation of 111 service.Contract award for future years to take place to secure strategic partner to deliver service and implement future modelOOH Programme Board to be stood down formally and monitoring of contract and 111 service to be led by the OOH Contract Monitoring Group (chaired by Assistant Director of Primary Care).In order to allow sufficient time and engagement for full consideration and evaluation of the options, discussions have been held at a very senior level within PTHB and with WG to consider service delivery for 2019/20. An option has been developed to refine the OOH base presence to reflect demand and improve value for money.Business Continuity Plan in place and updated to include 111 pathway.Integrated OOH Primary & Community Care Programme Meeting.Collaborative agreement signed October 2019.OOH Quarterly Performance Meeting with Shropdoc, Swansea Bay and 111 to ensure compliance with standards, which feeds into the CAG.All Wales Operational & IT Group includes health boards, Shropdoc and		<table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Contract award to be concluded</td><td>DPCMH/D FIIT</td><td>March 2020</td></tr><tr><td>PTHB unable to review and measure aspects of the OOH standards. Access to all data is now available. Accurate data reporting discussion continues between PTHB, 111, Shopdoc and Advanced. Accurate end to end reporting required.</td><td>DPCMH</td><td>November 2019</td></tr><tr><td>Establish and implement a Cluster Development Framework</td><td>CEO/Prog Director PC</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Improve the approach to equitable access & sustainability (out of hours / in hours) through deployment of Sustainability Toolkit.</td><td>CEO/Prog Director PC</td><td>In line with Annual Plan for 2019-20</td></tr></tbody></table>		Action	Lead	Deadline	Contract award to be concluded	DPCMH/D FIIT	March 2020	PTHB unable to review and measure aspects of the OOH standards. Access to all data is now available. Accurate data reporting discussion continues between PTHB, 111, Shopdoc and Advanced. Accurate end to end reporting required.	DPCMH	November 2019	Establish and implement a Cluster Development Framework	CEO/Prog Director PC	In line with Annual Plan for 2019-20	Improve the approach to equitable access & sustainability (out of hours / in hours) through deployment of Sustainability Toolkit.	CEO/Prog Director PC	In line with Annual Plan for 2019-20																														
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111. Any unfilled shifts and associated risks are reported to GOLD and SILVER on-call.	Scope the scaling-up of Choose Pharmacy and improve prescribing effectiveness	Prog Director PC	In-line with Annual Plan for 2019-20
	Further strengthen engagement between primary care and OOH (in line with response to Internal Audit report)	Prog Director PC	In-line with Annual Plan for 2019-20
Current Risk Rating		Additional Comments	
2 x 4 = 8		It is proposed that this risk is de-escalated to Directorate level, as we have awarded a contract, which is robust and is working very well.	

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CRR 010 Risk that: resources (financial and other) are not fully aligned to the health board's priorities Risk Impacts on: Organisational Priorities underpinning Well-being Objectives 1 to 8		Director Lead: Chief Executive Assuring Committee: Performance and Resources Committee Date last reviewed: May 2020																						
Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 3 x 4 = 12 Target: 2 x 4 = 8 Date added to the risk register May 2018		Rationale for current score: During Quarter 1 2020/21 resources are more directly aligned to COVID-19 Response which has become the key priority. The draft, revised Interim Annual Plan for 2020/21 outlines the re-prioritisation of resources to meet the balance of priorities across the organisation, including COVID-19.																						
Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">Clear prioritisation/direction from Welsh Government in terms of response to COVID-19 pandemic.The development of an interim, revised Annual Plan to enable agreement of re-prioritisation.Clear Financial Control Procedures in place to manage expenditure relating to COVID-19, including regular returns to WGWorkforce Plan for implementing the COVID-19 ResponseResources allocated to priority areas for fast-tracking supportive action in relation to COVID-19 and non-COVID-19 activity (e.g. Digital)Approved IMTP signals confidence in planning and deliveryDevelopment of an Organisational Development FrameworkAssessment of organisational capability including staff survey, WAO and Internal Audit, external review workStrengthened Regional Partnership Board working and ICF management – potential for further investment		Mitigating actions (What more should we do?) <table><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr><tr><td>Revised workforce plan for phase 2 Response Plan</td><td>CEO/DWOD</td><td>Early June 2020</td></tr><tr><td>Resource (Financial) Plan - revised for rest of Q1 including forward look</td><td>DFIT</td><td>End May 2020</td></tr><tr><td>Further implementation of digital solutions to support COVID and non-COVID activity (Q1)</td><td>DFIT</td><td>End June 2020</td></tr><tr><td>Development of a Workforce Futures Strategic Framework and its implementation</td><td>CEO/DWOD</td><td>In-line with Annual Plan 2019/20</td></tr><tr><td>Development of an Innovative Environments Strategic Framework and its implementation</td><td>CEO/DPP</td><td>In-line with Annual Plan 2019/20</td></tr><tr><td>Development of a Digital First Strategic Framework and its implementation</td><td>CEO/DFIT</td><td>In-line with Annual Plan 2019/20</td></tr></table>		Action	Lead	Deadline	Revised workforce plan for phase 2 Response Plan	CEO/DWOD	Early June 2020	Resource (Financial) Plan - revised for rest of Q1 including forward look	DFIT	End May 2020	Further implementation of digital solutions to support COVID and non-COVID activity (Q1)	DFIT	End June 2020	Development of a Workforce Futures Strategic Framework and its implementation	CEO/DWOD	In-line with Annual Plan 2019/20	Development of an Innovative Environments Strategic Framework and its implementation	CEO/DPP	In-line with Annual Plan 2019/20	Development of a Digital First Strategic Framework and its implementation	CEO/DFIT	In-line with Annual Plan 2019/20
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Development of a Digital First Strategic Framework and its implementation	CEO/DFIT	In-line with Annual Plan 2019/20																						
Current Risk Rating 4 x 4 = 16		Additional Comments																						

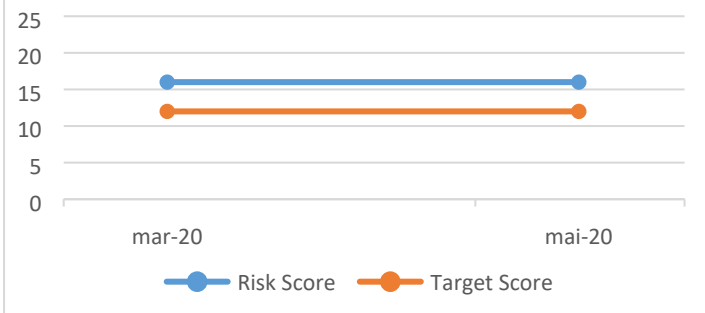
CRR 012		Executive Lead: Director of Therapies & Health Sciences																			
Risk that: the health board does not comply to the Welsh Language standards, as outlined in the compliance notice		Operational Lead: Welsh Language Services Manager																			
Risk Impacts on: Organisational Priorities underpinning WBO 1 to 8		Lead Board Committee: Performance and Resources Committee																			
Date last reviewed: May 2020																					
Risk Rating – (likelihood x impact): Initial: 4 x 3 = 12 Current: 4 x 3 = 12 Target: 2 x 3 = 6 Date added to the risk register March 2019	 <table><caption>Risk Score Data</caption><thead><tr><th>Month</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>mar-19</td><td>12</td><td>6</td></tr><tr><td>jun-19</td><td>12</td><td>6</td></tr><tr><td>sep-19</td><td>12</td><td>6</td></tr><tr><td>dec-19</td><td>12</td><td>6</td></tr><tr><td>mar-20</td><td>12</td><td>6</td></tr></tbody></table>	Month	Risk Score	Target Score	mar-19	12	6	jun-19	12	6	sep-19	12	6	dec-19	12	6	mar-20	12	6	Rationale for current score <ul style="list-style-type: none">Absence of 'More than just words' action planBaseline assessment indicates non-compliance of the Welsh Language StandardsThe findings of a recent Internal Audit identified that compliance with Welsh Language Standards needs improvement. Response to be agreed but no capacity to make changes at the current time due to COVID-19.	
Month	Risk Score	Target Score																			
mar-19	12	6																			
jun-19	12	6																			
sep-19	12	6																			
dec-19	12	6																			
mar-20	12	6																			
Controls (What are we currently doing about the risk?) <ul style="list-style-type: none">Undertaken a baseline assessment of current position against the Welsh Language standardsEstablished a Welsh Language Steering GroupAppointment of a Welsh speaking Welsh Language Service Improvement ManagerImprovement Plan in developmentTemporary appointment of a translator in the Communications and Engagement Team		Mitigating actions (What more should we do?) <table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Implement Welsh Language Improvement Plan</td><td>DPCMH</td><td>In line with Annual Plan for 2020-21</td></tr><tr><td>Formulate response to Internal Audit report</td><td>DoTHS</td><td>31 May 2020</td></tr><tr><td>Implement response to Internal Audit report</td><td>DPCMH</td><td>TBD</td></tr></tbody></table>		Action	Lead	Deadline	Implement Welsh Language Improvement Plan	DPCMH	In line with Annual Plan for 2020-21	Formulate response to Internal Audit report	DoTHS	31 May 2020	Implement response to Internal Audit report	DPCMH	TBD						
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Formulate response to Internal Audit report	DoTHS	31 May 2020																			
Implement response to Internal Audit report	DPCMH	TBD																			
Current Risk Rating 4 x 3 = 12		Additional Comments Due to COVID-19 the Welsh Language Manager has been redeployed, and most activity around Welsh Language has been stood down. However, this has not impacted on the overall risk score.																			

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CRR 013 Risk that: Services provided are fragile, not sustainable, and impact on PTHB ability to achieve National Outcome Framework measures		Lead Director: Director of Primary, Community & Mental Health Services Lead Board Committee: Performance and Resources Committee and Experience, Quality and Safety Committee (for experience, quality and safety of commissioned services) Date last reviewed: May 2020																									
Risk Impacts on: Organisational Priorities underpinning WBO 4 – specifically 4.3																											
Risk Rating – (likelihood x impact): Initial: 4 x 4 = 16 Current: 4 x 3 = 12 Target: 3 x 2 = 6 Date added to the risk register July 2019	 <table><caption>Risk Rating Data</caption><thead><tr><th>Month</th><th>Risk Score</th><th>Target Score</th></tr></thead><tbody><tr><td>Jul-19</td><td>12</td><td>6</td></tr><tr><td>Sep-19</td><td>12</td><td>6</td></tr><tr><td>Nov-19</td><td>12</td><td>6</td></tr><tr><td>Jan-20</td><td>12</td><td>6</td></tr><tr><td>Mar-20</td><td>12</td><td>6</td></tr><tr><td>May-20</td><td>12</td><td>6</td></tr></tbody></table>	Month	Risk Score	Target Score	Jul-19	12	6	Sep-19	12	6	Nov-19	12	6	Jan-20	12	6	Mar-20	12	6	May-20	12	6	Rationale for current score In reach services commissioned from English and Welsh providers, were frequently cancelled / re-booked due to main provider pressures. Services had been continually re-organised at short notice by Directorate teams with limiting any harm to patients or impact on NOF measures.				
Month	Risk Score	Target Score																									
Jul-19	12	6																									
Sep-19	12	6																									
Nov-19	12	6																									
Jan-20	12	6																									
Mar-20	12	6																									
May-20	12	6																									
Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)																									
<ul style="list-style-type: none">Most services are currently on reduced scale due to COVID-19 with little or no in reach provided, thus risk of service failure currently reducedWork with providers of services to in reach are active in response to recent WG guidance on 'essential services'Implementation of the Strategic Commissioning Framework (for whole system commissioning) includes in reach services commissioned via SLA was in place but currently being managed through direct links with providers including attendance by AD Commissioning at some Silver forumExecutive Delivery and Performance Group (including consideration of fragile services)Scrutiny by Performance & Resources CommitteeScrutiny by Experience, Quality and Safety CommitteeInternal AuditsContract Quality and Performance Review Meetings for the 15 NHS Providers, SLA issues as standing agenda itemNHS LTA and SLA Overview (and approval process)Currently performance monitoring by WG has been paused due to COVID-19Regular waiting list management meetings and Theatre Scheduling meetingsDGH and Specialised Services workstream in place led by Director of Planning and Performance		<table><thead><tr><th>Action</th><th>Lead</th><th>Deadline</th></tr></thead><tbody><tr><td>Develop robust demand and capacity modelling to inform SLA commissioning (4.3)</td><td>DPCMH</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Robustly manage the performance of all providers of planned care services for in Powys via SLA processes (4.3)</td><td>DPCMH</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Programme of work to strengthen effective processes to develop and manage SLA performance (4.3)</td><td>DPCMH</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Review specialty plans for in reach services, locate and review plans for repatriation (4.3)</td><td>DPCMH</td><td>In line with Annual Plan for 2019-20</td></tr><tr><td>Review of service levels increasing being undertaken in line with England and NHS Wales guidance to inform Phase 2 plan</td><td>DPCMH</td><td>31 May 2020</td></tr><tr><td>Review lessons learnt from ways of working including implementation of consultant connect to assist future models of delivery</td><td>DPCMH</td><td>30 June 2020</td></tr><tr><td>Interaction with silver commands across neighbours through PTHB command and control mechanisms</td><td>DPP</td><td>Ongoing</td></tr></tbody></table>	Action	Lead	Deadline	Develop robust demand and capacity modelling to inform SLA commissioning (4.3)	DPCMH	In line with Annual Plan for 2019-20	Robustly manage the performance of all providers of planned care services for in Powys via SLA processes (4.3)	DPCMH	In line with Annual Plan for 2019-20	Programme of work to strengthen effective processes to develop and manage SLA performance (4.3)	DPCMH	In line with Annual Plan for 2019-20	Review specialty plans for in reach services, locate and review plans for repatriation (4.3)	DPCMH	In line with Annual Plan for 2019-20	Review of service levels increasing being undertaken in line with England and NHS Wales guidance to inform Phase 2 plan	DPCMH	31 May 2020	Review lessons learnt from ways of working including implementation of consultant connect to assist future models of delivery	DPCMH	30 June 2020	Interaction with silver commands across neighbours through PTHB command and control mechanisms	DPP	Ongoing	
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Interaction with silver commands across neighbours through PTHB command and control mechanisms	DPP	Ongoing																									

<ul style="list-style-type: none">▪ Monthly RTT meetings with WG Planned Care Lead – Performance Division▪ Secured additional WG RTT funding and follow up funding▪ Medical / Clinical Staffing group being established to scope medium and long term opportunities which will deliver sustainable services within PTHB			
4 x 3 = 12	Historically, key services impacted are Care of the Elderly Ward and Community Staffing Provision. Ophthalmology, Endoscopy, Trauma and Orthopaedics		

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CRR 014		Lead Director: Director of Public Health	
Risk that: Potential adverse impact on business continuity and service delivery arising from a pandemic outbreak of an infectious disease (COVID-19)		Lead Board Committee: Executive Committee, Experience Quality and Safety Committee	
Risk Impacts on: Impact on the health and wellbeing of the population, patients and visitors and on the continuity of a range of NHS systems and services, including workforce, support services and supply chain.		Date last reviewed: May 2020	
Risk Rating (likelihood x impact): Initial: 4 x 4 = 16 Current: 4 x 4 = 16 Target: 3 x 4 = 12		Rationale for current score: Likelihood: 'Likely'. Currently, there is a high probability that a pandemic outbreak of a high consequence infectious disease will affect all parts of the UK, including Powys. Although new cases of COVID-19 are slowing in response to population level interventions, the absence of herd immunity or an effective vaccine means that the likelihood of a large scale outbreak remains likely across all parts of the UK, including Powys. Any potential future lifting of population measures may also come with an element of increased risk.	
Date added to the risk register February 2020		Impact: 'Major'. Using reasonable worst case planning assumptions, the impact of an outbreak on the population, as well as demand within the health and care system, would be major. COVID-19 presents four harms to the population: - 1. The direct harm arising from the disease itself; 2. The harm caused by an overwhelmed NHS; 3. The harm caused by stopping other non-COVID activity; and 4. The wider harm to wellbeing caused by population level measures in response to COVID-19.	
Controls (What are we currently doing about the risk?)		Mitigating actions (What more should we do?)	
1. PTHB Pandemic Framework invoked. 2. Governance Framework Structures in place to provide leadership and clear accountability for decision making. 3. COVID-19 Implementation Plan in place. 4. COVID-19 Risk Register in place. 5. Demand and capacity work undertaken to put in place measures to respond to a reasonable worst case scenario across all service areas. 6. Working as part of the wider system in Wales through participation in regional and national planning and response arrangements. 7. Regular updates on COVID-19 issued via COVID-19 Updates to support effective communication processes across the health board.		Action Local Resilience Forum arrangements may need to be invoked at some point in the future, depending on the scale of the outbreak and the effectiveness of the public health response.	Lead DPH
		Following the reduction in new cases of COVID-19 due to the impact of population level measures, local and national planning for the next phase of the response is underway. This will centre on keeping the reproductive (R) value of COVID-19 below 1, while also re-starting some elements of non-COVID activity.	Deadline May 2020
			Lead CEO
			Deadline May 2020

Current Risk Rating	Additional Comments
4 x 4 = 16	

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Powys THB Finance Department

Financial Performance Report

Board Item 3.1a

Period 12 (March 2020)
FY 2019/2020

Date Meeting: 27th May 2020

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Introduction

Subject:	FINANCIAL PERFORMANCE REPORT FOR MONTH 12 OF 2019-2020
Approved & Presented by:	Pete Hopgood, Interim Director of Finance
Prepared by:	Sam Moss, Assistant Director of Finance
Other Committees and meetings considered at:	Performance & Resources Committee Delivery & Performance Group

PURPOSE:
This paper provides the Board with an brief overview of the 2019/2020 Financial Position pending submission of the completed draft Annual Accounts on 22 nd May 2020.
RECOMMENDATION:
It is recommended that the Board: <ul style="list-style-type: none">• DISCUSS and NOTE the Revenue position.• DISCUSS and NOTE the Capital Position.• NOTE PSPP position.

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):		
Strategic Objectives:	• Focus on Wellbeing	✗
	• Provide Early Help and Support	✗
	• Tackle the Big Four	✗
	• Enable Joined up Care	✗
	• Develop Workforce Futures	✗
	• Promote Innovative Environments	✗
	• Put Digital First	✗
	• Transforming in Partnership	✓
Health and Care Standards:	• Staying Healthy	✗
	• Safe Care	✗
	• Effective Care	✗
	• Dignified Care	✗
	• Timely Care	✗
	• Individual Care	✗
	• Staff and Resources	✓
	• Governance, Leadership & Accountability	✗

Approval/Ratification/Decision	Discussion	Information
	✓	

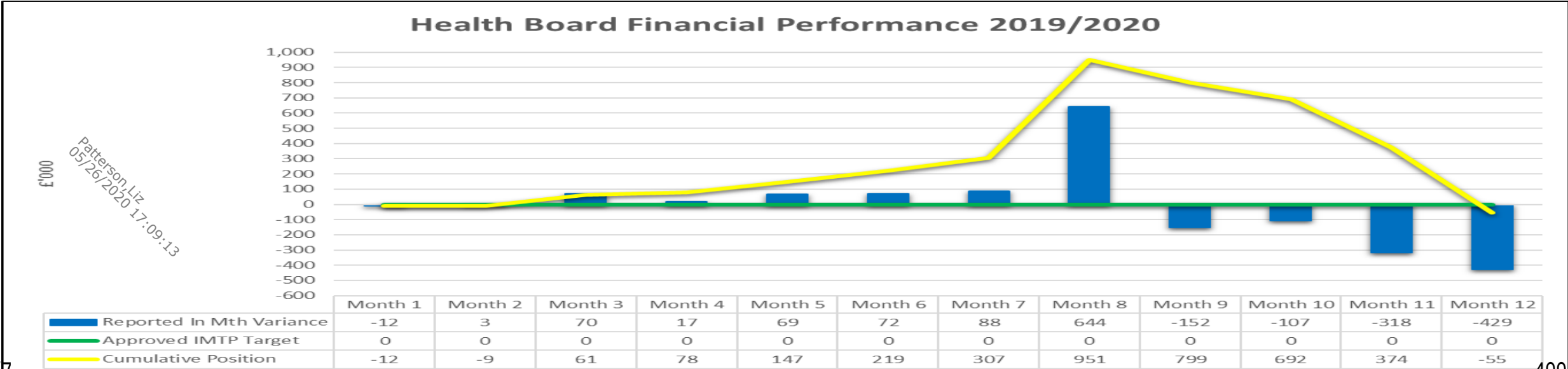
	2019-20 Original Date	2019-20 Revised Date	Action
Submission Draft Position to WG all Trusts and LHBs	Tuesday 7 th April	Tuesday 7 th April	Complete
Submission Monthly Monitoring Reports to WG all Trusts and LHBs	Friday 24 th April 17:00h	Friday 24 th April 17:00h	Complete (copy Appendix 1)
Draft Accounts - submission by all Trusts and LHBs	Tuesday 28 th April 17:00h	Friday 22 May 17:00h	o/s
Final Accounts - submission by WAO on behalf of Trusts and LHBs	Friday 29 May (Noon)	Tuesday 30 June (Noon)	o/s

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Revenue		
Financial KPIs : To ensure that net operating costs do not exceed the revenue resource limit set by Welsh Government	Value £'000	Trend
Reported in-month financial position – deficit/(surplus) – Green	-429	↓
Reported year end financial position – deficit/(surplus) – Green	-55	↓
Planned year end forecast – deficit/(surplus) – Forecast Green	0	→

Capital		
Financial KPIs : To ensure that the costs do not exceed the capital resource limit set by Welsh Government	Value £'000	Trend
Capital Resource Limit	3,200	↓
Reported year to date expenditure	3,197	↑
Reported year end forecast – deficit/(surplus) – Forecast Green	-3	↓

PSPP		
PSPP Target : To pay a minimum of 95% of all non NHS creditors within 30 days of receipt of goods or a valid invoice	Value £'000	Trend
Cumulative year to date % of invoices paid within 30 days (by number) Q4 – Forecast Green	96.4%	↓



Overall Summary of Variances @ Mth 12 YTD £000's

	BUDGET YTD	ACTUAL YTD	VARIANCE YTD
01 - Revenue Resource Limit	(326,170)	(326,170)	0
02 - Capital Donations	(176)	(176)	0
03 - Other Income	(6,743)	(7,414)	(670)
TOTAL INCOME	(333,089)	(333,759)	(670)
05 - Primary Care - (excluding Drugs)	44,131	43,695	(436)
06 - Primary care - Drugs & Appliances	28,299	29,386	1,087
07 - Provided services -Pay	78,886	78,402	(485)
08 - Provided Services - Non Pay	19,837	15,721	(4,116)
09 - Secondary care - Drugs	997	1,087	89
10 - Healthcare Services - Other NHS Bodies	129,742	133,865	4,123
12 - Continuing Care and FNC	13,608	14,620	1,012
13 - Other Private & Voluntary Sector	2,964	2,348	(616)
14 - Joint Financing & Other	6,755	6,711	(44)
15 - DEL Depreciation etc	3,509	3,508	(1)
16 - AME Depreciation etc	4,360	4,361	1
18 - Profit\Loss Disposal of Assets	0	0	0
TOTAL COSTS	333,089	333,704	615
TOTAL	(0)	(55)	(55)

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Powys THB Finance Department

Financial Performance Report - Appendices

Period 12 (March 2020)
FY 2019/2020

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Embedded below are extracts from the Period 12 Monthly Monitoring Return submitted to Welsh Government on 24th April 2020

MMR Narrative



Microsoft Word
Document

MMR Key Tables



Microsoft Excel
Worksheet

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Powys THB Finance Department

Financial Performance Report

Board Item 3.1b

Period 1 (April 2020)
FY 2020/21

Date Meeting: 27th May 2020

Patterson, Liz
05/26/2020 17:09:13



Subject:	FINANCIAL PERFORMANCE REPORT FOR MONTH 1 OF 2020-21
Approved & Presented by:	Pete Hopgood, Interim Director of Finance
Prepared by:	Sam Moss, Assistant Director of Finance
Other Committees and meetings considered at:	Performance & Resources Committee Delivery & Performance Group

PURPOSE:
This paper provides the Board with an update on the April 2020 (Month 1) Financial Position including Financial Recovery Plan (FRP) delivery.
RECOMMENDATION:
It is recommended that the Board: <ul style="list-style-type: none">DISCUSS and NOTE the Month 1 2020/21 financial position.NOTE that action will be required in 2020/21 to ensure full achievement of any brought forward and in year savings targets.DISCUSS and NOTE the Capital Position.

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):		
Strategic Objectives:	• Focus on Wellbeing	✗
	• Provide Early Help and Support	✗
	• Tackle the Big Four	✗
	• Enable Joined up Care	✗
	• Develop Workforce Futures	✗
	• Promote Innovative Environments	✗
	• Put Digital First	✗
	• Transforming in Partnership	✓
Health and Care Standards:	• Staying Healthy	✗
	• Safe Care	✗
	• Effective Care	✗
	• Dignified Care	✗
	• Timely Care	✗
	• Individual Care	✗
	• Staff and Resources	✓
	• Governance, Leadership & Accountability	✗

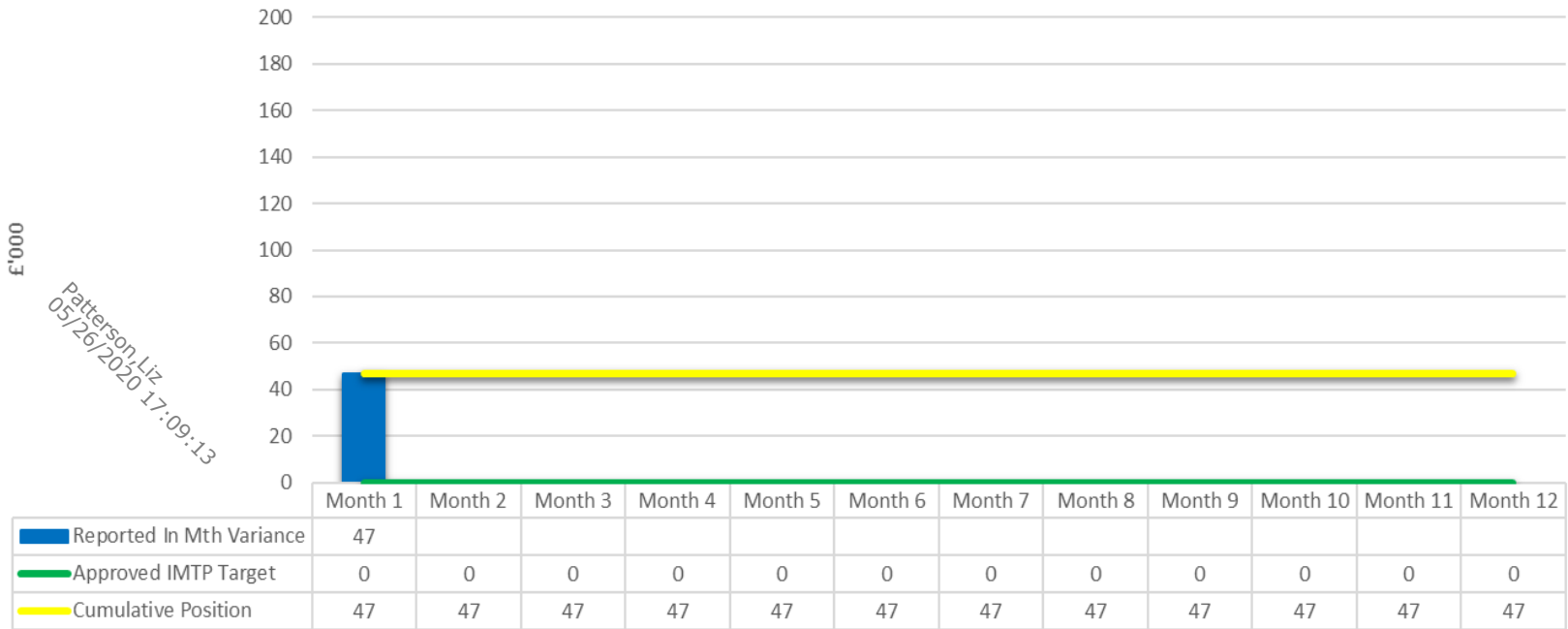
Approval/Ratification/Decision	Discussion	Information
	✓	

Revenue		
Financial KPIs : To ensure that net operating costs do not exceed the revenue resource limit set by Welsh Government	Value £'000	Trend
Reported in-month financial position – deficit/(surplus) – Amber	47	↑
Reported Year To Date financial position – deficit/(surplus) – Amber	47	↑
Planned year end forecast – deficit/(surplus) – Forecast Green	0	→

Capital		
Financial KPIs : To ensure that the costs do not exceed the capital resource limit set by Welsh Government	Value £'000	Trend
Capital Resource Limit	1,908	→
Reported Year to Date expenditure	110	→
Reported year end forecast – deficit/(surplus) – Forecast Green	0	→

PSPP		
PSPP Target : To pay a minimum of 95% of all non NHS creditors within 30 days of receipt of goods or a valid invoice	Value £'000	Trend
Cumulative year to date % of invoices paid within 30 days (by number) Q1 – Forecast Green	Not provided until end Q1	→

Health Board Financial Performance 2020/21



Powys THB 2020-21 IMTP was recognised by WG as approvable on 19th March 2019. The plan is balanced and represented by the green line of the chart opposite.

At Month 1 for a number of areas no data is available and so it is assumed that in some areas spend will match the IMTP budgets/plan.

Spend in relation to Covid -19 is included in the overall position but is offset by an anticipated allocation for WG, so is not directly contributing to the £0.047m overspend in Mth 1.

Excluding Covid-19 the areas of overspend have been primary care drugs, based on 19/20 trends and CHC costs. The table on the next slide provides an overall summary.

Overall Summary of Variances @ Mth 1 YTD £000's

	BUDGET YTD	ACTUAL YTD	VARIANCE YTD
01 - Revenue Resource Limit	(27,741)	(27,741)	0
02 - Capital Donations	(11)	(11)	0
03 - Other Income	(448)	(444)	3
TOTAL INCOME	(28,200)	(28,196)	3
05 - Primary Care - (excluding Drugs)	3,296	3,266	(30)
06 - Primary care - Drugs & Appliances	2,348	2,433	85
07 - Provided services -Pay	6,532	6,465	(68)
08 - Provided Services - Non Pay	1,768	1,590	(178)
09 - Secondary care - Drugs	84	84	0
10 - Healthcare Services - Other NHS Bodies	11,577	11,760	184
12 - Continuing Care and FNC	1,198	1,257	59
13 - Other Private & Voluntary Sector	195	187	(8)
14 - Joint Financing & Other	906	906	(0)
15 - DEL Depreciation etc	292	292	0
16 - AME Depreciation etc	4	4	0
18 - Profit\Loss Disposal of Assets	0	0	0
TOTAL COSTS	28,200	28,244	44
TOTAL	(0)	47	47

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Original Plan 2020/21 = £5.5m

Workstream	Original 2020/21 £
Medicines Mangt	492,339
Pathways	2,629,623
Procurement, Non Pay & CHC	741,558
Workforce Efficiency	1,623,916
Total	5,487,436

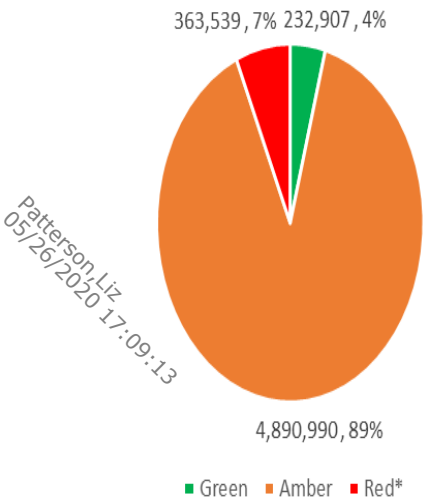
Original Target 2020/21 = £5.6m

As result C-19 outbreak a full review of all schemes was undertaken at end April and using information available at time it was assessed that likely delivery would be £3.3m based on number assumptions

Revised Plan 2020/21 = £3.3m

Workstream	Revised 2020/21 £
Medicines Mangt	371,254
Pathways	1,545,655
Procurement, Non Pay & CHC	482,890
Workforce Efficiency	896,050
Total	3,295,849

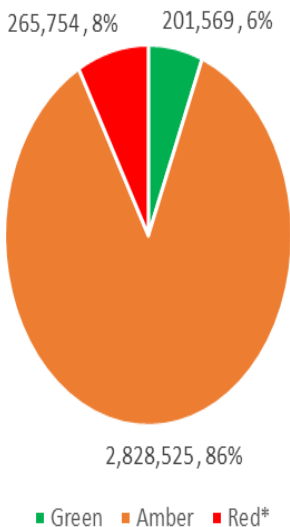
RAG Rating Original Plan



Movement from Original Plan = £2.2m
Current assumption is this will be funded by WG

Further details on the Savings positons, the assumptions underpinning the revised plan and actions going forward are documented in the WG Narrative Report attached to Appendix 1

RAG Rating Revised Plan



Summary Forecast Covid-19 Revenue Expenditure 2020/21

	Q1 Only		2020/21	
Areas			£ m	£m
Pay		0.5		3.8
Non Pay				
- PC	0.2		0.9	
- PPE	0.2		1.4	
- Provider	0.6		2.1	
- Block LTA	0.5		2.3	
				6.7
Non Delivery Savings		1.3		2.2
Total Spend		3.3		12.7

Note – above table excludes any capital costs

Key Assumptions Support Forecast Covid-19 Revenue Expenditure 2020/21

Timeframe

- Costs for 12 month period from April 2020– March 2021

General Assumptions

- Cost April as per Ledger and May assumed in line April
- Forecast June 2020 – March 2021 based on flexibility to increase beds up to 199

Pay

- Based on Workforce model required to support 199 beds
- Additional costs included for facilities
- Variable pay costs based on Covid-19 FCP process

Non Pay

- Equipment excludes any costs in relation to the all Wales procurement process based on the assumption this will be centrally funded
- PPE costed based on current modelling
- LTA pressures are based on current block arrangements compared to IMTP plan
- Other costs identified via Covid-19 Cost Centre (B259)

Table 1: Risk Reflected MMR Mth 1

Risk	£ '000	Likelihood
Under delivery of Amber Schemes included in Outturn via Tracker	- 3,094	Medium
Continuing Healthcare	- 500	High
Prescribing	- 860	High
Pharmacy Contract	-	Low
WHSSC Performance	- 500	Medium
Other Contract Performance	-	Medium
GMS Ring Fenced Allocation Underspend Potential Claw back	-	Low
Dental Ring Fenced Allocation Underspend Potential Claw back	- 295	Low
Anticipated COVID Allocations not received	- 12,601	Medium
Non-Delivery Underlying Assumptions IMTP	- 1,352	Low
Total	- 19,201	

Table 2: Opportunities Reflected MMR Mth 1

Opportunity	£ '000	Likelihood
Reduction SLA Agreements England	525	Low
Funding Slippage / Divert Funding to C-19	2,298	Medium
Total	2,823	

Note – full details on the risks listed above can be found in the WG Narrative Report attached to Appendix 1

Key Messages

In summary the key issues being managed to support the financial position:

- Health Board has an approvable IMTP for 2020/21 which had a number of assumptions detailed in the Resources Plan presented to Board, but in summary:
 - Savings target agreed in IMTP need to be met
 - HB must identify opportunities to support financial position
 - General expenditure to remain at 19/20 level.
- Covid-19 represented a risk to the organisation but the Mth 1 position and current year end forecast exclude the impact of all expenditure either incurred to date or planned to be incurred in the future on the assumption that this will be funded by WG. The MMR submitted on 18th May 2020 forecasts £12.7m of costs associated with Covid 19 for 2020/21.
- Savings required and agreed by the Board in the IMTP was £5.6m. Whilst there were plans to deliver this the Covid-19 pandemic has had a significant impact of the HB ability to deliver. The assessment undertaken at end April reduced the likely delivery to £3.3m and this could reduce further pending a further review at end May.
- There are further potential risks to the position which are detailed on page 6 of the report.

Summary

In summary this paper identifies that:

- PTHB is reporting an over spend at month 1 2019/20 of £0.47M.
- Within the £0.047m is an assumption that the HB will receive £0.877m of funding from WG to support the Covid-19 pressures.
- PTHB has an assumed £3.3M savings against the target of £5.6M. Again it is assumed any shortfall will be funded by WG.
- PTHB has an Capital Resource Limit of £1.908M and has spend £0.110M.
- PTHB continues to forecast a balanced year end position subject to the actions and risks as identified in the report. But will be undertaking a full assessment the financial position in Q1 for expenditure and risks outside of Covid-19.

Powys THB Finance Department

Financial Performance Report - Appendices

Period 1 (April 2020)
FY 2020/21

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Embedded below are extracts from the Period 1 Monthly Monitoring Return submitted to Welsh Government on Reporting Day 11

MMR Narrative



Powys tHB 2020-21 Month 1 Monitoring Return Narrative signed.pdf

MMR Key Tables



Microsoft Excel
Worksheet

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AGENDA ITEM: 3.2a

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	BOARD COMMITTEES: CHAIRS ASSURANCE REPORTS	
Approved and Presented by:	Board Secretary	
Prepared by:	Head of Risk and Assurance	
Other Committees and meetings considered at:	The content of each of the reports has been subject to the consideration of the relevant Board Committee Chair.	

PURPOSE:

The purpose of this report is to provide the Board with an update on the work of the Board Committees.

RECOMMENDATION(S):

It is recommended that the Board RECEIVES and DISCUSSES the summary assurance reports appended to this covering paper.

Approval/Ratification/Decision	Discussion	Information
x	✓	x

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

DETAILED BACKGROUND AND ASSESSMENT:

ASSURANCE REPORTS FROM COMMITTEE CHAIRS

The following Chair's Assurance Reports are appended for the information of the Board (including confirmed minutes of previous committee meetings):

- Experience Quality and Safety Committee: A summary of the meeting published on the health board's website, alongside the Committee Chair's report of the meeting held on 16 April 2020 is attached. **(Item 4.2ai)**
- Audit, Risk & Assurance Committee: The Committee Chair's report of the meeting held on 18 May 2020 is attached. **(Item 4.2aii)**
- Charitable Funds Committee: The Committee Chair's report of the meeting held on 3 February 2020 and subsequent Chairs Actions is attached **(Item 4.2aiii)**

There have been no meetings of the Strategy and Planning Committee or Performance and Resources since the date of the last meeting of the Board. An update on the work of the Executive Committee will be provided at the next meeting.

NEXT STEPS:

Further updates from the Chairs of the Board Committees will be received at the Board meeting scheduled for 29 July 2020.

POWYS TEACHING HEALTH BOARD

SUMMARY OF THE EXPERIENCE, QUALITY & SAFETY COMMITTEE MEETING HELD ON THURSDAY 16 APRIL 2020

Committee Meetings of Powys Teaching Health Board are meetings held in public under the Public Bodies (Admission to Meetings) Act 1960. However, the COVID-19 Public Health emergency and the associated instruction to Stay At Home has meant that Board resolved to hold the Experience Quality and Safety Committee on 16th April 2020 virtually and in private with a summary of the proceedings made available within a week of the meeting.

Present:

Melanie Davies	Vice-Chair (Committee Chair)
Trish Buchan	Independent Member (Committee Vice-Chair)
Vivienne Harpwood	PTHB Chair
Owen James	Independent Member
Frances Gerrard	Independent Member

In Attendance:

Carol Shillabeer	Chief Executive
Alison Davies	Director of Nursing and Midwifery
Julie Rowles	Director of Workforce, OD and Support Services
Stuart Bourne	Director of Public Health
Wyn Parry	Medical Director
Claire Madsen	Director of Therapies and Health Sciences
Rani Mallison	Board Secretary

Apologies for absence:

Susan Newport	Independent member
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Committee Support:

Experiences, Quality & Safety
Committee: 16 April 2020
Chair's Report to PTHB Board

Page 1 of 22

Board Meeting
27 May 2020
Agenda Item: 3.2ai

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CORONAVIRUS (COVID-19) OVERVIEW

The Chief Executive provided an overview of the development regarding COVID-19 to the Committee. It was reported that there had been a need to reprioritise, plan, prepare and implement. A 5 point plan had been approved by the Board on 25 March 2020. The health board would be addressing key outstanding areas and the risks held. Some of the key areas of risks were highlighted to the Committee and would be discussed in more detail later in the meeting.

NON-COVID-19 ACITIVITY

The Chief Executive reported that the initial duration of the COVID-19 period had been estimated at 6 weeks, this had been adjusted to a longer period likely to last several months. A report has been commissioned to develop mechanisms for planned and non-urgent care. An assessment would be made of areas in which short term actions are required to avoid possible harm and recommendations for action would be developed including management arrangements.

STAFFING OF THE CLINICAL RESPONSE MODEL

The Director of Nursing presented a paper and requested that the Committee:

- Ratify the approach being taken to staff the clinical response model
- Note Welsh Government's position in relation to the Nurse Staffing Levels (Wales) Act 2016
- Ratify the recommendation that the Annual Report due in May 2020 as a requirement of the Nurse Staffing Levels (Wales) Act 2016, is indefinitely postponed.

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The Committee RATIFIED the approach being taken to staff the clinical response model and the recommendation that the annual report due in May 2020 as a requirement of the Nurse Staffing Levels (Wales) Act 2016, is indefinitely postponed.

The Chief Executive NOTED that both areas would be kept under review.

PPE ARRANGEMENTS

The Director of Public Health reported that work had been undertaken regarding stock, supply chain management, distribution and strategic and governance arrangements for PPE. A Centralised Hub had been implemented in Bronllys for PTHB.

Supplies were being provided on a continuous basis to the 6 main sites in Powys (including 10 wards) as well as MIU's, midwives, mental health, district nurses and X-Ray radiography departments. A generic PTHB COVID-19 email account has been established and any requests for PPE outside of the aforementioned areas are handled by this account accordingly.

The Strategy for PPE includes the following 3 areas:

- Reduction in demand (sessional use, bundling of care)
- Rational and appropriate use in line with national IPC guidance
- Co-ordination of supply chain

It was reported that the Military had been supporting PTHB on logistics and a weekly PPE co-ordination group had been developed with a provider focus. A virtual PPE team had also been developed.

The Director of Public Health advised that Public Health bodies in the UK had confirmed sustained community transmission in the previous week which had implications for the use of PPE. The Committee was assured that PPE continues to be a focused area of work.

STAFF WELLBEING & SUPPORT ARRANGEMENTS

The Director of Workforce and OD provided a presentation regarding Staff Wellbeing and noted that the current period is a testing and uncertain period for staff.

The presentation provided a summary of:

- Support arrangements in place:
 - Daily bulletin
 - Silvercloud available without referral
 - Regular meetings with Trade Unions
 - Occupational Health Wellbeing Hub

- Support arrangements under development:
 - Links with the Citizens Advice Bureau
 - Expanding counselling provision
 - Short surveys
 - Charitable Funds support

The Vice Chair noted the activities of the work stream and expressed that thanks be passed to all staff on behalf of the Committee.

Owen James raised that the Charitable Fund had identified potential to add value through support. The Committee welcomed the confirmation that the Charitable Funds Manager had commenced in post.

ETHICAL FRAMEWORK

The Medical Director reported to the Committee that the Ethical Framework had been published and had been adopted by all Ethical Committees in Wales. It was agreed that the Medical Director would circulate the framework post-Committee to Independent Members for information.

CLINICAL DECISION MAKING

The Medical Director provided an update and noted that the 3 core principles of the framework would be underlined by what care would be provided in Powys, how it would be provided and how it would be provided safely.

It was suggested that the role of Powys would be to support and provide step-down care to COVID-19 and non-COVID-19 patients. The challenge would be defining those patients who are to receive care within the PTHB Community Hospitals.

All principles in the framework had been based on the Ethical Framework and the Medical Director expressed that equity of care must be carefully considered. It was noted that supporting the rehabilitation of patients is a strength in Powys and the health board should remain fluid on the type of patients that are cared for within its community hospitals.

The Chief Executive raised that work was ongoing into the Clinical Decision Making to ensure risks are mitigated without compromising the level of care provided. It was noted as essential that the pathway, risks and monitoring had been appropriately assessed.

It was AGREED that when the Clinical Decision Making had been approved by the Gold Command Group an update would be provided to the next available Board Briefing.

ANY OTHER URGENT BUSINESS

The Chief Executive provided the following update regarding the CQC review into SaTH:

- The report has suggested an overall rating of inadequate
- Inadequacies had been identified in a range of areas including caring and safety
- SaTH continues to be in special measures
- PTHB remained committed to holding Executive to Executive meetings during the COVID-19 period.

It was AGREED that a more in-depth discussion would be held by the Committee on 4th June 2020.

DATE OF THE NEXT MEETING

4th June 2020



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

Reporting Committee:	Experience, Quality and Safety Committee
Committee Chair	Mel Davies
Date of last meeting:	16 April 2020
Paper prepared by:	Head of Risk and Assurance

KEY DECISIONS / MATTERS CONSIDERED BY THE COMMITTEE

The approved minutes of the meeting of Experience, Quality and Safety Committee (EQS) held on 4 February 2020 are appended to this report.

The Board is asked to note that the following matters were discussed at EQS on 16 April 2020. The Committee RATIFIED the approach being taken to staff the clinical response model and the recommendation that the annual report due in May 2020 as a requirement of the Nurse Staffing Levels (Wales) Act 2016, was indefinitely postponed.

- Review of Action Log
- Coronavirus (COVID-19) overview
- Non-COVID Activity
- Staffing and Clinical Response Model
- PPE Arrangements
- Staff Wellbeing and Support arrangements
- Ethical Framework
- Clinical Decision Making

A summary of key issues discussed is provided below.

Action Log

In light of the COVID-19 pandemic it was agreed that action would be reviewed and prioritised for the duration of the period. The Chief Executive provided an update on prioritisation in line with COVID-19, the Committee noted that the update was an initial judgement and would require further discussion and ratification from other Executives.

Coronavirus (COVID-19) Overview

An overview of the development regarding COVID-19 was presented to the Committee. It was reported that there had been a need to reprioritise, plan, prepare and implement. The health board would be addressing key outstanding areas and the risks held. Some of the key areas of risks were highlighted to the Committee and would be discussed in more detail later in the meeting.

Non-COVID Activity

It was reported that the initial duration of the COVID-19 period had been estimated at 6 weeks, this had been adjusted to a longer period likely to last several months. A report has been commissioned to develop mechanisms for planned and non-urgent care. An assessment would be made of areas in which short term actions are required to avoid possible harm and recommendations for action would be developed including management arrangements.

Staffing of the Clinical Response Model

The Committee received a paper regarding the staffing of the Clinical Response Model and where requested to:

- Ratify the approach being taken to staff the clinical response model
- Note Welsh Government's position in relation to the Nurse Staffing Levels (Wales) Act 2016
- Ratify the recommendation that the Annual Report due in May 2020 as a requirement of the Nurse Staffing Levels (Wales) Act 2016, is indefinitely postponed.

The Committee RATIFIED the approach being taken to staff the clinical response model and the recommendation that the annual report due in May 2020 as a requirement of the Nurse Staffing Levels (Wales) Act 2016, is indefinitely postponed.

The Chief Executive NOTED that both areas would be kept under review

PPE Arrangements

The Committee was informed that work had been undertaken regarding stock, supply chain management, distribution and strategic and governance arrangements for PPE. A Centralised Hub had been implemented in Bronllys for PTHB.

Supplies were being provided on a continuous basis to the 6 main sites in Powys (including 10 wards) as well as MIU's, midwives, mental health, district nurses and X-Ray radiography departments. A generic PTHB COVID-19 email account has been established and any requests for PPE outside of the aforementioned areas are handled by this account accordingly.

The Strategy for PPE includes the following 3 areas:

- Reduction in demand (sessional use, bundling of care)
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It was reported that the Military had been supporting PTHB on logistics and a weekly PPE co-ordination group had been developed with a provider focus. A virtual PPE team had also been developed.

It was advised that Public Health bodies in the UK had confirmed sustained community transmission in the previous week which had implications for the use of PPE. The Committee was assured that PPE continues to be a focused area of work.

Staff Wellbeing and Support arrangements

A presentation regarding Staff Wellbeing was provided and it was noted that the current period is a testing and uncertain period for staff.

The presentation provided a summary of:

- Support arrangements in place:
 - Daily bulletin
 - Silvercloud available without referral
 - Regular meetings with Trade Unions
 - Occupational Health Wellbeing Hub
- Support arrangements under development:
 - Links with the Citizens Advice Bureau
 - Expanding counselling provision
 - Short surveys
 - Charitable Funds support

The Committee noted the activities of the work stream and expressed that thanks be passed to all staff on behalf of the Committee.
The Committee welcomed confirmation that the Charitable Funds Manager had commenced in post.

Ethical Framework

It was reported to the Committee that the Ethical Framework had been published and had been adopted by all Ethical Committees in Wales.

Clinical Decision Making

An update was provide to the Committee and it was noted that the 3 core principles of the framework would be underlined by what care would be provided in Powys, how it would be provided and how it would be provided safely.

It was suggested that the role of Powys would be to support and provide step-down care to COVID-19 and non-COVID-19 patients. The challenge would be defining those patients who are to receive care within the PTHB Community Hospitals.

All principles in the framework had been based on the Ethical Framework and it was expressed that equity of care must be carefully considered. It was noted that supporting the rehabilitation of patients is a strength in Powys and the health board should remain fluid on the type of patients that are cared for within its community hospitals.

It was raised that work was ongoing into the Clinical Decision Making to ensure risks are mitigated without compromising the level of care provided. It was noted as essential that the pathway, risks and monitoring had been appropriately assessed.

It was AGREED that when the Clinical Decision Making had been approved by the Gold Command Group an update would be provided to the next available Board Briefing.

Any Other Urgent Business

The Committee recieved the following update regarding the Care Quality Commission review into Shrewsbury and Telford Hospitals NHS Trust (SaTH):

- The report had suggested an overall rating of inadequate
- Inadequacies had been identified in a range of areas including caring and safety
- SaTH continued to be in special measures
- PTHB remained committed to holding Executive to Executive meetings during the COVID-19 period.

It was AGREED that a more in-depth discussion would be held by the Committee on 4th June 2020.

NEXT MEETING

The next meeting of EQS will be held on 4 June 2020.

Appendix 1

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Experiences, Quality
Committee: 16 April 2020
Chair's Report to PTHB Board



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

Board Meeting
27 May 2020
Agenda Item: 3.2ai

**POWYS TEACHING HEALTH BOARD
EXPERIENCE, QUALITY & SAFETY COMMITTEE**

CONFIRMED

**MINUTES OF THE MEETING HELD ON 4 FEBRUARY 2020
BOARD ROOM, GLASBURY HOUSE, BRONLLYS**

Present:

Melanie Davies
Trish Buchan
Susan Newport
Owen James

Vice-Chair (Committee Chair)
Independent Member (Committee Vice-Chair)
Independent Member
Independent Member

In Attendance:

Carol Shillabeer
Alison Davies
Julie Rowles
Jamie Marchant

Chief Executive
Director of Nursing and Midwifery
Director of Workforce, OD and Support Services
Director of Primary Care, Community & Mental Health
Director of Public Health
Medical Director
Director of Therapies and Health Sciences
Board Secretary
Deputy Director of Workforce & OD
Assistant Director of Quality & Safety
Assistant Medical Director
Assistant Director of Commissioning Development

Stuart Bourne
Wyn Parry
Claire Madsen
Rani Mallison
Mark McIntyre
Wendy Morgan
Jeremy Tuck
Clare Lines

Observers:

Elaine Matthews

Wales Audit Office

Apologies for absence:

Julie Rowles
Wyn Parry
Frances Gerrard
Katrina Rowlands

Director of Workforce, OD and Support Services
Medical Director
Independent member
Assistant Director of Nursing

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Committee Support:

Stella Parry

Committee Secretary

EQS/19/85	<p>WELCOME AND APOLOGIES FOR ABSENCE</p> <p>The Vice-Chair welcomed Members and attendees to the meeting, and CONFIRMED there was a quorum present. Apologies for absence were NOTED as recorded above.</p>
EQS/19/86	<p>DECLARATIONS OF INTERESTS</p> <p>No interests were declared.</p>
EQS/19/87	<p>UNCONFIRMED MINUTES OF THE EXPERIENCE, QUALITY AND SAFETY COMMITTEE MEETING HELD ON 3 DECEMBER 2019</p> <p>The minutes of the previous meeting held on 3 December 2019 were AGREED as being a true and accurate record.</p>
EQS/19/88	<p>MATTERS ARISING</p> <p>EQS/19/70: Trish Buchan raised that at the IPC meeting it was noted that the attendance to ANTT assessor training was poor. Alison Davies confirmed that she would meet with the ICP Senior Nurse to discuss and address this.</p> <p>EQS/19/71: It was confirmed that HIW will be visiting PTHB to inspect the Maternity Services week beginning 10 February 2020 with feedback due to be received on 14 February 2020. PTHB will be the last Welsh Health Board to be inspected. The Committee also noted that the HIW Governance Review into the Maternity Notification Group is due at the end of March 2020. The Maternity Notification Group is a sub-group of the Quality Governance Group. Melanie Davies noted that the commissioning position with regard to maternity is concerning. Rani Mallison confirmed that a further briefing on Maternity Services will be undertaken during the In-Committee meeting.</p> <p>EQS/19/67: Owen James queried whether the Committee Action Log could include an additional column stating the due date. Rani Mallison confirmed this and noted that in</p>

	future updates will be collated prior to circulation of the Action Log.
EQS/19/89	<p>COMMITTEE ACTION LOG</p> <p>EQS/19/75 (Clinical Audit Plan & Update): It was queried how quickly this item would return to the Committee. It was confirmed that the item would return to the next meeting on 2 April 2020 Action: Board Secretary. Carol Shillabeer noted that the Board approved the Clinical Quality Framework on 29 January 2020 and will be working with the Executive Team on a delivery plan including timescales. A CAP will be developed before the 1st of April 2020 and will be reviewed by this Committee on 2 April 2020. Action: Board Secretary</p> <p>EQS/19/72 (In-patient Mortality Quarterly Review): It was noted that the Q3 review would not be available until the end of March. Carol Shillabeer confirmed that a substantive item would be brought to the Committee on 2 April 2020. Action: Medical Director</p> <p>EQS/19/70: It was confirmed that all EQS/19/70 actions on the Action Log will be updated in Item 3.2.</p> <p>EQS/19/54 (IPC Training): Trish Buchan requested how PTHB received assurance that visiting clinicians are compliant with training. Wendy Morgan agreed that information will be collated and circulated with Committee members Action: Assistant Director of Quality & Safety</p> <p>It was confirmed that EQS/19/72 (CHKS Briefing) and EQS/19/68 (SIs Policy) will be transferred to the Board Action Log. Action: Board Secretary.</p>
ITEMS FOR APPROVAL/RATIFICATION/DECISION	
There are no items for inclusion in this section.	
ITEMS FOR DISCUSSION	
EQS/19/90	<p>COMMISSIONING ASSURANCE FRAMEWORK, ESCALATION REPORT</p> <p>Clare Lines presented the paper to the Committee highlighting providers in Special Measures or scored as</p>

	<p>Level 4 following the December 2019 PTHB Internal Commissioning Assurance Meeting (ICAM). There are:</p> <ul style="list-style-type: none"> • 4 providers with services in Special Measures • 1 provider at Level 4 <p>The report provided an update on a number of serious matters, particularly in relation to Shrewsbury and Telford Hospitals NHS Trust (SaTH).</p> <p><u>Worcestershire Acute Hospitals NHS Trust (WAHT)</u></p> <p>WAHT was placed in special measures in December 2015. The Care Quality Commission (CQC) published a report on the 20th September 2019 following an inspection visit between the 14th and 29th May 2019, which recommended to NHS England Improvement (NHSEI) that the Trust is removed from special measures once a system wide support package from NHSEI is in place. The Committee noted the positive update that Royal Worcester Hospital's (RWHs) mortality indicators have now returned to normal, that the small numbers at RWH can lead to volatility and that the Board can attain assurance by monitoring each unexpected death.</p> <p><u>Wye Valley NHS Trust (WVT)</u></p> <p>Whilst WVT has made significant progress reducing some of the key risks in the shared risk based plan over the last year, PTHB is not yet at a stage to seek de-escalation from the CEO level. The Medical Director has sought further information about maternity services and in particular caesarean rates. The CQC has recently finished an inspection of WVT. The final report is not yet in the public domain, however a number of areas have been identified requiring significant improvement. It was also noted that the Emergency Department (ED) is struggling with few alternatives available at present.</p> <p><u>Betsi Cadwaladr University Health Board (BCUHB)</u></p> <p>Claire Lines expressed that BCUHB is not a main patient flow for Powys. BCUHB remains in special measures and faces a challenging improvement agenda. An unannounced HIW inspection of maternity services in Wrexham has taken place, this will be discussed in more detail In-Committee.</p>
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	<p><u>Shrewsbury and Telford Hospitals NHS Trust (SaTH)</u> SaTH is the main provider of District General Hospital (DGH) care for North Powys residents. The Executive Committee and relevant Board Committees have been receiving updates through the CAF Escalation Report since SaTH was placed in special measures. The CQC have undertaken inspections throughout 2018/19 and have raised concerns and received section 31 notices regarding, the Emergency Department (ED), Maternity Services, Sepsis and Children leaving the ED. These matters will be discussed in more detail In-Committee. SaTH remains at the highest level of escalation and NHSEI have called a meeting to identify ways to decrease the pressures in SaTH. Carol Shillabeer confirmed that a risk based plan is in place and conversation is due to be held with the National Medical Director of NHS England.</p> <p><u>Cwm Taf Morgannwg University Health Board (CTUHB)</u> It was noted that PTHB have joined with Aneurin Bevan University Health Board (ABUHB) to work strengthening assurance with CTUHB regarding maternity with the CAF as a basis for this work.</p> <p>Melanie Davies noted the apparent fragilities in ED and maternity and suggested PTHB be proportionate in their response. Owen James queried the service received by neighbouring Health Boards. Clare Lines reminded the Committee that the CAF only escalated the negative aspects.</p> <p>Carol Shillabeer thanked Claire Lines for the report and noted the improvements that PTHB have made using their small influence.</p>
EQS/19/91	<p>QUALITY PERFORMANCE: QUALITY INDICATORS OVERVIEW, SERIOUS INCIDENTS EXCEPTION REPORT AND COMPLAINTS EXCEPTION REPORT</p> <p>Carol Shillabeer presented the item to the Committee it was noted the difficulty in perfecting performance reports, this is recognised and aligned with the Clinical Quality Framework under Goal 5. It was requested that the Committee Members consider what is needed for a quality</p>

	<p>performance report as well as discussion and comment on the key aspects. Several variations of performance report have been used in recent years.</p> <p>It was raised that this framework will not be considered in isolation but will work alongside the National Outcomes Framework. This will raise challenges in differentiating what is about quality and what is about the whole system. There are several different lenses through which to consider quality, access, workforce etc. It was also noted that work is currently underway to combine the Public Health Outcomes Framework and the Social Services Outcome Framework.</p> <p>Carol Shillabeer summarised the National Outcome Framework Key Indicators, noting that these had been discussed at Board on January 29 2020, however, these will also be reviewed at this Committee with an emphasis on quality and effectiveness of care. The following quality indicators were flagged:</p> <ul style="list-style-type: none"> • Serious Incidents: Indicator Red currently, distance to travel to meet 80% IMTP trajectory. 5 point plan has been implemented. As of 5th November 2019 36 historic incidents remained incomplete. Carol Shillabeer confirmed that 21 have now been investigated and closed. 4 more are due for closure in February. • Delayed transfers of care • Complaints: It was noted that PTHB has struggled with the timeliness of responses in the past, however, response quality has been reasonable. There were 70 open complaints in October 2019, this has now been reduced to 24. Progress is being made, and achieving the IMTP 80% target is feasible. • Training for staff regarding Dementia: Detailed assessment into this issue is required. • Timeliness of Care • Follow Ups: 57 follow ups, 100% delayed <p>Owen James queried the trend regarding indicators. Carol Shillabeer confirmed that generally the indicators are increasing in number, however, are moving more towards outcome measures as opposed to process driven measures.</p>
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	<p>Owen James queried the role of workarounds etc. in giving a view of patient experience. Carol Shillabeer observed that the report does not give an indication of the culture on wards etc. This is the broader intelligence that sits alongside the measures.</p> <p>Melanie Davies queried the links between outcomes and assurance. Carol Shillabeer confirmed that Welsh Government are moving towards this direction. There are no plans for the year ahead but work is ongoing in this area.</p> <p>Jamie Marchant raised the importance of triangulation of data and expressed caution at only looking at single metrics.</p> <p>Carol Shillabeer confirmed that this work will be taken forward and Independent Members were invited to have input and to provide further feedback and comments outside of the meeting.</p> <p>Melanie Davies expressed her thanks for the report and noted that the direction of travel in this area is positive.</p>
EQS/19/92	<p>REGULATORY INSPECTIONS REPORT</p> <p>Wendy Morgan provided the Committee with an update on the most recent Regulatory Inspections undertaken and also any planned inspections the health board have been notified of. It was reported that a key theme identified by HIW is the positive and excellent staff engagement with patients, creating a positive patient experience. In relation to improvements needed, there are no concerns regarding emerging themes, however, there are several environmental and estates related issues identified as in need of improvement. The following inspection were discussed:</p> <ul style="list-style-type: none"> • <u>Review of Integrated Care: Focus on Falls – September 2019 (HIW)</u> • <u>Felindre Ward, Bronllys Hospital – November 2019 (HIW)</u> • <u>Llewellyn Ward, Bronllys Hospital – October 2019 (HIW)</u> <p>Trish Buchan queried whether a HIW tracker has been implemented. Rani Mallison confirmed that it has and an</p>

	<p>update on its progress will provided to the Committee under the next agenda item.</p> <p>Carol Shillabeer expressed that tracking and learning from recommendations is key.</p>
EQS/19/93	<p>HIW RECCOMENDATIONS TRACKING REPORT</p> <p>Rani Mallison presented the update to the Committee and noted that this is the first report of its type to be received the Experience, Quality and Safety Committee which builds on the Audit Recommendations tracker that reports to the Audit, Risk and Assurance Committee.</p> <ul style="list-style-type: none"> • 27 Recommendation have been completed since October 2019 • 21 require improvement • 18 Recommendations with Revised Timescales for Q4 <p>It was noted that updates have been received since the paper was circulated and the position has improved further.</p> <p>Melanie Davies expressed her thanks for the overview and noted how neatly the report links with audit recommendations. Rani Mallison confirmed that further work is due to take place with the Assistant Director of Quality and Safety and her team and noted that as the tracker matures prioritisation will be brought to the Committee.</p>
EQS/19/94	<p>CLINICAL NEGLIGENCE AND PERSONAL INJURY CLAIMS REPORT</p> <p>Wendy Morgan summarised the repot noting that PTHB has a small number compared to others with only 8 on file, the level of detail shared must be limited due to patient data therefore this item will be discussed in more detail In-Committee.</p> <p>It was reported that PTHB does not employ any solicitors therefore NWSSP is utilised. The themes throughout the report highlighted risk assessments, equipment and training as key issues.</p>

EQS/19/95	<p>MENTAL HEALTH ACT COMPLIANCE REPORT</p> <p>Joy Garfitt presented the report to the Committee. The purpose of the report was to assure the Committee that Powys Teaching Health Board are compliant with the Mental Health Act, using the most recent quarterly performance data in relation to the Hospital Managers' Scheme of Delegated Duties under the Mental Health Act 1983 and the functions, including section 23.</p> <p>The following Errors and Defective Applications were reported to the Committee for Q3:</p> <ul style="list-style-type: none"> • Rectifiable Errors - 12 occasions (Mostly grammatical errors or misspellings) • Fundamentally Defective Errors – 0 <p>It was reported that a Fundamentally Defective Error was reported in Quarter 2 due to a missed signature, this was reported as the first Fundamentally Defective Error for some time. It was reported that learning has been implemented and training has been delivered to the whole MH team.</p> <p>The following detentions under the relevant Section of the Act were reported to the Committee:</p> <ul style="list-style-type: none"> • Section 4 (Emergency Holding Power): Not used in Q3, used fewer than 5 times in Q2. • Section 5 (Holding Power for Assessment): Used fewer than 5 times in Q3, used 7 times since Q2. • Section 2 (Admission for Assessment): Used 23 times in Q3, 11 times in Q2. Q3 was reported as busy especially in adult and older adult services. • Section 3 (Admission for treatment): Used 10 times in Q3, fewer than 5 times in Q2. • Section 136 (Policing Holding): Section 136 was used on seventeen occasions during the 6 month period 1 July to 31 December 2019 (Quarter 2 on 10 occasions and Quarter 3 on 7 occasions) <p>Owen James queried if the large numbers for Section 2 in Q3 are seasonal. Joy Garfitt noted a seasonal increase in the run-up to the festive period however raised that very difficult to track and predict trends, especially in adults.</p>
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	<p>Joy Garfitt noted that the Section 136 detentions have all been reviewed and have all been deemed appropriate and noted that no police cells were used as a place of safety.</p> <p>It was noted that the advocacy service is pending renewal and that an All Wales design is being discussed. Trish Buchan raised the issue with advocacy services and queried whether a piece of work would be possible seeking the perspective of patients on CMO on their perspective of the service. Joy Garfitt confirmed that this can be explored.</p> <p>It was queried whether the correct data is being collected. Joy Garfitt reiterated the data reported to the Committee is to provide assurance that Powys Teaching Health Board are compliant with the Mental Health Act. If there were issues in the broader service they would be brought to his Committee. Joy Garfitt expressed that she would be happy to invite the IM's to the 136 suite to give an understanding of the MH environment.</p> <p>Melanie Davies thanked Joy Garfitt for the report. Carol Shillabeer noted that an update on Serious Incidents relating to Mental Health would be provided In-Committee.</p>
EQS/19/96	<p>WELSH LANGUAGE STANDARDS REPORT</p> <p>Claire Madsen provided the Committee with an update and noted that she had met with Carol Shillabeer and the Welsh Language Minister. It was reported that the Minister recognises the challenges and is sympathetic as long as progress is being made.</p> <p>It was reported there is now a substantive Service Improvement Manager for Welsh Language and Equality.</p> <p>Melanie Davies recognised the improvements made and welcomed the substantive post.</p>
EQS/19/97	<p>STRATEGIC EQUALITY PLAN</p> <p>Claire Madsen provided the report and noted that consultation has begun with the Assistant Director of Communications and Engagement and the Improvement Manager for Welsh Language and Equality to identify priorities aligned with the ITMP.</p>

	<p>It was reported that lots of responses have been received and the plan will be presented to the Board on 25th March 2020.</p> <p>Trish Buchan raised that the use of the Cover Paper impact assessment could be strengthened. Rani Mallison confirmed that this is currently being re-assessed with the Director of Planning and Performance.</p>
EQS/19/98	<p>PODIATRY INTERNAL AUDIT FOLLOW UP</p> <p>Jamie Marchant reported to the Committee that in 2018/19 a 'No Assurance' Internal Audit Report was received regarding Podiatry Services which required a temporary redesign of the service.</p> <p>In October 2019 a re-inspection was undertaken which received a 'Limited Assurance' rating which was reported to Audit, Risk and Assurance Committee on 14 January 2020. It was noted that a detailed action plan had now been formulated, an advertisement has been published for Internal Head of Podiatry and a paper has been taken to Executive Committee to redesign the service permanently (This will also be considered by the CHC and Strategy and Planning Committee).</p> <p>Trish Buchan recognised the impact of staff turnover and queried if any harm had been caused to patients. Carol Shillabeer confirmed that there had been an incident 2 years ago and highlighted the difficulties in attracting and retaining staff due to the current model. Claire Madsen raised that there is a National Shortage with low numbers in training.</p>
EQS/19/99	<p>COMMITTEE RISK REGISTER</p> <p>Rani Mallison presented the Committee Risk Register which will be standing item on the agenda. It was noted that no updates have been made to the register since 3 December 2019 and that work is continuing to develop the Directorate Risk registers.</p>
ITEMS FOR INFORMATION	
EQS/19/100	COMMITTEE WORKPLAN 2019/20

	The Committee NOTED the work plan.
EQS/19/101	ARMED FORCES COVENANT (PRESENTED TO EXECUTIVE COMMITTEE ON 6TH NOVEMBER 2019) The Committee RECEIVED and NOTED the Armed Forces Covenant.
EQS/19/102	REVIEW OF PRIMARY CARE CAHMS (PRESENTED TO EXECUTIVE COMMITTEE ON 6TH NOVEMBER 2019) The Committee RECEIVED and NOTED the review of Primary Care CAHMS.
EQS/19/103	RESPONSE TO INTERNAL AUDIT REPORT: SAFEGUARDING – EMPLOYMENT ARRANGEMENTS AND ALLEGATIONS (REASONABLE ASSURANCE) The Committee RECEIVED and NOTED the Response to Internal Audit Report: Safeguarding – Employment Arrangements and Allegations (Reasonable Assurance).
OTHER MATTERS	
EQS/19/104	ITEMS TO BE BROUGHT TO THE ATTENTION OF THE BOARD AND OTHER COMMITTEES There were no items to be reported.
EQS/19/105	ANY OTHER URGENT BUSINESS There were no items to be reported.
EQS/19/106	DATE OF THE NEXT MEETING 2 nd April 2020, 10:00am – 1:00pm, Board Room, Glasbury House, Bronllys Hospital

Reporting Committee:	Audit, Risk and Assurance Committee
Committee Chair	Tony Thomas
Date of last meeting:	18 May 2020
Paper prepared by:	Head of Risk & Assurance
KEY DECISIONS / MATTERS CONSIDERED BY THE COMMITTEE	
<p>As Chair of the Audit, Risk & Assurance Committee I am pleased to provide the Board with a summary of the matters discussed and reviewed by the Committee when it met on 18 May 2020. The confirmed minutes of the meeting held on 9 March 2020 are appended to this report (Appendix 1).</p> <p>The Committee considered the following reports at the March meeting:</p> <ul style="list-style-type: none"> a) Application of Single Tender Waiver b) Financial Control Procedure: COVID-19 c) Head of Internal Audit Report and Opinion for 2019-20 d) Internal Audit Reports, 2019-20 <ul style="list-style-type: none"> a. Welsh Risk Pool Claims Management (Substantial Assurance) b. Capital Assurance Follow Up (Substantial Assurance) c. Outpatients – Planned Activity (Reasonable Assurance) d. Estates Assurance Follow Up (Reasonable Assurance) e. Financial Safeguarding: Estates Team Led Work (Reasonable Assurance) f. Financial Safeguarding: Support Services Led Work (Reasonable Assurance) g. Risk Management and Board Assurance (Limited Assurance) h. Welsh Language Standards Implementation (Limited Assurance) e) External Audit: <ul style="list-style-type: none"> a. Letter from Auditor General b. Letter from Engagement Director f) Approach to the Management of Audit Recommendations during COVID-19 g) Approach to Risk Management during COVID-19 h) Draft Financial Statements 2019-20 	

i) Draft Annual Accountability Report, 2019-20

The following items were escalated for the attention of the Board:

- Financial Control Procedure: COVID-19
- 2 x 'Limited Assurance' Audit Reports
- 4 x 'Reasonable Assurance' Audit Reports
- 2 x 'Substantial Assurance' Audit Reports
- External Audit: Letter from Engagement Director
- Approach to the Management of Audit Recommendations during COVID-19
- Approach to Risk Management during COVID-19
- Draft Financial Statements 2019-20

COMMITTEE ACTION LOG

ARA/19/68 (Designated list of Investigative Officers): The Serious Incidents Policy is scheduled for Board, 27 May 2020.

ARA/19/111 (Revised Local Counter Fraud Workplan 2020/21): The Workplan is scheduled for Audit, Risk & Assurance Committee, 25 June 2020

APPLICATION OF SINGLE TENDER WAIVER

The Committee received the following Single Tender Waivers for ratification made between 1 March 2020 and 30 April 2020.

Single Tender Reference	Request to waive QUOTE or TENDER threshold?	Name of Supplier	Item	Reason for Waiver	Date of Approval	Value £	Length of Contract	Prospective/ Retrospective	Appendix Ref
POW1920018	Quote	Health Matters Education Ltd	Supply of Training Materials in health matters for Children	Sole supplier	13/03/2020	£12,672	N/A Goods	Prospective	A1

The Committee RATIFIED the Single Tender Waiver.

FINANCIAL CONTROL PROCEDURE: COVID-19

COVID-19 - Financial Guidance to NHS Wales' Organisations was issued by the Director General for Health & Social Care / NHS Wales Chief Executive on 30th March 2020. This outlined the need to maintain excellent stewardship and governance at a time of significant disruption to the standard operating practices of NHS Wales.

Following the publication of the guidance an interim FCP was drafted by Finance for PTHB, with the aim of outlining the changes required to existing FCP's and SFI to meet the challenges and pace of dealing with the Covid-19 Pandemic as well as outlining the new procedures required to manage the Covid-19 expenditure.

The Committee RATIFIED the current version (#3) of the COVID-19 Financial Control Procedure and NOTED the process by which the document had been approved during April 2020.

HEAD OF INTERNAL AUDIT REPORT AND OPINION FOR 2019-20

The committee was informed that the Head of Internal Audit's opinion is that *'the Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively.'*

INTERNAL AUDIT REPORTS, 2019-20

The following updates were presented to the Committee:

- a) Welsh Risk Pool Claims Management - *Substantial Assurance*
- b) Capital Assurance Follow Up - *Substantial Assurance*
- c) Outpatients – Planned Activity – *Reasonable Assurance*
- d) Estates Assurance Follow Up – *Reasonable Assurance*
- e) Financial Safeguarding: Estates Team Led Work – *Reasonable Assurance*
- f) Financial Safeguarding: Support Services Led Work – *Reasonable Assurance*
- g) Risk Management and Board Assurance – *Limited Assurance*
- h) Welsh Language Standards Implementation – *Limited Assurance*

The Committee RECEIVED the management action plans for all reports and will monitor tracking of progress through the audit recommendation tracking process.

EXTERNAL AUDIT

The Committee RECEIVED and NOTED the following reports which set out the arrangements for external audit (Audit Wales) during the period of COVID-19:

- a) Letter from Auditor General
 - b) Letter from Engagement Director
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APPROACH TO THE MANAGEMENT OF AUDIT RECOMMENDATIONS DURING COVID-19

The Committee was presented the management of Audit Recommendations approach and were requested to:

- APPROVE the re-prioritised approach for audit recommendation implementation, as outlined;
 - NOTE the status of audit recommendations as reported in March 2020; and
 - NOTE that a trajectory for implementation during the COVID-19 pandemic will be brought forward to the Committee in June 2020, based on an agreed re-prioritised approach.
-

APPROACH TO RISK MANAGEMENT DURING COVID-19

The approach to risk management was presented to the Committee. The report specified the management approach for:

- Management of Strategic Risks during COVID-19;
 - Management of COVID-19 Specific Risks; and
 - Management of Operational Risks during COVID-19.
-

DRAFT FINANCIAL STATEMENTS 2019-20

The Committee was provided with the Draft Financial Statements and noted that the accounts would be subject to statutory audit by Grant Thornton.

It was confirmed that PTHB had achieved the following financial targets and statutory duties for 2019/20:

- Operational in-year financial balance has been achieved, reporting a surplus of £0.055M
- Cash contained within cash limit
- Capital financial balance

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PTHB will meet the target dates for preparing and submitting the draft annual accounts to Welsh Government and Grant Thornton by 22nd May 2020. PTHB is on course to meet the target date to submit the audited accounts to be approved by the Audit, Risk and Assurance Committee on 25th June 2020, Health Board on 29th June 2020 and Welsh Government by the final submission date of 30th June 2020.

DRAFT ANNUAL ACCOUNTABILITY REPORT, 2019-20

The Committee received the Draft Annual Accountability Report, 2019-20 and was requested to consider the report and provide any feedback to inform the final development of its content ahead of submission to Welsh Government on 22nd May 2020. PTHB is on course to meet the target date to submit the Annual Accountability Report to be approved by the Audit, Risk and Assurance Committee on 25th June 2020, Health Board on 29th June 2020 and Welsh Government by the final submission date of 30th June 2020.

ITEMS FOR ESCALATION TO THE BOARD

- Financial Control Procedure: COVID-19
- 2 x 'Limited Assurance' reports
- 2 x 'Substantial Assurance' reports
- 4 x 'Reasonable Assurance' reports
- External Audit: Letter from Engagement Director
- Approach to the Management of Audit Recommendations during COVID-19
- Approach to Risk Management during COVID-19
- Draft Financial Statements 2019-20

NEXT MEETING

The next meeting of ARA will be held on 25 June 2020.

ATTACHED

Previous Confirmed Minutes from ARA 9 March 2020

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Appendix 1



AUDIT, RISK & ASSURANCE COMMITTEE

CONFIRMED

MINUTES OF THE MEETING HELD ON MONDAY 9 MARCH 2020 BOARD ROOM, GLASBURY HOUSE, BRONLLYS HOSPITAL

Present:

Tony Thomas	Independent Member – Finance (Committee Chair)
Mark Taylor	Independent Member – Capital and Estates
Ian Phillips	Independent Member – ICT

In Attendance:

Pete Hopgood	Director of Finance, Information and IT
Len Cozens	Head of Local Counter Fraud Services
Jackie Wilding	CHC Observer
Barrie Morris	External Audit (Grant Thornton)
Sarah Pritchard	Head of Financial Services
Elaine Matthews	External Audit (WAO)
Felicity Quance	Internal Audit
Osian Lloyd	Deputy Head of Internal Audit
Helen Higgs	Head of Internal Audit
Rani Mallison	Board Secretary
Jayne Lawrence	Assistant Director of Primary Care Services
Carol Shillabeer	Chief Executive
Dave Thomas	External Audit (WAO)
Jacqui Wilding	CHC Observer
Stuart Bourne	Director of Public Health (for item 3.1d)

Committee Support

Caroline Evans	Head of Risk and Assurance
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Apologies for absence:

Mel Davies	Vice Chair
Matthew Dorrance	Independent Member – Local Authority

ARA/19/103	<p>WELCOME AND APOLOGIES</p> <p>The Committee Chair welcomed everyone to the meeting and confirmed that a quorum was present. Apologies for absence were noted as recorded above.</p>
ARA/19/104	<p>DECLARATIONS OF INTERESTS</p> <p>The Committee Chair INVITED Members to declare any interests in relation to the items on the Committee agenda. None were declared.</p>
ARA/19/105	<p>MINUTES FROM THE PREVIOUS MEETING FOR RATIFICATION</p> <p>The minutes of the meeting held on 14 January 2020 were RECEIVED and AGREED as being a true and accurate record.</p>
ARA/19/106	<p>MATTERS ARISING FROM PREVIOUS MEETINGS</p> <p>The Chair stated the pre-meeting held a discussion with the Head of Counter Fraud Services, and this had arised in a successful conclusion.</p>
ARA/19/107	<p>COMMITTEE ACTION LOG</p> <p>ARA/19/89: Rani Mallison confirmed that the Structured Assessment will be included in the Committee's workplan for next year.</p> <p>ARA/19/87: Pete Hopgood stated he has not received an update from procurement colleagues regarding the European Journal, and will follow this up.</p> <p>ARA/19/77: Rani Mallison stated that the CEO is unable to attend the Committee today in light of planning around Covid19, and requested that the ICF report is deferred to the next meeting.</p> <p>Action: Board Secretary</p>

	<p>ARA/19/68: Rani Mallison stated that work is ongoing in respect of the Serious Incidents Policy will be presented to the Experience, Quality and Safety Committee for approval in April.</p>
ARA/19/108	<p>SINGLE TENDER WAIVERS (STWs)</p> <p>Sarah Pritchard presented the STW request made between 1 January 2020 and 29 February 2020 and signed by the Chief Executive.</p> <p>Mark Taylor questioned if the STW is retrospective, not prospective. Sarah Pritchard stated that it is prospective, and that patients would not be sent for treatment until the STW is approved by the Committee.</p> <p>After discussion, the Committee RATIFIED the approval of the one STW (Dental Surgical Interventions for Children and Young Adults [£30,000]).</p>
ARA/19/109	<p>COUNTER FRAUD POLICY & RESPONSE PLAN</p> <p>The Committee Chair stated this is Len Cozens' last meeting as Len is moving onto another role, and thanked Len for all of the work that has been done, which has resulted in substantial improvements on previous arrangements.</p> <p>Len Cozens thanked the Committee for all of its support.</p> <p>Len Cozens presented the report, which provides a review and update of the Counter Fraud Policy & Response Plan. The Fraud, Bribery and Corruption Standards for NHS Bodies (Wales) produced by the NHS Counter Fraud Authority requires organisations to put in place a Counter Fraud, Bribery and Corruption Policy, which must be approved by the executive body or senior management team.</p> <p>The Committee APPROVED the Counter Fraud Policy & Response Plan.</p>
ARA/19/110	<p>FCP 021: BUDGETARY CONTROL PROCEDURE</p> <p>Pete Hopgood presented the Budgetary Control Procedure, which has been revised in line with Internal Audit recommendations, to ensure that the document remains relevant and reflects best practice. The key changes include:</p>

	<ul style="list-style-type: none"> • Clarifying and timescales on the publication of the annual letter of accountability to principle budget holders; • Any unallocated funds held in reserves will be reported within the Risks & Opportunities section of the Board Report; • New approach for scrutinising and approving all Business Cases and bids via the IBG process; • Clarification on the IMTP and Budget Setting process; • Revised process for recording and approving budget virements. <p>Rani Mallison stated the policy will help address the recommendation from WAO within the Structured Assessment, in respect of budget letters.</p> <p>The Committee APPROVED the FCP 021: Budgetary Control Procedure.</p>
ARA/19/111	<p>COUNTER FRAUD WORKPLAN 2020/21</p> <p>Len Cozens presented the Local Counter Fraud Workplan 2020/21. The Fraud, Bribery and Corruption Standards for NHS Bodies (Wales) produced by the NHS Counter Fraud Authority require the nominated Local Counter Fraud Specialist (LCFS) and Director of Finance at each health body to agree, at the beginning of each financial year, a written work plan which outlines the LCFS' projected workload for that year.</p> <p>Len Cozens stated the plan will need to be revisited following completion of the self-review tool. In addition, the LCFS is currently on sick leave, so the plan may need to be adjusted in terms of available days. Any adjustments to the plan will be discussed with the Director of Finance, and will be brought to the next Audit, Risk & Assurance Committee.</p> <p>Action: Head of Local Counter Fraud Services / Director of Finance</p> <p>The Committee RECEIVED and NOTED the content of the report.</p>
ARA/19/112	<p>AUDIT RECOMMENDATIONS TRACKING, JANUARY 2020</p> <p>Rani Mallison presented the report, which provides an overview of the current position relating to the implementation of Audit Recommendations, arising from reviews undertaken by Internal Audit and External Audit (Wales Audit Office).</p> <p>Rani Mallison stated the team will shortly be working on development of the Annual Report, and it will be helpful to</p>

	<p>show the improvement on the implementation of audit recommendations within the Annual Report.</p> <p>Ian Phillips stated it would be helpful to have one overall appendix that states where the key issues are. Rani Mallison noted that this was included in the appendices but would look to make this more visible.</p> <p>The Committee RECEIVED and NOTED the content of the report.</p>												
ARA/19/113	<p>INTERNAL AUDIT PROGRESS REPORT</p> <p>Helen Higgs presented the report, which informs the Committee of progress with the 2019/20 Internal Audit Plan as recorded at March 2020. Progress against the plan is as follows: -</p> <table border="1"> <tr> <td>Number of audits finalised</td><td>20</td></tr> <tr> <td>Number of audits issued at draft</td><td>2</td></tr> <tr> <td>Number of audits in progress</td><td>7</td></tr> <tr> <td>Number of audits not started</td><td>0</td></tr> <tr> <td>Year-end reporting</td><td>(2)</td></tr> <tr> <td>Total number of audits in 2019/20 plan</td><td>29</td></tr> </table> <p>Helen Higgs informed the Committee the plan is on track to deliver.</p> <p>The Committee RECEIVED and NOTED the content of the report.</p>	Number of audits finalised	20	Number of audits issued at draft	2	Number of audits in progress	7	Number of audits not started	0	Year-end reporting	(2)	Total number of audits in 2019/20 plan	29
Number of audits finalised	20												
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Number of audits not started	0												
Year-end reporting	(2)												
Total number of audits in 2019/20 plan	29												
ARA/19/114	<p>INTERNAL AUDIT PLAN 2020/21</p> <p>Helen Higgs presented the Internal Audit Plan 2020/21, which details the audits to be undertaken and an analysis of the corresponding resources. The purpose of Internal Audit is to provide the Accountable Officer and the Board, through the Audit, Risk & Assurance Committee, with an independent and objective annual opinion on the overall adequacy and effectiveness of the organisation's framework of governance, risk management, and control.</p> <p>Helen Higgs stated that the plan has been developed in collaboration with Directors, sub-committees and the Board Secretary. The plan has also been discussed with the Executive Committee.</p> <p>The Board Secretary stated that planning this year was really helpful, with IMs fully engaged.</p>												

	The Committee RECEIVED and NOTED the content of the report.
ARA/19/115	<p>INTERNAL AUDIT REVIEWS <u>Reasonable Assurance Rating</u></p> <p>a) Primary Care Clusters</p> <p>Osian Lloyd reported that the review identified one high, three medium and one low priority findings. Specifically, the audit focused on the following areas:</p> <ul style="list-style-type: none"> • cluster plans, their format and content and compliance with the requirements of the Welsh Government framework guides; • whether planning is two-way, particularly looking at how the health board inputs in cluster level plans, and how those plans are then reflected throughout the health board's IMTP; • the level of support given to the clusters by the health board in terms of Workforce and Finance resource; • the processes by which clusters provide assurance reporting to the Board; • whether oversight, leadership, performance monitoring and support is given to the PCCs through health board management and their supporting teams; and • whether mechanisms are in place to ensure that changes arising from the continuously improving cluster working are being communicated to the public and that the cluster model operating is delivering sustainable services. <p>Ian Phillips stated that culture, maturity and ethos of cluster development is important, and questioned whether this will be considered as part of the reporting process. Rani Mallison stated the Director of Primary, Community and Mental Health Services is developing a Governance Framework, built on a national governance model for clusters.</p> <p>b) Organisational Development Strategic Framework</p> <p>Osian Lloyd reported that the review identified two medium priority findings. Specifically, the audit focused on the following areas:</p> <ul style="list-style-type: none"> • the process by which the health board determined its key priorities required to deliver the new strategic framework;

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	<ul style="list-style-type: none"> • engagement with key stakeholders on the proposed changes; • management of the implementation of the organisational development priorities, including clarity on roles and responsibilities; • the processes by which the Board receive assurance reporting of the implementation progress of the framework; and • management of risks and issues associated with the implementation of the framework. <p>c) Dental Services: Monitoring of the GDS Contract Follow-up</p> <p>Osian Lloyd reported that the review identified two low priority findings.</p> <p>The 'follow-up review opinion' provides an assurance level against the implementation of the agreed action plan.</p> <p>Helen Higgs stated that the review focuses on progress of implementation of the recommendations from the previous review, as opposed to a full review based on the original audit scope.</p> <p>Ian Phillips stated he is pleased to see a tightening up of the contract monitoring and review, but has concerns around the unintended consequences of this, including access to GDP Services, as a result of disincentivising Dentists.</p> <p>Pete Hopgood stated the health board needs to ensure it sets the contract at the right level to enable reinvestment that can improve access elsewhere.</p> <p>Osian Lloyd stated that practices are expected to deliver 95% of their annual allocation.</p> <p>Rani Mallison stated that the Commissioning Assurance Framework in respect of GDS is presented to the Performance & Resources Committee.</p> <p>Ian Phillips asked how quickly are we receiving information in respect of underperformance, and are those performance arrangements timely and robust.</p> <p>Pete Hopgood stated there is regular monthly review of UDA performance.</p> <p>Osian Lloyd stated there is a mid-review stage.</p> <p>Ian Phillips asked if there is a level of variability that makes it difficult to see under or over performance.</p>
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	<p>Pete Hopgood stated that historic data enables us to see patterns and triggers.</p> <p>Tony Thomas asked if there is discussion between health boards to avoid going out to the private sector in respect of Children's Services.</p> <p>Jayne Lawrence stated that the health board has recently been made aware of an alternative solution through a Cwm Taf Paediatric specialist, which provides a NHS pathway. The health board is now linking with Cwm Taf to obtain further detail.</p> <p>d) Information Technology Service Management</p> <p>Osian Lloyd reported that the review identified two medium and one low priority findings.</p> <p>The key objective areas of the review were as follows:</p> <ul style="list-style-type: none"> • IT services are appropriately designed, provided and managed with reference to an appropriate framework (ITIL); • service desk provision is appropriate and appropriate request for service fulfilment management practices are followed; and • appropriate documented processes are in place for change, incident, event, problem, release and deployment management. <p>Pete Hopgood confirmed that actions owned by non-PTHB employees due to the section 33 agreement have been signed off.</p> <p>Ian Phillips stated the user experience didn't feature in the audit, and that we might want to consider that going forward. Helen Higgs stated that there is a review scheduled for next year in respect of access to systems, which should encompass this query.</p> <p>e) Machynlleth Hospital Primary & Community Care Project</p> <p>Felicity Quance reported that the review identified one high, four medium and one low priority findings.</p> <p>The focus of the audit was directed to the following areas:</p> <p>Governance arrangements:</p> <ul style="list-style-type: none"> • assurance that adequate governance arrangements were in place, including management ownership, defined roles and responsibilities, together with clear defined accountability and delegation arrangements; and
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	<ul style="list-style-type: none"> • assurance that generally accepted project management techniques were appropriately applied and reported. <p>Approvals:</p> <ul style="list-style-type: none"> • assurance that appropriate internal/external approval mechanisms were applied as the project progressed through key junctures; and • assessment of the adequacy of the arrangements to develop the business case, including assurance that lessons learnt from previous projects were applied and that scrutiny comments were adequately addressed. <p>Appointment and Contracting</p> <ul style="list-style-type: none"> • assurance that appropriate contract documentation had been completed in accordance with the current phase of the project to protect the interests of the THB. This included any novation (where required) from the prior contractor and clarity of design liability. <p>Cost monitoring and reporting</p> <ul style="list-style-type: none"> • assurance that there was effective control and reporting of time and cost position; costs associated with the novation of design responsibility were clearly understood, challenged and reported; and the Project Board were effectively informed on any impact on the value for money assessment. <p>Additional issues</p> <ul style="list-style-type: none"> • identification and assessment of any additional key issues affecting the progression of the project. <p>Mark Taylor stated that the management response in respect of the timeliness of signing of contract documentation is vague in terms of how we are evidencing the intention to the signatories.</p> <p>Rani Mallison stated this she would discuss this with the Director of Planning.</p> <p>Action: Board Secretary</p> <p>Mark Taylor noted the management response in respect of recommendation 6 (lessons learnt), but asked that the lessons learnt exercises be shared with the Committee.</p> <p>Action: Board Secretary</p> <p>Felicity Quance stated the Machynlleth Project is on next year's Internal Audit Plan, and the recommendations raised within this report will be followed up.</p> <p>Mark Taylor stated there is a gap in terms of the FBC being report through Board without going through a Committee</p>
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	<p>initially. Rani Mallison stated that it should be reported through Performance and Resources prior to Board.</p> <p>Mark Taylor stated concern over clinical input signified by the attendance at meetings on page 27 of the report. Mark stated that if someone isn't going to attend they should be either not relevant or should nominate someone to attend on their behalf. Felicity Quance stated that a review of the ToR has been requested, questioning the appropriateness of the individuals named as nominated representatives, and challenging for non-attendance.</p> <p>The Committee RECEIVED the Internal Audit update.</p>
ARA/19/116	<p>WALES AUDIT OFFICE REPORTS: a) PRIMARY CARE SERVICES IN WALES</p> <p>Jayne Lawrence joined the meeting via conference call. Jayne Lawrence presented the report to the Committee which detailed the progress of the Primary Casre Model for Wales. It was reported that many elements are in place across Powys however there is a lack on consistency, this is aligned with the recommendations made within the report. The report concluded that changes have been occurring across wales however at different paces.</p> <p>It has been agreed with Welsh Government that the IMTP would be the mechanism for tracking rpgress against the recommendations within the report for Powys. It was noted that the IMTP includes 3 cluster specific IMTPs in Powys. The report also refereneced the additional £10m recurring funding for Wales (just over £400k for Powys) for clusters.</p> <p>The Committee was assured that the Director of Primary, Community Care and Mental Health and the Assistant Director of Primary Care Servoces have been developing a revised cluster framework and Terms of Reference for Powys alongside the cluster leads to ensure appropriate representation. The strategic programme for Primary Care has 7 work streams and has been set up to increase the pace of the model.</p> <p>It was noted that the workstream prograame action plan has been approved by the National Primary Care Board and has been shared with CEO's across Wales.</p> <p>The Committee RECEIVED the Structured Assessment.</p>

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EXTERNAL AUDIT: PROGRESS REPORT

Elaine Matthews presented the progress report, which provides an update on progress in relation to both financial and performance audit work, as well as information on the Auditor General's programme of NHS-related studies and publications as well as Good Practice Exchange events.

The following provides an update of work recently completed and/or underway:

Topic	Status	Executive lead	Committee report date
Follow up (2018): Orthopaedics	Fieldwork	Director of Planning and Performance	TBC
AGW review (2019): Review of the effectiveness of counter fraud arrangements	Fieldwork	Director of Finance	TBC
All Wales Thematic Review (2019): Quality governance arrangements	Scoping	TBC	TBC

The Committee RECEIVED the Audit Progress Report.

ARA/19/118

EXTERNAL AUDIT PLAN 2020/21

Barrie Morris presented the External Audit Plan for 2020/21 to the Committee.

It was noted that the Financial Audit has started with key risk identified as being:

- Management override of Controls
- Healthcare Commissioning Contracts

Work is underway regarding the risks and update meetings have been held periodically throughout the year with the Director of Finance and IT and the Head of Financial Services. Other areas for consideration included, ministerial in relation to implementation of a schemes pays initiative and IFRS 16 in respect of leases. Once the Audit has been completed there will be a full hand over with WAO in respect of next years audit.

Mark Taylor queried if the lessons learned and ongoing work in Maternity Services across Wales will form part of the thematic

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	<p>performance or audit quality work. Elaine Matthews noted that HIW has done a lot of work on Maternity Services and Rani Mallison raised that this item is reported to Experience, Quality and Safety Committee.</p> <p>The Committee NOTED that Anthony Veale will be taking over as financial lead for WAO following the handover from Grant Thornton.</p>
ARA/19/119	<p>COMMITTEE RISK REGISTER</p> <p>Rani Mallison presented the Committee Risk Register to the Committee. It was noted that no updates have been made to the register since 14 January 2020 and that work is continues to develop the Directorate Risk registers and Directorate Assurance Mapping.</p>
ARA/19/120	<p>COMMITTEE WORKPLAN 2019/20</p> <p>Rani Mallison presented the workplan, which outlines planned pieces of work and any amendments made since the last meeting. It was noted that this will be the final version of the 2019/20 plan and planning for 2020/21 workplan will be undertaken. The Corporate Governance team will be in contact with the relevant teams for population over the coming weeks. The Committee RECEIVED and NOTED the content of the report.</p>
ARA/19/121	<p>IMPLEMENTATION OF IFRS 16 – LEASES</p> <p>Sarah Pritchard provided an update to the Committee noting that as the National Lead for this work, meetings have been held monthly on a national basis. The full impact won't be within PTHB's accounts formally until 20/21 however an estimation will be included in 19/20 accounts. The core area of work has been assessing all of the Health Boards leases. One of the main difficulties is that peppercorn leases (buildings the Health Board occupy) have to be valued, these are due to be formally valued by the District Valuers office on 1st April 2020.</p>
ARA/19/122	<p>ITEMS TO BE ROUGHT TO THE ATTENTION OF THE BOARD AND OTHER COMMITTEES</p> <p>The Chair requested that continued satisfaction with the Audit Recommendation Tracking process and the 4 Reasonable Assurance Audit Reports are shared with the Board.</p>
ARA/19/123	<p>ANY OTHER URGENT BUSINESS</p>

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	There was no other urgent business for discussion, and the Chair declared the meeting closed at 11.26 am.
ARA/19/124	DATE OF NEXT MEETING 27 April 2020, 01:30pm, Boardroom, Glasbury House, Bronllys

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Reporting Committee:	Charitable Funds Committee
Committee Chair	Owen James
Date of meeting:	3 February 2020
Paper prepared by:	Charity Manager
KEY DECISIONS / MATTERS CONSIDERED BY THE COMMITTEE	
<p>The confirmed minutes of the previous meeting of the Charitable Funds Committee held on 15 October 2019 are appended to this report.</p> <p>The Charitable Funds Committee last met on 3 February 2020. At that meeting the matters discussed were:</p> <ul style="list-style-type: none"> • Action Log • PTHB Charity Manager, Business and Job Description (for Approval) • Bids to Charitable Funds (for Approval) • Expenditure Approved Under Delegated Authority since the last meeting (for Ratification) • Small Grants Scheme Update <p>-----</p> <p>PTHB Charity Manager, Business and Job Description (for Approval)</p> <p>The members NOTED that the job description has been evaluated and approved by PTHB Workforce and the role will be employed directly through the Health Board, not the Charitable Fund.</p> <p>The members recognised the need for the post as a key role referenced in the Charitable Funds Strategy.</p> <p>It was NOTED that the Interim Strategy is in place to develop a long-term Charitable Funds Strategy that this position will inform. The</p>	

members NOTED the importance of having a designated position to ensure donated money is spent appropriately.

The Committee APPROVED the funding of the position.

CHARITABLE BIDS FOR APPROVAL

Three applications for funding were presented for consideration and approved for funds to be released:

1. Psycho Sexual Training (£3,200): to address an upcoming gap in service provision and support staff, patients and volunteers.
2. Staff Excellence Awards (£6,500): an opportunity to have a positive impact on staff welfare.
3. Ystradgynlais Hospital Therapeutic Garden (£23,000): to create a calm and restorative space for patients and their families.
4. Tawe Ward Garden (£12,000): to create a therapeutic space as the previous bid, specifically for the Tawe Ward.

EXPENDITURE APPROVED UNDER DELEGATED AUTHORITY SINCE THE LAST MEETING (FOR RATIFICATION)

The Committee received an update detailing expenditure approved by those with relevant delegations during October 2019, with a combined value of £3,661.

The Committee RATIFIED the expenditure approved under delegated authority.

SMALL GRANTS SCHEME UPDATE

The Committee RECEIVED Interim feedback from Round 1 of the Small Grants Scheme operated in collaboration with PAVO.

Following review of the objectives the Committee CONFIRMED that the scheme could progress to Round 2, which commenced from the 27th February 2020.

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It was NOTED that a representative from the Health Board will have an overview of the schemes but will not need to attend to review all applications.

The Committee NOTED that the profile of the scheme will be raised alongside new branding for the charity.

The following Items were presented for Information:

- **Charitable Funds Income Report**

The Committee RECEIVED the report, which provides an update on Income received for the period 1st October 2019 to 31st October 2019.

There were no significant donations received by the charity in this period.

- **Charitable Funds Investment Report**

The Committee RECEIVED the Investment Fund Performance Quarterly Report for their information and NOTED:

- The performance of the CCLA investment portfolio for the quarter to 30th September 2019.
- The Realised gain on investment at disposal of CCLA Investment on 17th October 2019 and its distribution to funds.

The Committee NOTED that there are more funds available to spend compared to previous years, which reflects the ambition of the charity.

- **Charitable Funds Expenditure Profile**

The Committee RECEIVED the report and noted that the format has been updated to reflect the new format used in the finance Board report.

- **Mums Matter Evaluation Report**

The Committee RECEIVED the report and NOTED the hard work that has supported the project. The Committee NOTED that it was positive to receive feedback that the project has made a difference.

OTHER BUSINESS

The committee had a short discussion regarding mobile scanning and the Big Four and whether this was something that the Committee can support. It was decided that a piece of scoping work would need to be

carried beforehand. It was confirmed that the item will be brought back to the Committee to consider.

The committee also discussed the refurbishment of the Bronllys Canteen and noted that progress was underway.

ITEMS TO BE BROUGHT TO THE ATTENTION OF THE BOARD

- **Approval and Appointment of Charity Manager Role**

At the previous Charitable Funds Committee Meeting (3rd February 2020) the Committee approved a new Charity Manager role with an appointment made shortly thereafter. The new Charity Manager, Abe Sampson, started in post on 6th April and joins the Health Board from a background in fundraising and communications in the Third Sector.

- **Approval of Digital Display Screens for Staff Areas**

Due to the disruption from COVID-19, the Committee has sought to consider urgent requests via chair's action outside of meetings.

An urgent proposal for the implementation and installation of digital display screens in staff areas across the Health Board (£26,800) was considered and approved by the committee in April. The screens will support frontline staff by providing up to date communications and messaging on a local, regional and national level. The proposal will be most beneficial to frontline staff without regular access to computers and emails

As of 15th May, all screens have now been implemented with at least one screen in every hospital across Powys. The communications will be managed by the Communications team with support from local controllers.

- **COVID-19 Support Funding**

The Charity is now a member of the NHS Charities Together association. As a member, the charity will receive several grants to distribute across the Health Board as part of the national COVID-19 fundraising campaign for NHS charities.

The charity has already received £49,500 to distribute as part of the first stage of funding, *urgent response to COVID-19*. This funding will shortly be made available to staff members, who can apply for funding through a fast track process. There will also be further funding stages to support community care pathways and the recovery phase.

The Charity Manager will coordinate the rollout and all funding decisions will be ratified by the Charitable Funds Committee.

NEXT MEETING

17 September 2020

An earlier meeting may be held in the interim following the cancellation of previous meetings due to COVID-19.

The Committee has been able to consider urgent requests by chair's action in the interim period.

Appendix 1

**MINUTES OF THE CHARITABLE FUNDS COMMITTEE MEETING
HELD ON TUESDAY 15 OCTOBER 2019
IN THE BOARD ROOM, BRONLLYS HOSPITAL**

Present:

Owen James	Independent Member (Committee Chair)
Tony Thomas	Independent Member (Committee Vice Chair)
Trish Buchan	Independent Member (Third Sector)
Mark Taylor	Independent Member (Estates)
Julie Rowles	Director of WOD
Pete Hopgood	Director of Finance and IT
Katrina Rowlands	Interim Director of Nursing

In Attendance:

Sarah Pritchard	Head of Financial Services
Rani Mallison	Interim Board Secretary
Rhiannon Hughes	Committee Secretary
Gail Turner-Radcliffe	External Audit (Grant Thornton)

Apologies

Vivienne Harpwood	Chair PTHB
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CF/19/37	<p>WELCOME & APOLOGIES FOR ABSENCE</p> <p>The Chair welcomed members and asked for brief introductions.</p> <p>Apologies for absence were noted as recorded above.</p>
CF/19/38	<p>DECLARATIONS OF INTEREST</p> <p>The Chair INVITED any declarations of interest in relation to items on the agenda. There were no declarations of interest.</p>
CF/19/39	<p>MINUTES OF PREVIOUS MEETING HELD ON 11 JUNE 2019</p> <p>The minutes of the meeting held on 11 June 2019 were RECEIVED and AGREED as being a true and accurate record, aside from the amendment below:</p>

	<ul style="list-style-type: none"> CF/19/30 CCLA Investment Management Fund Performance Report – Quarter 4 , 2018/19 - It was AGREED that it should not state “final report of CCLA” as there are further reports due including one for September. <p>Action: Head of Financial Services</p> <p>Trish Buchan queried whether the Service Reserves Policy on page 3 has been agreed to reflect the year coming forward.</p> <p>Sarah Pritchard responded that the strategy discussions at the development session after this current meeting will determine whether it is formalised more into the strategy for future years.</p>
CF/19/40	<p>ACTION LOG</p> <p>The Committee RECEIVED the Action Log and the following matters were discussed:</p> <p>a) CF/19/27 Waste Management – the date needs to be amended to the 14th October. It has also not yet been approved but members AGREED to revisit this item under Any Other Business.</p> <p>Action: Head of Financial Services</p> <p>b) CF/19/10 Charitable Funds Expenditure Profile - Owen James queried whether this item should be highlighted in red. Sarah Pritchard will look at this for the next meeting. It was AGREED that Corporate Governance will look at revamping reports in general to ensure they fit into the financial report programme.</p> <p>Action: Board Secretary</p> <p>c) CF/18/41 Mental Health Charitable Funds Expenditure Plan - It was AGREED that Rani Mallison would pick up this action. It requires being embedded into the wider work for all Board Members visibility in Powys to tie in together.</p> <p>Action: Board Secretary</p>
ITEMS FOR APPROVAL, RATIFICATION OR DECISION	
CF/19/41	<p>2018/19 CHARITABLE FUNDS ANNUAL REPORTS AND ACCOUNTS (FOR APROVAL)</p> <p>The Powys Teaching Health Board (PTHB) as Corporate Trustee must provide to the Charity Commission by 31st January 2020, an Annual Report and Accounts that have</p>

been subject to Independent Examination by Audit and approved by the PTHB Board.

Prior to the items being discussed, Tony Thomas queried the need for impact assessments as there appear to be no impacts. Rani Mallison commented that impact assessments should be included for strategic decisions in case of any potential impacts.

Members RECEIVED the annual report and Sarah Pritchard provided an overview of the content, to include:

- a) In terms of Charity Commission thresholds, the charity has not exceeded the threshold so the Charity has been reverted to an independent examination.
- b) Grant Thornton is undertaking the work as independent examiner on behalf of the Wales Audit Office.
- c) No reports have been made as yet but the Audit, Risk and Assurance Committee will receive documents for information at the 11th November meeting.
- d) When the Annual Report and Accounts have been signed off by the Board Chair and Chief Executive (prior to the signing of the Auditor General for Wales), the submission to the Charity Commission will be undertaken before 31st January 2020.
- e) Members NOTED that on page 9 (Annual Review: Our Activities) that total income received was £211,330 which included £24,000 for legacies.

It was NOTED that on page 10 the term “unrealised loss” on the header for Investment Assets was an error and should read “unrealised gain”.

Action: Head of Financial Services

Trish Buchan asked what the unrestricted spend figure for 2018/19 was. Sarah Pritchard explained that the unrestricted spend was £2.5 million.

Mark Taylor queried what the £150,000 in the report was. Sarah Pritchard responded that this is the restricted fund.

Trish Buchan also asked if the money accrued any interest. Sarah Pritchard responded that interest is built on the fund and realised on the sale of the fund.

Tony Thomas commented that the first period was with the introduction of new managers and queried if there is any comparison on performance with CCLA. Sarah Pritchard

	<p>responded that the CCLA are attending this committee on 5th December, but for the time being it was too early to tell.</p> <p>Owen James asked if there were comparisons able to be made from this year and last year, to which Pete Hopgood suggested that a one page dashboard for display would be useful. Rani Mallison commented that perhaps a power point slide would be beneficial to highlight key messages at the next Board meeting.</p> <p>Trish Buchan queried whether this complies with a standard template. Sarah Pritchard confirmed that it complies with legal requirements (statement of recommendation).</p> <p>Gail Turner-Radcliffe confirmed that a long report outlining the next steps will be available in due course for Committee approval. It will then be received by the board for approval, before it goes to the Auditor General for sign off. The Chair thanked the Committee for the work under taken.</p> <p>The Committee APPROVED the report.</p>
CF/19/42	<p>BIDS TO CHARITABLE FUNDS (FOR APPROVAL)</p> <p>The Committee discussed the following Bids seeking approval from Charitable Funds:</p> <p>1. Bronllys Dining Room refurbishment</p> <p>This is a new bid to update and improve the existing Bronllys Dining Room which has not had equipment updated since the 1970s. Tony Thomas was very supportive of the scheme and idea. However he did have concerns over whether this should be funded by the Core fund and not a charitable fund, through the usual budget run process, being the responsibility of the health board and not the charity.</p> <p>Julie Rowles explained that refurbishment would not happen if core funding were to be relied on. It would not be prioritised under those circumstances but is recognised that investment would improve the space; creating a more serviceable area for refreshments for staff and visitors, and as a staff and visitor well-being area. It was commented that health and safety considerations may mean that a bid could be put in for core funding, but utilising the space can form part of charity funding as it would benefit both staff and visitors.</p>

	<p>It was DISCUSSED that the same principle could apply to other dining rooms within the Health Board, but as Bronllys is larger than others, it would be used as a pilot.</p> <p>Trish Buchan commented that as a visitor it is inconvenient and at times difficult having to travel off site to find refreshments and a quiet comfortable space. The site would benefit from the fund, and is needed for visitors and patients. Trish Buchan did query whether it complies with the terms of charity (deed of trust), but is in favour.</p> <p>Owen James queried if it were a statutory function to have a staff and visitor dining room. Julie Rowles responded that it was not statutory function. Owen James agreed that this however would be an enhancement.</p> <p>Katrina Rowlands supports the enhancement of the environment for the health and wellbeing of staff and visitors, and commented that this would create a suitable environment.</p> <p>Mark Taylor supports this bid, but queried whether this would be a similar bid to those made by the Estates and Facilities Directorate to refresh and improve facilities over site. It was commented that the health board should advertise what has been done, with strong signage and directions to facilities on site. If the Estates bid is successful, would this be an add-on and would it be possible to lever in some more money for these schemes. It was thought that perhaps Facilities however was not included in the specification from Estates.</p> <p>Owen James also commented on the lack of signage to advertise the facilities. Julie Rowles mentioned the improved menu from the dining room, but commented that signage was not included in the bid cost. This can be picked up with Wayne Tannahill (Head of Estates and Property).</p> <p>Pete Hopgood supports the bid.</p> <p>Owen James remarked that the outside looks shabby and queried why this had also not been included in the bid. Julie Rowles will check to see if external refurbishment in the form of painting will be included in the price.</p> <p>Action: Director of Workforce & Organisational Development</p>
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Mark Taylor asked about how accessible the dining room was for those with accessibility needs. Julie Rowles commented that there is a ramp.

Tony Thomas asked for clarification over VAT as the rules for charity are different. Sarah Pritchard responded that some VAT may be able to be reclaimed which may change the figure. It was AGREED that a discretion was to be added to the minutes to state that the figure can be amended when VAT has been determined. Julie Rowles commented that full procurement may reduce the cost as well.

Action: Head of Financial Services

Sarah Pritchard feels that this bid may meet the criteria of the South and Mid Legacy which stands at £875,000.

Julie Rowles commented that if the refurbishment at Bronllys is a success, other sites may also require updating. It was AGREED that usage will be monitored over the next 12 months to determine how successful the refurbishment has been before updating other sites.

The committee APPROVED the bid.

2. Step into Health; Armed Forces to Civilian Recruitment Transition and Recruitment Branding.

This is a national campaign to recruit Armed Forces leavers into roles at the Health Board. Mark Taylor queried that on page 11, there appeared to be a typing error regarding the number of jobs advertised. It should read 62 vacancies per month.

Action: Director of Workforce & Organisational Development

Trish Buchan asked whether these posts are available across the Health Board and if they are an accurate indication of the number of roles. Julie Rowles commented that you may for example, have 5 posts per nursing vacancy to be filled Health Board wide.

It was NOTED that staff managing the system would be dealing with the whole process of "Stepping into Health"

from responding to queries during live chats, managing the media site and any walks ins.

Trish Buchan enquired about what proportion of the army come through to Brecon. Julie Rowles commented that it was difficult to quantify as this would be open to army, navy and RAF leavers.

Tony Thomas asked if the armed forces champion for the health board (Mel Davies – Vice Chair) has input into this. It was commented that Stuart Bourne is the executive lead and leads the group that the Vice Chair sits on, so the assumption is that the Lead and Forces Champion would be aware.

The Committee APPROVED the bid.

3. Institute of Psychosexual Medicine Diploma and Training

The Committee were asked to consider the bid to train 2 current practitioners to IPM diploma level, within the Powys Sexual Health Team to meet the demand of current referrals as part of a recommendation from NHS choices. This is along with 4 practitioners in Mental Health Services to early support level. Trish Buchan asked if this was part of core training and in terms of sustainability if people will be back funded to access the course. Katrina Rowlands commented that this is an enhancement of a particular role and not a basic requirement. Backfill is provided for training, but there is no mention of backfill on this occasion, Katrina will check this.

Action: Director of Nursing

Rani Mallison commented that this forms part of the sexual health programme. The Committee AGREED that this item is to come back to be looked at under strategic context.

Action: Board Secretary

Mark Taylor queried why this came to committee. It was commented that it had been approved but not delegated to a specific charity. Powys general purpose fund doesn't have a charitable fund associated that could be used as a local fund in this area. The Charitable Funds Committee therefore makes the decision on this.

	<p>Rani Mallison and Owen James discussed looking at the scheme of delegation. Trish Buchan mentioned that there are some areas where investors are not always keen to invest in, and sexual health is unfortunately one area.</p> <p>Katrina Rowlands queried what the expectation was for this. Rani Mallison explained that this is succession planning and is to be supported through core funding with a supporting executive paper. Katrina Rowlands would like to get more clarity and will pick this up outside of the meeting.</p> <p>Action: Director of Nursing / Board Secretary</p> <p>The Committee AGREED the bid – however it will return to this item in future if it is appropriate.</p>
CF/19/43	<p>EXPENDITURE APPROVED UNDER DELEGATED AUTHORITY SINCE THE LAST MEETING (FOR RATIFICATION)</p> <p>The Committee received an update from Sarah Pritchard, detailing expenditure approved by those with relevant delegations during May to September 2019, with a combined value of £69,414.</p> <ul style="list-style-type: none"> a) The South and Mid Community Legacy – Rhiannon Jones as previous Director of Nursing approved the Healthy Start initiative within a local primary school to provide outdoor gym equipment. b) Additional funding for the Garden Area of Brecon Hospital for patients – Approved in July, this was agreed outside of this Committee. <p>There was a discussion on the possible upgrading of clock faces to make them more readable.</p> <p>Trish Buchan is pleased to see the butterfly symbol badges still in circulation 5 years after the initial launch.</p> <ul style="list-style-type: none"> c) Katrina Rowlands queried justification for the purchase of the MSc in Diabetes under Items Approved in August 2019 PADR development. The Committee discussed that the MSc should have come from core funding and not charity. Sarah Pritchard explained that the MSc was supported by clinical authorisation and approved for charitable funds with the justification being that upskilling a member of staff would enhance services. Owen James commented that this should be part of wider plan and not just for enhancement. If this

	<p>was needed in order to do the role it should come from core. Mark Taylor asked if there are there conditions attached for the person being trained. It was expressed that staff may complete the training and then leave the organisation. Are there any measures in place to prevent this from happening, or for the individual to have to pay back the money if they left within a certain time frame? Julie Rowles commented that this had been considered previously in general but not put into practice. For this item, paying for the service is an opportunity to reinvest the money into training as the service provider who previously provided training has now changed and there is scope for going out to tender, which may save money.</p> <p>d) There was a discussion regarding the nebulizers approved in July and whether the funding for these should have come from core and not charity funds. Owen James commented that a judgement is made on the initial purchase of equipment falling under core funding, then any additional items purchased are seen as enhancements to services.</p> <p>The Committee RATIFIED the expenditure approved under delegated authority.</p>
ITEMS FOR INFORMATION	
CF/19/44	<p>CHARITABLE FUNDS INCOME REPORT</p> <p>The Committee RECEIVED the report, which provides an update on Income received for the period 1st June to 30th September 2019.</p> <p>During June 2019 the THB received a legacy payment of £67,457.78 for Breconshire War Memorial Hospital with no conditions stated on its intended use.</p> <p>It was commented that perhaps the car park would benefit from some of the money.</p>
CF/19/45	<p>CHARITABLE FUNDS INVESTMENT REPORT</p> <p>The Committee RECEIVED the Investment Fund Performance Quarterly Report for their information.</p>

	<p>It was commented that CCLA used to report but PTHB didn't see those reports. Brewin Dolphin will formally report to PTHB and provide a presence at Committees where required.</p> <p>Owen James asked if the committee felt that Brewin Dolphin attendance at the meeting in December would be too early. It was AGREED that Brewin Dolphin would be invited to a meeting towards the end of the financial year as our focus needs to be on items other than the investment report.</p> <p>Action: Interim Board Secretary</p>
CF/19/46	<p>ANY OTHER URGENT BUSINESS</p> <p>As AGREED members revisited item CF/19/27 a) Waste Management Recycling bins documented under section CF/19/40.</p> <p>It was AGREED that this needed refocus, rewording and Chair's action. Sarah Pritchard provided a summary of the report. There was a suggestion for joint funding for the recycling initiative with the comments made that Core funding could pick up the cost of clinical and back office waste and Charity Funds could be used for waste management in public areas. Pete Hopgood commented that there is a match funding process.</p> <p>The Committee AGREED that this should be included in the Board session on environmental sustainability.</p> <p>Action: Interim Board Secretary</p> <p>Tony Thomas discussed the approach of Powys County Council in particular the statutory responsibility and annual targets, and queried what liaison PTHB had undertaken with Powys County Council. Julie Rowles explained that Powys County Council provides the contract, but recycling is segregated from the general waste, with a separate arrangement for clinical waste.</p> <p>Tony Thomas asked if there was an offer from Powys County Council to support a full approach for all types of waste. Julie Rowles responded that this could be built into the contract when it goes out to tender. It was AGREED that a paper will go out to the Executive Team outlining these issues.</p> <p>Action: Interim Board Secretary</p> <p>Tony Thomas then went on to ask if Powys County Council could financially support this, and queried whether this would raise the cost. There was an expectation of liaison for this.</p>

Julie Rowles would need to check if this conversation included the impact that may have.

Action: Director of Workforce & Organisational Development

Owen James had spoken to Steven Bromley. He was under the impression that waste was separately sorted. Julie Rowles thought that black bags went to landfill, but were not sorted prior to that.

Trish Buchan agreed to the importance of segregating waste and recycling but assumed the Health Board was already removing plastic cups and single use items. A recent Freedom Of Information request was received by all health boards in Wales regarding this. Rani Mallison commented that following the Board Development session, there is a greater focus on sustainability. Over time the strategic approach will come forward as part of an action plan.

Mark Taylor asked what the committee gets for its money as the bills are not itemised. He also asked strategically what would happen if the realised cost is greater to maintain the recycling service than the cost of recycling. Would the council charge more? Julie Rowles responded that there would be no additional cost for PTHB as there would be no additional staff time noted.

Tony Thomas felt that the tender will be difficult. There is a risk of a possible increase in cost.

Mark Taylor queried what would happen if too many items/bins were purchased and stored but not then used. Julie Rowles confirmed that the Health Board would only order what was needed with no additional orders. Mark Taylor also queried whether the County Council has considered that additional resources would be needed for the operational process. Julie Rowles agreed to check for any additional costs for the operational process, and to pull off a framework, perhaps from another organisation.

Action: Director of Workforce & Organisational Development

The committee AGREED to support the one off purchase of bins with any associated costs to be picked up by the IMTP sustainability section, on the condition that there is no additional cost from Powys County Council in terms of replacements. It was commented that PTHB should raise the

	<p>issue of reducing waste for cost saving purposes with Powys County Council.</p> <p>Before the procurement is agreed, the board will need to decide on the strategic approach.</p>
CF/19/47	<p>DATE OF NEXT MEETING</p> <p>Thursday, 5 December 2019 at 2.00pm.</p>



AGENDA ITEM: 3.2b

BOARD MEETING		DATE OF MEETING: 27 May 2020	
Subject :	SUMMARY OF JOINT COMMITTEE ACTIVITY		
Approved and Presented by:	Carol Shillabeer, Chief Executive		
Prepared by:	Corporate Governance Manager		
Considered by Executive Committee on:	Not before paper submitted to the Board		
Other Committees and meetings considered at:	Information contained in the papers appended to this report have been considered by the relevant joint committees.		
PURPOSE:			
<p>The purpose of this report is to provide an update to the Board in respect of the matters discussed and agreed at recent meetings of the Joint Committees of the Board</p> <ul style="list-style-type: none">▪ Welsh Health Specialised Services Committee (WHSSC);▪ Emergency Ambulance Service Committee (EASC); and▪ NHS Wales Shared Services Partnership Committee (NWSSPC). <p>It also provides an update in respect of the Mid Wales Joint Committee for Health and Social Care (MWJC).</p>			
RECOMMENDATION(S):			
<p>It is recommended that the Board:</p> <ul style="list-style-type: none">▪ NOTES the updates contained in this report in respect of the matters discussed and agreed at recent Joint Committee meetings.			
Approval/Ratification/Decision	Discussion	Information	
x	✓	x	

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	✓
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	✓
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

EXECUTIVE SUMMARY:

This report provides an update of the recent activities of the three Joint Committees of the PTHB Board:

- Welsh Health Specialised Services Committee (WHSSC);
- Emergency Ambulance Service Committee (EASC);
- NHS Wales Shared Services Partnership (NWSSP).

DETAILED BACKGROUND AND ASSESSMENT:

Welsh Health Specialised Services Committee (WHSSC)

The Welsh Health Specialised Services Committee held a meeting on the 10th March 2020 and a virtual meeting on 12th May 2020. The papers for the meeting are available at:

<http://www.whssc.wales.nhs.uk/2019-20-whssc-joint-committee>

and

<http://www.whssc.wales.nhs.uk/2020-21-whssc-joint-committee>

The WHSSC Committee Chair's Report for the meeting held on 10th March 2020 is attached at **Item 4.2bi**.

Patterson, Liz
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THE WHSSC Committee Chairs Report for the meeting held on 12 May 2020 is attached at **Item 4.2bii.**

Emergency Ambulance Services Joint Committee (EASC)

The Emergency Ambulance Services Committee held its latest public meeting on 10th March 2020. The papers for the meeting are available at:

<http://www.wales.nhs.uk/easc/committee-meetings>

The EASC Committee met on 12 May 2020 by skype and the Chairs Report for that meeting is attached at **Item 4.2biii.**

NHS Wales Shared Services Partnership Committee (NWSSP)

NWSSP held its last meeting on 16 January 2020 reported to the March 2020 Board. There are no further meetings publicised.

Mid Wales Joint Committee for Health and Social Care

The meeting scheduled for 23 March 2020 was cancelled. The next meeting is listed for 29th June 2020.

NEXT STEPS:

Updates will continue to be brought to each scheduled meeting the Board.

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WELSH HEALTH SPECIALISED SERVICES COMMITTEE JOINT COMMITTEE MEETING – MARCH 2020

The Welsh Health Specialised Services Committee held its latest public meeting on 10 March 2020. This briefing sets out the key areas of discussion and aims to ensure everyone is kept up to date with what is happening in Welsh Health Specialised Services.

The papers for the meeting are available at:

<http://www.whssc.wales.nhs.uk/2019-20-whssc-joint-committee>

Action log & matters arising

Members noted the action log.

Chair's Report

The Chair reported that Kieron Donovan had been appointed as Chair of the Welsh Renal Clinical Network for three years commencing 1 April 2020. The Chair also reported that she would be asking Emrys Elias to become Vice Chair of the WHSSC Joint Committee with immediate effect.

Managing Director's Report

Members noted the content of the Managing Director's report and, in particular, the key recommendations set out in guidance issued by the Society of Cardiothoracic Surgeons on the management of thoracic trauma that would be reflected in both the Thoracic Surgery and Major Trauma Service Specifications that were due to go out to consultation.

Major Trauma Commissioning Assurance and Governance Arrangements

Members received a report providing a description of the proposed commissioning governance structure and interfaces with operational delivery for the South Wales Trauma Network.

Members noted the information presented within the report; and approved the proposed commissioning governance structure for the South Wales Trauma Network subject to a review at 12 months.

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Value Based Commissioning Plan

Members received a report advising them of the efficiency savings achieved in 2019-20, describing the approach and process WHSSC followed to develop the value based commissioning plan 2020-23 and outlining the priority initiatives within the value based commissioning plan identified for 2020-21 and how these initiatives would provide value to patients, families and the health service.

Members discussed the possibility of expanding the Plan to look at entire pathways and agreed that seeking patient input would be important and would influence the direction of travel of the work. To that end it was noted that the WHSSC QA team was supporting the process and developing Patient Reported Outcome Measures and Patient Reported Experience Measures.

Members:

- Noted the efficiency savings achieved in 2019-20;
- Noted the efficiency savings already incorporated within the ICP 2020-23;
- Noted the approach and process WHSSC has followed to develop the value based commissioning plan 2020-23;
- Noted that at this point only provisional highly prudent values have been assigned to these schemes pending further detailed examination by the WHSSC team;
- Supported the priority value based commissioning initiatives identified for implementation in 2020-21; and
- Supported that the WHSSC team progress enabling actions including necessary contracting changes via the Finance Sub Group.

Neonatal Transport Review Recommendations

Members received a report setting out the key recommendations from the Review of the South Wales Neonatal Transport Service and seeking support for the implementation process to commission a permanent 24 hour neonatal transport service.

Members:

- Noted the Independent Review of the South Wales Neonatal Services; and
- Supported the recommendations made by Management Group at the extraordinary meeting on 27 February 2020 (Appendix 2).

Specifically, members:

- Supported the requirement for a 24/7 neonatal transport service for south and west Wales, noting that residents from the BCU Health population already have a 24/7 service;
- Supported Management Group recommendations that the future model will be commissioned from a lead provider;

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- Supported the establishment of a Task and Finish Group to develop a service specification for the service and implementation process for a 24/7 model;
- Supported further work to be undertaken by the Finance Sub Group to define and clearly set out the funding of the clinical components of a 24 hours service on the principle will be that the commissioning of a 24 hour service will not de-stabilise the current neonatal intensive care units;
- Supported the request that in parallel, the Maternity and Neonatal Network undertake demand and capacity modelling of both the number of maternity beds and cots required across the region; and
- Approved delegated authority to Management Group to agree an interim solution on the basis that this will be within the resource identified within the 2020/21 Integrated Commissioning Plan (ICP).

Annual Cycle of Business

Members received a report providing them with the Draft Joint Committee Annual Business Cycle 2020-21.

Members noted and supported the content of the report, including the schedule of meetings for 2020-21.

Other reports

Members received the Integrated Performance Report for December 2019 and the Financial Performance Report for Month 10 of 2019-20.

Members also received the update reports from the following joint sub committees and advisory groups:

- Management Group; and
- All Wales Individual Patient Funding Request Panel.



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WELSH HEALTH SPECIALISED SERVICES COMMITTEE JOINT COMMITTEE MEETING – MAY 2020

The Welsh Health Specialised Services Committee held its latest public meeting on 12 May 2020 with a 'consent agenda', as described on the WHSSC website. This briefing sets out the key areas of consideration and aims to ensure everyone is kept up to date with what is happening in Welsh Health Specialised Services.

The papers for the meeting are available at:

<http://www.whssc.wales.nhs.uk/2020-21-whssc-joint-committee>

Minutes of Previous Meeting

The minutes of the meeting of 10 March 2020 were taken as read and approved.

Action log & matters arising

Members noted there were no outstanding actions or matters arising.

Chair's Report

The Chair's Report, including approval of appointment of the Vice Chair and ratification of two Chair's Actions, was taken as read.

Managing Director's Report

The Managing Director's report, including updates on the South Wales Major Trauma Network and ATMPs, was taken as read.

Commissioning Welsh Independent Sector Hospitals Capacity

A paper providing an update on the progress in commissioning Welsh independent sector hospitals capacity on behalf of Health Boards for the period of the COVID-19 situation was taken as read.

Commissioning Specialised Services during the COVID-19 Pandemic

The Director of Planning summarised a paper providing a description of the proposed WHSS Team approach to commissioning specialised services during the next phase of the COVID-19 pandemic that reflected the approach of the Welsh Government Framework for Recovery; Leading

Wales Out of the Coronavirus Pandemic, the joint CMO/CNO Framework of Ethical Values and Principles for Healthcare Delivery as well as the output of the CEO group provided to the NHS CEO. Members acknowledged that even the delivery of essential services would need to recognise a balance of risk for patients, where the risk of harm arising from COVID-19 infection would need to be understood and taken into account by all parties when taking decisions on clinical treatment. The proposed approach received support from members.

Adult Thoracic Surgery for South Wales – Consultant Workforce Cover for the Major Trauma Centre – Detail of Joint Committee Decisions

A paper providing the detail of the decisions made at the July 2019 Joint Committee meeting regarding thoracic surgery consultant workforce cover for the major trauma centre and clarifying the agreed handling of the expected Society of Cardiothoracic Surgery Guidelines on the management of thoracic trauma was taken as read.

WHSSC Corporate Risk and Assurance Framework

A paper providing an update on the WHSSC risk management framework as at 29 February 2020 and the approach being taken to risk management during the COVID-19 pandemic was taken as read.

Financial Performance Report – Month 12 2019/20

A paper that set out the financial position for WHSSC for the 12th month of 2019-20, including a reported under spend of £6.5m for the year, was taken as read.

Other reports

Members also took as read the update reports from the following joint sub committees and advisory groups:

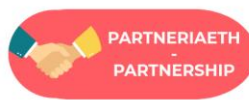
- Management Group;
- Integrated Governance Committee;
- Quality & Patient Safety Committee;
- All Wales Individual Patient Funding Request Panel; and
- Welsh Renal Clinical Network Board.



Tim Gwasanaethau Iechyd
Arbenigol Cymru
Welsh Health Specialised
Services Team



PARCH
RESPECT



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WALES

Pwyllgor Gwasanaethau
Ambiwlans Brys
Emergency Ambulance
Services Committee

Reporting Committee	Emergency Ambulance Services Committee
Chaired by	Chris Turner
Lead Executive Directors	Health Board Chief Executives
Author and contact details.	Gwenan.roberts@wales.nhs.uk
Date of last meeting	12 May2020

Summary of key matters including achievements and progress considered by the Committee and any related decisions made.

An electronic link to the papers considered by the EAS Joint Committee is provided via the following link: <http://www.wales.nhs.uk/easc/may-2020>

Chris Turner (Chair), welcomed Members to the first virtual meeting (using the Skype platform) of the Emergency Ambulance Services Committee.

Prior to the presentation of the provider report, the Chair formally thanked Jason Killens and all of the staff at WAST for their excellent response to the Covid 19 Pandemic.

The Chair also thanked the Chief Executives of health boards and their staff for their exceptional work and commitment in responding so well to the unprecedented situation. Members expressed their sincere sympathies and condolences to the families, friends and colleagues at WAST and those in the wider health service who had died during the time of this pandemic.

CHIEF AMBULANCE SERVICES COMMISSIONER'S REPORT

Stephen Harrhy presented an update on the following areas:

- **Year End Accounts** – Members noted that the draft year end accounts had been received and there were no problems or risks anticipated with finalising and submitting to the Audit and Risk Committee at Cwm Taf Morgannwg UHB in June 2020.
- **Ministerial Ambulance Availability Task Force** – Members noted that the plans for the Taskforce were currently on hold and the Minister had been informed. Consideration would be given when the work would formally recommence.
- **Annual Governance Statement** – Members noted that this was in the drafting stage and would be submitted to the Audit and Risk Committee at Cwm Taf Morgannwg in June 2020.
- **Emergency Medical Retrieval and Transfer Service (EMRTS)** – Members noted the work to develop the commissioning framework and the work to develop 24/7 working. The EMRTS Delivery Assurance Group would discuss and develop detailed operational plans for approval at a future Committee meeting.
- **EASC Integrated Medium Term Plan (IMTP)** – Members noted that a letter of support had been received from the Welsh Government for the EASC IMTP although the planning processes were now on hold.

- **Co-Chair Task and Finish Group** – Members were reminded that the CASC had been asked to work with the fire and rescue service; this work had been put on hold. Further information would be shared when available.
- **Ambulance Quality Indicators (AQIs)** – Members noted that performance targets were on hold, although data continued to be collected; Stats Wales had paused the publication of the AQIs.
- **Meetings with WAST** – Members noted that the CASC had a weekly meetings with the Chief Executive of WAST. A Quality and Delivery meeting was held last week and the CASC reported that progress was being made.
- **EASC Management Group** - Members noted that the Group would recommence shortly and would work on developing the 'new normal' in line with the requirements of the operating framework.
- **Covid response** – Members noted that the CASC and the EASC teams had continued to work closely with WAST and commended the positive way in which the WAST Executive Team and all of the staff had responded to the pandemic. Members noted that in terms of the additional expenditure related to the pandemic response, this was being monitored and this would not be the responsibility of health boards to fund. Members noted that the importance of the revised financial plan and clarification of the additional expenditure incurred by WAST.

PROVIDER ISSUES

The update report from the Welsh Ambulance Services NHS Trust (WAST) was received and in presenting the report Jason Killens highlighted key areas which included:

Pandemic and response

- Members noted that the team at WAST had aimed to double their capacity across key operational areas. Areas highlighted included
 - the 111 service which had seen a 350% increase in the number of calls received, additional staff had been recruited and the online symptom checker was operational.
 - More call handling capacity had been developed in Swansea and Cwmbran (2) with the potential to open an area in North Wales if required. This approach allowed safe working practices, conforming to social distancing rules, to operate in call centres.
 - The surge in activity over the most recent weekend which saw the highest peak in activity over the last 3 months.
 - 999: capacity had been doubled.
 - Emergency Medical Services: the limiting factor was the availability of vehicles.
 - Workforce issues: weekly overtime had doubled, support had been received from the military and underlying sickness absence had reduced.
 - Performance: good outturn performance at over 65% across Wales in April and also expected in May.
 - Non-emergency patient transport services had been maintained for renal and oncology patients.

Activity and performance

- Amber performance had improved from the beginning of the financial year, activity reduced, production and lost hours had all contributed which was the best position for a number of years.

Demand and Capacity Review - Implementation progress

Overview of the work to date was provided which included:

- Members noted that WAST had also retained this review as priority work during the Covid 19 pandemic response.
- Aim to recruit a net additional 136 WTE staff and the majority would be emergency medical technicians (EMT).
- Undertaken virtual recruitment events and virtual online training courses.
- Had already secured 40.28 WTE staff required and were also aiming to over-recruit the numbers of paramedics due to some slippage in the programme.
- Members noted that the Demand and Capacity Review was undertaken across NHS Wales and did not include the anticipated changes as a result of the Grange University Hospital opening.
- Members noted that other developments and plans were on hold (apart from the work with the Grange Hospital).

Non-Emergency Patient Transport Service (NEPTS)

- Members noted that work was continuing to improve the national booking process.
- The Demand and Capacity Review of NEPTS had now been reconvened and was being managed through the NEPTS Delivery Assurance Group.

WAST Integrated Medium Term Plan (IMTP)

- Members noted that the WAST Board had approved the IMTP and a letter in support had been sent by the CASC although the planning processes had been put on hold by the Welsh Government.
- Members noted that WAST would respond to the new operating framework and intended to submit on 18 May.

Regional Escalation

- Members noted that this process had been disrupted due to the response required for the Covid 19 pandemic.
- The WAST team suggested that it would need to continue to refine plans for the previously agreed revised regional escalation process in the future to weave in learning and management of activity due to the impact of the pandemic.

In receiving and noting the WAST provider report Members highlighted:

- The excellent progress made with the recruitment of staff and asked whether health boards also searching for additional staff had impacted on WAST. A further opportunity to discuss recruitment, for example of paramedics, across NHS Wales would be considered.
- Performance issues - in terms of the improving trend but also of the variation in performance across Wales.
- The Amber performance was positive.
- Further discussions would need to take place in relation to how the extra resources (136WTE staff) would be deployed.
- The additional capacity in the transfer and discharge service and plans for the medium and long term which was encouraging.
- The impact on WAST staff during the pandemic and the challenges faced; Jason Killens explained that efforts were being made to capture the learning and not lose the agile way in which staff were responding.

- Matters relating to personal protective equipment (PPE) and the impact in relation to the time taken to respond to incidents. The issue remained on aerosol generating procedures and cardiac arrest in relation to the type of PPE used.
- Additional information was sought regarding performance and the possibility that due to the reduction in demand coupled with increased production that this would impact more on red performance.
- The evaluation of winter was raised and the work to do in planning for the next winter period alongside the Covid 19 impact. It was suggested and agreed that it would be helpful to undertake more planning than normal to ensure the NHS would be able to respond effectively. Members noted that WAST would increase the ambulance fleet by 100 new vehicles but would retain the older vehicles for an additional 12 months to ensure a contingency for the fleet.
- Additional staff were also trained and available such as the Fire and Rescue service staff. The impact of the winter in the Southern Hemisphere would also be monitored and WAST were keen to work closely with Health Boards in taking this work forward.

Key risks and issues/matters of concern and any mitigating actions

- Handover delays and red performance
- WAST staff recruitment

Matters requiring Board level consideration and/or approval

-

Forward Work Programme

Considered and agreed by the Committee.

Committee minutes submitted	Yes	✓	No	
Date of next meeting	14 July 2020			

Patterson, Liz
05/26/2020 17:09:13

AGENDA ITEM: 3.3

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	SUMMARY OF PARTNERSHIP BOARD ACTIVITY	
Approved and Presented by:	Carol Shillabeer, Chief Executive	
Prepared by:	Corporate Governance Manager	
Considered by Executive Committee on:	Not before paper submitted to the Board	
Other Committees and meetings considered at:	Information contained in the papers appended to this report have been considered by the relevant partnership board.	

PURPOSE:

The purpose of this report is to provide an update to the Board in respect of the matters discussed and agreed at recent partnership board meetings, including the following:

- Powys Public Services Board (PSB);
- Regional Partnership Board (RPB);
- Joint Partnership Board (JPB).

RECOMMENDATION(S):

It is recommended that the Board DISCUSSES and NOTES the updates contained in this report in respect of the matters discussed and agreed at recent partnership board meetings.

Ratification	Discussion	Information
✗	✓	✗

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	✓
	2. Provide Early Help and Support	✓
	3. Tackle the Big Four	✓
	4. Enable Joined up Care	✓
	5. Develop Workforce Futures	✓
	6. Promote Innovative Environments	✓
	7. Put Digital First	✓
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	✓
	2. Safe Care	✓
	3. Effective Care	✓
	4. Dignified Care	✓
	5. Timely Care	✓
	6. Individual Care	✓
	7. Staff and Resources	✓
	8. Governance, Leadership & Accountability	✓

BACKGROUND:

Powys Teaching Health Board is a member of the following partnership boards:

- The Powys Public Services Board (PSB): established by the Well-being of Future Generations (Wales) Act 2015. Its role is to improve the economic, social, environmental and cultural well-being of Powys through better joint working across all public services. This includes a yearly review of the Powys Wellbeing Plan to show progress.
- The Powys Regional Partnership Board (RPB): established under the Social Services and Well-being (Wales) Act 2014, which came into force in April 2016. Its key role is to identify key areas of improvement for care and support services in Powys and to identify opportunity for integration between Social Care and Health.
- The Joint Partnership Board (JPB): established under The National Health Service Bodies and Local Authorities Partnership Arrangements (Wales) Regulations 2000 (S.I. 2000/2993 (W.193)) made under section 33 of the NHS (Wales) Act 2006. JPB brings together County Council and Powys Teaching Health Board to provide strategic leadership to ensure effective partnership working across organisations within the county for the benefit of Powys' citizens.

This report provides an update in relation to the work of these Partnership Boards, and draws Board's attention to the following issues.

DETAILED BACKGROUND AND ASSESSMENT:

The COVID-19 pandemic has impacted on partnership meetings. The current position is outlined below:

Powys Public Services Board (PPSB)

The meeting of PPSB listed for the 19 March 2020 was postponed due to COVID-19. A new date for this meeting has yet to be arranged.

Regional Partnership Board (RPB)

The RPB was due to meet on 20th April 2020. The meeting was cancelled due to COVID-19 and a new date for this meeting is being sought.

Joint Partnership Board (JPB)

The next meeting of the JPB originally planned for May 2020 is now due to be held on 16th June 2020.

NEXT STEPS:

Updates will continue to be brought to the Board and where necessary, specific decision making matters will be scheduled.

Patterson, Liz
05/26/2020 17:09:11

AGENDA ITEM: 3.4

BOARD MEETING		DATE OF MEETING: 27 May 2020
Subject :	SUMMARY OF ACTIVITY OF THE BOARD'S ADVISORY FORA	
Approved and Presented by:	Board Secretary	
Prepared by:	Corporate Governance Manager	
Other Committees and meetings considered at:	Not presented at any other meeting	

PURPOSE:

The purpose of this report is to provide the Board with an update on the work of the Board's Advisory Groups:

- Local Partnership Forum
- Stakeholder Reference Group
- Healthcare Professionals Forum

RECOMMENDATION(S):

It is recommended that the Board RECEIVES and DISCUSSES the update report appended to this report.

Approval/Ratification/Decision	Discussion	Information
x	✓	x

Patterson, Liz
05/26/2020 17:09:13

THE PAPER IS ALIGNED TO THE DELIVERY OF THE FOLLOWING STRATEGIC OBJECTIVE(S) AND HEALTH AND CARE STANDARD(S):

Strategic Objectives:	1. Focus on Wellbeing	
	2. Provide Early Help and Support	
	3. Tackle the Big Four	
	4. Enable Joined up Care	
	5. Develop Workforce Futures	
	6. Promote Innovative Environments	
	7. Put Digital First	
	8. Transforming in Partnership	✓
Health and Care Standards:	1. Staying Healthy	
	2. Safe Care	
	3. Effective Care	
	4. Dignified Care	
	5. Timely Care	
	6. Individual Care	
	7. Staff and Resources	
	8. Governance, Leadership & Accountability	✓

DETAILED BACKGROUND AND ASSESSMENT:

Powys Teaching Health Board has a statutory duty to take account of representations made by persons who represent the interests of the communities it serves, its officers and healthcare professionals. To help discharge this duty, a Board may be supported by Advisory Groups to provide advice to the Board in the exercise of its functions.

PTHB's Advisory Groups include a Local Partnership Forum, a Stakeholder Reference Group and a Healthcare Professionals' Forum.

- Local Partnership Forum (LPF): The LPF's role is to provide a formal mechanism where PTHB, as employer, and trade unions/professional bodies representing PTHB employees work together to improve health services for the citizens served by PTHB - achieved through a regular and timely process of consultation, negotiation and communication.
- **Stakeholder Reference Group (SRG): The SRG provides a forum to facilitate engagement and active debate amongst stakeholders from across the communities served by PTHB, with the aim of reaching and presenting a cohesive and balanced stakeholder perspective to inform PTHB's decision making.**

The SRG's role is distinctive from that of Community Health Councils (CHCs), who have a statutory role in representing the interests of patients and the public in their areas. The SRG shall represent those stakeholders who have an interest in, and whose own role and activities may be impacted by the decisions of PTHB. Membership may include community partners, provider organisations, special interest and other groups operating within Powys. It does not cover those stakeholders whose interests are represented within the remit of other Advisory Groups established by PTHB, e.g., the Healthcare Professionals' Forum and Local Partnership Forum.

- **Healthcare Professionals Forum (HPF): The HPF's role is to provide a balanced view of healthcare professional issues to advise the Board of PTHB on local strategy and delivery. It does this by facilitating engagement and debate amongst the wide range of clinical interests within PTHB's area of activity, with the aim of reaching and presenting a cohesive and balanced healthcare professional perspective to inform the Board's decision making.**

LATEST UPDATE

- **Local Partnership Forum: Arrangements for meetings of the LPF were amended as a result of the COVID-19 pandemic with formal meetings suspended and replaced by fortnightly briefings. These have been held on 17 April 2020, 1st May 2020 and 15th May 2020 with meetings planned to continue on a fortnightly basis until the end of June 2020.**
- **Stakeholder Reference Group: The SRG has not met and there has been no communication with SRG participants since the last meeting of the Board. Arrangements for the SRG are due to be reviewed during 2020/21. This timeframe for this will be kept under review as the COVID-19 pandemic progresses.**
- **Healthcare Professionals Forum (HPF): The HPF is due to be established in 2020/21, in-line with the Annual Governance Programme. This timeframe for this will be kept under review as the COVID-19 pandemic progresses.**

NEXT STEPS:

The next update will be presented to the Board in 29th June 2020.

Patterson, Liz
05/26/2020 17:09:13

Board Committees: Joint
Advisory Groups

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Board Meeting
27 May 2020
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