



Llywodraeth Cymru
Welsh Government

The NHS (Pharmaceutical Services) (Wales) Regulations 2020

Non-statutory Guidance for
Local Health Boards

Mae'r ddogfen yma hefyd ar gael yn Gymraeg.
This document is also available in Welsh.

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Executive summary

Section 82A of the National Health Service (Wales) Act 2006 (the “2006 Act”)¹ requires each local health board (LHB) to assess the pharmaceutical needs for its area and to publish a statement of its assessment and of any revised assessment. Termed a “pharmaceutical needs assessment” (PNA), the NHS (Pharmaceutical Services) (Wales) Regulations 2020 (the “2020 Regulations”) set out the minimum information that must be contained within a PNA and also outline the process that must be followed in the development of the PNA.

This guidance has been produced to assist LHBs in the development of their PNAs which must be produced under the new statutory duty set out in the 2006 Act and 2020 Regulations.

In summary, the 2020 Regulations provide:

- The definition of pharmaceutical services (regulation 2) – chapter 1
- The date by which the first PNA must be published (regulation 5) – chapter 2
- When LHBs are required to publish a subsequent assessment or supplementary statement (regulation 6) – chapters 2 and 6
- The minimum information that must be contained within a PNA (regulations 3, 4 and 8 and schedule 1) – chapter 4
- The minimum consultation process that each LHB is required to undertake during the development of its PNA (regulation 7) – chapter 5, and
- How the PNA is to be published (regulation 9) – chapter 6.

LHBs are under a statutory duty to prepare and publish a PNA. It is imperative that sufficient resources, both human and financial, are identified and that there is LHB Director-level support for the document and the process to produce it. Due to the potentially serious consequences of not following due process in developing the PNA, it is recommended that LHBs include production of the PNA in the LHB risk register. LHBs may wish to keep the PNA on the risk register once published and may wish to consider how robust and effective it is. In practice, one way of doing this is, on a regular basis, reviewing and reporting to LHB Directors the number of applications that have been determined against it, how many appeals were subsequently made, and the number of decisions made by the LHB that were upheld on appeal.

A robust PNA will have inputs from public health, commissioning and contracting, and a range of other stakeholders, as well as medicines management, to avoid the commissioning of pharmaceutical services in isolation, disconnected from other commissioning decisions.

The introduction of PNAs will also change the basis for applications to open new or additional premises. From 1 October 2021 applications for new or additional premises will be based on current or future needs that have been identified in a LHB’s PNA. These needs may be for pharmaceutical services in general or for a specific pharmaceutical service. Applications for outline consent and premises approval by doctors who wish to dispense, or dispense to new areas, will also be based on current or future needs identified in a LHB’s PNA.

Applications from existing pharmacy and dispensing appliance contractors (referred to as ‘contractors’ in this document) who wish to relocate to new premises will also be based on current or future needs identified in a LHB’s PNA. However, where a contractor needs to

¹ <http://www.legislation.gov.uk/ukpga/2006/42/contents>

relocate for business reasons, for example the demolition of premises, such applications do not have to be based on current or future needs identified in a LHB's PNA.

The "necessary or expedient test" for applications for new or additional premises has been replaced by the new market entry test whereby a LHB may grant an application only if it is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the LHB and which have been included in the LHB's PNA.

Section 83(6)(n) of the 2006 Act gives new powers to LHBs to take action where there are concerns regarding the provision of pharmaceutical services by contractors. It includes the ability for LHBs to impose sanctions such as remedial or breach notices, withholding payments and ultimately removal from a pharmaceutical list. These powers are collectively referred to in this document as "market exit".

It must be noted that these sanctions are not a means to terminate services. Their aim is to ensure consistent provision of pharmaceutical services by contractors and dispensing doctors, in compliance with their terms of service.

These sanctions do not apply to dispensing doctors. Where there are concerns around compliance with the dispensing terms of service set out in Schedule 7 (Terms of service for doctors providing pharmaceutical services) of the 2020 Regulations these are dealt with under the practice's primary medical services contract.

In summary, in relation to market exit, the 2020 Regulations provide for:

- Local dispute resolution before serving remedial notices or breach notices (regulation 49) – chapter 10
- The issuing of remedial notices (regulation 50) – chapter 11
- The issuing of breach notices (regulation 51) – chapter 12
- Payment withholdings alongside the issue of a notice (regulation 52) – chapters 11 to 13
- Removal of listings following the issuing of remedial and/or breach notices (regulation 53) – chapter 14
- Rights of appeal against LHB decisions (regulation 54) – chapter 15

Chapter 1: Introduction

The Guidance

This non-statutory guidance is a working document which accompanies publication of the 2020 Regulations. It may be subject to amendment as and when there are changes to the 2020 Regulations or associated legislation.

The primary purpose of this guidance is to help all those working in LHBs responsible for:

- publishing a PNA and subsequent revised assessments
- determining applications for new or additional and for the relocation of existing premises, and applications for outline consent and/or premises approval, and
- using the performance related sanctions.

It may also be of assistance to other stakeholders such as applicants, contractors and representative committees.

The 2020 Regulations themselves are not, in the main, set out verbatim here. In order to make the guidance easier to read the specific applicable provisions have, in most cases, been paraphrased. However all those responsible for implementing or applying the law must bear in mind that it is the law that must be complied with, not the contents of this guidance.

This document's legal status is that it is non-statutory. It is an analysis of the legislative provisions together with appropriate notes of guidance, designed to assist decision-makers. It is not an authoritative statement of the law. In practice there is no substitute for referring to the law itself or seeking professional legal advice as to what the law says and how it applies in particular circumstances. It is essential to understand that decisions must be taken in accordance with the law, and not simply based on the analysis and advice contained in this guidance (or indeed any other commentary on the law).

Furthermore, although it is hoped that LHBs will find this guidance helpful, LHBs are not obliged to take it into consideration when formulating their decisions. Their own understanding of the law is fundamentally a matter for them.

Unless otherwise indicated, a reference to a regulation in this guidance is a reference to that provision within the 2020 Regulations.

Brief background

In 2010 the then Minister for Health and Social Services established a Task and Finish Group to review the regulatory framework, to consider Welsh Government policy on “control of entry” (the process by which applications for new or additional premises are submitted and determined) and the provision of pharmaceutical services by health professions other than pharmacists (e.g. doctors). The aim of the Group was to make recommendations for changes to legislation, if appropriate, to bring about a long-term, cost effective and sustainable system which would afford patients appropriate access to pharmaceutical services.

In 2011 the Welsh Government consulted on the recommendations of the Task and Finish Group. The consultation *Proposals to reform and modernise the National Health Service (Pharmaceutical Services) Regulations 1992* sought views on proposals to deliver a new approach for determining applications to provide pharmaceutical services in Wales based more on an assessment of local needs by LHBs. However it was recognised that to make such a change required the creation and inclusion of appropriate powers in the 2006 Act.

Following the consultation, the NHS (Pharmaceutical Services) (Wales) Regulations 2013 (the “2013 Regulations”) came into force on 10 May 2013 but did not contain provisions to introduce PNAs.

The Public Health (Wales) Act 2017 (“the 2017 Act”) inserted Section 82A into the 2006 Act, which places a new duty on LHBs in Wales to prepare and publish an assessment of need for pharmaceutical services. Section 82A also gave the Welsh Ministers powers to make regulations setting out the requirements for PNAs in Wales. The 2017 Act also amended Section 83 of the 2006 Act so that regulations made in accordance with Section 83 may provide grounds for removal of a person from the pharmaceutical list that are not connected with a

person's fitness to practise (i.e. a market exit regime).

Intended effect and beneficial outcomes

The intended effect of introducing PNAs is to improve the planning and delivery of pharmaceutical services in Wales by ensuring LHBs robustly consider the pharmaceutical needs of their populations and align services more closely with them. This will require LHBs to take a more integrated approach to identifying the pharmaceutical needs of populations, including considering the contribution of all pharmaceutical services providers (e.g. pharmacies and dispensing doctors). LHBs will use these assessments to identify where:

- additional contractor premises are required;
- additional dispensing by doctors is required;
- existing providers are adequately addressing pharmaceutical needs; and
- where additional services are required from existing contractors.

The change in approach will provide contractors with increased certainty, reducing business risk and allowing them to invest in the delivery of wider services.

Importantly, contractors will also become more responsive to the needs of the populations they serve, and provide services effectively to address identified pharmaceutical needs. Where there is a lack of quality or inconsistent delivery, LHBs will be able to implement improvement measures. These could include taking action against particular contractors for persistent breaches of terms and conditions of service for example. This should result in contractors providing services more consistently and to a higher standard, and ensure that contractors provide services in locations where they are needed. These changes will also make decisions about the inclusion of new premises onto the pharmaceutical lists more transparent. Ultimately, the changes will allow for improvement in the quality and consistency of pharmaceutical services across Wales.

Legislative framework

Section 80 of the National Health Service (Wales) Act 2006 (the "2006 Act") places a duty on LHBs to make arrangements for the provision of the pharmaceutical services that are set out in subsections 80(3)(a) to (d). These core pharmaceutical services are essentially dispensing services. There is a duty on Welsh Ministers to make regulations governing the way in which LHBs make these arrangements.

Section 81 of the 2006 Act sets out arrangements that Welsh Ministers may make for the provision of additional pharmaceutical services. Additional pharmaceutical services are defined as services of a kind that do not fall within Section 80. Section 81 gives Welsh Ministers the power to give directions to a LHB:

- requiring it to arrange for the provision of additional pharmaceutical services (referred to as advanced services), or
- authorising the LHB to arrange for the provision of pharmaceutical services if it so wishes (referred to as enhanced services).

Section 83 of the 2006 Act contains the core of the Welsh Ministers' regulation making powers in relation to the provision of the pharmaceutical services and, amongst other things, sets out

the requirement for regulations to require a LHB to prepare and publish a pharmaceutical list, and sets out the tests which those persons wishing to provide pharmaceutical services must pass in order to do so (previously known as the 'control of entry test').

Section 84 sets out a requirement for Welsh Ministers to provide for rights of appeal against decisions that are made by LHBs in exercise of powers conferred upon them by regulations made under Section 83.

Part 7 of the 2017 Act made provision to amend the 2006 Act in respect of pharmaceutical services. Section 111 of the 2017 Act inserted a new Section 82A into the 2006 Act conferring powers on the Welsh Ministers to make regulations in respect of PNAs. The Public Health (Wales) Act 2017 (Commencement No.4) Order 2019 brought Part 7 of the 2017 Act into force on 1 April 2019. As a result, the Welsh Ministers may now make subordinate legislation setting out requirements for PNAs in Wales.

Part 2 of the 2020 Regulations imposes the legal requirements on LHBs to prepare and publish their PNAs.

The 2020 Regulations come into force on 1 October 2020. Once the 2020 Regulations come into force, LHBs will have until 1 October 2021 to prepare and publish their PNA.

Within the first 6 months of the 2020 Regulations coming into force, applications to be included on a pharmaceutical list may still be made under the 2013 Regulations.

However, there will be a 6 month standstill period in which health boards will be unable consider applications to open new premises or grant consent for dispensing doctors between April and October 2021. This is to enable health boards to have a 6 month window to deal with any outstanding applications made under the 2013 Regulations and to finalise and publish their first PNA.

Once the standstill comes to an end and all of the provisions of the 2020 Regulations will be in force, all applications will have to set out how they meet needs identified within that PNA.

Applications to relocate will be able to be made to health boards uninterrupted from the date on which the 2020 Regulations come into force. Between October 2020 and October 2021, such applications must be made in accordance with the 2013 Regulations' relocation provisions. From 1 October 2021, all relocation applications will need to be made in accordance with the 2020 Regulations.

Definition of pharmaceutical services

"Pharmaceutical services", are defined within the 2020 Regulations as all pharmaceutical services that fall within Section 80 and 81 of the 2006 Act, namely:

- essential services, and
- advanced and enhanced services set out in Directions made by the Welsh Government (as published in the Drug Tariff).

The following, as outlined in Regulation 10 of the 2020 Regulations, are included in a pharmaceutical list. They are:

- pharmacy contractors, and
- dispensing appliance contractors.

Dispensing doctors also provide a level of pharmaceutical services. However, only the provision of those services set out in terms of service in Schedule 7 of the 2020 Regulations fall within the legal definition of pharmaceutical services. LHBs should note, therefore, that reviews of compliance and concordance under the Dispensary Services Quality Scheme are outside the definition of pharmaceutical services. In addition other services provided by dispensing doctors which may also be provided by pharmacies, for example smoking cessation and the provision of emergency hormonal contraception (EHC) also fall outside the definition of pharmaceutical services.

Whilst provisions for “local pharmaceutical services” are included within chapters 2 and 3 of Part 7 of the 2006 Act they have not yet been enacted within regulations. If that should change then the provision of local pharmaceutical services would also fall within the definition of pharmaceutical services.

Governance

As LHBs are under a statutory duty to prepare and publish a PNA they should ensure that their PNA is signed off by their LHB Directors in the open section of a meeting. LHBs will therefore need to align with the dates of their LHB Directors meetings when planning their timeline for the development of their PNA.

When identifying who should be part of the core group that is leading on the development of the PNA, LHBs should ensure that any conflicts of interest are declared and managed appropriately.

Part 1: Pharmaceutical needs assessments

Chapter 2: Pharmaceutical needs assessments – publication/timelines

Introduction

This chapter looks at the timescales for the publication of LHBs' first PNAs and revised assessments.

First PNAs

The 2020 Regulations place LHBs under a duty to publish their first PNA by 1 October 2021 (regulation 5). In the context of this guidance and the 2020 Regulations, the “first” PNA means the first PNA developed in line with the legislative requirements and published on or before 1 October 2021.

Subsequent PNAs

Under the 2020 Regulations LHBs are under a duty to, as a minimum, publish a revised assessment within five years of their previous publication (regulation 6(1)(a)). Each time a revised assessment is produced a full consultation as provided for in regulation 7 must be undertaken. LHBs must note that it is not permitted to simply update sections on their PNA to reflect changes in data. LHBs must undertake a fair and thorough assessment of the new data and determine the implications for pharmaceutical needs in the area. The only exception to this is in relation to the map of provider locations that must be included (see chapter 4).

LHBs are able to produce a revised assessment within the five year period should they wish to coincide the publication cycle of their PNA with that of another needs assessment they are under a statutory duty to publish (regulation 6(1)(b)), for example Local Well-being Plans produced under the Well-being of Future Generations (Wales) Act 2015.

In addition, LHBs will need to consider whether they need to make a new assessment of their pharmaceutical needs after identifying changes to the availability of pharmaceutical services that may have occurred since publication of a previous PNA, where those changes are relevant to the granting of applications to open new or additional pharmacy premises (regulation 6(2)). However, where the LHB is satisfied that making a revised assessment would be a disproportionate response to those changes then it would not be required to produce a new PNA. This is an objective assessment that the LHB must make itself on a case by case basis.

Chapter 3: LHB localities

Introduction

This chapter looks at how LHBs could divide their geographic area into distinct localities for the purposes of identifying health needs and assessing service provision for commissioning purposes.

Paragraph 4(a) of Schedule 2 to the 2020 Regulations requires LHBs to set out in their PNA how they have determined the localities for their areas.

As part of developing other needs assessments LHBs may, for example, have already used electoral wards (either individually or combining two or more), super output areas (SOAs) or both, or clusters in order to reflect the particular needs of their populations.

Electoral wards are the key building block of UK administrative geography, being the spatial units used to elect local government councillors in metropolitan and non-metropolitan districts and unitary authorities.

A SOA is a way of collecting and publishing small area statistics. They are of a more consistent size than electoral wards, which can vary from just 100 residents to 30,000, and as such will better allow the needs of the population to be assessed. SOAs will not be subject to frequent boundary change, so may be more suitable for comparison over time. In addition, they will build on the existing availability of data for census output areas.

Background

Previously when considering the adequate provision of pharmaceutical services, LHBs will have used different mechanisms to divide their area.

Under the previous control of entry arrangements, LHBs will have determined applications based on “neighbourhoods”. Under the new arrangements applications will be based on current or future needs identified in the relevant PNA and therefore the concept of neighbourhoods in this context will cease to exist.

LHBs should bear in mind that the concept of neighbourhoods will **not** continue under the new legislative provisions. Therefore, the previous arrangements for determining control of entry will no longer apply. It is in any case unlikely that a LHB would wish to continue to use the concept of neighbourhoods for its whole area. Not only would this be time-consuming, it is unlikely that relevant health and demographic information is available on a neighbourhood-by-neighbourhood basis.

In addition, LHBs with rural areas will have controlled localities i.e. areas that are rural in character, and since May 2013 may have also determined “reserved locations” within some of these controlled localities. Reserved locations are a specialist determination, which allow a dispensing doctor to continue to provide dispensing services in such localities even if a pharmacy opens nearby.

Localities

Regulation 8(1)(c) of the 2020 Regulations requires LHBs to have regard to the different needs of different localities within their area. LHBs will therefore need to decide how they are going to divide their area up based on this requirement. It is unlikely that a LHB will be able to develop a PNA which does not differentiate the geographic, demographic or social characteristics of its population simply by adopting a single locality for its entire area. If a LHB believes it should do so, it will need to set out the reasons why it considers this appropriate.

Where LHBs divide their areas, they will need to determine the basis on which they do so. It is likely that the most appropriate mechanism will be to adopt the approach taken in other needs assessments. Where a LHB decides not to do so, it should explain why not.

There is no right or wrong way of determining the localities that are used for the PNA. It is suggested that localities are either determined on the consistent availability of health needs data, or on the usual planning and commissioning sub-divisions of the LHB's area e.g. clusters or networks. The PNA must provide an explanation as to why the localities have been chosen.

Ultimately, it is for the LHB to decide how to divide its area. This decision needs to be taken at an early stage, as it will fashion the development of the PNA. LHBs should bear in mind that whatever basis they adopt, it will need to be sufficient to permit future consideration of applications for market entry.

Chapter 4: Information to be contained in pharmaceutical needs assessments

Introduction

This chapter looks at the minimum requirements for PNAs as set out in Schedule 1 to the 2020 Regulations. LHBs must ensure that their PNA contains the information set out in Schedule 1 (regulation 4(1)) but they are free to include any additional information they consider pertinent to their population.

Assessment of local needs

Regulation 8(1)(b) requires LHBs to have regard to the demography of their area when undertaking a PNA. In addition, paragraph 4(b) of Schedule 1 to the 2020 Regulations requires LHBs to set out in their PNA how they have taken into account:

- the different needs of different localities in their area, and
- the different needs of members of different groups in their area who share a common attribute in respect of one, or more than one, of the protected characteristics listed in the Equality Act 2010.

Protected characteristics

The following are protected characteristics under the Equality Act 2010:

- age;
- gender;
- proposed, commenced or completed reassignment of gender;
- disability;
- race;;
- religion or belief; and
- sexual orientation.

In addition to the above the PNA will need to take into account information such as:

- deprivation;
- birth rates;
- life expectancy;
- deaths;
- household characteristics;
- car ownership; and
- economic activity.

The LHB's public health team and the Public Health Wales Observatory² are a source of up-to-date information on local health needs and their data should be considered in the production of the PNA.

² <http://www.publichealthwalesobservatory.wales.nhs.uk/home>

Ultimately, LHBs should aim to:

- gain a complete picture of the populations within their area, and how their needs differ;
- identify specific communities with particular health needs or poor health, such as travellers, migrant workers, those living in specific areas (as defined in terms of electoral wards of SOAs) or demographic data;
- enable comprehensive benchmarking against comparable populations; and
- give a clear view of needs, both met and unmet.

LHBs will need to identify the need for pharmaceutical services across the whole of a 24 hour period and on weekends, public and bank holidays.

LHBs will also need to identify any seasonal trends or variations in population, e.g. holidaymakers, visitors and temporary (holiday) caravan sites, and ensure that their needs are identified at this stage.

In addition, LHBs should look at the differing lifestyles of the population and the impact of this on the need for pharmaceutical services.

General health need is not the same as the need for pharmaceutical services and LHBs should be aware of the differences in their area between those health needs that may be met using pharmaceutical services, and those that cannot be met through the provision of pharmaceutical services.

In assessing the general health need of their population LHBs will have identified a range of needs, some of which can be met by pharmaceutical services, others that cannot. LHBs will therefore need to identify which of the general health needs can be met by pharmaceutical services and then how they wish to commission such services. Only those that can be met through pharmaceutical services should be included in the PNA.

Current provision of pharmaceutical services

In order to assess the adequacy of provision of pharmaceutical services, LHBs will need to identify and map the current provision of pharmaceutical services. The data used should be the most up-to-date available to ensure the PNA is as robust as possible.

This will include:

- pharmaceutical services provided within the LHB's area by pharmacies, dispensing appliance contractors and dispensing doctors which are necessary to meet the need for pharmaceutical services in its area (paragraph 1(a), Schedule 1);
- pharmaceutical services provided outside the LHB's area by pharmacies, dispensing appliance contractors and dispensing doctors which contribute towards meeting the need for pharmaceutical services in its area (paragraph 1(b), Schedule 1); and
- pharmaceutical services that are either provided inside or outside the LHB's area by pharmacies, dispensing appliance contractors and dispensing doctors which, whilst they aren't necessary to meet the need for pharmaceutical services, nevertheless affect the LHB's assessment of the need for pharmaceutical services in its area as they have, for

example led to improvements or better access to pharmaceutical services (paragraph 1(c), Schedule 1).

LHBs must ensure they include pharmaceutical services provided by pharmacies, dispensing doctors and dispensing appliance contractors.

In order to identify out of area providers LHBs will wish to refer to data published by Primary Care Services of the NHS Wales Shared Services Partnership³. The report “Pharmacy / Practice Dispensing Data” will allow LHBs to identify where prescriptions written by GP practices and other services within their area are dispensed whether that is by contractors in their area or elsewhere in Wales. This data is published on a monthly basis and so will need to be aggregated before being analysed.

Primary Care Services also publishes data on a monthly basis on the number of items dispensed by each contractor and the number of claims made for the provision of certain advanced and enhanced services – the “Dispensing Contractor Activity by Service” report.

It may be necessary for other information to be requested from contractors via contractor questionnaires. However, it is recommended only that information which is not already available to the LHB is requested from contractors in order to reduce the administrative burden on them. Where a LHB identifies that it requires specific information from contractors, it is recommended that they discuss this with either Community Pharmacy Wales or their Local Medical Committee (LMC) and agree a template for the collection of such information.

LHBs should analyse service provision through the 24-hour period to ensure they have adequate provision to meet patient needs, particularly if GP practices are required to extend their opening hours at evenings and weekends.

Pharmaceutical services provision by GPs

Within their PNA, LHBs will need to include information on the area or areas that their dispensing doctors have outline consent to dispense to, along with information on which premises those doctors have premises approval for.

It is suggested that LHBs either include maps of their controlled localities within their PNA or provide the web link (URL) to where they are published on the LHB’s website.

Information on the number of items dispensed by each dispensing doctor is also published by Primary Services as part of the “Dispensing Contractor Activity by Service” reports. However, it should be noted that this information will also include those items which dispensing doctors have personally administered, a service that falls outside the definition of pharmaceutical services.

Other NHS services

Having identified pharmaceutical services provided by those on a pharmaceutical list and the dispensing doctor list, LHBs will need to identify any other NHS services which affect the need for pharmaceutical services in general or for a specific pharmaceutical service (paragraph 2,

³ <http://www.primarycareservices.wales.nhs.uk/data-publications>

Schedule 1). “NHS services” is defined within regulation 2 of the 2020 Regulations as services provided as part of the health service in Wales.

These services could either:

- increase the need for pharmaceutical services because, for example, they lead to prescriptions being written which then need to be dispensed, or
- reduce the need for pharmaceutical services because, for example, they lead to a reduction in the number of prescriptions which need to be dispensed.

Other NHS services that may increase the need for pharmaceutical services include:

- services within hospitals which lead to prescriptions being written which are then dispensed within primary care rather than within the hospital pharmacy; or
- prescriptions being written by community nurses or other healthcare professionals within primary care such as dentists.

NHS services which reduce the need for pharmaceutical services may include:

- prison and hospital pharmacies;
- provision of medication by out of hours providers;
- personal administration of certain items by GP practices; and
- provision of public health services such as smoking cessation, witnessed consumption and Emergency Hormonal Contraception by other providers.

Non-NHS services

The 2020 Regulations require LHBs to have regard to the provision of pharmaceutical services and other NHS services. However, LHBs may also wish to have regard to other services that, whilst falling outside the definitions of pharmaceutical services and other NHS services, will affect the need for pharmaceutical services within their area.

One such example is the provision of services to Welsh residents by contractors in England. In order to identify prescriptions that have been dispensed in England LHBs will need to refer to data published by NHS Prescription Services of the NHS Business Services Authority⁴. The report entitled “Practice prescribing dispensing data” will allow LHBs to identify where in England their prescriptions have been dispensed and by whom. Again the data is published monthly so will need to be aggregated.

LHBs may also wish to take account of private services that may be offered by contractors, either in return for payment by the patient or at no charge. One such service may be the provision of a delivery service. However, care should be taken in placing too much weight on such services as they can be withdrawn at any point in time and cannot be contractually ensured.

Patient and public engagement

⁴ <https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/dispensing-contractors-data>

Whilst there is no specific requirement to engage with patients and the public other than as part of the 60 day consultation (see chapter 5), it is strongly recommended that this is undertaken whilst the PNA is being drafted. This will help ensure that conclusions made within the PNA are well informed.

LHBs will wish to consider seeking views of patients and the public on the following topics:

- how premises are accessed, e.g. on foot, on a bicycle, by public or private transport, and how long it takes;
- which day is, or days are, the most convenient time to access services;
- what time is, or times are, the most convenient to access services;
- what influences someone's choice of premises e.g. close to home, close to work, close to their GP practice; and
- comments on services.

Ideally engagement would be both face to face and online in order to get as representative a response as possible. Consideration should be given as to how hard-to-reach groups can be involved. LHB communications and engagement teams will be able to assist in this, as well as local authorities who will often have established methods of reaching communities.

Gaps in provision of pharmaceutical services

Having assessed local needs and the current provision of services, the LHB must then consider whether there are any gaps that need to be filled to meet a:

- current need for pharmaceutical services, or pharmaceutical services of a specified type (paragraph 3(a), Schedule 1), and/or
- need for pharmaceutical services, or pharmaceutical services of a specified type, in specified future circumstances (paragraph 3(b), Schedule 1).

It should be noted that only those needs which immediately require meeting, or will arise during the five year lifetime of the PNA, are to be included.

When considering whether there will be any future needs for pharmaceutical services, LHBs will need to take into account the following:

- changes in the demand for services – this could be as a result of population growth in general or because of a new housing development or regeneration project;
- the introduction of new pharmaceutical services;
- changes in the way that people access services – for example highways changes and projects may lead to a change in the way that people can access pharmaceutical services, either making it easier or harder for them to access current providers;
- changes in the provision of primary medical services – this could include the relocation of a GP practice or practices into new premises, and practices merging with the closure of premises;
- co-location of a range of services into new premises;
- changes over the border in a neighbouring LHB's area which affect how residents access pharmaceutical services or their need for pharmaceutical services; and
- the LHB's estates strategy (regulation 8(2)).

Examples of needs that LHBs may identify include:

- inadequate provision of essential services at certain times of the day or week;
- opening hours that do not reflect the needs of the local population;
- no provision of EHC in areas of high teenage pregnancy;
- areas with little or no access to pharmaceutical services;
- areas with high levels of smoking but no provision of smoking cessation services; and
- adequate provision of dispensing services, but patients are unable to access the wider range of essential and advanced services.

Having identified a gap in current service provision, or a gap that will arise within the five year lifetime of the PNA, LHBs will need to ensure that they clearly articulate them as current or future needs. LHBs should ensure that they state:

- what service is, or what services are, required;
- the hours that the service is, or services are, required;
- the day or days of the week on which the service is required; and
- the location for the service or services.

By clearly articulating what the need is, LHBs will be in a better position to consider applications to meet that need, and will also be better able to ensure the need is subsequently met.

Maps

LHBs are required to include a map within their PNA that identifies the premises at which pharmaceutical services and dispensing services are provided (paragraph 5, Schedule 1). This may well need to be refreshed on a regular basis to ensure it shows all premises and is as up-to-date as possible. Regulation 4(2) requires LHBs to keep the map as up-to-date as far as is practicable, and confirms that this may be done without producing an accompanying supplementary statement and without having to rewrite and consult on an amended PNA.

Due to the geographical size of LHB areas it may not be possible to identify, on a single map, each individual set of premises at which pharmaceutical services and dispensing services are provided. Consideration should therefore be given to including a series of maps at locality level which should allow individual premises identification due to the smaller geographic area covered.

Where LHBs do not already have access to mapping software to facilitate this they may find that their local authority, or one of their local authorities, can assist in the production of maps. LHBs should ensure that maps produced can be reproduced within their PNA without breaching copyright. In addition, they must be capable of being reproduced by those receiving copies of the PNA.

LHBs may wish to consider using their maps to show the services that are provided at each of the premises, and also the times at which these services are provided as this may assist in identifying any gaps that exist.

Mapping travel times can also be a useful way to identify gaps in the provision of services. A map showing how long it takes people to access premises at which pharmaceutical services in general are, or a specific service is, provided may be useful in identifying where gaps in the

provision of pharmaceutical services occur. It would then be for the LHB to determine whether in those areas where people are unable to access services within a specified time there is a need for the provision of pharmaceutical services. Local knowledge will need to be applied in order for the LHB to identify whether there is a gap in service provision or not.

Maps can also be used to identify specific health needs of a population and then layer on service provision and activity. For example, the number of smokers within a population can be over-laid with the locations of smoking cessation services to establish whether those services are best located.

When using maps to identify whether gaps exist or not LHBs will need to take into consideration the provision of pharmaceutical services over their border in neighbouring LHB areas or in England which their population may access.

Chapter 5: Consultation

Introduction

The Regulations require LHBs to consult on each new draft PNA. This is a valuable opportunity to engage with stakeholders and other interested parties on the LHB's proposals for their area. It also provides LHBs with an opportunity, if necessary, to correct any perceived issues or errors that may be identified with the PNA as part of the consultation exercise and before it is finalised.

What the legislation says

LHBs are required to undertake a 60 day consultation on a draft of their PNA (regulation 7). When LHBs are in a position to start their consultation they must:

- publish their draft PNA on the LHB's website (regulation 7(2)), and
- within 24 hours of doing so notify certain persons that it has been published and the date by which any consultation response must be provided to the LHB (regulation 7(3)).

LHBs must publish their draft PNA on their website for a minimum of 60 days.

Those persons who must be consulted on the draft PNA are:

- a) the Local Pharmaceutical Committee for Wales i.e. Community Pharmacy Wales;
- b) the Local Medical Committee (LMC) for the LHB's area (where more than one LMC covers the LHB's area then all of them must be consulted);
- c) pharmacy contractors and any dispensing appliance contractors on its pharmaceutical lists;
- d) any pilot scheme pharmacy with whom the LHB has made arrangements for the provision of any local pharmaceutical services (presently there will be no such providers as the local pharmaceutical services provisions with the 2006 Act have not been enacted);
- e) the persons on its dispensing doctors list (if it has one);
- f) any person with whom the LHB has made arrangements for the provision of dispensing services (these are persons who are providing a dispensing service under the primary medical services provisions rather than the 2020 Regulations or preceding pharmaceutical services regulations);
- g) any provider of primary medical services in its area (i.e. a GMS contractor, APMS contractor or a LHBMS practice);
- h) any Community Health Council for its area and any other group representing patients, consumers or a community in its area which in the opinion of the LHB has an interest in the provision of pharmaceutical services in its area;
- i) any Regional Partnership Board for its area;
- j) any local authority for its area;
- k) any NHS Trust in its area; and
- l) any neighbouring LHB (regulation 7(1)).

Regulation 7(4) states that if any of the persons listed above requests a copy of the draft PNA in hard copy form, the LHB must, as soon as is practicable and in any event within 14 days, supply a hard copy of the draft to that person (free of charge).

Where a neighbouring LHB (LHB2) is notified and its LMC is different to that of the LHB consulting on their PNA, then LHB2 must:

- consult their LMC before making a response to the consultation, and
- have regard to any representation received from their LMC when making its response to the consultation (regulation 7(5)).

The list of consultees contained above is not exhaustive. A LHB may consider it relevant to consult other individuals or bodies, including:

- contractors on a neighbouring LHB's pharmaceutical list;
- primary care clusters;
- NHS England and NHS Improvement, Local Pharmaceutical Committees, health and wellbeing boards and clinical commissioning groups in England; and
- other Regional Partnership Bodies.

Those to be consulted

The 60 day consultation period will provide an opportunity for interested parties to make representations in relation to the findings of the draft PNA and for the LHB to consider amendments to their assessment prior to its publication. There is no right of appeal in relation to a draft PNA or the final published assessment. Therefore, it is important that the LHB engages interested parties before and during the LHB's consultation.

It may be a consultee does not agree with the LHB's findings, based on the available evidence, to identify gaps or otherwise in the provision of pharmaceutical services. For example, the consultee may have local knowledge of the circumstances of the area which they believe has not been considered during the assessment, or of how the local population accesses services in the area under consideration. The consultation on the draft PNA is therefore an important opportunity for the LHB to consider local knowledge held by others, and to consider any factors which a consultee thinks relevant, in advance of publishing its final PNA.

LHBs may wish to provide a consultation reply form to be used by those who wish to respond to the consultation. This will allow the LHB to gain views on certain aspects of the draft PNA in a structured way, but will be flexible enough for respondents to raise issues that are of particular concern to them.

LHBs should therefore consider carefully whether any:

- conclusions reached in preparing their PNA are reasonable, proportionate and have been sufficiently evidenced; and
- comments received from consultees on the draft PNA have been addressed in the final PNA.

Paragraph 4(c) of Schedule 1 to the 2020 Regulations requires a report of the consultation to be included in the final version of the PNA. This should include a summary of the questions asked of the consultees, their responses, any changes made to the PNA as a result and, where changes haven't been made, an explanation as to why not.

It is vitally important that the process for completing a PNA is transparent.

The assessment must result in the right decision for the needs of the area's population, but it must be demonstrated that all the evidence (including consultation responses) has been considered, whether the LHB chooses to agree with it or not. Each decision within the PNA must be adequately reasoned.

Chapter 6: Publication and supplementary statements

Introduction

Once finalised, a completed PNA must be published on the LHBs website, along with any supplementary statements that are issued following publication. A supplementary statement should be issued when there is a change to the availability of pharmaceutical services.

What the legislation says

Regulation 9 of the 2020 Regulations places a duty on LHBs with regard to making their PNAs available.

LHBs must ensure that the final, signed-off PNA is available on their website in a location that can be easily found by applicants or any other party who may have an interest (regulation 9(1)(a)).

In addition, as NHS Wales Shared Services Partnership is responsible for processing changes to the pharmaceutical lists and their website currently hosts the necessary forms, LHBs may also wish to consider providing them with the web link to their PNA.

Subsequent PNAs must also be published on the LHB's website (regulation 9(1)(b)) as must any supplementary statements (regulation 9(1)(c)).

If a LHB receives a request for a hard copy of its PNA it must provide one within 14 days, free of charge (regulation 9(2)).

Supplementary statements

Regulation 6(3) makes provision for LHBs to issue supplementary statements. These should be issued where:

- there has been a change to the availability of pharmaceutical services since the publication of the PNA;
- this change is relevant to the granting of applications referred to in Section 83 of the 2006 Act (i.e. applications to open a new pharmacy, to relocate or to provide additional services); and
- the LHB is satisfied that a revised PNA would be a disproportionate response, or is already in the course of publishing its next PNA, and is satisfied that immediate modification of its PNA is essential in order to prevent detriment to the provision of pharmaceutical services in its area.

If there are changes either to the needs for pharmaceutical services or to the availability of pharmaceutical services within the five-year cycle, and those changes are relevant to market entry applications, the LHB will need to consider whether or not to go through the process of revising its PNA. However, the LHB does not need to go through that process, if to do so would be a disproportionate response to the changes. In coming to that decision on proportionality, the LHB will need to have regard to the fact that if the changes are to *needs*, the LHB will not have the option of a supplementary statement, but if the changes are to the *availability* of

services, the LHB will have that option.

Supplementary statements are simply a statement of fact, and do not make any assessment on the impact of the change on the need for pharmaceutical services.

Where a LHB publishes a supplementary statement it must notify those bodies listed in regulation 7(1) as soon as is reasonably practicable (regulation 6(4)).

Once issued, the supplementary statement becomes part of the PNA and so is to be taken into consideration when determining applications submitted under regulations 15 to 20 of the 2020 Regulations. Effectively, they are an update of what the PNA says about the availability of pharmaceutical services. They are not a vehicle for updating what the PNA says about the needs for pharmaceutical services.

If a LHB is in any doubt as to whether to issue a supplementary statement or to publish a revised PNA, it should seek legal advice.

Supplementary statements must be published on the LHB's website alongside the PNA (regulation 9(1)(c)). LHBs must ensure that whoever issues the supplementary statement has the delegated authority to do so.

The following examples suggest possible changes in circumstance which may mean a revised assessment or supplementary statement is needed, as well as the factors LHBs may want to consider in determining the appropriate course of action.

Revised PNA or supplementary statement?

Example: in its first PNA, the LHB identifies that a housing development is anticipated to commence in the second year of its PNA and that there would be a need for the provision of pharmaceutical services to the development at the point of occupation of the hundredth house. Subsequently, they are advised that the development has been delayed for four years.

In this instance, it may be disproportionate to revise the assessment in year 2, particularly as the future need is linked to a specific event namely the occupation of the hundredth house. The LHB would not issue a supplementary statement as there have been no changes to the availability of pharmaceutical services.

Example: a contractor with several outlets in the LHB area gives notice that it intends to close some, or all, of these outlets.

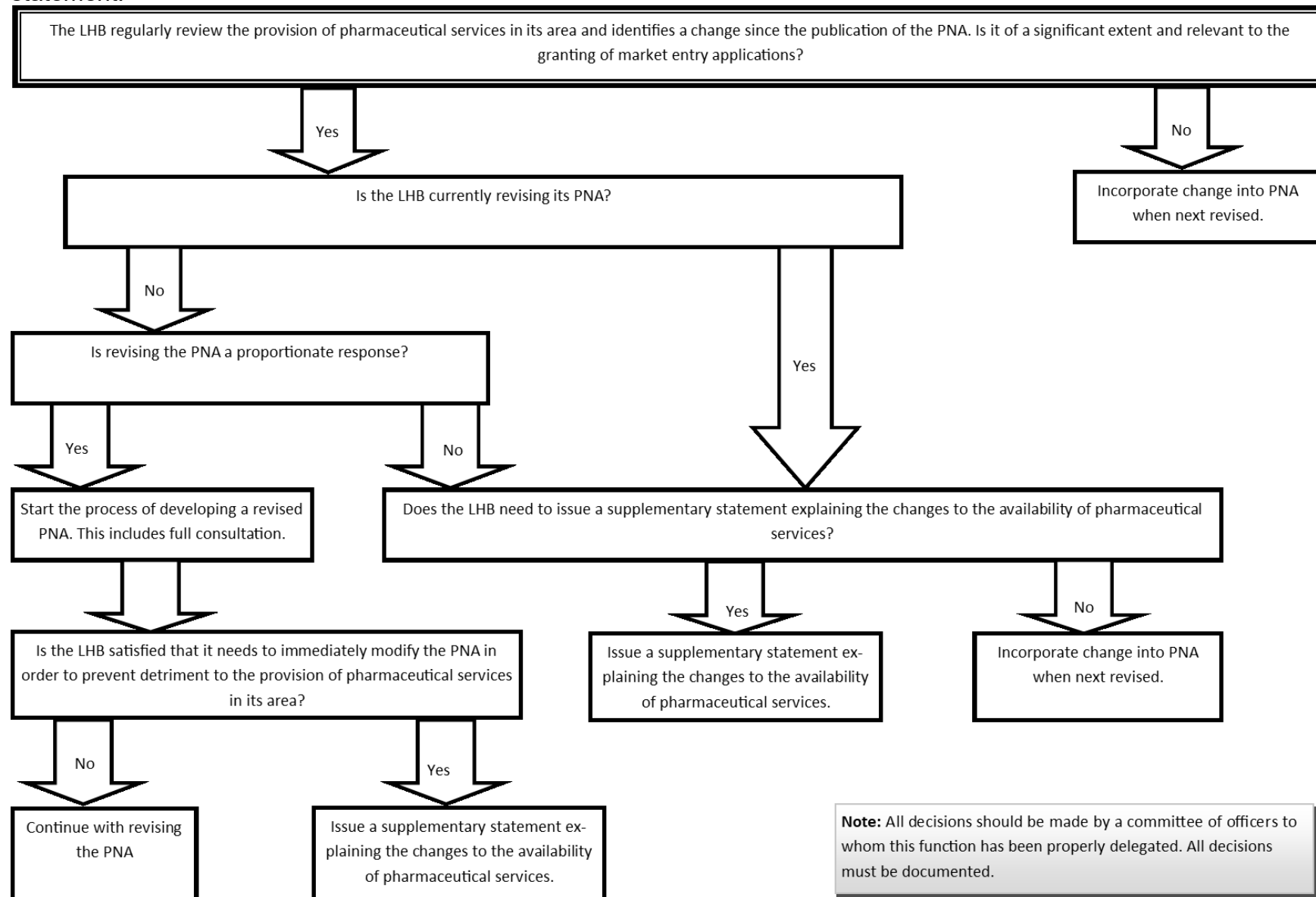
The LHB would need to be satisfied that it could continue to secure provision of services for its population following the closures. The LHB may, therefore, need to consider what alternative providers of services there are and whether closure of all, or some, of the outlets warranted a full-scale revision of the PNA, or whether that would be disproportionate, taking into account all relevant circumstances. If the change in the availability of pharmaceutical services is likely to have an impact on whether or not to grant an application, a supplementary statement could be issued.

Example: the current need for another provider of pharmaceutical services is identified within the PNA for a locality. The LHB subsequently receives and grants an application.

At the point when the pharmacy opens, the LHB may issue a supplementary statement confirming that this had happened.

2020 Regulations: Non-statutory Guidance for LHBs

The flowchart below will guide LHBs through the process of determining whether to revise the PNA and/or to issue a supplementary statement.



Part 2: Market entry

Chapter 7: General principles

Governance arrangements

Schedule 3 to the 2020 Regulations outlines the procedures that must be followed by the LHB in determining applications for inclusion. In summary, these are:

- Unless stated otherwise, a LHB may determine an application submitted to it in such manner as it thinks fit (paragraph 1(1), Schedule 3);
- A LHB must follow the procedure in regulation 15(4) in respect of an application submitted to it which does not contain all of the information that an applicant is required to provide in accordance with Schedule 2 (paragraph 1(2), Schedule 3);
- A LHB 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 the respective applicants and any other individual or body relevant to the application (paragraph 1(3), Schedule 3);
- In a controlled locality, where a LHB considers two or more applications 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 (paragraph 1(4), Schedule 3).

Missing information

Regulation 15(4) of the 2020 Regulations provides for situations where an application is incomplete as not all the information required by Schedule 2 has been provided.

Where a LHB considers that an application doesn't contain all the required information it may request the missing relevant information or documentation from the applicant within a specified period of time.

The applicant must, within the specified period of time:

- provide any information or documentation reasonably requested;
- notify the LHB that there is to be a delay in providing the requested information or documentation, set out the reasons why there will be a delay, and specify a date by which they will provide the information or documentation; or
- notify the LHB that it considers that the information or documentation has been unreasonably requested, and seek a review by the LHB of the reasonableness of the request.

The consequences of this provision are:

- if the applicant refuses to comply with a request for missing information or documentation – the application is treated as withdrawn; and/or
- if the applicant fails to provide the requested information or documentation by a later date, where the LHB was satisfied that the reasons for the delay and the length of the delay are for good cause – the application is treated as withdrawn.

Where the applicant has sought a review of the LHB's request, if the review determines that any of the requested information or documentation:

- must still be provided but the applicant fails to provide it within the new timescale - the application is treated as withdrawn; or
- need not be provided - the LHB's request is to be treated as withdrawn to the extent that it relates to the information or documentation that no longer needs to be provided. It should be noted that there may still be some missing information or documentation that is to be provided.

Timetable for determining applications

A LHB must endeavour to determine an application as soon as is practicable after its receipt (Paragraph 2 of Schedule 3).

Persons prohibited from taking part in decision-making on applications

Paragraph 3 of Schedule 3 to the 2020 Regulations states that no person is to take part in determining an application if they are:

- a person who is included in a pharmaceutical list or dispensing doctor list maintained by the LHB, or are an employee of such a person;
- a shareholder, director or company secretary of a company which runs a retail pharmacy business in the area of the LHB;
- a provider of primary medical services in the area of the LHB;
- an APMS contractor in the area of the LHB, 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
- employed or engaged by the LHB for the purposes of providing primary medical services within an LHBMS practice.

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.

Oral hearings

A LHB may require an oral hearing to be held if it considers it is necessary to hear oral representations before determining such an application (Paragraph 11 of Schedule 3).

If the LHB does decide to hold an oral hearing, it must give no less than 14 days' notice of the time and place of the hearing to:

- the applicant, and
- any person who has made representations on the application under paragraph 8(4) of Schedule 3.

It must also:

- advise the applicant who has been given notice of the hearing; and
- advise those notified they may make oral representations relating to the application at the hearing.

The applicant or a person who made representations on the application under paragraph 8(4) of Schedule 3 and wishes 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 applicant or the person who has made representations is unable to attend the hearing in person.

A LHB may determine the procedure to be followed at the oral hearing (Paragraph 11(4) of Schedule 3) and is not bound by any recommendation arising from it (paragraph 11(5), Schedule 3).

Regulation 15(6) of the 2020 Regulations states the LHB may request information or documentation at any time after it receives an application and before it is determined. LHBs should, however, note that where an application is to be notified to persons listed in paragraph 9 of Schedule 3 then all the information and documentation that it will take into account when determining the application must be shared with those persons. It is therefore recommended that consideration is given as to whether there is missing information or documentation prior to the notification of applications under paragraph 9 of Schedule 3.

Conditional inclusion in pharmaceutical lists not on fitness grounds

LHBs have two new additional grounds for including an applicant in a pharmaceutical list subject to a condition which does not relate to the applicant's fitness.

The first relates to applicants who are offering more than 40 core opening hours (or more than 30 hours if a dispensing appliance contractor). A PNA may, for example, identify the need for pharmaceutical services to be provided for more than 40 core opening hours per week and under the 2020 Regulations applicants will be able to undertake to have more than 40 core opening hours.

Where an applicant undertakes to be open for more than 40 core opening hours the LHB will need to have a conversation with them to agree the times at which and/or days on which the additional opening hours will be (regulation 46(1)(a)(ii)). If the application is granted having regard to the applicant's undertaking and the subsequent agreement, when the LHB includes the applicant and their premises in the pharmaceutical list the LHB will need to issue a direction in relation to the total number of core opening hours, setting out the times at which and days on which the additional core opening hours will be.

Example

The PNA identifies a current need for a new pharmacy to be open for 10 hours a day, seven days a week providing a specified range of services. An application is submitted by Pestle & Mortar Ltd that offers to meet that need by having core opening hours of 08.00 to 18.00 Monday to Sunday inclusive.

Whilst the application is being processed, the LHB has a discussion with Pestle & Mortar Ltd and they agree the following:

- The pharmacy's 40 core opening hours will be 09.00 to 17.00 Monday to Friday
- The pharmacy's additional core opening hours will be:
 - 08.00 to 09.00 and 17.00 to 18.00 Monday to Friday, and
 - 08.00 to 18.00 Saturday and Sunday

The application is subsequently granted and, on the day the applicant and their premises are included in the LHB's pharmaceutical list, the LHB issues a direction confirming that the pharmacy has a total of 70 core opening hours and that the additional opening hours are 08.00 to 09.00 and 17.00 to 18.00 Monday to Friday, and 08.00 to 18.00 Saturday and Sunday.

The second ground is where an applicant undertakes to provide directed services in response to a need identified in the LHB's PNA. The undertaking is:

- to provide the directed services mentioned in the application, if the LHB commissions them within three years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates;
- if the directed services are commissioned, to provide them in accordance with an agreed service specification; and
- not to withhold agreement to a service specification unreasonably.

In this instance, the inclusion of the applicant and their premises is subject to the applicant providing the services, and not to unreasonably withhold agreement to the service specification if the LHB commissions the services from them, within three years. This is to safeguard against a contractor applying to meet a need for a particular service identified in a PNA, only to withdraw from providing that service shortly after.

This condition applies to the applicant and any future owner of the pharmacy, and the LHB may not vary or remove the condition (regulation 47(4)).

Chapter 8: Applications for inclusion in a pharmaceutical list

Information to be included in applications under regulations 15 and 16 of the 2020 Regulations

Applications under regulation 15(1) must include the information set out in Part 1, Schedule 2 (regulation 15(2)) and where an application does not, the LHB has the power to request the missing information or documentation (see chapter 7).

Where regulation 16 applies, paragraph 13 of Schedule 2 requires the applicant to state why they believe their application will meet a need identified in the LHB's PNA. In addition, where the premises are within a controlled locality, the applicant must state their reasons why they consider 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 (Paragraph 14 of Schedule 3).

Part 2, Schedule 2 sets out the fitness information and undertakings that must be provided as part of an application for inclusion in a pharmaceutical list (regulation 15(2)). The exception to this requirement is set out in regulation 60 and applies to bodies corporate with a home LHB (regulation 15(3)).

Charges for applications

The charges applicable to applications for inclusion, relocation and any other amendment to a pharmaceutical list are contained within the [Pharmaceutical Services \(Fees for Applications\) \(Wales\) Directions 2013](#).

Regulation 15

Regulation 15(1) makes provision for the following types of application:

- an application from a person who wishes to be included in a pharmaceutical list maintained by the LHB for the first time;
- an application from a person who is already included in a pharmaceutical list maintained by the LHB, but wishes to either open additional premises, relocate to different premises or provide additional services to those currently provided at their premises; and
- an application from a person who is included in a pharmaceutical list for a neighbouring LHB and who wishes to relocate to premises in the area of the LHB to whom they are applying.

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 person satisfies the LHB they have the level of knowledge of English which, in the interests of that individual and the persons making use of the pharmaceutical services to which the application relates, is necessary for the provision of those pharmaceutical services in the area of the LHB (regulation 15(7)).

All applications made under regulation 15(1) will be determined in accordance with regulation 16 (determination of applications to be included in or to make amendment to a pharmaceutical

list).

However this does not apply to the following types of applications:

- applications involving relocation within a LHB's area – regulation 19 applies;
- applications involving relocation between neighbouring LHB areas – regulation 20 applies;
- applications involving temporary relocation – regulation 21 applies;
- applications involving a change of ownership – regulation 22 applies.

The procedures to be followed by a LHB when determining applications under regulation 15(1) are set out in Parts 1 and 3 of Schedule 3 to the 2020 Regulations.

Regulation 16 – Current or future needs

Where the applicant is not already included in the LHB's pharmaceutical list, the LHB must first consider whether the applicant is a fit and proper person. Regulation 16(5) permits the LHB to:

- defer consideration of the application on fitness grounds in accordance with regulation 36;
- refuse the application on fitness grounds in accordance with regulation 37; or
- impose conditions on the grant of the application in accordance with regulation 38 i.e. conditional inclusion.

Regulation 16(1) sets out the new market entry test, namely, where the premises specified in an application are not within a controlled locality the LHB may grant the application only if it is satisfied that:

- it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type;
- in the LHB's area; and
- which has been included in the LHB's PNA in accordance with Schedule 1.

It should be noted that the LHB does not have to grant the application. However, where a LHB is minded to refuse an application which would meet a need included in its PNA, it will need to provide reasonable grounds for the refusal and robustly document its decision.

The prejudice test (regulation 16(2)) still applies to an application that is in a controlled locality but not a reserved location, and this must be considered before the LHB considers the market entry test in regulation 16(1).

Regulation 16(3) confirms that the prejudice test in regulation 16(2) does not apply where the premises specified in an application are situated in a reserved location.

Where an application does not offer to meet a need identified in the LHB's PNA, regulation 16(4) directs the LHB to refuse that application. It should be noted that, unlike regulation 15(1), the LHB must refuse an application if it does not meet an identified need.

Regulation 19 – Relocations within a LHB area

Regulation 19 makes provision for three different types of relocation application within a LHB's area.

The first, in regulation 19(1), relates to the situation where a person has successfully applied under regulation 15(1)(a), but before the end of the relevant period (as defined in regulation 23 (procedure following grant of an application)), notifies the LHB that they wish to change the premises from which they intend to provide the pharmaceutical services specified in the application.

In that scenario, the LHB may amend the premises specified in the original application if it is satisfied that—

- the change is a relocation;
- 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
- the relocation still meets the need for a pharmaceutical service identified in the LHB's PNA.

Under regulation 15(1)(b)(ii), a contractor may apply to relocate from listed premises to new premises. Regulation 19(2)(a) allows the LHB to grant such an application if it is satisfied that the relocation is to meet a need for a pharmaceutical service identified in the relevant PNA and:

- the provision of pharmaceutical services will not be interrupted (except for such period as the LHB may for good reason permit);
- 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 21 (applications involving temporary relocation); and
- would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the LHB's area, or in a controlled locality in the area of a neighbouring LHB where that locality is within 1.6 kilometres of the new premises.

This provision means that whilst a contractor can apply to relocate to meet a need identified in the PNA, if the LHB is of the opinion that to grant such an application would result in a significant change to the arrangements that are in place for the provision of pharmaceutical services then the application can be refused. In practice this is likely to cover situations where the contractor is applying to relocate from an area where there are no other providers of pharmaceutical services, thereby leaving a gap in provision in that area.

Regulation 19(3)(b) allows the LHB to grant a relocation application submitted under regulation 15(1)(b)(ii) where it is satisfied that the relocation is not to meet a need for a pharmaceutical service identified in the relevant PNA but:

- 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;
- the same pharmaceutical services will be provided at the new premises as are provided at the listed premises;

- the provision of pharmaceutical services will not be interrupted (except for such period as the LHB may for good reason permit);
- 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 21 (applications involving temporary relocation);;and
- would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the LHB's area, or in a controlled locality in the area of a neighbouring LHB where that controlled locality is within 1.6 kilometres of the new premises.

Regulation 20 - Relocations between neighbouring LHB areas

In addition to relocations within a LHB's area, a contractor may also apply to relocate to meet a need in a neighbouring LHB area (regulation 20). This may be particularly useful in instances where a town or village is located close to or across a boundary and a more suitable premises is identified across that boundary.

Regulation 20 allows a LHB to grant such an application if it is satisfied that:

- the change is a relocation to meet a need identified in its PNA;
- 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;
- the provision of pharmaceutical services will not be interrupted (except for such period as the LHB may for good reason permit);
- 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 21 (applications involving temporary relocation);
- would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the LHB's area, or in a controlled locality in the area of a neighbouring LHB where that controlled locality is within 1.6 kilometres of the new premises; and
- the person consents to the removal of the premises from the pharmaceutical list maintained by the LHB in whose area the current premises are located with effect from the date on which provision of pharmaceutical services from the new premises commences.

Example

A pharmacist located in Ystalyfera (Swansea Bay) identifies a more suitable premises but it is located across the border in Ystradgynlais (Powys). Provided that a need has been identified in the PNA for Powys THB and the new location is not significantly less accessible, the regulations would allow the contractor to apply to relocate, providing all other conditions are met.

Chapter 9: Rurality matters

Introduction

Pharmacies may not always be viable in every part of the LHB, especially in more rural areas. Patients will still need to receive their NHS-prescribed medicines promptly, efficiently, conveniently and to a high standard. That is where the services of dispensing doctors can, and do, play a vital role; ensuring patients receive their medicines from the surgery's dispensary without having a possibly very lengthy journey to their nearest pharmacy.

Controlled localities

The overall objective of defining rural areas as “controlled localities” is to ensure that people living in rural areas have access to pharmaceutical services which are no less adequate than would be the case in areas that are not controlled localities, for example, in towns and cities. A controlled locality is an area which has been determined, either by the LHB/a predecessor organisation or on appeal by the Welsh Ministers, to be “rural in character” (Regulation 13).

Areas that have not been formally determined as rural in character and therefore controlled localities, are not controlled localities unless and until the LHB determines them to be. Such areas may be considered as rural because they consist of open fields with few houses but they are not a controlled locality until they have been subject to a formal determination.

Similarly, any area that is determined not to be rural in character cannot be a controlled locality, even if it has some features of a rural area, for example, low population density. Where the LHB determines that an area which was once determined to be rural in character no longer is such, it shall cease to be a controlled locality.

Any areas that were a controlled locality as of 30 September 2020, or are determined to be a controlled locality by virtue of the application of regulation 63(2) of the 2020 Regulations (transitional provisions), continue to be a controlled locality until such time as the LHB, or on appeal the Welsh Ministers, determines otherwise. The effect of this provision is that any area determined as a controlled locality before the 2020 Regulations came into force, continues to be a controlled locality once the 2013 Regulations have been revoked and the 2020 Regulations are in force.

To be a controlled locality an area must be ‘rural in character’. This is not something which can be subject to rules such as density or distribution of population, or the number of trees; it is essentially a matter of common sense. Experience has shown that photographs and documents can be an unreliable basis for determining rurality questions. Some areas can be easily identified as rural in character from internet research as they consist solely of fields, woods and/or forests, with no housing or employment, and others are clearly not rural in character as they are towns or cities. However, for those areas that fall in between, or where the edge of a controlled locality needs to be identified around an urban area, it will be necessary to undertake a site visit.

Judgement will need to depend on local knowledge of the circumstances. Factors to be taken into account include:

- environmental – the balance between different types of land use;
- employment patterns (bearing in mind that those who live in rural areas may not work there);
- the size of the community and distance between settlements;
- the overall population density;
- transportation – the availability or otherwise of public transport and the frequency of such provision including access to services such as shopping facilities; and
- the provision of other facilities, such as recreational and entertainment facilities.

A rural area may be characterised by a limited range of local services where people have to travel for many of their day to day needs such as work, leisure, education and shopping. It need not have high level of agricultural employment, as many residents may commute to jobs in local towns.

LHBs should be aware of misconceptions about rurality. The fact that an area is not classified as a controlled locality or that a decision is taken to remove such a classification, does not necessarily mean that it is urban.

Maps of controlled localities

Under Paragraph 7 of Schedule 3, LHBs continue to be under a duty to precisely delineate the boundary of any controlled locality that is determined on a map, or to remove the delineated boundary of a locality that has ceased to be a controlled locality. Such maps are to be made available for inspection and should be included in the LHB's PNA.

It is important that the boundaries of controlled localities are clearly marked, using appropriate geographical markers, for example rivers, not simply the squared off grid markings overprinted on Ordnance Survey maps. They should also be at a sufficient level of detail to enable any enquirer to tell whether any particular location falls within a controlled locality or not.

Determination that an area is a controlled locality

Changes can occur to the appropriate designation of an area, particularly where an urban area is expanding into the surrounding countryside, or where there has been a substantial development permitted in what has hitherto been a controlled locality. The reverse is much rarer but can happen, for example, where an industrial area in the country (for example mining) ceases.

If there are no maps showing defined controlled localities available or there is doubt that an area is rural, the LHB should assure itself that where patients receive pharmaceutical services from their doctor, they reside in properly determined controlled localities. Where the LHB identifies such areas that have not been so determined, or where they have no evidence that they have been determined, they should work with the LPC (Community Pharmacy Wales) and LMC and follow the procedures set out below. Additionally, the LHB should not take any further action on any application it may have received until it, or Welsh Ministers on appeal, has determined whether the application is in a controlled locality or not.

The LHB may at any time consider and determine whether or not an area is a controlled locality, or is part of a controlled locality (Regulation 13(2)). In addition, the LMC or the LPC for its area may apply to the LHB asking it to consider the status of a defined area. The only

restriction on such determinations is where the LHB, or on appeal the Welsh Ministers, has considered whether or not an area is a controlled locality, or is part of a controlled locality, within the last five years.

The five year period begins with the date of the determination the LHB, or if that determination was appealed, the date of the decision of that appeal (Regulation 13(3)(a)).

However, if the LHB is satisfied that within that five year period there has been a substantial change in circumstances in relation to that area then it may reconsider the matter afresh (Regulation 13(3)(b)).

What does a “*substantial change of circumstances*” mean?

An exception to the five year rule outlined above, allows for an area to be reconsidered within five years if the LHB is satisfied that there has been a substantial change of circumstances.

This will be a matter of fact and degree for the common sense of the LHB. Each case should be considered individually on its merits. For example, changes might have occurred:

- in the size of the local population, through the development of a new housing estate, or the rundown of use of an area;
- in transport facilities;
- from the construction of an airport, a motorway or railway, or closure of a railway which has divided an area;
- in the level of services available.

It is therefore important that the LHB ensures that accurate records are maintained of when determinations are made in order to ensure it meets the requirements of regulation 13(3)(a).

Consideration of whether or not an area is rural in character

Subject to the five year bar referred to in Regulation 13, an LHB can at any time consider whether or not an area is rural in character and must do so whenever it receives an application from the LMC or LPC to consider (or reconsider) the rurality of a specified area. A GP practice should consult the LMC (or the LPC if a pharmacy contractor) if they wish questions of rurality to be considered.

An LHB will need to be clear whether an area has been designated as a controlled locality and may need to go on to consider whether or not an area is rural in character whenever it receives:

- an application by a GP practice for outline consent where the rurality of all or any part of the specified area has never been considered by the LHB, or where there is doubt about whether all or part of the specified area is rural in character; or
- an application for preliminary consent for a pharmacy, where there is any doubt about whether or not the location specified for the premises is rural in character.

Following receipt of an application for outline consent from a GP or preliminary consent from a pharmacy contractor, the LHB may decide that it must first determine whether or not the application is in a controlled locality before it can go on to consider the application as the status

of the area could affect the outcome of the application. After it has given notice of the intention to undertake a controlled locality determination the LHB must defer consideration of the application until:

- it has determined the status of the area and the period for bringing an appeal relating to that determination has ended; or
- the date of the determination of any such appeal (paragraph 5 of Schedule 3).

Where the LHB decides to consider whether or not an area is rural or is asked to, it must notify:

- the LMC in its area;
- the LPC (Community Pharmacy Wales);
- the Community Health Council for the area; and
- any GP practice or any person included in the LHB's pharmaceutical list who, in the opinion of the LHB, might be affected by the determination.

Those notified have 30 days in which to make representations in writing to the LHB (paragraph 4 of Schedule 3).

Once the LHB has determined whether or not the area is a controlled locality, or part of a controlled locality, it will then need to consider whether the provision of:

- primary medical services by a provider of such services (other than itself) i.e. GP practices;
- pharmaceutical services by a pharmacy or dispensing appliance contractor included in its pharmaceutical list; or
- pharmaceutical services by a doctor

is likely to be adversely affected as a consequence of that determination.

Where the LHB is of the opinion that such provision is likely to be adversely affected it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under which GPs dispense to their eligible patients (paragraph 6 of Schedule 3). This is colloquially referred to as 'gradualisation' and essentially means that the LHB may decide to allow GPs to continue to dispense to their patients who live in the area that is no longer a controlled locality, or no longer part of one, for a fixed period of time.

Once the status of the area has been determined, the decision must be communicated to those who were given notice under paragraph 4(2) of Schedule 3.

Once the 30 day appeal period has ended and any appeals have been dealt with then the LHB must:

- precisely delineate the boundaries of the controlled locality on a map, or remove the delineated boundary of a locality that has ceased to be a controlled locality (paragraph 7(1)(b)(i) of Schedule 3);
- give a doctor who is affected reasonable notice of any conditions that have been imposed under paragraph 6 of Schedule 3 as a result of the determination, i.e. any gradualisation period (paragraph 7(1)(b)(ii) of Schedule 3); and
- proceed to determine any applications that were deferred pending the outcome of the

controlled locality determination (paragraph 7(1)(b)(iii)).

Reserved locations

Where an application is submitted under regulations 15 or 18 for premises, or a relevant location that is within a controlled locality, the LHB must also consider whether or not they are, or it is, in a reserved location (Regulation 17).

Regulation 17(4) states that 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. However, a location is not a reserved location if the LHB considers that, if a pharmacy were to operate from that 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 (Regulation 17(5)).

If the application is granted under regulation 17(2), the person included in the LHB's pharmaceutical list in respect of those premises may apply to the LHB to make a further determination as to whether, on the date of the application, those premises are in a reserved location.

The prejudice test

In controlled localities the prejudice test applies as it did under the 2013 Regulations.

Regulation 16(3) confirms that the prejudice test does not apply where the premises, or the relevant location, specified in the application is within a reserved location.

Within their application the applicant is required to set out their reasons as to why they consider 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, or relevant location, in the application is located (paragraph 45 of Schedule 2).

In determining the application, the LHB (or the Welsh Ministers on appeal) must refuse the application where it is of the opinion that to grant it would prejudice the proper provision of those services listed above (regulation 16(2)(a)).

Appeals determined under the 1992 and 2013 Regulations have taken the view that the proper provision of primary medical services or pharmaceutical services in any area means that people in that area should have available to them primary medical services and pharmaceutical services and that those services should be of the standard which providers of such services are obliged to provide in order to comply with their respective terms of service.

The fact that the granting of an application could lead to the reduction in the level or standard of services does not, of itself, constitute prejudice to proper provision. It should also be noted that

the burden of proof will rest with the person who maintains that the proper provision would be prejudiced, not on the applicant.

In considering questions of prejudice, it is important that the LHB focuses only on those services which have to be provided within the terms of service of primary medical services and pharmaceutical services provision. The fact that non-NHS services or NHS services provided above the standard set by the terms of service may be curtailed should not be regarded as relevant.

A mere reduction in the total level of service provided by a particular pharmacy or GP practice is not of itself prejudice. Prejudice arises where the service that people can rightly expect to be provided by the NHS has in some respect ceased or otherwise be curtailed or withdrawn without proper substitution in the area.

Arrangements for the provision of pharmaceutical services by doctors

Under Regulation 11(1), each LHB must prepare and maintain a dispensing doctor list of doctors with whom it has made an arrangement in accordance with Regulation 26 of the 2020 Regulations to provide pharmaceutical services to their patients who reside within the area of the LHB.

Regulation 11(2) sets out the information which must be included in such lists, for example the name of the doctor, the area for which they have outline consent and the date on which it took effect, and the address of the premises for which the doctor has premises approval.

Part 6 of the 2020 Regulations makes provision for applications by doctors for inclusion in, or amendment to, dispensing doctor lists.

Regulation 26(1) makes provision for LHBs to make an arrangement with a doctor to provide pharmaceutical services to a patient included on the practice's patient list, 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; or
- b) is resident in a controlled locality, at a distance of more than 1.6km from any pharmacy, and the doctor has outline consent and premises approval for the patient's address; or
- c) is resident in a controlled locality and any pharmacy within a distance of 1.6km 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 doctor has outline consent and premises approval for the patient's address.

The serious difficulty rule

Patients wishing to rely upon the 'serious difficulty' rule in Regulation 26(1)(a) must:

- a) have made a request in writing to the LHB for the doctor to provide him or her with pharmaceutical services on the basis of serious difficulty due to distance or inadequacy of means of communication, and
- b) the LHB is satisfied that the patient would have serious difficulty in obtaining any necessary drugs or appliances for those reasons.

What does the “serious difficulty” rule mean?

The rule states a patient must satisfy the LHB that they would have serious difficulty in obtaining any necessary drugs and appliances from a pharmacy contractor by reason of distance or inadequacy of means of communication. It applies to any patient, not just those who live in rural areas. Each application should be looked at individually on its own merits, in the light of:

- the patient’s personal circumstances;
- the local arrangements for primary medical services and pharmaceutical services;
- the distance and terrain involved;
- transport facilities;
- the existence of collection and delivery service; and
- the availability and possible use of a telephone.

In making an arrangement with a doctor to dispense to a patient under the serious difficulty rule, regulation 26(3) states that the LHB must give reasonable notice in writing to the doctor of when the arrangement is to take effect, unless the doctor satisfies the LHB that:

- they do not normally provide pharmaceutical services to patients; or
- the patient would not have serious difficulty in obtaining drugs and appliances from a pharmacy because of the distance or adequacy of means of communication.

Provision of pharmaceutical services by doctors other than under the serious difficulty rule

Where a doctor wishes to dispense to patients other than under the serious difficulty rule, the patient must live within a controlled locality and be more than 1.6km from a pharmacy and the following conditions must first be in place under regulation 26(1)(b) or (c) and (4):

- 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 31 (taking effect of outline consent and premises approval); and
- d) any conditions imposed under the 2020 Regulation 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 or patients under regulation 26 (1)(b) or (c).

Regulation 26(5) confirms that references to outline consent, premises approval and conditions imposed include references to those in effect under the 2013 Regulations. Regulation 26(7) confirms that where an arrangement to provide pharmaceutical services was in effect immediately before the 2020 Regulations, that arrangement will have effect as though made under Regulation 26 of the 2020 Regulations. This means that doctors will not need to reapply for outline consent and premises approval when the 2013 Regulations are revoked.

Provision of pharmaceutical services to temporary patients

Where a doctor provides pharmaceutical services to their registered patients under regulation 26 they may also provide necessary pharmaceutical services to a person who has been accepted as a temporary patient (Regulation 27).

Outline consent and premises approval

As under the 2013 Regulations, doctors who wish to start dispensing to a new area may apply to the LHB for outline consent and premises approval for that area.

However, under the 2020 Regulations any such applications must be to meet a current or future need identified in the LHB's PNA and the doctor must first apply to the LHB under regulation 30 for outline consent and premises approval (Regulation 30(1)). Applications for outline consent and premises approval that are not based on a need for pharmaceutical services, or pharmaceutical services of a specified type, which have been included in the PNA must be refused by the LHB (Regulation 30(5)(d)).

Under Regulation 30(2) a doctor who has outline consent which has taken effect under regulation 31 may submit an application for premises approval for:

- additional practice premises at which they wish to provide pharmaceutical service or
- practice premises to which they wish to relocate.

Applications to the LHB under this regulation must be made in writing and provide the information set out in Part 4 of Schedule 2.

Part 3: Market exit

Introduction

Part 9 of the 2020 Regulations deals with the performance-related sanctions and market exit. Where a contractor breaches their terms of service, a LHB may issue a remedial notice or breach notice, depending on the nature of the breach and having first undertaken local dispute resolution. Whether a remedial notice or a breach notice is issued will depend on whether or not the breach can be remedied.

Alongside issuing a notice, if the breach is a failure to provide a service that the contractor is required to provide, the LHB may also withhold remuneration.

Before considering whether or not to issue a notice, with or without a payment withholding, the LHB must first attempt local dispute resolution. There are, however, four specific instances, set out in Regulation 49(3) where local dispute resolution does not have to be undertaken. These are outlined on pages 44 and 45.

The ultimate sanction is removal of the premises from a pharmaceutical list.

LHBs should note that their powers to take action under Part 9 of the 2020 Regulations should only be used to address concerns relating to the provision of pharmaceutical services at a specific set of premises.

Where a LHB has concerns about a contractor's fitness to practise it should use the powers set out in Part 8 of the 2006 Act, following the procedures set out in regulations 39 to 44 of the 2020 Regulations. These include contingent removal, removal and suspension. For example, a contractor who runs pharmacies across the LHB's area may be a suitable person to run a pharmacy and may be able to run one efficiently, but there may be local failings such as repeated breaches of terms of service which means that one particular set of premises needs to be removed from the LHB's pharmaceutical list.

The powers contained within Part 9 of the 2020 Regulations do not apply to the provision of pharmaceutical services by dispensing doctors. Where there are concerns around compliance with the dispensing terms of service set out in Schedule 7 of the 2020 Regulations these are dealt with under the practice's primary medical services contract.

Chapter 10: Local dispute resolution

LHBs will have existing relationships with their contractors, and will use informal procedures to resolve any concerns that are identified in relation to non-compliance with the terms of service. This is the process that would generally occur at monitoring visits where the LHB identifies an area of concern and the contractor agrees to address this issue, i.e. agreement that a contractor is not compliant with one or more of their terms of service requirements, and an agreed action plan is drawn up with timescales to remedy this. These relationships will help to avoid bureaucracy and cost for both parties.

The market exit provisions within the 2020 Regulations build upon those existing relationships. Where the informal procedures do not resolve concerns, the LHB will be able to move to the first stage of the performance related sanctions set out in Part 9 of the 2020 Regulations, namely local dispute resolution.

It is a condition of the inclusion of a contractor in a pharmaceutical list that they will make every reasonable effort to communicate with the LHB with a view to resolving any dispute between the two parties relating to the contractor's compliance with their terms of service (regulation 48(1)).

Similarly regulation 49(1) requires the LHB to make every reasonable effort to communicate and co-operate with a contractor with a view to resolving any dispute relating to a contractor's compliance with their terms of service.

It is therefore incumbent on both parties to make every reasonable effort to communicate and co-operate. Regulation 49(2) also requires the LHB to make every reasonable effort to communicate and co-operate with a local pharmaceutical committee (Community Pharmacy Wales) where the contractor invites them to participate in the attempts to resolve the dispute.

The 2020 Regulations do not provide a definition for 'reasonable' efforts, however, it is expected that LHBs will:

- use a variety of methods to engage with a contractor, e.g. by phone, email, in writing or face to face, confirming any verbal communications in writing;
- contact a contractor more than once; and
- ensure that communications are received e.g. requesting read and delivery receipts for emails; sending written communications as "signed for"; and evidence of receipt by the contractor is kept.

Where the LHB is unable to resolve a concern regarding non-compliance with a contractor's terms of service through local dispute resolution, the next stage in a performance management procedure is the issuing of breach or remedial notices and the possible withholding of remuneration.

However, local dispute resolution may not always be appropriate and regulation 49(3) sets out the four circumstances where a LHB may move straight to issuing a breach or remedial notice.

The first of these is where the LHB is satisfied that the dispute relates to a matter that has already been the subject of dispute resolution under the 2020 Regulations between it and the

contractor, and there are no new issues of substance that justify delaying the issuing a breach or remedial notice (regulation 49(3)(a)).

Example

At a monitoring visit, it was noted that a dispensing appliance contractor (DAC) has failed to develop the standard operating procedures (SOPs) required by **paragraph 17(3)(c)(v) of Schedule 6** to the 2020 Regulations. Following discussions at the visit, the DAC agreed to produce the SOPs within three months.

The LHB undertakes a follow-up visit four months later and the DAC has not developed the SOPs as agreed previously and has no good cause for this. Following further discussions between the LHB and the DAC, the LHB is not satisfied that the DAC intends to produce the SOPs and decides to issue a remedial notice under **regulation 50**.

If, however, the DAC had good cause not to have developed the SOPs within the agreed timescale, for example the premises had flooded and service provision had been temporarily suspended whilst repair work was undertaken, the LHB may then agree to a further period of time within which they are to be developed rather than issue a remedial notice.

The second is where the LHB is satisfied that it is appropriate to proceed immediately to issuing a notice under regulation 51 because premises are not, or have not been, open during core opening hours or supplementary opening hours without good cause (regulation 49(3)(b)(i)). This does not include temporary suspensions of service provision where the contractor has complied with the terms of service.

Thirdly, the LHB may move straight to issuing a notice where it is satisfied that to do so will protect the safety of any person to whom a contractor may provide pharmaceutical services (regulation 49(3)(b)(ii)).

Example

A pharmacy contractor has agreed to provide a needle exchange scheme as an enhanced service but it becomes apparent on a visit to the pharmacy that some of the materials being received from drug misusers, for example used needles, are being left in open bins. The LHB is satisfied that the safety of both staff and visitors to the premises is compromised by this and decides to issue a breach notice.

Finally, the LHB may move straight to issuing a notice where it is satisfied that this will protect it from material financial loss.

Example

A pharmacy claims for more discharge medicines reviews (DMRs) than it is entitled to do within a financial year. The LHB raises this issue with the contractor and it becomes apparent that there are no systems in place to identify:

- the number of DMRs that the contractor may undertake in a year; or
- the number of DMRs that have been claimed.

Chapter 11: Remedial notices

Regulation 50 makes provision for a LHB to issue remedial notices to contractors where they breach a term of service and the breach is capable of remedy. The effect of the notice is to require the contractor to “make good” the breach.

Breaches that are capable of remedy

In order for a remedial notice to be issued, the contractor must be able to remedy or “make good” the breach. These types of notice would, therefore, be suitable for the following examples of breaches:

- failures to make available a practice leaflet;
- lack of SOPs required by the terms of service;
- failure to undertake the pharmacy-based audit; or
- failure to appoint a clinical governance lead.

Process and regulatory provisions

Before issuing a remedial notice, the LHB must seek to discover the grounds for the potential breach, first to establish whether or not there are grounds to skip local dispute resolution and second to ensure that issuing a remedial notice is the most appropriate action to take.

In order to be valid, the remedial notice must include the following information:

- the nature of the breach – the breach notice must state what the contractor has, or has not, done and which term of service this breaches. The LHB must reference the term of service in the relevant Schedule to the 2020 Regulations, for example failure by a pharmacy contractor to produce a practice leaflet is a breach of paragraph 28(3)(a)(i) of Schedule 4;
- the steps the contractor must take, to the LHB’s satisfaction, in order to remedy the breach, for example to produce a practice leaflet that complies with the approved particulars;
- the period during which the required steps must be taken (“the notice period”), for example within two months (but see the next paragraph); and
- an explanation of how the contractor may exercise their right of appeal under regulation 54(1)(a) i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to Welsh Ministers within 30 days of the date on which the contractor was notified of the decision to issue a remedial notice.

The notice period for remedy of the breach must not be less than 30 days, unless the LHB is satisfied that a shorter period is appropriate to protect:

- the safety of any persons to whom the contractor may provide pharmaceutical services; or
- the LHB from material financial loss (regulation 50(3)).

Example

At a monitoring visit, it becomes apparent that pharmacy technicians are undertaking a particular enhanced service that is outside their area of competence. In this case, the safety of persons receiving that service is at risk and the LHB may require the contractor, via a remedial notice, to stop the provision of the enhanced service by pharmacy technicians with immediate effect and for only accredited pharmacists to provide this service. Additionally, the contractor is required to identify and contact all persons who took part in the enhanced service with a pharmacy technician in order to invite them in for a review with an accredited pharmacist within 30 days.

As the contractual relationship is between the LHB and the contractor at the premises at which the breach has arisen, remedial notices are to be sent to those premises. However, it is considered good practice to include the superintendent pharmacist or head office (if available) of the contractor as a copy recipient in any notice that is issued.

Once the contractor has taken the required steps to remedy the breach the LHB must, as soon as is practicable, verify that the action is to the required standard.

A LHB may vary or revoke a remedial notice issued in accordance with regulation 50 at any time after it has been issued.

Remedial notices and withholdings

Where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service that the contractor is required to provide, a remedial notice may also include a withholding of remuneration (regulation 50(4)).

Remuneration refers to the payments made to the contractor for the provision of pharmaceutical services, as set out in the Drug Tariff or a determination by a LHB in relation to the remuneration for an enhanced service under regulation 56. It does not include reimbursement paid to a contractor in relation to drugs and appliances dispensed against a valid NHS prescription.

A remedial notice may provide that for the period of time during which the contractor:

- failed to provide the service, or provide it to a reasonable standard, the LHB will withhold all or part of the remuneration due in respect of that period (regulation 50(4)(a)); and
- is taking the required steps/completing the required actions set out in the remedial notice, the LHB will withhold all or part of the remuneration due in respect of that period (regulation 50(4)(b)(i)).

Should the contractor take the required steps/complete the required actions sooner than the date specified in the remedial notice, then they may submit a claim to the LHB for the restoration of that withheld remuneration (regulation 50(4)(b)(ii)).

If, following receipt of a claim for the restoration of any withheld remuneration, the LHB refuses to restore all or part of the remuneration that has been withheld, it must notify the contractor of that decision. The notification must include:

- a statement of the reasons for the LHB's decision; and
- an explanation of how the contractor may exercise their right of appeal under regulation 54(1)(b) to the Welsh Ministers i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the Welsh Ministers within 30 days of the date on which the contractor received the remedial notice (regulation 50(7)).

Chapter 13 sets out further matters that are to be taken into account by LHBs prior to determining whether or not to withhold remuneration as part of a remedial notice.

Chapter 12: Breach notices

Regulation 51 makes provision for LHBs to issue breach notices to contractors where they breach a term of service but the breach is not capable of remedy. The effect of the notice is to require the contractor not to repeat the breach.

Breaches that are not capable of remedy

The following are examples of breaches that a contractor cannot remedy. Failures to:

- open on a specific day or days, or at specific times of the day or days, in line with agreed core and supplementary opening hours;
- offer to deliver specified appliances to patients;
- offer a reasonable supply of disposable bags and wipes to patients using specified appliances;
- deal with past complaints; or
- provide updated fitness to practice information within the prescribed time.

Process and regulatory provisions

Before issuing a breach notice the LHB must seek to discover the grounds for the alleged breach. This is to ensure that issuing a breach notice is both proportionate and the most appropriate action to take.

In order to be valid, the breach notice must include:

- the nature of the breach (including reference to the specific term of service that the contractor has breached); and
- how the contractor may exercise their right of appeal under regulation 54(1)(c) to the Welsh Ministers i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the Welsh Ministers within 30 days of the date on which the contractor received the breach notice (regulation 51(2)).

Example

A pharmacy with core opening hours on a Saturday and Sunday applies to the LHB to close on Saturday 26 and Sunday 27 December which are neither public nor bank holidays. The LHB refuses the application and the contractor subsequently appeals to the Welsh Ministers. The Welsh Ministers uphold the LHB's decision and the contractor is required to open the pharmacy premises on those days and provide pharmaceutical services for its core opening hours.

The pharmacy fails to open on the days in question and after establishing that there was no good cause for this, the LHB decides that it is satisfied that it is appropriate to proceed with issuing a breach notice under regulation 51.

The LHB issues a breach notice under regulation 51 advising:

- that the contractor is in breach of paragraph 23(1)(a) of Schedule 5 by failing to ensure the provision of pharmaceutical services from the pharmacy premises on Saturday 26 and Sunday 27 December; and
- the contractor may exercise their right of appeal under regulation 54(1)(c) by sending a notice including a concise and reasoned statement of the grounds of the appeal to the Welsh Ministers within 30 days of the date of the breach notice.

As the contractual relationship is between the LHB and the contractor at the premises at which the breach has arisen, breach notices are to be sent to those premises. However, it is considered good practice to include the superintendent pharmacist or head office (if available) of the contractor as a copy recipient in any notice that is issued.

A LHB may vary or revoke a breach notice issued in accordance with regulation 51 at any time after it has been issued.

Breach notices and withholdings

A breach notice may also provide for the withholding of remuneration by the LHB where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that the contractor is required to provide (regulation 51(3)).

Remuneration refers to the payments made to the contractor for the provision of pharmaceutical services, as set out in the Drug Tariff or a determination by a LHB in relation to the remuneration for an enhanced service under regulation 56. It does not include reimbursement paid to a contractor in relation to drugs and appliances dispensed against a valid NHS prescription.

If the breach relates to a failure to provide, or a failure to provide to a reasonable standard a service the contractor is required to provide, a LHB may choose to permanently withhold remuneration for that service for the period the service was not provided.

Chapter 13 sets out further matters that are to be taken into account by LHBs prior to determining whether or not to apply a payment withholding as part of a breach notice.

Chapter 13: Payment withholdings - supplementary matters

Regulation 52 sets out additional matters which LHBs must have regard to prior to determining that a payment withholding is to be applied.

LHBs must note that a payment withholding may only be applied in connection with the issuing of a remedial or breach notice. It is not a sanction in its own right.

Payments may only be withheld by the LHB if:

- it is satisfied that the breach to which the withholding relates is, or was, without good cause;
- the amount to be withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it; and
- it includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and are to be (where applicable), withheld (Regulation 52(1)).

Remuneration may be withheld for the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service. The LHB may withhold all or part of the remuneration due to the contractor under the Drug Tariff in respect of that period.

The LHB needs to have regard to the reasons for the breach if it is to determine whether or not a withholding, as well as the amount of the withholding, is justified and proportionate. The LHB cannot simply apply the sanction without contacting the contractor for an explanation for the breach. The LHB must be satisfied that the withholding of remuneration is justified and so must make every reasonable effort to communicate with the contractor to establish the grounds for the breach. If the contractor fails to communicate with the LHB, the LHB is entitled to consider the information it has and whether this discloses justifiable grounds to withhold payment.

Factors likely to contribute to whether or not the amount of a withholding is justified and proportionate may include:

- the amount of money the contractor has saved by not being in compliance;
- the impact of the breach on patient safety;
- the duration of the breach; and
- the impact of the breach in the context of the statutory scheme.

The withholding of remuneration as a result of issuing a remedial or breach notice is without prejudice to the arrangements that are in place for the recovering of overpayments under regulation 57 and the Drug Tariff (regulation 52(3)).

Calculating how much to withhold

LHBs should note that the ability to withhold remuneration is not a system of punishment by fines of specific amounts. Any decision to withhold remuneration must be justified and proportionate and LHBs cannot escalate the amount withheld if a contractor repeatedly breaches a term of service.

LHBs should consider the fees and allowances paid to contractors, as well as the nature of the breach in order to calculate a level of withholding that is justifiable and proportionate. In determining that amount, it is not necessary to demonstrate actual loss or damage. There is a fundamental difference between a civil liability for breach of a statutory duty (which is essentially about compensation for actual loss or damage), and a penalties scheme as is set out in the 2020 Regulations for such a breach (which applies whether or not actual loss or damage is proven). LHBs do not need to calculate a precise value of the service that has not been performed, or has not been performed to the requisite standard, in order to make a withholding.

In some (but not all) cases, the starting point for the amount of the withholding is likely to be the money that the contractor has saved by not providing the required service or not providing it to the requisite standard. For example, if a contractor had failed to produce a practice leaflet, deducting 10% of the payments for one month would not be proportionate to the breach.

However, a monthly deduction, of a reasonable amount reflecting what it might cost to produce a reasonable stock of the leaflet should both have the desired effect by creating an incentive to comply, and be an amount that could straightforwardly be explained to the contractor as justified and proportionate.

Conversely, a monthly penalty of the full annual cost of an acceptable system of clinical governance, pending the introduction of such a system in the new pharmacy premises, would be disproportionate in this example.

Even if the saved costs are the frequent starting point, it is likely that the amount of a withholding will generally relate to more factors than simply those costs. For example, a starting point for the proportionate level of penalty where a contractor has failed to open in core or supplementary opening hours without good cause might be a realistic estimate of the costs it is likely to have saved itself in doing so. However, it might also be appropriate to include in the withholding an amount to dissuade contractors from such closures. If it was simply the case that the closure was cost neutral, the contractor might think it was worth, for example, closing early on the eve of a public or bank holiday because ultimately, there was no financial loss to itself in doing so and possibly a gain to itself, for example, in terms of staff relations.

Amounts to deter future breaches or shortcomings

In determining any deterrent amount, the LHB may wish to consider the following four additional factors. First and foremost is the issue of the impact on patient safety. Taking the Christmas closure example in the previous chapter where a pharmacy with core opening hours on a Saturday and Sunday unsuccessfully applied to close on Saturday 26 and Sunday 27 December but still closed on those days, the deterrent amount will need to reflect the potential seriousness of the consequences of the breach for those patients who, as a result of the closure, may have had to go without prescribed medicines over the holiday period.

The second issue of general relevance is the duration of the breach. As will be clear from the holiday example, a breach of short duration in some contexts will be more significant than a breach of longer duration in others. In general terms, the longer the breach continues the more justifiable and proportionate it will be to withhold a greater amount.

Third, the size of the contractor's NHS business may frequently be relevant. Just as the costs

saved from not opening will depend on the extent of the contractor's NHS business (and consequently the loss of NHS income arising from the failure to open), so also will the value of the deterrent amount. For a deterrent amount to have an impact on behaviour, the LHB will need to have regard to the overall NHS income of the business. The LHB should note in this respect that the total turnover of the business (i.e. NHS plus retail sales income – both pharmaceutical and non-pharmaceutical) is not a material consideration. The deterrent amount should be based only on the value of the NHS business to the contractor at the premises to which the breach relates.

Fourth, regard will need to be had to the broader policy and objects of the legislation, and how that has been compromised. For example, in considering the appropriate withholding for an unauthorised closure, regard may need to be had to the overarching nature of the payment scheme and the size of the withholding may need to reflect the fact that the system of establishment payments is partly there to guarantee access to services at particular locations.

Each of the above factors should be considered on their own merits in the context of the specific case. However, LHBs should also consider the totality of the breach and may offset some factors against each other in order to mitigate the totality and inform any deterrent amount imposed.

Chapter 14: Removal of premises from a pharmaceutical list: cases relating to remedial or breach notices

Introduction

Regulation 53 deals with the removal of premises from the LHB's pharmaceutical list where failings have not been addressed by the issuing of remedial and/or breach notices. This is an extreme sanction, equivalent to the terminating of contracts with GPs, dentists and optometrists.

Regulation 53(2) differentiates between removing a contractor completely from a pharmaceutical list and removing one of the contractor's premises;

- Where a contractor has several premises included in a LHB's pharmaceutical list, regulation 53 would lead to the removal of only the premises at which the breach, or breaches, of the terms of service relate. The contractor would remain included in the LHB's pharmaceutical list in respect of their other premises.
- Where a contractor has only one set of premises included in a LHB's pharmaceutical list regulation 53 would lead to the removal of the contractor and those premises.

LHBs should remember that this action does not necessarily mean the premises will close (although this may well be the outcome depending on the ratio of NHS to private turnover). It is requiring the pharmacy to cease providing pharmaceutical services. The power within regulation 53(1) to remove premises is a discretionary power. LHBs are not directed by the regulations to remove premises from the pharmaceutical list following the issuing of remedial and/or breach notices, unlike the provisions within regulation 40 (removal on fitness grounds).

Regulation 53(2) ensures that removal of any particular set of premises from the pharmaceutical list is by reference only to the breach or remedial notices issued in respect of those premises. The LHB cannot remove all of, or any other of, the contractor's premises if it has only issued notices regarding issues at one of them. Where a contractor has more than one set of premises listed on the LHB's pharmaceutical list and the LHB wants to remove the contractor completely, it would need to bring a fitness to practise case under Part 8 of the 2006 Act. However, if the contractor has only one set of premises on the LHB's pharmaceutical list, the LHB may remove the contractor from its pharmaceutical list under this regulation.

Grounds to remove

The LHB has four discretionary grounds on which to remove a contractor from its pharmaceutical list (if it only has one set of premises), or to remove a particular premises for that contractor.

The first is where the contractor has failed to comply with the steps set out in the remedial notice in order to remedy the breach, and the LHB is satisfied that it is necessary to remove the contractor or those particular premises from its pharmaceutical list in order to protect:

- the safety of any persons to whom the contractor may provide pharmaceutical services; or
- the LHB from material financial loss (regulation 53(1)(a)).

In order for a LHB to remove premises on this basis the breach would have to be significant. It would be neither justifiable nor proportionate, for example, to remove premises following the issuing of a remedial notice in relation to the lack of a practice leaflet.

The second ground is where the contractor has breached their terms of service, and has repeatedly been issued with remedial or breach notices or both in relation to the same term of service (regulation 53(1)(b)(i)).

The third is where the contractor has previously been issued with a remedial or breach notice in relation to the same term of service, and the LHB is satisfied that the contractor is likely to persist in breaching that term of service without good cause (regulation 53(1)(b)(ii)). In order to be satisfied that the contractor is likely to persist, the LHB must have documented evidence to support this.

Example

The LHB has evidence that a pharmacy whose core hours include Saturdays from 09:00 - 14:00 has failed to open on Saturdays for the last three months. A breach notice has failed to precipitate any change in compliance, and following discussions with the contractor, the LHB is satisfied that it has good cause to believe that this failure to open will continue.

Finally, premises may be removed where the contractor has repeatedly been issued with remedial or breach notices or both in relation to different terms of service and the LHB is satisfied that the contractor is likely to persist in breaching their terms of service without good cause (regulation 53(1)(b)(iii)). This provision therefore deals with the 'persistent offender'.

Good record-keeping by the LHB of failures to comply with the terms of service is essential in order to provide robust evidence on which to base decisions to issue breach or remedial notices.

A LHB need not take into account the reasons for the breaches (or likely breaches) if it has made every reasonable effort to communicate with the contractor to discover the reasons but has not been able to discover them (regulation 53(4)).

A LHB may only remove a contractor (if the contractor only has one set of premises on the LHB's pharmaceutical list) or one of the contractor's premises if:

- the removal is justifiable and proportionate, having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them; and
- the LHB includes in the notice of its decision to the contractor, its duly justified reasons for its decisions (regulation 53(3)).

What is justifiable and proportionate?

What is justifiable and proportionate is a judgement call for the LHB based on the facts and evidence it has before it and on a case by case basis. As there is likely to be considerable scope for challenges to such a fundamental decision, the LHB should consider seeking legal advice in respect of any possible application of regulation 53.

Example

- A contractor fails to produce a practice leaflet and fails to comply with a remedial notice which requires them to produce one. In this instance, removal from the pharmaceutical list is unlikely to be justifiable. The LHB may decide that by withholding payments of an amount that reflects the cost of producing such a leaflet is a justified and proportionate approach and may also wish to take account of the contractor's compliance record when considering whether or not to commission enhanced services from that contractor.
- A contractor fails to open one of its premises on a bank holiday when directed to do so. The LHB has records to show that the contractor regularly fails to open at these premises and that it has repeatedly issued breach notices requiring the contractor to open in line with its contracted opening hours, and has subsequently withheld payments. The LHB has received a number of complaints from patients who had gone to the pharmacy on the bank holiday in order to have prescriptions dispensed. The LHB decides it is likely that the contractor will continue to persist in breaching this term of service to open in line with its contracted hours and believes, on the evidence it has, it would be justifiable and proportionate to remove the contractor from a pharmaceutical list under regulation 53(3).

As removal is the ultimate sanction available to a LHB, with far-reaching consequences for the community and for staff employed by the contractor, the decision to remove a contractor should not be taken lightly.

At the stage removal would be considered, every other option should have been explored and exhausted. However, if the removal of a contractor is justifiable and proportionate to protect patients or the LHB from material financial loss; and the LHB has reason to believe that the contractor will likely continue to either be in breach or make further repeated breaches, the LHB should consider proceeding with seeking a contractor's removal.

Removal process

Regulation 53(5) sets out the process that LHBs must follow when considering whether or not to remove premises from their pharmaceutical list. Where a LHB is minded to remove premises under regulation 53 it must:

- give the contractor at least 30 days' notice that it is minded to remove the premises;
- as part of that notification advise the contractor that they may make written representations with regard to the proposed action as long as they are sent to the LHB within 30 days beginning with the date of notification by the LHB;
- as part of that notification advise the contractor that they may make oral representations with regard to the proposed action, provided the contractor notifies the LHB that it wishes to make representations within 30 days and then attends the hearing arranged by the LHB; and
- consult with Community Pharmacy Wales, as the LPC (regulation 53(5)).

If the contractor wishes to make oral representations, they or their representative must attend the hearing that the LHB arranges.

What constitutes reasonable notice of the hearing will depend on the facts of the case. Only where patient safety is at significant risk should the LHB consider giving just one working day's notice, and such a short timescale would probably require wholly exceptional circumstances, given the powers to undertake fitness to practice suspensions that are available under the 2006 Act. It is suggested that the hearing is arranged prior to the letter being sent to the contractor, thereby affording them at least 30 days' notice.

At the hearing, which the contractor may or may not have asked to attend, the LHB will make its decision having taken into account any written or oral representations made by the contractor.

If the decision is made to remove the contractor's premises from the pharmaceutical list then the LHB must notify the contractor of that decision and regulation 53(6) requires the following information to be included in that notification:

- a statement of the reasons for the decision; and
- an explanation of how the contractor may exercise their right of appeal under regulation 54(1)(d).

The LHB may need to have regard to any obligations arising from residual lease commitments if, as a result of action to remove the premises or business from its pharmaceutical list, a contractor were subsequently to decide to close completely. The LHB will wish to bear in mind that action to remove a contractor from a pharmaceutical list does not, in itself, equal action to close the premises or business entirely. Nevertheless, depending on overall NHS income, subsequent closure could be an unavoidable result of de-listing. However, depending on the nature and severity of the breach, these are not, of themselves, sufficient grounds to override removal of a contractor's premises where the nature of the breach warrants it.

Chapter 15: Rights of appeal

Regulation 54 sets out a contractor's right to appeal the LHB's use of the performance related sanctions.

The following decisions are appealable by the contractor:

- the issuing of a remedial notice under regulation 50 including:
 - the specified steps that a contractor must take that are in the notice;
 - the duration of the notice period in the notice;
 - any decision to provide for a withholding of remuneration that is included in the notice; and
 - the amount of any withholding.
- a decision not to restore remuneration, as provided for in a remedial notice, or to restore a smaller amount;
- the issuing of a breach notice under regulation 51 including:
 - any decision to provide for a withholding of remuneration that is included in the notice; and
 - the amount of any withholding.
- a decision to remove premises from a pharmaceutical list under regulation 53(1).

In order to exercise their right of appeal the contractor must notify the Welsh Ministers with a valid notice of appeal within 30 days of the date on which they were notified of the decision that is being appealed. Appeals under this section are to be emailed to:

pharmacy.appeals@gov.wales

Regulation 54(2) confirms that a notice of appeal is only valid if it is made in writing and includes a concise and reasoned statement of the grounds of the appeal.

Although a LHB may have made the decision to remove the premises from its pharmaceutical list regulation 54(3) confirms that this decision does not take effect until either:

- the end of the 30 day appeal period, if no appeal is made; or
- where an appeal is made, it has been determined by the Welsh Ministers and the LHB's decision is not overturned.

Schedule 4 to the 2020 Regulations sets out how appeals will be dealt with by the Welsh Ministers.

Following the removal of the premises, the LHB will need to consider whether the loss has affected the availability of pharmaceutical services and any potential implications to the PNA.

Appendix 1 - Glossary of terms and phrases defined in the 2020 Regulations

The following definitions are set out in regulation 2 of the 2020 Regulations—

Term	Explanation
“the 1992 Regulations” (“Rheoliadau 1992”)	means the National Health Service (Pharmaceutical Services) Regulations 1992 as in force immediately before 10 May 2013;
“the 2005 Regulations” (“Rheoliadau 2005”)	means the National Health Service (Pharmaceutical Services) Regulations 2005 as in force immediately before 1 September 2012;
“the 2013 Regulations” (“Rheoliadau 2013”)	means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013() as in force immediately before 1 October 2020;
“the 2006 Act” (“Deddf 2006”)	means the National Health Service (Wales) Act 2006;
“additional opening hours”	is to be construed, as the context requires, in accordance with paragraph 23(11) of Schedule 5 or paragraph 13(10) of Schedule 6, or both;
“advanced electronic signature” (“llofnod electronig uwch”)	means an electronic signature which meets the following requirements— it is uniquely linked to the signatory; it is capable of identifying the signatory; it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under the signatory's sole control; and it is linked to the data signed in such a way that any subsequent change in the 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

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“appliance use review service” (“gwasanaeth adolygu defnyddio cyfarpar”)

“appropriate non-proprietary name” (“enw amherchnogol priodol”)

“appropriate batch issue” (“swp-ddyroddiad priodol”)

“bank holiday” (“gŵyl banc”)

“batch issue” (“swp-ddyroddiad”)

“Charges Regulations” (“Rheoliadau Ffioedd”)

“child” (“plentyn”)

Ministers for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);

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; 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; 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;

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;

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— is generated by a computer and not signed by a repeatable prescriber;

relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;

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 specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007;

means a person who has not attained the age of 16 years;

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“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 7 of these Regulations;
“contingent removal” (“dileu yn ddigwyddiadol”)	means removal from a pharmaceutical list contingently, within the meaning of section 108 of the 2006 Act (contingent removal);
“controlled locality” (“ardal reoledig”)	means an area which a Local Health Board has determined to be rural in accordance with regulation 13 (areas that are controlled localities), which the Welsh Ministers have determined on appeal, in accordance with Parts 1 and 2 of Schedule 4, to be rural or which is a controlled locality by virtue of the operation regulation 13(1);
“core hours”	means the hours during which pharmacy, or appliance contractor, premises must be open by virtue of paragraph 23(1) of Schedule 5, or paragraph 13(1) of Schedule 6;
“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 director of a body corporate; or 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 26 (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 11 (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 55 (the Drug Tariff and

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“electronic communication” (“cyfathrebiad electronig”)

“electronic prescription” (“presgripsiwn electronig”)

“electronic prescription form” (“ffurflen bresgripsiwn electronig”)

“electronic repeatable prescription” (“presgripsiwn amlroddadwy electronig”)

“electronic signature” (“llofnod electronig”)

“electronic signature creation data”

“employment” (“cyflogaeth”)

“equivalent body” (“corff cyfatebol”)

“equivalent list” (“rhestr gyfatebol”)

“essential services” (“gwasanaethau hanfodol”)

remuneration of NHS pharmacists and NHS appliance contractors);
has the meaning given in section 15(1) of the Electronic Communications Act 2000 (general interpretation);

means an electronic prescription or an electronic repeatable prescription;

means data created in an electronic form for the purpose of ordering a drug or appliance which—

is signed with a prescriber’s advanced electronic signature;

is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service; and

does not indicate that the drug or appliance ordered may be provided more than once;

means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription”;

means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;

means unique data which is used by the signatory to create an electronic signature;

includes unpaid employment and employment under a contract for services;

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;

means a list kept by an equivalent body;

for NHS pharmacists means the services specified in paragraph 3 of

“EEA”(“AEE”)

“ETP service” (“gwasanaeth TPE”)

“General Pharmaceutical Council Register” (“Cofrestr y Cyngor Fferyllol Cyffredinol”)

“GMS contract” (“contract GMC”)

“GMS contractor” (“contractwr GMC”)

“GMS Regulations” (“Rheoliadau GMC”)

“health care professional” (“proffesiynolyn gofal iechyd”)

“the Health and Care Professions Council register” (“cofrestr y Cyngor Proffesiynau Iechyd a Gofal”)

“independent nurse prescriber” (“nyrs sy’n rhagnodi’n annibynnol”)

“joint discipline committee” (“cyd-bwyllgor disgyblu”)

“LHBMS” (“GMBILI”)

Schedule 5 and for NHS appliance contractors means the services specified in paragraphs 3 to 12 of Schedule 6;

means the European Economic Area created by the EEA Agreement;

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;

means the register maintained under article 19 of the Pharmacy Order 2010 (establishment, maintenance of and access to the Register);

means a general medical services contract under section 42 of the 2006 Act (general medical services contracts: introductory);

means a party to a GMS contract, other than the Local Health Board;

means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004;

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;

means the register established and maintained by the Health and Care Professions Council under article 5 of the Health and Social Work Professions Order 2002;

means a person—

who 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 and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber; has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 (interpretation);

means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act (primary medical services);

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“LHBMS practice” (“practis GMBIL”)

“licensing or regulatory body” (“corff trwyddedu neu reoleiddio”)

“list” (“rhestr”),

“listed premises” (“mangre restredig”)

“Local Health Board” (“Bwrdd Iechyd Lleol”)

“Local Medical Committee” (“Pwyllgor Meddygol Lleol”)

“Local Pharmaceutical Committee” (“Pwyllgor Fferyllo
Lleol”)

“local pharmaceutical services” (“gwasanaethau fferyllo
lleol”)

“medical performers list” (“rhestr cyflawnwyr meddygol”)

“minor relocation” (“mân adleoliad”) (for the purposes of regulation 33)

“national disqualification” (“anghymhwysiad cenedlaethol”)

means a practice providing LHBMS;

means any body that licences or regulates any profession of which the person is or has been a member, and includes any body which licences or regulates any such profession in a country other than the United Kingdom;

unless the context otherwise requires, means a pharmaceutical list or a dispensing doctor list;

means the premises that are included in—

a pharmaceutical list; or

a dispensing doctor list pursuant to regulation 11 (preparation and maintenance of dispensing doctor lists);

means a Local Health Board established under section 11 of the 2006 Act (local health boards);

means a committee recognised under section 54 of the 2006 Act (local medical committees);

means a committee recognised under section 90 of the 2006 Act (local pharmaceutical committees);

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;

means a list of doctors prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004;

Where it relates to a GMS contractor, means a relocation of practice premises where—

(a) the pharmaceutical services specified in the application that would have been provided at the practice premises specified in the original application will be provided at the new practice premises, and

(b) the location of the new practice premises would not be significantly less accessible for the patients who access the practice premises specified in the original application.

means—

a national disqualification as mentioned in section 115(2) and (3) of

	<p>the 2006 Act (national disqualification); a national disqualification as mentioned in section 159(2) and (3) of the National Health Service Act 2006 (national disqualification); any decision in Scotland or Northern Ireland corresponding to a national disqualification under section 115(2) and (3) of the 2006 Act; and any other decision that was a national disqualification for the purposes of the 2005 Regulations;</p>
"NHS appliance contractor" ("contractwr cyfarpar GIG")	<p>means a person who is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;</p>
"NHS Business Services Authority" ("Awdurdod Gwasanaethau Busnes y GIG")	<p>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;</p>
"NHS pharmacist" ("fferyllydd GIG")	<p>means— a registered pharmacist; or person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968, whose name is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;</p>
"NHS services" ("gwasanaethau GIG")	<p>means services provided as part of the health service in Wales;</p>
"non-electronic prescription form" ("ffurflen bresgripsiwn anelectronig")	<p>means a prescription form which falls within sub-paragraph (a) of the definition of a "prescription form";</p>
"non-electronic repeatable prescription" ("presgripsiwn amlroddadwy anelectronig")	<p>means a prescription which falls within sub-paragraph (a)(i) of the definition of "repeatable prescription";</p>
"non-proprietary name" ("enw amherchnogol")	<p>means a name which is, or which is a permitted variation of— an International Nonproprietary Name (INN); an International Nonproprietary Name Modified (INNMod); a British Approved Name (BAN);</p>

“notice” (“hybysiad”)

“nurse independent prescriber” (“nyrs-ragnodydd annibynnol”)

“Nursing and Midwifery Register” (“Cofrestr Nyrsio a Bydwreigiaeth”)

“optometrist independent prescriber” (“optometrydd-ragnodydd annibynnol”)

“originating events” (“digwyddiadau cychwynnol”)

“outline consent” (“cydsyniad amlinellol”)

a British Approved Name Modified (BANM); or
an approved name,
and for this purpose these names (and their permitted variations)
have the same meanings as in a list of names which has been
prepared and caused to be published by the British Pharmacopoeia
Commission and which has not been superseded;

means a notice in writing;

means a person—

whose name is registered in the Nursing and Midwifery Register;
against whose name in that register is recorded an annotation or
entry signifying that they are qualified to order drugs, medicines and
appliances as—

a nurse independent prescriber, or

a nurse independent/supplementary prescriber, and

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;

means the register maintained by the Nursing and Midwifery Council
under article 5 of the Nursing and Midwifery Order 2001
(establishment and maintenance of register);

means a person—

who is an optometrist registered in the register of optometrists
maintained under section 7 of the Opticians Act 1989 (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
against whose name is recorded an annotation signifying that the
optometrist is qualified to order drugs, medicines and appliances as
an optometrist independent prescriber;

means the events that gave rise to the conviction, investigation,
proceedings, suspension, refusal to admit, conditional inclusion,
removal or contingent removal that took place;

has the meaning given to it in regulation 30(1)(a) (outline consent and

“outstanding pharmacy application” (“cais am fferyllfa yn yr arfaeth”)

“paramedic independent prescriber” (“parafeddyg-ragnodydd annibynnol”)

“patient list” (“rhestr cleifion”)

“pharmaceutical discipline committee” (“pwyllgor disgyblu fferyllol”)

“pharmaceutical list” (“rhestr fferyllol”)

“pharmaceutical services” (“gwasanaethau fferyllol”)

“pharmacist independent prescriber” (“fferyllydd-ragnodydd annibynnol”)

“pharmacy” (“fferyllfa”)

premises approval);

has the meaning given to it in regulation 31(11) (taking effect of outline consent and premises approval);

means a person—

who is registered as a paramedic in Part 8 of the Health and Care Professions Council register; and

against whose name is recorded in Part 8 of that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber; 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;

has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992;

means a list that a Local Health Board is required to prepare and maintain under regulation 10 (preparation and maintenance of pharmaceutical lists);

means pharmaceutical services that fall within section 80 and 81 of the 2006 Act and includes directed services;

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 (which relates to registers and the registrar) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber; means—

listed premises under regulation 10 (preparation and maintenance of pharmaceutical lists) at which pharmaceutical services are provided by an NHS pharmacist pursuant to arrangements made to section 80 of the 2006 Act; or

premises where under a pharmacy pilot scheme under section 92 of

“physiotherapist independent prescriber” (“ffisiotherapydd-ragnodydd annibynnol”)

“pilot scheme” (“cynllun peilot”)

“podiatrist or chiropodist independent prescriber”
 (“podiatrydd-ragnodydd neu giropodydd-ragnodydd
 annibynnol”)

“practice premises” (“mangre practis”),

“preliminary consent” (“cydsyniad rhagarweiniol”)

“premises approval” (“cymeradwyaeth mangre”)

“prescriber” (“rhagnodydd”)

the 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);

means a person—

who is a physiotherapist, and

against whose name in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2002 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

has the same meaning as the term “pilot scheme” in section 92(2) of the 2006 Act (pilot schemes);

means a person—

who is a podiatrist or a chiropodist, and

against whose name in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2002 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

in relation to a provider of primary medical services, means 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 pharmaceutical services are to be provided under the contract or practice statement;

has the meaning given to it in regulation 18 (applications for preliminary consent and effect of preliminary consent);

has the meaning given to it in regulation 30(1)(b) (outline consent and premises approval) and includes temporary premises approval granted under regulation 34(13) (premises approval: additional and new premises after outline consent has taken effect) or residual premises approval granted under regulation 35(9) (premises approval: practice amalgamations);

means a doctor, dentist, pharmacist independent prescriber,

	independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist or chiropodist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or a supplementary prescriber;
“prescription form” (“ffurflen bresgripsiwn”)	means— 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 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();
“provider of primary medical services” (“darparwr gwasanaethau meddygol sylfaenol”)	means a GMS contractor, APMS contractor or an LHBMS practice;
“Regional Partnership Board” (“Bwrdd Partneriaeth Rhanbarthol”)	has the meaning given to it in regulation 1(4) of the Partnership Arrangements (Wales) Regulations 2015;
“registered pharmacist” (“fferyllydd 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;
“registered radiographer” (“radiograffydd cofrestredig”)	means a person registered in Part 11 of the Health and Care Professions Council register;
“relevant APMS contractor” (“contractwr GMDdA perthnasol”),	in relation to any doctor, means— the APMS contractor, where the doctor is an APMS contractor, or where the doctor is not the APMS contractor, the APMS contractor by whom the doctor is employed or engaged;
“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 the doctor is not a GMS contractor, the GMS contractor by whom the doctor is employed or engaged;

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“relevant list” (“rhestr berthnasol”)

means—

a pharmaceutical list or an equivalent list; or
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, 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;

“relevant pharmaceutical needs assessment” (“asesiad perthnasol o anghenion fferyllol”)

means the pharmaceutical needs assessment of the relevant Local Health Board that is current at the time that the Local Health Board takes its decision to grant or refuse an application, unless in the opinion of the Local Health Board (or on appeal the Welsh Ministers) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment;

“Remission of Charges Regulations” (“Rheoliadau Peidio â Chodi Tâl”)

means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007;

“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 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;

an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the

“repeatable prescription” (“presgripsiwn amlroddadwy”)

“reserved location” (“lleoliad neilltuedig”)

2006 Act in relation to APMS contracts which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations; or employed or engaged by—

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;

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 a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing services 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;

means a prescription contained in a form provided by a Local Health Board which—

is either—

generated by computer but signed by a repeatable prescriber, or a form created in an electronic format, identified using a repeatable prescriber’s code, transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service and is signed with a repeatable prescriber’s advanced electronic signature;

is issued or created to enable a person to obtain pharmaceutical services; and

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;

has the meaning given to it by regulation 17(4) (locations in controlled localities that are reserved locations);

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“restricted availability appliance” (“cyfarpar argaeledd cyfyngedig”)

“Scheduled drug” (“cyffur Atodlen”)

“serious shortage protocol” (“protocol prinder difrifol”)

“signatory”

“specified appliance” (“cyfarpar penodedig”)

means an appliance which is approved for particular categories of persons or particular purposes only;

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);

means—

in the case of a prescription only medicine, a serious shortage protocol for the purposes of regulation 226A of the Human Medicines Regulations 2012 (sale etc. by a pharmacist in accordance with a serious shortage protocol); or

in the case of any other drug or appliance, a written protocol that—
is issued by the Welsh Ministers in circumstances where Wales or any part of Wales is, in the opinion of the Welsh Ministers, experiencing or may experience a serious shortage of—

a specified drug or appliance, or

drugs or appliances of a specified description,

provides for the supply by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical or local pharmaceutical services, where there is an order on a prescription form or a repeatable prescription for—

the specified drug or appliance, or

a drug or appliance of the specified description,

of a different product or quantity of product to the product or quantity of product ordered, subject to such conditions as may be specified in the protocol, and

specifies the period for which, and the parts of Wales (which may be all of Wales) in which, the protocol is to have effect;

means a natural person who creates an electronic signature;

means—

	any of the following appliances listed in Part IXA of the Drug Tariff— a catheter appliance (including a catheter accessory and maintenance solution), a laryngectomy or tracheostomy appliance, an anal irrigation system, a vacuum pump or constrictor ring for erectile dysfunction, or a wound drainage pouch; an incontinence appliance listed in Part IXB of the Drug Tariff; or 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— the stoma appliances to be customised are listed in Part IXC of the Drug Tariff; the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and that modification is based on the patient’s measurements or a record of those measurements and, if applicable, a template;
“SSP” (“PPD”)	means a serious shortage protocol;
“superintendent” (“uwcharolygydd”)	has the same meaning as in section 71 of the Medicines Act 1968 (bodies corporate);
“supplementary opening hours”	is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 5 or paragraph 13(3)(a) of Schedule 6, or both;
“supplementary prescriber” (“rhagnodydd atodol”)	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 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber; 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;

“therapeutic radiographer independent prescriber”
 (“radiograffydd therapiwtig-ragnodydd annibynnol”)

“Tribunal” (“Tribiwnlys”)

a person—

who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001 (establishment and maintenance of register) which relates to chiropodists and podiatrists, dieticians, paramedics, physiotherapists or radiographers, and

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

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;

means a person—

who is a registered radiographer, and

against whose name is recorded in Part 11 of the Health and Care Professions Council register—

an entitlement to use the title “therapeutic radiographer”; and

an annotation signifying that they are qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber; and

means the First-tier Tribunal established under the Tribunals, Courts and Enforcement Act 2007.

Appendix 2 - Breach & Remedial Notices– Draft template

Name of contractor:

Address of premises:

Date of inclusion in the pharmaceutical list for the area of [insert name of health board]:

This is a remedial notice issued under regulation 50 of the NHS (Pharmaceutical Services) (Wales) Regulations 2020.

Term of service that has been breached: [insert specific term of service]

Nature of the breach:

[Insert details]

Steps you are required to take, to our satisfaction, in order to remedy the breach:

[Insert details]

The required steps must be completed by:

[Insert details]

[insert the following where relevant]

[Withholding of payments]

We have also determined that payment withholdings are to apply in respect of this breach.

[insert reasoning for decision to withhold payments]

[insert details of how much or which fees or allowances are to be withheld and the reasoning for withholding that amount or those fees or allowances]

The withholding relates to the period from [insert date] to [insert date].]

You have a right of appeal to the Welsh Ministers against the issuing of this remedial notice **[and to withhold payments]**. Should you choose to appeal then you should send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this notice to pharmacy.appeals@gov.wales.

Please note that should you fail to comply with the requirements of this remedial notice we reserve the right to exercise our powers to take further action in relation to your inclusion in the pharmaceutical list in respect of the above named premises. This may include removal of the premises from the pharmaceutical list under regulation 53 of the NHS (Pharmaceutical Services) (Wales) Regulations 2020.

Dated:

Signed:

on behalf of [insert name of health board]

Print name:

Template Breach Notice

Name of contractor:

Address of premises:

Date of inclusion in the pharmaceutical list for the area of [insert name of health board]:

This is a breach notice issued under regulation 51 of the NHS (Pharmaceutical Services) (Wales) Regulations 2020.

Nature of the breach:

You are required to not repeat the breach again.

[insert the following where relevant]

[Withholding of payments]

We have also determined that payment withholdings are to apply in respect of this breach.

[insert reasoning for decision to withhold payments]

[insert details of how much or which fees or allowances are to be withheld]

The withholding relates to the period from [insert date] to [insert date].]

You have a right of appeal to the Welsh Ministers against the issuing of this remedial notice **[and to withhold payments]**. Should you choose to appeal then you should send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this notice to pharmacy.appeals@gov.wales.

Please note that should you fail to comply with the requirements of this remedial notice we reserve the right to exercise our powers to take further action in relation to your inclusion in the pharmaceutical list in respect of the above named premises. This may include removal of the premises from the pharmaceutical list under regulation 53 of the NHS (Pharmaceutical Services) (Wales) Regulations 2020.

Dated:

Signed:

on behalf of [insert name of health board]

Print name