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National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

Consultation on draft Regulations

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

Overview

This consultation concerns the making of the NHS (Pharmaceutical Services) (Wales) Regulations 2020 which revoke and replace NHS (Pharmaceutical Services) (Wales) Regulations 2013.

Pharmaceutical Needs Assessments, which will be introduced by the 2020 Regulations, are an assessment of the availability of pharmaceutical services.

Health boards in Wales will be required to conduct pharmaceutical needs assessments from 01 April 2020.

How to respond

Please complete the questionnaire at the back of this document and email or post it to the addresses below.

Further information and related documents

Large print, Braille and alternative language versions of this document are available on request.

The Welsh Government has conducted a Regulatory Impact Assessment which is published at:

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The contact details for the Information Commissioner's Office are:

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National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

Consultation on draft Regulations

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FOREWORD

I am pleased to launch this consultation which sets out the detail of the draft National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

Much work has been done by the Welsh Government in recent years to move health services which were traditionally provided in hospitals into the community, closer to where the patient lives. Many GP practices now offer services which patients will have previously accessed via hospital out-patient departments. Minor surgical procedures are now common place in the GP surgery and no longer the sovereignty of our hospitals.

Similarly we have concentrated significant effort in transforming community pharmacy to one which delivers services that traditionally would have been delivered by general practitioners. All pharmacies are now able to provide the Common Ailments Service and many undertake medicines use reviews, including on discharge from hospital, administer flu vaccinations and provide advice and support on smoking cessation and emergency contraception. By moving services of this kind into our communities we have made professional advice and support more accessible to the public, as well as freeing up GPs to focus on dealing with patients with more complex health needs.

Community pharmacies have an integral role in shaping and contributing to improvements in public health. They are located in villages, towns and city centres across Wales. Many are open six, and occasionally seven, days a week. Community pharmacies are generally patients' first, and often their most frequent, point of contact with a healthcare professional. As such, they are uniquely well positioned to make a wide range of services easily available to local people and to contribute to the easing of pressure on General Practitioners' time, as well as signposting patients from hospital services to those more appropriately dealt with in the community setting.

The current regulatory regime and approach has been in place for over 27 years and no longer adequately reflects the way in which the role of community pharmacies has changed in that time.

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 will introduce the requirement for each health board to conduct and publish a pharmaceutical needs assessment for its area and to determine applications to provide National Health Service pharmaceutical services against that assessment. They also introduce arrangements for dealing with breaches of terms of service by NHS pharmacists and NHS appliance contractors.

In order to maximise the public health role of community pharmacies, the introduction of pharmaceutical needs assessment makes a fundamental change to the way in which decisions about pharmaceutical services in Wales are made by health boards, shifting from one driven by applications from pharmacy contractors and focussed heavily on the dispensing of prescriptions, to one which is alert and responsive to the broader pharmaceutical needs of local communities.

This consultation also considers the amendment of the criteria which persons must satisfy in order to provide pharmaceutical services, previously known as 'control of entry' which

we are now referring to as 'market entry', which I believe better reflects the way in which pharmaceutical services are governed.

The new Regulations complement the measures the Welsh Government has taken since 2017 to transform the delivery of the Community Pharmacy Contractual Framework to one where more clinical services are delivered by community pharmacies. I am confident communities will benefit from the proposed changes to the way pharmaceutical services are planned in Wales to better meet the needs of local communities.

I look forward to receiving responses from as many people as possible across Wales.

Vaughan Gething AM
Minister for Health and Social Services

DETAIL OF CONSULTATION

What is the subject of this consultation?

This consultation sets out the detail of the Welsh Government's proposals to change the way in which pharmaceutical services are provided in Wales through the introduction of pharmaceutical needs assessments.

The proposed draft NHS (Pharmaceutical Services) (Wales) Regulations 2020 (the 2020 Regulations) will introduce the requirement for health boards to conduct pharmaceutical needs assessments and, as a consequence, also change the criteria for making applications by those persons wishing to provide NHS pharmaceutical services in Wales. They will revoke and replace the NHS (Pharmaceutical Services) (Wales) Regulations 2013 (the 2013 Regulations).

This consultation sets out in detail those changes to the current regulatory framework, it does not cover every provision of the draft 2020 Regulations as not all provisions require updating. A copy of the draft 2020 Regulations is annexed to this consultation.

This consultation document has been prepared by the Welsh Government and applies in relation to Wales only.

What is the purpose of this consultation?

To seek the views of health boards, persons who may apply to provide NHS pharmaceutical services or dispensing doctor services, professional bodies with an interest in NHS pharmaceutical services, as well as other stakeholders and the wider public on the draft 2020 Regulations proposed by the Welsh Ministers.

Who will this consultation be of most interest to?

The proposed changes will be particularly relevant to health boards, persons who may wish to apply to provide NHS pharmaceutical services and representative bodies.

Consultation questions are found at the end of the Summary, at page 33.

Introduction

Background

The NHS Pharmaceutical Services (Wales) Regulations 2013 set out the current arrangements, known as 'control of entry', under which pharmaceutical services are provided in Wales. In addition to setting out the conditions under which pharmacists can apply to provide NHS pharmaceutical services, and the terms and conditions under which those services will be provided, the regulations make special provision for areas that are rural in character and they prescribe the circumstances in which, in those areas, doctors can apply for and be granted the right to provide pharmaceutical services to their patients. These are commonly known as 'dispensing doctors'.

There are three main providers of NHS pharmaceutical services in Wales:

- Community pharmacies
- Dispensing doctors
- Dispensing appliance contractors

There are also a small number of pharmacies that do not provide NHS pharmaceutical services. These are not included in the health board pharmaceutical list and are unable to provide NHS pharmaceutical services but can supply over the counter medicines.

There are over 700 community pharmacies providing NHS services in Wales. Whilst the exact number fluctuates from year to year, the current arrangements governing NHS pharmaceutical services have resulted in a stable market with little net change in community pharmacy numbers over time. In the last ten years community pharmacy numbers in Wales have been largely unchanged

Around 74.7 million prescriptions are dispensed in community pharmacies in Wales every year¹. Furthermore, pharmacies are high street retailers, routinely visited by people who do not consider themselves to be ill. Each visit is, therefore, an opportunity to engage with members of the public about their lifestyle and to make a contribution to improving their health and wellbeing.

A positive relationship exists between deprivation and pharmacy numbers, with pharmacies more prevalent in more economically deprived areas, meaning that access is generally better in areas with the greatest need². In addition, dispensing doctors principally serve rural locations.

Community pharmacies also provide a convenient and less formal environment for those who cannot, or do not wish to, visit other kinds of health services. For example, many provide emergency contraception, smoking cessation and sexual health advice, and in 2012 Wales was the first part of the UK to introduce free seasonal influenza vaccination

¹ Statistics for Wales release (<https://gov.wales/community-pharmacy-services-april-2017-march-2018>)

² [Distribution of community pharmacies and deprivation in Wales](#)

for those aged 65 and over or in at-risk groups from community pharmacies on a national basis.

The current system

The Welsh Government establishes the overall structure in which community pharmacies operate by providing the legislative and policy framework. Within the framework, the responsibility for planning and providing pharmaceutical services is vested in health boards who must plan health services to meet the needs of their resident populations. This includes determining the number and location of pharmacies in their areas.

The general duty to provide NHS pharmaceutical services, as with other aspects of NHS primary care services, is conferred directly on health boards under the NHS (Wales) Act 2006 (the 2006 Act). Health boards manage local lists of approved providers, referred to as pharmaceutical lists, and the inclusion of pharmacy premises on pharmaceutical lists entitles the pharmacy to provide NHS pharmaceutical services at those premises.

These arrangements govern the provision of NHS pharmaceutical services and not the right to open and conduct a pharmacy business in Wales. That is dealt with under separate UK-wide legislation, the Medicines Act 1968.

The Welsh Ministers have extensive powers and duties to make regulations and to issue directions to health boards, which govern the detail of the NHS pharmaceutical services system in Wales. This includes specifying the terms of service for NHS pharmacists and the application of the control of entry test, which is the test that must be satisfied before a health board may grant an application for entry, or amend an entry, on the pharmaceutical list.

Currently those persons wishing to provide NHS pharmaceutical services submit an application to the health board in accordance with the 2013 Regulations. The health board then decides whether or not the application satisfies the relevant test. The 2013 Regulations allow for the health board's decision to be challenged by lodging an appeal with the Welsh Ministers.

The current system of NHS pharmaceutical services delivery is therefore driven by those who wish to provide NHS pharmaceutical services. It is they who decide which services they wish to provide and from what location.

This means that the current system is reactive to applications and health boards are not able to plan where pharmacies are located or direct which services must be provided from those locations.

Rationale for change

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 and the provision of pharmaceutical services by health professions other than pharmacists (e.g. doctors) and 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 NHS pharmaceutical services in Wales based more on an assessment of local needs by health boards. 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 2013 Regulations came into force on 10 May 2013 but did not contain provisions to introduce pharmaceutical needs assessments.

The Public Health (Wales) Act 2017 (the 2017 Act) inserted section 82A into the 2006 Act which makes provision for a new duty for health boards in Wales to prepare and publish an assessment of need for pharmaceutical services. Section 82A gave the Welsh Ministers powers to make regulations setting out the requirements of pharmaceutical needs assessments in Wales. The 2017 Act also amends 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 pharmaceutical needs assessments is to improve the planning and delivery of pharmaceutical services by ensuring the health boards robustly consider the pharmaceutical needs of their populations and align services more closely with them. This will require health boards 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). Health boards will use these assessments to identify where additional pharmacies are required; where existing providers are adequately addressing pharmaceutical needs; and where additional services are required from existing pharmacies.

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

Importantly, pharmacies 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 consistent delivery, health boards will be able to implement improvement measures. These could include taking action against particular pharmacies for persistent breaches of terms and conditions of service. This should result in pharmacies providing services more consistently and to a higher standard, and ensure that pharmacies provide services in locations where they are needed. These changes will also make decisions about the inclusion of new pharmacies onto the pharmaceutical lists more transparent. Ultimately, the changes will allow for improvement in the quality and consistency of NHS pharmaceutical services across Wales.

Policy, legislative framework and regulation

Section 80 of the 2006 Act places a duty on health boards 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 health boards 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 health board (i) requiring it to arrange for the provision of additional pharmaceutical services, or (ii) authorising the health board to arrange for the provision of pharmaceutical services if it wishes.

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 health board 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 (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 health boards 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 in to the 2006 Act conferring powers on the Welsh Ministers to make regulations in respect of pharmaceutical needs assessments. 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 of pharmaceutical needs assessments in Wales.

The 2013 Regulations will be revoked and replaced by the 2020 Regulations. Part 2 of the draft 2020 Regulations imposes the legal requirements on health boards to complete pharmaceutical needs assessments.

The intention is for the 2020 Regulations to come into force on 1st April 2020. Once the 2020 Regulations come into force, health boards will have six months to prepare and publish their pharmaceutical needs assessment.

The Legislative Process

Part of the amendments made to the 2006 Act by the 2017 Act requires a statutory instrument containing the first regulations pursuant to section 82A (pharmaceutical needs assessments) may not be made unless a draft of the instrument has been laid before, and approved by resolution of, the National Assembly for Wales. The 2020 Regulations will therefore follow the National Assembly for Wales' affirmative legislative procedure.

Developing the detailed requirements

A working group was established in November 2015 to develop the detailed requirements for conducting a pharmaceutical needs assessment and to review and amend the tests

and procedures as they apply to the provision of NHS pharmaceutical services. The group, which has met on a number of occasions since its establishment, consists of health board pharmacy leads with knowledge of the existing control of entry system and expertise in community pharmacy, NHS Shared Services Partnership primary care (pharmacy) leads, who have expertise in the process of determining control of entry applications, and Welsh Government staff. The group has made a significant contribution to the development of the Welsh Government's policy on pharmaceutical needs assessments, including the resultant proposals contained within the 2020 Regulations.

Impact on Businesses

It is assumed that all persons who wish to apply to provide NHS pharmaceutical services in Wales (particularly multiple and national retail pharmacies) will have to invest in understanding the new legislation.

It is envisaged there will be minimal one-off familiarisation costs to business; where businesses will have to read and understand the Regulations.

It is not anticipated the proposed changes will present any other impact on the day to day operations of businesses providing NHS pharmaceutical services.

Pharmaceutical Needs Assessments

Background

The current regulatory regime and approach has been in place for more than 27 years and does not adequately reflect the way in which the role of pharmacies has changed in that time. In the last 10 years community pharmacy numbers in Wales have remained largely unchanged, however prescription volumes have grown by over 40% (from 53.1 million in 2005/6 to 74.7 million in 2017/18).

Under the current arrangements, when determining applications, health boards only consider the pharmaceutical services defined under section 80 of the 2006 Act. Broadly speaking this relates only to the dispensing of prescriptions. The onus on deciding when, and in relation to which, applications to provide pharmaceutical services are made rests with the applicants.

Community pharmacies are increasingly providing additional services, including the provision of emergency contraception, influenza vaccinations and support to stop smoking. Furthermore since 2017 the Welsh Government has developed the Community Pharmacy Contractual Framework (CPCF) to include the delivery of more clinically based services and has reconfigured its funding to align with this model of service provision.

Currently decisions about whether pharmacies are allowed to provide NHS pharmaceutical services are made on the basis of whether there is adequate access to pharmacies for the dispensing of prescriptions and not whether additional services are offered or needed. This has the effect that pharmacies wishing to offer additional services may not be able to enter the market, because the market entry test fails to recognise these additional services and whether they would support addressing local health needs.

Finally, there are existing provisions in the 2006 Act which allow a health board to remove a person from a pharmaceutical list where there are fitness to practice concerns. These fitness matters are set out in section 107(2) to (4) of the 2006 Act and relate to situations where it is determined that a person is no longer fit to be included in the pharmaceutical list for reasons of fraud, unsuitability or efficiency of service provision. There are no express powers in the existing Regulations to remove a person or an entry in respect of premises from a pharmaceutical list on other grounds, specifically those relating to performance and delivery of services. The draft 2020 Regulations provide such powers, introduce performance related sanctions and a market exit regime.

In publishing a pharmaceutical needs assessment, a health board will be making a statement of where it believes pharmaceutical services are needed; where it would like existing contractors to increase their provision; relocate premises and as a consequence deliver a better distribution of premises; or apply to open an additional pharmacy.

NHS (Pharmaceutical Services) (Wales) Regulations 2020

Part 1 – Interpretation

Part 1 sets out the definitions for the purposes of the draft Regulations. There are also some minor amendments to this section which amend existing, or insert new, definitions

as consequence of the introduction of pharmaceutical needs assessments, whereas some others, for example, account for changes to European Union legislation which have been made as a consequence of the UKs intention to exit the European Union.

The definition of pharmaceutical services has been changed so as to include all pharmaceutical services that fall within section 80 and 81 of the NHS Wales Act 2006 and includes directed services.

Question 1: Do you agree that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services for the purposes of the Regulations?

Part 2 - Pharmaceutical needs assessments

Part 2 sets out the requirements relating to the production of pharmaceutical needs assessments.

Requirement to conduct pharmaceutical needs assessment

Each health board is required to complete and publish an assessment of the need for pharmaceutical services in its area (See: Regulation 3(1)³).

The health board must consider all pharmaceutical services that are provided by persons on the pharmaceutical list, dispensing of drugs and appliances by a person on the dispensing doctor list and local pharmaceutical services provided under a pilot scheme (See: Regulation 3(2)).

Question 2: Do you agree that the health board should be placed under an obligation to consider all pharmaceutical services and are there any other persons providing those services that should be considered?

Information to be contained in Pharmaceutical Needs Assessments

Pharmaceutical needs assessments must contain specific information (See: Regulation 4).

The information contained in a pharmaceutical needs assessment is set out in Schedule 1 of the 2020 Regulations and includes:

³ All references to a regulation in this section of the consultation document are to regulations contained in the draft NHS (Pharmaceutical Services) (Wales) Regulations 2020 at Annex 1.

- Current service provision
- Gaps in service provision
- Other relevant services: current provision
- Dispensing services
- Other NHS services, including health board provided services, dispensing doctors etc.
- An explanation of how the assessment was made, including how it has determined the localities in its area; and how it has taken account of the needs of the different localities and population groups within its area
- A map identifying where pharmaceutical services are currently being provided

Each health board must, in so far as is practicable, keep up to date the map which it includes in its pharmaceutical needs assessment (without needing to republish the whole of the assessment or publish a supplementary statement) (See: Regulation 4).

Question 3: Do you believe there is anything that could be added to the list of required information to improve the content of a pharmaceutical needs assessment?

Publishing pharmaceutical needs assessment and subsequent assessments

A health board must publish its first pharmaceutical needs assessment within 6 months of the date on which the Regulations come into force (See Regulation 5).

After it has published its first pharmaceutical needs assessment, each health board must publish a statement of its revised assessment at any point within, but no later than, 5 years of its previous publication of a pharmaceutical needs assessment, having regard to any other needs assessments the health board is under a statutory duty to publish (See Regulation 6(1)) for example, the health board's Health Needs Assessment by virtue of the requirements set out in the Sustainable Development and the Wellbeing of Future Generations (Wales) Act 2015.

Question 4: Do you believe the five year period between assessments to be appropriate?

After identifying changes to the circumstances in its area that might mean its published pharmaceutical needs assessment will need revising, the health board must as soon as is reasonably practicable make a revised assessment unless it is satisfied it is disproportionate to do so (See Regulation 6(2)).

Question 5: Do you agree the health board should be under a duty to revise its pharmaceutical needs assessment once it considers there are significant changes to the circumstances in its area; for example when a large housing development takes place?

Consultation on pharmaceutical needs assessments

When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each health board must consult on the contents of the assessment the following persons:

- The Local Pharmaceutical Committee
- The Local Medical Committee for its area, plus any neighbouring LMC it considers will have an interest
- The persons on its pharmaceutical lists and its dispensing doctors list (if it has one)
- Any pilot scheme pharmacy with whom the health board has made arrangements for the provision of any local pharmaceutical services
- Any person with whom the health board has made arrangements for the provision of dispensing services
- Any provider of primary medical services in its area
- Any relevant Community Health Council or patient, consumer or community group in its area which in the opinion of the health board has an interest in the provision of pharmaceutical services in its area
- Any Local Authority for its area
- Any NHS Trust in its area
- Any neighbouring health board

(See Regulation 7(1)).

Question 6: Do you agree with the list of persons who must be consulted on the contents of an assessment?

Question 7: Are there any other persons who should be consulted?

A draft of the proposed pharmaceutical needs assessment must be published on the website of the health board for a minimum of 60 days (See Regulation 7(2)).

The health board must, no later than 24 hours after the draft pharmaceutical needs assessment is published notify the persons listed as consultees in regulation 7(1) (set out above) that a draft of the proposed pharmaceutical needs assessment has been published on the health board website and the date by which any consultation response must be provided to them (See Regulation 7(3)).

If a consultee requests a copy of the draft pharmaceutical needs assessment in hard copy form, the health board 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) (See Regulation 7(4)).

Where a health board is notified in accordance with paragraph (3) and there is a Local Medical Committee for its area that is different to the Local Medical Committee consulted under paragraph (1)(b), the health board notified must consult that Committee before making its response to the consultation and must have regard to any representation received from the Committee when making its response to the consultation (See Regulation 7(5)).

The 60 day consultation period will provide an opportunity for interested parties to challenge the findings of the draft pharmaceutical needs assessment and for the health board to consider amendments to their assessment prior to its publication. There is no right of appeal in relation to a draft proposed pharmaceutical needs assessment or the final published assessment. Therefore, it is important that interested parties engage in the health boards' consultation. It may be a consultee does not agree with the findings a health board has made, 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 that has not been considered during the assessment, or of how the local population accesses services in the area under consideration. The consultation on the proposed draft is an therefore an important opportunity to raise any factors which the consultee thinks the health board should consider in advance of publishing their final pharmaceutical needs assessment.

Question 8: Do you agree with the process for the health board's publishing of its assessment?

Matters for consideration when making assessments

In preparing their pharmaceutical needs assessment, health boards must have regard to the following:

- any assessment of relevant needs prepared under section 82A of the NHS Wales Act 2006 (i.e. previous pharmaceutical needs assessments);
- the demography of the area
- the different needs of each of the localities in the health board area
- the effect of pharmaceutical services provided under arrangements with neighbouring health boards
- the effect of dispensing services or other NHS services provided outside its area;

(See Regulation 8(1)).

The health board must also take account of any likely future needs (See Regulation 8(2)).

Question 9: Are there any other factors a health board should have regard to when making an assessment?

Market Entry

Part 3 – Pharmaceutical lists and dispensing doctor lists

Part 3 sets out the requirements for health boards to prepare and maintain pharmaceutical and dispensing doctor lists for their area.

Preparation and maintenance of pharmaceutical lists

Health boards will still be required to prepare and maintain a pharmaceutical list (including dispensing appliance contractors) and a dispensing doctor list (See Regulations 10 and 11).

Any pharmaceutical list (including dispensing appliance contractors) and a dispensing doctor list that is the current list immediately before the 2020 Regulations come into force will remain so when the 2020 Regulations come into force (See Regulations 10(4) and 11(6)).

Question 10: Do you consider it appropriate to maintain existing pharmaceutical and dispensing doctor lists when the 2020 Regulations come into force?

Part 4 – Determination of controlled localities

Part 4 makes provision for health boards to determine applications which seek to define parts of the health board area as controlled localities.

Areas that are controlled localities

Any area that was defined as a controlled locality for the purposes of the 2013 Regulations continues to be a controlled locality for the purposes of the 2020 Regulations (See Regulation 13).

Question 11: Do you agree to the maintaining of previously defined controlled areas?

Part 5 - Applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to the pharmaceutical list

Part 5 sets out the types of applications in respect of inclusion in or amendment to pharmaceutical lists and the tests which a health board must apply to determine those applications.

Inclusion onto the pharmaceutical list and Preliminary Consent

The current position under the 2013 Regulations is that any application for a new pharmacy or dispensing GP practice must satisfy the health board that it is necessary or expedient to approve it (the “*necessary or expedient test*”). Ultimately, a contractor must make the case to the health board that there is insufficient provision of pharmaceutical services to meet the need of the population of the neighbourhood.

We intend to change the test which an application must satisfy to one that relies upon the health board’s latest pharmaceutical needs assessment. If a health board identifies a need for pharmaceutical services in a specific location, applications to meet that need can be made and subsequently approved. If, however, no need is identified in the pharmaceutical needs assessment the application is unlikely to be approved. In all places within the 2013 Regulations, all references to the ‘Necessary or Expedient’ test will be replaced with the following new test:

“... the Local Health Board 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 area of the relevant Local Health Board and which will have been included in the pharmaceutical needs assessment of that Local Health Board ...” (e.g. see Regulation 16(1))

Question 12: Do you consider the change of test as a consequence of the introduction of pharmaceutical needs assessment to be appropriate?

Question 13: Are there any other criteria that should be applied to this test?

Relocation of pharmacy premises

A contractor may need or wish to relocate for a number of reasons.

Currently, a health board must grant an application made by a person under regulation 8(1)(b)(ii), of the 2013 Regulations, to relocate from listed premises to new premises at which the person intends to provide the same pharmaceutical services if it is satisfied that

- (a) the change is a minor relocation;
- (b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (c) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises;
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow); and

- (e) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 15 (applications involving temporary relocation).

A move of premises made under the above criteria has been known as minor relocation.

The 2020 Regulations remove the concept of minor relocation.

The Welsh Ministers acknowledge there are two broad circumstances under which pharmacies may wish to move premises within a health board area:

- (i) where a move is to meet a need identified in the pharmaceutical needs assessment, e.g. a move over a large distance (See Regulation 19(2)(a)).
- (ii) where a move is for business purposes and does not meet a need for pharmaceutical services as identified in the health board's pharmaceutical needs assessment, e.g. due to the expiry of a buildings lease (See Regulation 19(2)(b)).

Pharmacies may also wish to move premises between neighbouring health boards. The Welsh Ministers have therefore made provision for an application to be made to the neighbouring health board and to be granted if the application meets a need identified in the pharmaceutical needs assessment of the neighbouring health board and for patients who are accustomed to accessing services at the existing premises, the location of the new premises is not significantly less accessible (See Regulation 20).

Question 14: Do you agree with the removal of minor relocation for premises?

Question 15: Do you consider a move between health board areas should only be allowed when a need has been identified in the health board's assessment and providing it does not disadvantage access by persons accustomed to accessing services in the current location?

Temporary relocation of pharmacy premises

Schedule 2 of the 2013 Regulations applies a standard set of procedural criteria across all applications for inclusion or amendment to the pharmaceutical and dispensing doctor lists; which includes a period of 30 days allowed for making representations on an application. Applications for temporary relocation are determined by the health board in accordance with Schedule 2 and therefore the implied quick determination of these is delayed by the 30 days period. Due to the circumstances in which a temporary relocation of premises would be required it was never intended that a period of 30 days would apply to the determination of temporary relocation applications or appeals.

To clarify the position the period of 30 days in which to comment on an application and subsequently on appeal has been removed from the 2020 Regulations (See Schedule 3 paragraph 8(4)).

Question 16: Do you have any comments to make on this consequential amendment.

Part 6 – Applications by dispensing doctors for inclusion or amendment to dispensing doctor lists

Part 6 sets out the applications which doctors can make in order to be able to fulfil the conditions on which they can then make arrangements with a health board to provide pharmaceutical services to their eligible patients in controlled localities.

Arrangements for the provision of pharmaceutical services by doctors

There are currently a number of types of application which result in a pharmacist, dispensing appliance contractor or dispensing doctor being included on the pharmaceutical or dispensing doctor lists. These include applications for preliminary consent (a new inclusion onto the pharmaceutical list); outline consent (for a dispensing doctor).

The current test which must be satisfied in order to be included in the lists contained in the 2013 Regulations will be changed to require applicants to base their applications for inclusion on a specific need identified in the most recent pharmaceutical needs assessment of the health board to which they are applying.

Controlled localities, reserved locations and dispensing doctors

To enable the objectives of the introduction of pharmaceutical needs assessment to apply equally across the whole of Wales it has been necessary to have the same test apply to dispensing doctor applications as pharmacy applications; i.e. to move the granting of an application to where it satisfies a need for pharmaceutical services as identified in the pharmaceutical needs assessment rather than whether the application is assessed on whether the provision of services is 'Necessary or Expedient'.

Therefore, where an application has not been refused under the prejudice test, the health board must refuse an application unless it is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant locality and which has been included in the relevant pharmaceutical needs assessment and which the doctor has applied for outline consent (See Regulation 30(5)(d)).

Any locations that have been determined as reserved locations or controlled localities will continue to be so (See Regulation 13), until such time as they may be reviewed in accordance with the 2020 Regulations.

There are no changes to the rules for reserved locations, or to the application of the prejudice test.

Part 7 – Fitness grounds and inclusion in and removal from pharmaceutical lists

Part 7 deals with fitness grounds and inclusion in and removal from pharmaceutical lists. It provides for the deferral and refusal of applications for inclusion in a pharmaceutical list on fitness grounds (regulations 36 and 37) together with an inclusion in a pharmaceutical list being subject to conditions (regulation 38). For certain fitness matters, including where a person has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over six months, a health board must remove a person from a pharmaceutical list pursuant to regulation 40 (removal from a pharmaceutical list for other reasons).

We have made no changes to these provisions.

Part 8 - Conditional inclusion in pharmaceutical lists: certain specific conditions that do not relate to fitness or performance

Part 8 sets out conditions that are to be imposed on NHS pharmacists and NHS appliance contractors as part of their terms of service with the health board, which include requirements relating to co-operation with the health board over local resolution of disputes (regulation 49). These Part 8 conditions are in addition to the principal terms of service for NHS pharmacists, which are in Schedule 5, and NHS appliance contractors, which are in Schedule 6.

Core opening hours

Provision is made for the listing of core hours on specific days and at specific times and for pharmacists and dispensing appliance contractors being required to provide and continue to provide those services at those days and times (See Regulation 46(1) and (2)).

Conditions relating to providing directed services

Where in the course of making an application a pharmacist or appliance contractor undertook to provide a directed service they must provide and continue to provide that service (See Regulation 47).

Conditions relating to local resolution of disputes over terms of service

It is a condition of the inclusion of each NHS pharmacist or NHS appliance contractor in a pharmaceutical list they make every reasonable effort to communicate with the health board with a view to resolving any dispute relating to compliance with the terms of service under which pharmaceutical services are provided (See Regulation 48).

Question 17: Do you have any comments on the criteria relating to inclusion in the list under specific conditions?

Market Exit and performance related sanctions

A health board may grant an application to provide NHS pharmaceutical services if it is satisfied the application meets a need for pharmaceutical services that has been identified in the pharmaceutical needs assessment and provided in accordance with the providers' respective terms of service. Within the draft 2020 Regulations, provisions relating to performance related sanctions and market exit have been included to support the delivery of pharmaceutical services in line with the findings of a pharmaceutical needs assessment.

Part 9 – Performance related sanctions and Market Exit

Part 9 sets out the arrangements for dealing with breaches of terms of service by NHS pharmacists and NHS appliance contractors (breaches by dispensing doctors are dealt with under their parallel arrangements for providing primary medical services to registered patients, which they must have in order to be providers of pharmaceutical services). In the first instance the health board must make every reasonable effort to resolve any terms of service dispute it has with a pharmacist or appliance contractor by local dispute resolution.

Where a dispute between an NHS pharmacist, or an NHS appliance contractor, and the health board cannot be resolved under the local dispute resolution procedures (or where that procedure may be by-passed), the NHS pharmacist or NHS appliance contractor faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (see regulations 50 to 52). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of an NHS pharmacist's or NHS appliance contractor's business premises from the relevant pharmaceutical list (see regulation 53).

Local dispute resolution before serving remedial notices or breach notices

Before issuing either a breach or a remedial notice, the health board must make every reasonable effort to communicate and co-operate with an NHS Pharmacy or NHS appliance contractor with a view to resolving any dispute between the NHS Pharmacy or appliance contractor and the health board relating to compliance with the terms of service (see Regulation 49(1)).

This does not apply where the health board is satisfied that a dispute relates to matter that has already been the subject of dispute resolution between the health board and the NHS pharmacy or appliance contractor and there are no new issues of substance that justify a delay in issuing a breach notice; or that it is appropriate to proceed immediately to issue a notice:

- because listed premises are, not or have not been open during core hours or supplementary opening hours without good cause,
- to protect the safety of any persons to whom an NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or

- to protect the health board from material financial loss.

(see Regulation 49(3))

A pharmacist or appliance contractor may invite a Local Pharmaceutical Committee (in Wales this is Community Pharmacy Wales) to participate in attempts to resolve the dispute (see Regulation 49(2)).

Question 18: Do you have any comments in relation to local dispute resolution prior to the issuing of a breach or remedial notice?

Breach of terms of service: remedial notices

Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is capable of remedy, the health board may by 'remedial notice' require the NHS Pharmacist or appliance contractor to remedy the breach.

To be valid a 'remedial notice' notice must include:

- The nature of the breach;
- The steps the NHS pharmacist or appliance contractor must take, to the satisfaction of the health board in order to remedy the breach;
- The period during which the steps must be taken ('the notice period'); and
- An explanation of how the NHS Pharmacist or appliance contractor's rights of appeal may be exercised.

The notice period must be not less than 30 days unless the health board is satisfied that a shorter notice is appropriate:

- to protect the safety of any persons to whom an NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or
- to protect the health board from material financial loss.

(See Regulation 50(1) & (2) & (3))

Question 19: Is there any other information a remedial notice should contain?

If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that an NHS pharmacist or NHS appliance contractor is required to provide, the

remedial notice may provide that the health board may withhold all or part of the remuneration due to the contractor in respect of that period.

Pending the contractor taking the steps to remedy the breach, the health board may withhold all or part of the remuneration due to the contractor under the following circumstances:

- For any period for which the contractor is in breach, the withheld payments attributable to that period will be permanent, and
- Once the contractor has taken the steps required, to the satisfaction of the health board, any withholding of payment that has taken place and which is attributable to the period when the contractor is no longer in breach is to be restored, provided that the contractor submits a claim.

The period referred to above may be longer than the notice period.

If the health board refuses to restore all or part of any withheld remuneration which is claimed above, it must notify the contractor of the decision as soon as is practicable, stating its reasons for the decision and an explanation of how the contractor's rights of appeal may be exercised.

A health board may vary or revoke a remedial notice at any time after it has been issued.

(See Regulations 50 (4) to 50(8))

Question 20: Are the terms under which the health board may withhold payment for a breach of services appropriate?

Breach of terms of service: breach notices

Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is not capable of remedy, the health board may issue a breach notice to require the contractor not to repeat the breach.

To be valid the breach notice must include:

- the nature of the breach
- an explanation of how the NHS Pharmacist or NHS appliance contractor's rights of appeal may be exercised.

(See Regulation 51(1) &(2))

Where the breach relates to the failure to provide or failure to provide a reasonable standard of service, the health board may withhold part or all remuneration due to the contractor in respect of that period.

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

The amount of remuneration withheld must be justifiable and proportionate in regard to the seriousness of the breach and reason for it.

Question 21: Do you have any comments about the process of issuing remedial and breach notices?

Removal of listing: cases relating to remedial notices and breach notices

The health board may remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list, or remove the listing of a particular listed premises, if the contractor:

- Fails to take the steps set out in a remedial notice and the health board is satisfied that it is necessary to remove the contractor or the listed premises to protect the safety of any person to whom the contractor provides pharmaceutical services.
Or
- Has breached their terms of service and has repeatedly been issued with remedial or breach notices and the health board believes it likely that breaching the terms of service will continue without good cause.

The health board may only remove particular premises from a NHS pharmacist or NHS appliance contractor's listing in a pharmaceutical list if the relevant breaches all relate to those particular premises (Regulation 53(2)).

Any removal from the pharmaceutical list must be justifiable and proportionate having regard to the nature and seriousness of the breaches of the terms of service and reasons for them. The health board must give the contractor a notice period of 30 days in advance of taking the decision to remove them from the list (Regulation 53(6)).

Question 22: Do you have any comments on the criteria for removal from the pharmaceutical list in relation to performance matters?

Appeals against market exit

An NHS pharmacist or NHS appliance contractor may, within 30 days of being notified by the health board, appeal to the Welsh Ministers against a health board decision to:

- issue a remedial notice
- issue a breach notice
- apply certain specified steps contained within a remedial notice
- the duration of the notice period specified in a remedial notice

- withhold remuneration
- the amount of remuneration withheld
- not restore remuneration or restore a smaller amount
- remove from the pharmaceutical list

(See Regulation 54).

Question 23: Do you have any comments with regard to the appealing health board decisions in relation to performance matters?

Part 10 - Payments to NHS pharmacists and NHS appliance contractors

Part 10 deals with payments to NHS pharmacists and NHS appliance contractors.

We have made no changes to these provisions.

Part 11 - Miscellaneous

Part 11 deals with miscellaneous matters, including transitional provisions for applications and appeals made under the 2013 Regulations before these Regulations come into force.

Transitional provisions

Any application made under the 2013 Regulations that has been received by a health board on or before 31 March 2020 will be determined in accordance with the provisions of the 2013 Regulations until that application is finally determined (See Regulation 63).

For a period of 6 months from the date that the 2020 Regulations come into force, a health board will not be able to consider or determine any application to be included in, or to make amendment to a pharmaceutical or dispensing doctor list.

Any applications made prior to the 2020 Regulations coming into force will still be considered during this standstill period, albeit in accordance with the relevant provisions from the 2013 Regulations.

This standstill period is intended to allow time for the health boards to complete their first Pharmaceutical Needs Assessments and to enable them to deal with any outstanding applications made under the 2013 Regulations.

Question 24: Do you agree with this 'standstill' period and these timescales?

Schedules

Schedules 1 to 8 deal with matters as follows:

- SCHEDULE 1: Regulation 4 – Information to be contained in a Pharmaceutical Needs Assessment
- SCHEDULE 2: Regulations 15, 18, 23, 29, 32 and 33 - Information to be included in applications to provide pharmaceutical services
- SCHEDULE 3: Regulations 13, 15 and 30 - Procedures to be followed by Local Health Boards to determine applications under the Regulations
- SCHEDULE 4: Regulations 14, 25, 45 and 54 - Appeals to the Welsh Ministers
- SCHEDULE 5: Regulation 12 - Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provisions of drugs
- SCHEDULE 6: Regulation 12 - Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances
- SCHEDULE 7: Regulation 12 - Terms of service for doctors providing pharmaceutical services
- SCHEDULE 8: Regulation 64 - Minor and consequential amendments

ENGAGEMENT AND CONSULTATION PROCESS

Consultation Process

An eight week consultation is being launched to provide interested parties with the opportunity to comment on these draft Regulations (“the 2020 Regulations”).

Any responses received as part of this consultation will be given careful consideration and a summary of the responses received will be published on our website.

Groups affected

The proposed draft Regulations will be particularly relevant to retail pharmacy businesses and all persons who currently provide or intend to provide NHS pharmaceutical services in Wales.

Consultation Response Form

Your name:

Organisation (if applicable):

email / telephone number:

Your address:

Q1: Do you agree that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services for the purposes of the Regulations?

Enter your response here:

Q2: Do you agree that the health board should be placed under an obligation to consider all pharmaceutical services and are there any other persons providing those services that should be considered?

Enter your response here:

Q3: Do you believe there is anything that could be added to the list of required information to improve the content of a pharmaceutical needs assessment?

Enter your response here:

Q4: Is five years an appropriate interval between pharmaceutical needs assessments?

Enter your response here:

Q5: Do you agree the health board should be under a duty to revise its pharmaceutical needs assessment once it considers there are significant changes to the circumstances in its area; for example when a large housing development takes place?

Enter your response here:

Q6: Do you agree with the list of persons who must be consulted on the contents of an assessment?

Enter your response here:

Q7: Are there any other persons who should be consulted?

Enter your response here:

Q8: Do you agree with the process for the health board's publishing of its assessment?

Enter your response here:

Q9: Are there any other factors a health board should have regard to when making an assessment?

Enter your response here:

Q10: Do you consider it appropriate to maintain existing pharmaceutical and dispensing doctor lists when the 2020 Regulations come into force?

Enter your response here:

Q11: Do you agree to the maintaining of previously defined controlled areas?

Enter your response here:

Q12: Do you consider the change of test as a consequence of the introduction of pharmaceutical needs assessment to be appropriate?

Enter your response here:

Q13: Are there any other criteria that should be applied to this test?

Enter your response here:

Q14: Do you agree with the removal of minor relocations for premises?

Enter your response here:

Q15: Do you consider a move between health board areas should only be allowed when a need has been identified in the health board's assessment and providing it does not disadvantage access by persons accustomed to accessing services in the current location?

Enter your response here:

Q16: Do you have any comments to make on this consequential amendment?

Enter your response here:

Q17: Do you have any comments on the criteria relating to inclusion in the list under specific conditions?

Enter your response here:

Q18: Do you have any comments in relation to local dispute resolution prior to the issuing of remedial notices?

Enter your response here:

Q19: Is there any other information a remedial notice should contain?

Enter your response here:

Q20: Are the terms under which the health board may withhold payment for a breach of services appropriate?

Enter your response here:

Q21: Do you have any comments about the process of remedial and breach notices?

Enter your response here:

Q22: Do you have any comments on the criteria for removal from the pharmaceutical list in relation to performance matters?

Enter your response here:

Q23: Do you have any comments with regard to appealing health board decisions in relation to performance matters?

Enter your response here:

Q24: Do you agree with this 'stand still' concept and these time scales?

Enter your response here:

Q25: Are there any unintended consequences created by the draft regulations you can foresee?

Enter your response here:

Q26: Are there any additional points you would like to make regarding the proposals set out in the draft regulations?

Enter your response here:

Responses to this consultation will be made public in a report and published on the Welsh Government's website.

If you would prefer your response to remain anonymous, please tick here: