



Department
of Health &
Social Care

Pharmaceutical needs assessments

Information pack for local authority health and wellbeing boards

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Preface

This information pack has no statutory standing, nor does it constitute non-statutory guidance, but it aims to support local authorities to interpret and implement their duties with regard to pharmaceutical needs assessments.

The rules themselves are not, in the main, set out “verbatim” in this document. In order to make it easier to read, the detailed rules have, in most cases, been paraphrased. However, all those responsible for administering or applying the law must bear in mind that it is the law that must be applied, not the interpretation that is set out below.

This document’s legal status is that it is an analysis of the rules of law together with appropriate notes of guidance, designed to assist health and wellbeing boards in producing pharmaceutical needs assessments within the framework of the law. It is not an authoritative statement of the law.

Summary

Section 128A of the National Health Service Act 2006 (NHS Act 2006) requires each health and wellbeing board to assess the need for pharmaceutical services in its area and to publish a statement of its assessment. Termed a ‘pharmaceutical needs assessment’, the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013, as amended (the 2013 regulations) set out the minimum information that must be contained within a pharmaceutical needs assessment and outline the process that must be followed in its development.

The 2013 regulations can be found on the legislation.gov.uk website¹. In summary they:

- define what is meant by pharmaceutical services (regulation 3),
- set out the minimum information requirements for a pharmaceutical needs assessment (regulation 4 and Schedule 1),
- confirm when the next pharmaceutical needs assessment is to be published, or where a new health and wellbeing board comes into being when it is required to publish its first pharmaceutical needs assessment (regulations 5 and 6),

¹ [NHS \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](http://legislation.gov.uk)

- set out the circumstances where a health and wellbeing board may need to produce a new pharmaceutical needs assessment sooner than the usual three yearly cycle, or when a supplementary statement may/must be published (regulation 6),
- set out the minimum consultation process that each health and wellbeing board is required to undertake during the development of its pharmaceutical needs assessment (regulation 8), and
- set out specific matters that the health and wellbeing board must consider when drafting its pharmaceutical needs assessment (regulation 9).

This information pack is intended to support local authority health and wellbeing boards in a practical way in understanding and implementing these requirements. The pack is set out as follows:

- chapter 1 gives an introduction to the requirements for pharmaceutical needs assessments,
- chapter 2 defines a number of the terms used in the regulations,
- chapter 3 provides an overview of the process of developing a pharmaceutical needs assessment,
- chapter 4 describes the engagement that should be undertaken whilst the document is being written,
- chapter 5 sets out the information that must be contained within the pharmaceutical needs' assessment,
- chapter 6 provides advice on how to identify gaps in the provision of pharmaceutical services,
- chapter 7 sets out the requirement to consult on a draft of the document, and
- chapter 8 sets out the requirements on the health and wellbeing board once the document is published.

There are three appendices:

- appendix 1 contains a suggested timeline,
- appendix 2 contains a decision-making flowchart in relation to the requirements set out in chapter 8, and

- appendix 3 contains three template supplementary statements.

Chapter 1 – introduction and legislative background

1. Introduction

If a person² wants to provide pharmaceutical services, they are required to apply to the NHS to be included in a pharmaceutical list. Pharmaceutical lists are compiled and as at October 2021 are held by NHS England and NHS Improvement. This is commonly known as the NHS “market entry” system.

Under the 2013 regulations, a person who wishes to provide pharmaceutical services must apply to NHS England and NHS Improvement to be included in the relevant pharmaceutical list by proving they are able to meet a need for, or improvements or better access to, pharmaceutical services as set out in the relevant pharmaceutical needs assessment. There are exceptions to this, such as applications for benefits not foreseen in the pharmaceutical needs assessment or to provide pharmaceutical services on a distance-selling (internet or mail order only) basis. The first pharmaceutical needs assessments were published by primary care trusts and were required to be published by 1 February 2011.

From April 2013, health and wellbeing boards became responsible for pharmaceutical needs assessments. Within this information pack we have included hints and tips to assist health and wellbeing boards in drafting their pharmaceutical needs assessment.

2. Legislative background

The Health and Social Care Act 2012 established health and wellbeing boards. It also transferred responsibility to develop and update pharmaceutical needs assessments from primary care trusts to health and wellbeing boards with effect from 1 April 2013. At the same time responsibility for using pharmaceutical needs assessments as the basis for determining market entry to a pharmaceutical list transferred from primary care trusts to NHS England and NHS Improvement.

The NHS Act 2006 (the “2006 Act”), amended by the Health and Social Care Act 2012, sets out the requirements for health and wellbeing boards to develop and update pharmaceutical needs assessments and gives the Department of Health and Social Care

² For the purposes of this document, a person may be a pharmacy contractor or a dispensing appliance contractor and may operate as a sole trader, partnership or body corporate.

powers to make regulations. The relevant extract from the 2006 Act can be found in the box below.

128A Pharmaceutical needs assessments

(1) Each Health and Well-being Board must in accordance with regulations--

- (a) assess needs for pharmaceutical services in its area, and
- (b) publish a statement of its first assessment and of any revised assessment.

(2) The regulations must make provision--

- (a) as to information which must be contained in a statement;
- (b) as to the extent to which an assessment must take account of likely future needs;
- (c) specifying the date by which a Health and Well-being Board must publish the statement of its first assessment;
- (d) as to the circumstances in which a Health and Well-being Board must make a new assessment.

(3) The regulations may in particular make provision--

- (a) as to the pharmaceutical services to which an assessment must relate;
- (b) requiring a Health and Well-being Board to consult specified persons about specified matters when making an assessment;
- (c) as to the manner in which an assessment is to be made;
- (d) as to matters to which a Health and Well-being Board must have regard when making an assessment.

3. Wider context

The Health and Social Care Act 2012 also amended the Local Government and Public Involvement in Health Act 2007 to introduce duties and powers for health and wellbeing boards in relation to joint strategic needs assessments. The aim of joint strategic needs assessments is to improve the health and wellbeing of the local community and reduce inequalities for all ages. They are not an end in themselves, but a continuous process of strategic assessment for the health and wellbeing needs of the local population. They will be used to determine what actions local authorities, the NHS and other partners need to take to meet health and social care needs and to improve health outcomes and address health inequalities.

The preparation and consultation on the pharmaceutical needs assessment should take account of the joint strategic needs assessments and other relevant strategies in order to prevent duplication of work and multiple consultations with health groups, patients and the public. The development of pharmaceutical needs assessments is a separate duty to that of developing joint strategic needs assessments as pharmaceutical needs assessments will inform commissioning decisions by local authorities, NHS England and NHS Improvement, and clinical commissioning groups. Health and wellbeing boards may therefore wish to note that pharmaceutical needs assessments, as a separate statutory requirement, cannot be subsumed as part of these other documents but can be annexed to them.

4. Implications for health and wellbeing boards

As the pharmaceutical needs assessment is a key document for those wishing to open new pharmacy or dispensing appliance contractor premises, and is used by NHS England and NHS Improvement (and, on appeal, NHS Resolution) to determine such applications, there are serious implications for health and wellbeing boards who fail to meet their statutory duties.

There is no right of appeal against the findings or conclusions within a pharmaceutical needs assessment. Health and wellbeing boards (although in reality this will be the local authority) therefore face the risk of a judicial review should they fail to develop a pharmaceutical needs assessment that complies with the minimum requirements for such documents as set out in the 2013 regulations, or should they fail to follow due process in developing their pharmaceutical needs assessment, e.g. by failing to consult properly or take into consideration the results of the consultation exercise undertaken, or fail to publish by the required deadlines.

In addition, a pharmaceutical needs assessment that does not meet the requirements of the 2013 regulations, or is poorly worded, may lead to:

- an increase in applications for premises that are not required,
- applications being granted when they should be refused and vice versa,
- applications for new pharmacy premises being granted but which do not meet the local authority's strategic plans, and
- an increase in the number of appeals against decisions made by NHS England and NHS Improvement.

Further information on the governance arrangements that should be put in place can be found in chapter 3.

Chapter 2: Understanding the regulations

1. What the legislation says

Regulations 3-9 and Schedule 1 of the 2013 regulations set out the requirements for pharmaceutical needs assessments. In summary:

- regulation 3 provides a definition of what is meant by the term pharmaceutical services (see below),
- regulation 4 and Schedule 1 set out the information that must be included, although health and wellbeing boards are free to include any other information that is felt to be relevant (see chapter 5),
- regulations 5 and 6 confirm when a new pharmaceutical needs assessment is to be published by and when a supplementary statement may or must be published (see chapter 8),
- regulation 7 is no longer applicable as it deals with the transitional period between 1 April 2013 and 1 April 2015,
- regulation 8 sets out the minimum consultation requirements (see chapter 7), and
- regulation 9 sets out matters that the health and wellbeing board is to have regard to (see chapter 5).

2. Definitions

Within the regulations there are a number of words and phrases that need to be understood in the context of pharmaceutical needs assessment. The most relevant ones are explained below.

2.1 Advanced services

Advanced services are those services that pharmacy and dispensing appliance contractors may choose to provide if they meet the required standards. Information on these standards and the services themselves are set out in the Pharmaceutical Services

(Advanced and Enhanced Services) (England) Directions 2013 which can be found in Part VIC of the Drug Tariff³.

As at October 2021, the following services may be provided by pharmacies:

- new medicine service,
- community pharmacy seasonal influenza vaccination,
- community pharmacist consultation service,
- hypertension case-finding service, and
- community pharmacy hepatitis C antibody testing service (currently until 31 March 2022).

In early 2022 a stop-smoking service will be introduced for patients who started their stop-smoking journey in hospital.

As at October 2021, the community pharmacy Covid-19 lateral flow device distribution service and community pharmacy Covid-19 medicines delivery service are also commissioned from community pharmacies. These may however not be commissioned when the pharmaceutical needs assessment is being drafted or published.

There are two appliance advanced services that pharmacies and dispensing appliance contractors may choose to provide:

- appliance use reviews, and
- stoma appliance customisation.

Further practical user information on each of the advanced services can be found on the Pharmaceutical Services Negotiating Committee's website⁴.

The pharmaceutical needs assessment will need to look at the provision of each of these services and identify any gaps in their provision.

2.2 Appliances

Whilst drugs are the most common healthcare intervention and a large proportion of the health and wellbeing board's population will be prescribed them on a regular or occasional

³ [Drug Tariff](#), NHS Business Services Authority

⁴ [Pharmaceutical Services Negotiating Committee](#)

basis, a smaller proportion will require access to appliances. Those that are available on the NHS are set out in Part IX of the Drug Tariff⁵ and include:

- catheters,
- dressings,
- elastic hosiery,
- hernia support garments,
- trusses,
- colostomy bags, and
- urostomy bags.

The pharmaceutical needs assessment will therefore need to consider access to both drugs and appliances.

Whilst pharmacies are required to dispense valid NHS prescriptions for all drugs, both they and dispensing appliance contractors may choose which appliances they provide in their normal course of business. They may choose to provide a certain type of appliance, or types of appliance, or they may choose to provide all appliances. Some pharmacies may choose not to provide any appliances. A large proportion of patients who are regular users of appliances will have them delivered, often by dispensing appliance contractors based in other parts of the country (see 'Dispensing appliance contractors' section below).

2.3 Controlled localities

Controlled localities are areas that have been determined to be 'rural in character' by NHS England and NHS Improvement (or a preceding organisation) or on appeal by NHS Resolution. There is no one factor that determines whether or not an area is rural in character; rather NHS England and NHS Improvement will consider a range of factors which may include population density, the presence or absence of facilities, employment patterns, community size and distance between settlements, and the availability of public transport.

⁵ [Drug Tariff](#), NHS Business Services Authority

Their importance comes into play in relation to the ability for a GP practice to dispense to its registered patients. In order to be dispensed to, as a starting point, the patient must live in a controlled locality, more than 1.6km (measured in a straight line) from a pharmacy.

2.4 Directed services

This is a collective term for advanced and enhanced services.

2.5 Dispensing appliance contractors

Dispensing appliance contractors are different to pharmacy contractors because they:

- only dispense prescriptions for appliances. They cannot dispense prescriptions for drugs
- are not required to have a pharmacist
- do not have a regulatory body
- their premises do not have to be registered with the General Pharmaceutical Council.

Dispensing appliance contractors tend to operate remotely, receiving prescriptions either via the post or the electronic prescription service, and arranging for dispensed items to be delivered to the patient. There are far fewer of them compared to pharmacies (there were 111 dispensing appliance contractors as at 30 June 2021 compared to 11,201 pharmacies). Consequently, not every health and wellbeing board will have a dispensing appliance contractor operating in their area, however residents will be accessing their services elsewhere in the country.

2.6 Dispensing doctors/practices

Whilst the majority of people living in the health and wellbeing board's area will have their prescriptions dispensed by a pharmacy, some will have them dispensed by their GP practice. In order to be dispensed to by their GP practice, a patient must meet the requirements in the regulations which in summary are:

- they must live in a controlled locality,
- they must live more than 1.6km (measured in a straight line) from a pharmacy,
- the practice must have approval for the premises at which they will dispense to them, and

- the practice must have the appropriate consent for the area the patient lives in.

NHS England and NHS Improvement is required to maintain and publish a dispensing doctor list for the area of each health and wellbeing board. However, if there are no controlled localities within a health and wellbeing board's area there will be no dispensing doctors.

GP practices may have premises within a town and still be able to dispense because some of their patients live in a controlled locality and meet the other requirements of the regulations. Dispensing practices are not required to have a pharmacist in their dispensary and their premises do not have to be registered with the General Pharmaceutical Council.

2.7 Distance selling premises

Distance selling premises are pharmacies, but the 2013 regulations do not allow them to provide essential services to people on a face-to-face basis. They will receive prescriptions either via the electronic prescription service or through the post, dispense them at the pharmacy and then either deliver them to the patient or arrange for them to be delivered using a courier, for example.

They must provide essential services to anyone, anywhere in England, where requested to do so. They may choose to provide advanced services, but when doing so must ensure that they do not provide any element of the essential services whilst the patient is at the pharmacy premises. As of 30 June 2021, there were 379 distance selling premises in England, based in 115 health and wellbeing boards. Not every health and wellbeing board therefore has one in their area, however it is likely that some of their residents will use one.

2.8 Enhanced services

Enhanced services are the third tier of services that pharmacies may provide and they can only be commissioned by NHS England and NHS Improvement. The services that may be commissioned are listed in the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (as amended) which can be found in the Drug Tariff⁶.

Whilst the local authority may commission public health services from pharmacies these do not fall within the legal definition of enhanced services and are not to be referenced as such in the pharmaceutical needs assessment. See 'locally commissioned services' below.

⁶ [Drug Tariff](#), NHS Business Services Authority

2.9 Essential services

All pharmacies, including distance selling premises, are required to provide the essential services. As of October 2021, there are seven essential services.

- (i) dispensing of prescriptions,
- (ii) dispensing of repeat prescriptions i.e. prescriptions which contain more than one months' supply of drugs on them. For example, an electronic repeatable prescription may say that the prescription interval is every 28 days and it can be repeated six times. This would give a patient approximately six months' supply of medication, dispensed every 28 days with the prescriber only needing to authorise them once.
- (iii) disposal of unwanted medicines returned to the pharmacy by someone living at home, in a children's home, or in a residential care home⁷.
- (iv) promotion of healthy lifestyles, which includes providing advice to people who appear to have diabetes, be at risk of coronary heart disease (especially those with high blood pressure), or smoke, or are overweight, and participating in six health campaigns where requested to do so by NHS England and NHS Improvement.
- (v) signposting people who require advice, treatment or support that the pharmacy cannot provide to another provider of health or social care services, where the pharmacy has that information.
- (vi) support for self-care which may include advising on over the counter medicines or changes to the person's lifestyle.
- (vii) discharge medicines service. This service was introduced in 2021 and aims to reduce the risk of medication problems when a person is discharged from hospital. It is estimated that 60 percent of patients have three or more changes made to their medicines during a hospital stay. However, a lack of robust communication about these changes may result in errors being made once the person has left hospital. In summary, under this service a pharmacist will review a person's medicines on discharge and ensure that any changes are actioned accordingly.

⁷ Residential care home' is defined in the 2013 regulations as an establishment which exists wholly or mainly for the provision of residential accommodation, together with board and personal care, for persons in need of personal care because of old age, mental or physical disability, past or present dependence on alcohol or drugs, any past illnesses, or past or present mental disorder.

Further information on the essential services requirements can be found in Schedule 4 of the 2013 regulations.

Dispensing appliance contractors have a narrower range of services that they must provide:

- dispensing of prescriptions.
- dispensing of repeat prescriptions.
- for certain appliances, offer to deliver them to the patient (delivering in unbranded packaging), provide a supply of wipes and bags, and provide access to expert clinical advice.
- where the contractor cannot provide a particular appliance, signposting or referring a patient to another provider of appliances who can.

Further information on the essential services requirements can be found in Schedule 5 of the 2013 regulations.

It should be noted that clinical governance is not an essential service. Instead it is a framework which underpins the provision of all pharmaceutical services.

2.10 Local pharmaceutical services

NHS England and NHS Improvement does not hold signed contracts with the majority of pharmacies. Instead, pharmacies provide services under a contractual framework and the terms of service are set out in the 2013 regulations.

The one exception to this rule is local pharmaceutical services. A local pharmaceutical services contract allows NHS England and NHS Improvement to commission services that are tailored to meet specific local requirements. It provides flexibility to include within a locally negotiated contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements set out in the 2013 regulations. The contract must, however, include an element of dispensing.

As of 30 June 2021, there were 23 local pharmaceutical services contracts in 21 health and wellbeing boards.

Care should be taken when using the term local pharmaceutical services as it has a specific meaning in the 2013 regulations. It must not be used to describe pharmaceutical services that are provided locally.

2.11 Locally commissioned services

Locally commissioned services is not a term that can be found within the 2013 regulations but is often used to describe those services commissioned from pharmacies by local authorities and clinical commissioning groups. As noted in the definition of enhanced services above, they are not enhanced services because they are not commissioned by NHS England and NHS Improvement.

Health and wellbeing boards should make reference to them in their pharmaceutical needs assessment as other NHS services (see below).

2.12 Necessary services

The 2013 regulations require the health and wellbeing board to include a statement of those pharmaceutical services that it has identified as being necessary to meet the need for pharmaceutical services within the pharmaceutical needs assessment. There is no definition of necessary services within the regulations and the health and wellbeing board therefore has complete freedom in this matter.

2.13 Opening hours

Pharmacies and dispensing appliance contractors have two different types of opening hours – core and supplementary.

In general pharmacies will have either 40 or 100 core opening hours per week, although some may have a number that is between 40 and 100, and some may have less than 40.

Dispensing appliance contractors are required to have not less than 30 core opening hours per week, although some may have more or less.

Core opening hours can only be changed by first applying to NHS England and NHS Improvement. As with all applications, they may be granted or refused.

Any opening hours that are over and above the core opening hours are called supplementary opening hours. They can be changed by giving NHS England and NHS Improvement at least three months' notice.

2.14 Other NHS services

Other NHS services are those services that are provided as part of the health service. They include services that are provided or arranged by a local authority (for example the public health services commissioned from pharmacies), NHS England and NHS

Improvement, a clinical commissioning group, an NHS trust or an NHS foundation trust. Examples are included in chapter 5.

It is anticipated that from April 2022 clinical commissioning groups will be replaced by integrated care boards that will be able to take on delegated responsibility for pharmaceutical services, and from April 2023 NHS England and NHS Improvement expects all integrated care boards to have done so. Health and wellbeing boards should therefore be aware that some services that are commissioned from pharmacies by clinical commissioning groups (and are therefore other NHS services) will move to the integrated care boards and will fall then within the definition of enhanced services.

2.15 Other relevant services

These are services that the health and wellbeing board is satisfied are not necessary to meet the need for pharmaceutical services but their provision has secured improvements, or better access, to pharmaceutical services.

Once the health and wellbeing board has determined which of all the pharmaceutical services provided in or to its area are necessary services, the remainder will be other relevant services.

2.16 Pharmaceutical services

Section 126 of the 2006 Act places an obligation on NHS England and NHS Improvement to put arrangements in place so that drugs, medicines and listed appliances ordered via NHS prescriptions can be supplied to persons.

Pharmaceutical services is a collective term for a range of services commissioned by NHS England and NHS Improvement. In relation to pharmaceutical needs assessments it includes:

- essential, advanced and enhanced services provided by pharmacies,
- essential and advanced services provided by dispensing appliance contractors,
- the dispensing service provided by some GP practices, and
- services provided under a local pharmaceutical services contract that are the equivalent of essential, advanced and enhanced services.

2.17 Unforeseen benefit applications

The pharmaceutical needs assessment sets out needs for, or improvements or better access to, a range of pharmaceutical services or one specific service. This then triggers applications to meet those needs or secure those improvements or better access.

However, there are two types of application which lead to the opening of new premises that are not based on the pharmaceutical needs' assessments – those offering unforeseen benefits and those for distance selling premises. In 2020, these two types of applications accounted for approximately 94 percent of the applications submitted to open new premises (approximately 27 percent and 67 percent respectively).

Where an applicant submits an unforeseen benefits application, they are offering improvements or better access that were not foreseen when the pharmaceutical needs assessment was written, but would confer significant benefits on people in the area of the health and wellbeing board.

Chapter 3: Overview of the process

There are eight key stages to developing a pharmaceutical needs assessment. A high-level timeline can be found in appendix 1 and this chapter provides a narrative for the process. The timeline assumes that health and wellbeing boards will have started the process of establishing their steering group and that the first meeting has been scheduled for October 2021. If that is not the case it should be possible to reduce the time allowed for various stages of the process, and these are highlighted in the following commentary.

1. Governance

The health and wellbeing board should ensure that there is board level sign-up to the process of developing the pharmaceutical needs assessment, and a named board member who will take overall responsibility for ensuring the document meets the regulatory requirements and is published in a timely manner.

As health and wellbeing boards are under a statutory duty to produce and publish their next pharmaceutical needs assessment in 2022, it is imperative that sufficient resources, both human and financial, are identified and that there is board level support for the development of the document. Due to the serious consequences of not following due process in developing the pharmaceutical needs assessment, it is recommended that the board includes production of the pharmaceutical needs assessment in the council's risk register.

It is strongly recommended that a steering group is established to support the process (see chapter 4) and this will need to be done early on, allowing members sufficient notice of the first meeting. An outline agenda for the first meeting can be found in chapter 4.

2. Gathering of health and demographic data

The gathering of the required health and demographic data can commence in advance of the first steering group meeting as it is information that will be held by the public health team. It will, however, require liaison with other departments and teams within the council, for example highways and planning teams for information on known housing developments, regeneration projects or transport developments that are current or will occur within the lifetime of the pharmaceutical needs assessment. Four weeks has been allowed for this within the timeline, however it may not take as long as this which will allow the timeline to be shortened if necessary, or more time made available for other elements of the project.

Once this data is gathered it will then need to be analysed, unless this has already been done as part of the joint strategic needs assessment (it is recognised that due to the ongoing Covid-19 pandemic the joint strategic needs assessment documents are unlikely to have been updated recently). Three weeks has been allowed for this within the timeline.

3. Public and contractor engagement

Whilst not required by the regulations it is strongly recommended that the views of the public are gathered. This will allow the health and wellbeing board to test some of its assumptions around how people may access services, for example, and provide useful information for the document.

Suggested topics for questions can be found in chapter 4 and it is suggested that the questionnaire starts shortly after the first steering group meeting, running for four weeks. Three weeks has been allowed in the timeline for analysis of the responses, however this could be shortened if most of the questions do not allow free text questions and if not many off-system responses (e.g. paper copies of the questionnaire) are received.

Similarly, it will also be necessary to gather information from those who are providing the services that is not otherwise already in the public domain. Suggested information that will need to be collected from contractors can be found in chapter 4. As with the public questionnaire, four weeks has been allowed for this in the timeline, with two weeks for analysis of responses as the questionnaire can be run solely online and the majority of questions are likely to have tick box answers.

4. Pharmaceutical services information

Much of the information on the provision of pharmaceutical services can be sourced from the NHS Business Services Authority website, with supplementary information from NHS England and NHS Improvement. However, some of it will need to be gathered from contractors via questionnaires.

Two weeks has been allowed in the timeline for the collation of this information with four weeks to analyse and map service provision - see chapter 5 for further information on this element of the project.

5. Analysis and drafting

As the required data and information is gathered the document can begin to be drafted. It is recommended that a checklist of the statements that must be included is produced in

order to ensure the document meets the requirements of the 2013 regulations. Twelve weeks has been allowed for in the timeline for this stage, although this could be shortened if required. The steering group will need to decide whether it wishes to receive chapters as they are drafted or whether it would prefer to wait until a complete full draft of the document is available,

6. Review and sign-off

Once the analysis and drafting is complete the steering group will then need to review the document, identify any gaps in provision that either currently exist or will arise within the three-year lifetime of the document and articulate these as needs for, or improvements or better access to, a pharmaceutical service or services. The next draft of the document can then be produced and shared with the steering group and two weeks has been allowed for this in the timeline.

The pharmaceutical needs assessment will then need to be signed off by the steering group or passed to the relevant committee or the board for sign-off prior to the consultation.

7. Consultation

The health and wellbeing board must consult with certain organisations about the contents of the pharmaceutical needs assessment at least once, and that consultation must run for a minimum period of 60 days. Further information on the consultation requirements can be found in chapter 7.

The timeline has allowed seven weeks for sign off of the document if this is to be done by the health and wellbeing board recognising that there will be a lead-in time for papers and that the board may not meet every month. The timeline schedules the consultation to start in June 2022. However if the board delegates sign-off of the consultation draft of the pharmaceutical needs assessment to the steering group the consultation can be brought forward by a number of weeks, or if the first meeting of the steering group does not take place in October then delegating sign-off of the consultation draft to the steering group will allow for time to be caught up.

8. Review, sign-off and publication

A report on the consultation must be included in the final version of the document, and the steering group will need to review the responses to the consultation and agree what, if any, changes are to be made to the document. A week has been allowed in the timeline for review of the responses and production of the first draft of the consultation report which

will be a summary of the responses received. The steering group will need to review the responses to the consultation, and agree its response to the points raised which is then to be included in the report. The steering group will also need to consider what, if any, changes needs to be made to the document as a result of the consultation. Not much time has been included in the timeline for this stage because if robust engagement has been undertaken throughout the process of drafting the document there should be no surprises from the consultation.

Once the document is finalised it will then need to be signed-off by the relevant committee or the health and wellbeing board and published. Four weeks has been allowed for in the timeline for this stage, and it assumes that there will be a committee/board meeting in September 2022. If that is not the case then the timeline will need to be amended accordingly.

The regulations are silent as to how or where it is published, however it is recommended that it is published on the local authority's website. If it is published on another website, then a link to that site must be included on the local authority's website, as the health and wellbeing board is under a duty to ensure that NHS England and NHS Improvement has access to the document and any supplementary statements that are included alongside it.

Chapter 4: Engagement

The health and wellbeing board will need to undertake engagement with the key stakeholders throughout the process of developing the pharmaceutical needs assessment, and this is a separate process to the formal consultation. This can be done via:

- the steering group,
- a public questionnaire, and
- contractor questionnaires.

1. Steering group

As noted in the previous chapter it is strongly recommended that a steering group is established to support the process, with representation from:

- the public health team,
- the communications and engagement team,
- the local pharmaceutical committee,
- the local medical committee if there are dispensing practices in the health and wellbeing board's area,
- Healthwatch,
- NHS England and NHS Improvement,
- the clinical commissioning group (noting that it will be replaced by the integrated care system with effect from 1 April 2022), and
- the integrated care system.

The primary role of the group is to advise and develop structures and processes to support the preparation of a comprehensive, well researched, well considered and robust pharmaceutical needs assessment, building on expertise from across the local healthcare community. Establishing the group will also ensure that the views of the main stakeholders are taken into account throughout the process of writing the document.

The steering group could report directly to the health and wellbeing board or to another committee in line with the council's usual reporting structures. The health and wellbeing

board will need to decide how much it wishes to delegate to the steering group; for example does it wish to sign-off the consultation version of the pharmaceutical needs assessment or will it delegate this to the group.

As there will be local experience of producing pharmaceutical needs assessments it may not be necessary for the steering group to meet on a monthly basis. As health and wellbeing boards will have some experience of producing a pharmaceutical needs assessment it may only be necessary for there to be four meetings.

At the first meeting the steering group would look to agree the following:

- the terms of reference for the group,
- the project timeline,
- how the area will be divided up into localities,
- the content of the contractor questionnaire or questionnaires depending on whether there are dispensing appliance contractors and dispensing doctors in the area as well as pharmacies,
- the content of the public engagement questionnaire, how it will be made available and any other ways of engaging with the public, and
- the structure of the document.

The second meeting would take place once a complete draft of the document is available and would consider whether there are any gaps in the provision of services currently, or any that will arise within the lifetime of the document. These are then to be articulated as needs, improvements, or better access.

A third meeting may be required to sign off the consultation version of the document either for recommendation to the health and wellbeing board or so that it can go out to consultation. Alternatively, this could be done via email.

The fourth meeting would be held after the consultation. At this meeting the group will review the responses to the consultation, consider whether any changes are to be made to the pharmaceutical needs assessment and agree the response to the consultation.

A final meeting may be required to sign off the final version of the document either for recommendation to the health and wellbeing board or so that it can be published. Alternatively, this could be done via email.

2. Members of the public

It would be difficult to draft a pharmaceutical needs assessment without involving patients and the public, and it is recommended that involving them is not left until the formal consultation. To this end it is recommended that views of patients and the public are sought at the same time as the contractor questionnaires are open.

To date the majority of engagement with the public has been via online questionnaires. However, health and wellbeing boards should be aware that not everyone can access the internet or read. Consideration should therefore be given as to how the views of those groups can be gained and Healthwatch and the council's communications and engagement team will be best placed to advise and assist with this. This could include views being sought at meetings, focus groups or via telephone calls. Engagement with harder to reach groups will also need to be considered as part of this process, as some patient groups are less likely to engage with general practice but may seek healthcare advice from other sources such as pharmacies. This is especially true where language barriers exist, or for groups that are not permanently resident in the area (such as Traveller and Gypsy communities).

Online questionnaires should be promoted as widely as possible, and the steering group may wish to consider the use of posters with QR codes displayed in pharmacies, GP practices, health centres etc. Consideration should also be given to providing flyers to be included in bags of dispensed medication by pharmacies and dispensing practices. Questionnaires can be included in the council's consultations section on the website which will then ensure that those who have registered for consultation alerts are made aware of it. The steering group may also wish to consider a press release.

Suggested questions for the questionnaire could include:

- (i) why do you usually visit a pharmacy?
- (ii) how often do you use a pharmacy?
- (iii) what time is most convenient for you to use a pharmacy?
- (iv) what day is the most convenient for you to use a pharmacy?
- (v) do you use the same pharmacy or different pharmacies?
- (vi) what influences your choice of pharmacy?
- (vii) is there a more convenient and/or closer pharmacy that you don't use and why is that?

(viii) how do you travel to the pharmacy and how long does it usually take?

Providing multiple choice answers will speed up analysis but free text options will be required for some of the questions.

As with the contractor questionnaires it is recommended that only the information that is required for the pharmaceutical needs assessment is asked for.

3. Contractors

Most of the information regarding the provision of pharmaceutical services is publicly available, however some will need to be sourced from the contractors themselves.

The most common information asked for in contractor questionnaires is:

- premises opening hours,
- services provided,
- premises facilities,
- services that could be provided,
- languages spoken,
- IT facilities, and
- private services that may be provided.

It is recommended that the contractor questionnaire is kept as short as possible and to only seek information that is required for the pharmaceutical needs assessment and cannot be sourced elsewhere.

NHS England and NHS Improvement will have records showing the core and supplementary opening hours for each pharmacy and dispensing appliance contractor (if any). As there is a process to be gone through to change those opening hours it is recommended that the health and wellbeing board uses the opening hours that NHS England and NHS Improvement holds.

Information on which advanced services are provided can be sourced from the NHS Business Services Authority website (see chapter 5), with information on the newer services available from NHS England and NHS Improvement as pharmacies may have signed up to provide one or more of them but not yet have had the opportunity to provide

the service(s). Information on any enhanced services that are commissioned and who provides them can also be provided by NHS England and NHS Improvement.

All pharmacies, with two exceptions, are now required to have a consultation room that is:

- clearly designated as a room for confidential conversations,
- distinct from the general public areas of the pharmacy premises, and
- a room where both the person accessing pharmaceutical services and a person performing pharmaceutical services are able to be seated together and communicate confidentially.

The two exceptions are:

- (i) distance selling premises, and
- (ii) pharmacies that NHS England and NHS Improvement have deemed to be too small to have a consultation room.

However, these pharmacies must have arrangements in place to enable confidential discussions as part of the provision of pharmaceutical services by telephone or another live audio link and a live video link.

NHS England and NHS Improvement will be able to confirm whether any pharmacies fall within the second bullet point above and the health and wellbeing board will be able to identify any distance selling premises from the pharmaceutical list for its area.

The information that health and wellbeing boards are most likely to need to ask as part of the contractor questionnaire are:

- (a) whether prescriptions for appliances are dispensed at the premises, and whether all appliances are provided or just specific types.
- (b) if the contractor provides a delivery service, whether it is free of charge or chargeable, and whether it is restricted to certain patient groups (noting that distance selling premises must deliver all dispensed NHS items without charge).
- (c) what languages are spoken each day at the premises other than English.
- (d) recognising that the demand for services is increasing, asking:

- (i) do they have capacity to manage that increase within their existing premises and staffing levels,
- (ii) if they do not, could they make adjustments to manage an increase in demand, or
- (iii) to confirm they do not have sufficient premises and staffing capacity and would have difficulty in managing an increase in demand.

The same questions can be asked of any dispensing appliance contractors and dispensing doctors in the health and wellbeing board's area.

Chapter 5: Information to be contained in pharmaceutical needs assessments

1. What the legislation says

Regulation 4 and Schedule 1 of the 2013 regulations outline the minimum requirements for pharmaceutical needs assessments. In addition, regulation 9 sets out matters that the health and wellbeing board is to have regard to.

In summary the regulations require a series of statements of:

- the pharmaceutical services that the health and wellbeing board has identified as services that are necessary to meet the need for pharmaceutical services;
- the pharmaceutical services that have been identified as services that are not provided but which the health and wellbeing board is satisfied need to be provided in order to meet a current or future need for a range of pharmaceutical services or a specific pharmaceutical service;
- the pharmaceutical services that the health and wellbeing board has identified as not being necessary to meet the need for pharmaceutical services but have secured improvements or better access;
- the pharmaceutical services that have been identified as services that would secure improvements or better access to a range of pharmaceutical services or a specific pharmaceutical service, either now or in the future; and
- other NHS services that affect the need for pharmaceutical services or a specific pharmaceutical service.

Other information that is to be included or taken into account is:

- how the health and wellbeing board has determined the localities in its area;
- how it has taken into account the different needs of the different localities, and the different needs of those who share a protected characteristic;
- a report on the consultation;
- a map that identifies the premises at which pharmaceutical services are provided;
- information on the demography of the area;

- whether there is sufficient choice with regard to obtaining pharmaceutical services;
- any different needs of the different localities; and
- the provision of pharmaceutical services in neighbouring health and wellbeing board areas.

This chapter looks at these requirements in more detail.

2. Localities

The regulations require the health and wellbeing board to divide its area up into localities. There is no right or wrong way of doing this, but it is suggested that the steering group uses existing boundaries such as:

- borough or district council boundaries should there be any,
- super output areas,
- electoral wards, or
- clinical commissioning group localities (recognising that clinical commissioning groups will cease to exist from 1 April 2022).

It may help to consider on what geographical basis the required information can be sourced – there is little to be gained by dividing the area up only to find that data cannot be sourced at that level.

Health and wellbeing boards should be mindful that the localities should not be so large that they mask variations in need, but not too small that the document becomes too unwieldy (the 2013 regulations also require the pharmaceutical needs assessment to have regard to the different needs of the different localities). Once the basis for the localities has been decided the justification for this must be included in the pharmaceutical needs assessment as this is a requirement of the 2013 regulations.

3. Demographic and health needs data

The 2013 regulations require the health and wellbeing board to have regard to the demography of its area. It is therefore recommended that the pharmaceutical needs assessment contains a chapter on the demographics of the population, and a second chapter on their general health needs.

Much of the required demographic data will already be available and contained within the joint strategic needs assessment. Health and wellbeing boards will wish to note that once their pharmaceutical needs assessment is published, any cross-reference in that pharmaceutical needs assessment to other published documents such as a specific version of the joint strategic needs assessment will be fixed at that point. In other words, relevant subsequent revisions to a joint strategic needs assessment following publication of the pharmaceutical needs assessment may not be adequately reflected in the pharmaceutical needs assessment unless the pharmaceutical needs assessment itself is subsequently revised. It is therefore recommended that information from other documents is copied into the pharmaceutical needs assessment rather than create a link between the pharmaceutical needs assessment and other documents.

Information on the current population and the changes expected within the three-year lifetime of the document will need to be included. Information on known housing developments (including the projected number of houses to be built within the three-year period) and regeneration projects will be available from the planning department. The highways department will be able to provide information on any highways developments that may affect, either positively or negatively, how people access services now and in the future. The Department of Health and Social Care Office for Health Improvement and Disparities' Strategic Health Asset Planning and Evaluation (SHAPE) application⁸ also contains demographic data that will be of use.

The joint strategic needs assessment and public health team will also be able to provide the required information on the health needs of the population. Other sources of such data include the Department of Health and Social Care Office for Health Improvement and Disparities' public health profiles⁹ and SHAPE application and GP quality and outcomes framework data published by NHS Digital¹⁰.

Health and wellbeing boards may wish to then include a chapter which looks at how the health needs of the population can be met by the provision of pharmaceutical services. It should be borne in mind that when assessing the need for pharmaceutical services, it is not possible for such services to meet all of the health needs of the population. By including a chapter which identifies those that can be met will help focus attention when it comes to the identification of any gaps in service provision.

Once the overall health needs of the population have been identified, along with those that can be met by the provision of pharmaceutical services, the pharmaceutical needs assessment will then need to identify the different needs of those who share a protected

⁸ [Department of Health and Social Care Office for Health Improvement and Disparities' Strategic Health Asset Planning and Evaluation application](#)

⁹ [Department of Health and Social Care Office for Health Improvement and Disparities' public health profiles](#)

¹⁰ [NHS Digital quality and outcomes framework](#)

characteristic as defined in the Equality Act 2010¹¹. It is recommended that the pharmaceutical needs assessment also identifies other patient groups that may exist within the area for example:

- university students (including how the relevant term times can impact on service needs),
- offenders,
- homeless and rough sleepers,
- refugees and asylum seekers,
- military veterans, and
- visitors to the area for business, holiday, sporting events or visiting friends and relatives.

This requirement of the regulations can be met by including a chapter which identifies the different patient groups within the health and wellbeing board's area and what their specific needs are for pharmaceutical services.

Information on the number of visitors to the area may be available on the Visit Britain website¹².

4. Provision of pharmaceutical services

NHS England and NHS Improvement is required to prepare, maintain and publish a list of

- the pharmacies in a health and wellbeing board's area (the pharmaceutical list),
- the dispensing appliance contractors (if any, also referred to as the pharmaceutical list),
- the dispensing doctors (if any, referred to as the dispensing doctor list), and
- a list of those providing services under a local pharmaceutical services contract (if any, referred to as the local pharmaceutical services list).

¹¹ [Chapter 1, Equality Act 2010](#)

¹² [Visit Britain inbound research and insights](#)

Health and wellbeing boards will therefore need to ask NHS England and NHS Improvement for a copy of the pharmaceutical list or lists and dispensing doctor list (if there is one) for their area. They may also wish to ask for a copy of the consolidated pharmaceutical and local pharmaceutical services list which pulls together all the lists as this will assist in the identification of out of area providers.

The pharmaceutical lists contain the organisation data service code (also known as the F code) for each of the pharmacies and dispensing appliance contractor premises. These codes will be required to assist in analysing service provision.

Information on the number of items dispensed by each pharmacy and dispensing appliance contractor, along with activity for some of the advanced services is available on the NHS Business Services Authority website.

- (a) pharmacy and appliance contractor dispensing data¹³ – each month a report is published which contains information on the provision of some of the essential and advanced services.
 - (i) number of items dispensed
 - (ii) number of new medicine service interventions claimed
 - (iii) number of appliance use reviews and stoma appliance customisations claimed
 - (iv) number of community pharmacist consultation service fees claimed
 - (v) number of Community Pharmacy Hepatitis C Antibody Testing Service Fees
 - (vi) number of Community Pharmacy Completed Transactions for Covid-19 Lateral Flow Device Distribution Service
- (b) information on the number of flu vaccinations given is available via Catalyst¹⁴ (individual log-ins not required).

All of the above information is provided on a national basis so the F codes will be needed to extract the relevant information.

Normally it would be recommended that the most recent financial year's activity data is used for the pharmaceutical needs assessment. However, the Covid-19 pandemic affected

¹³ [NHS Business Services Authority, pharmacy and appliance contractor dispensing data monthly reports](#)

¹⁴ [NHS Business Services Authority, Catalyst public insight portal](#)

the provision of many pharmaceutical services such that activity levels for 2020/2021 are unlikely to be an accurate reflection of the level of provision that would normally be seen. It is therefore suggested that health and wellbeing boards consider using data from the two financial years of 2019/2020 and 2020/2021 and as much data for 2021/2022 as is available, noting that information is not published until three months after the services were provided. For example, activity undertaken in July 2021 will not be published until 10 October 2021.

Inclusion of this data within the pharmaceutical needs assessment will allow any effect of the pandemic on service provision to be identified and explained. For example, the number of new medicine service reviews undertaken is likely to be lower in 2020/2021 due to national and local lockdowns and pharmacies focussing on dispensing prescriptions and dealing with requests for support, not because pharmacies chose not to offer the service.

Information on the remaining advanced services and any enhanced services that may be commissioned is available from NHS England and NHS Improvement, particularly for the new advanced services where pharmacies may have signed up to provide the service but have not yet had the opportunity to provide it.

Information on the number of dispensing patients registered with dispensing GP practices is also available via Catalyst in the 'practice list size and GP count' report.

As well as identifying the provision of pharmaceutical services by contractors within the health and wellbeing board's area the pharmaceutical needs assessment will also need to identify provision by contractors who are outside of the area. In order to do this the organisation data codes for all the services that generate prescriptions will be required. These can be either be provided by the clinical commissioning group or sourced from NHS Digital¹⁵.

Services that generate prescriptions include the GP practices but may also include the following:

- GP out of hours providers,
- GP extended access hubs,
- prisons (although many prescriptions for patients in prison are dispensed under separate contracts and so do not fall within the definition of pharmaceutical services),
- urgent care centres and walk-in centres,

¹⁵ [NHS Digital, organisation data service portal](#)

- substance misuse services,
- end of life services, and
- community nursing teams.

Once the list of services and codes has been collated it will then be possible to identify where all the prescriptions written are dispensed using the monthly practice prescribing dispensing data reports published by NHS Business Services Authority¹⁶. It should be noted that these reports are very large as they contain information on where all the prescriptions written in England are dispensed. However, once the information relevant to the health and wellbeing board's area is extracted it will be easier to manipulate.

The data can be analysed by:

- prescribing service so as to identify the total number of items prescribed in a fixed period by each practice and service, and
- dispenser which will allow the identification of out of area providers of the dispensing service.

Once the out of area providers have been identified they can be classified as either a pharmacy or dispensing appliance contractor by using the consolidated pharmaceutical list. They can also be identified by distance selling premises using that list if required.

Experience shows that the most common reasons for prescriptions being dispensed out of area are:

- they are dispensed by a contractor that is just over the border in a neighbouring health and wellbeing board's area,
- the prescription was for an appliance and was dispensed by a dispensing appliance contractor,
- the patient chose to use a distance selling premises.

In addition, whilst several hundred different out of area pharmacies may have dispensed prescriptions the majority are dispensed by a much smaller number of pharmacies or dispensing appliance contractors.

¹⁶ [NHS Business Services Authority, practice prescribing dispensing data monthly reports](#)

Information on the provision of other pharmaceutical services by out of area providers is not available. However, it can be assumed that as some people will have their prescription dispensed out of area they will also access other services out of area. It is not necessary to identify where all services are provided; it can merely be noted that people may have accessed other essential services, and also advanced and enhanced services, from an out of area provider.

Health and wellbeing boards will need to decide on the cut-off point for data collection. It will take a number of months between starting the process and getting to the point of signing off the consultation version of the document and during that time it is possible that things will change, for example pharmacies may open, close or relocate, new services may be commissioned or ceased to be commissioned. It is recommended that a cut-off point is set once all the required data has been collated and this is clearly stated throughout the document for example:

- as at November 2021 there are 150 pharmacies included in the pharmaceutical list for the area of Anytown Health and Wellbeing Board;
- in the first four months of 2021/2022, 140 of the 150 pharmacies had provided a total of 3,750 new medicine service reviews; and
- at the time of drafting (November 2021), 50 of the 150 pharmacies had signed up to provide the new hypertension case-finding service advanced service. It is anticipated that more will sign-up to provide the service over the coming months and this will be reviewed after the consultation.

Any changes that subsequently occur can then be noted and included in the post-consultation version of the document. Health and wellbeing boards will, however, need to note that if any of the changes to service provision or availability are such that they create a gap and this leads to the identification of a new need, improvements or better access, a second period of consultation on that will need to be undertaken, although it does not need to be for 60 days.

5. Necessary services

Once the provision of all pharmaceutical services has been identified it will then be necessary to identify those that are necessary services. These are defined within the 2013 regulations as those that are necessary to meet the need for pharmaceutical services and could be provided within or outside of the health and wellbeing board's area.

As noted in chapter 2 the 2013 regulations do not include a definition of what is a necessary service and what is not, so health and wellbeing boards have complete discretion as to how they go about this.

There are two potential ways to define which services are necessary services

- (a) by the type of service, for example all essential services and certain advanced and enhanced services; or
- (b) by pharmacy, location, or time and day of the week that services are provided. This may be harder where, for example, there are four pharmacies in a town all providing the same range of services at approximately the same times of the day and days of the week. The health and wellbeing board may have difficulty in deciding which are necessary and which are other relevant services (see below).

Once it has determined which services are necessary services the health and wellbeing board will need to include a statement to this effect within the pharmaceutical needs assessment. It then needs to go on to describe the current provision of these services i.e. where they are provided and the times they are provided at.

6. Other relevant services

The remaining pharmaceutical services are therefore deemed to be other relevant services and a statement to this effect is to be included in the pharmaceutical needs assessment. It then needs to go on to describe the current provision of these services i.e. where they are provided and the times they are provided at.

7. Other NHS services

The 2013 regulations then require the pharmaceutical needs assessment to include a statement of the other NHS services that the health and wellbeing board considers affect the need for pharmaceutical services. It is recommended that these are included as a separate chapter.

Those NHS services that reduce the need for pharmaceutical services, in particular the dispensing service, include:

- hospital pharmacies,
- personal administration of items by GP practices,

- GP out of hours service (as it may give patients a course of treatment rather than a prescription),
- public health services commissioned by the local authority (as this reduces the need for such services to be commissioned as enhanced services),
- prison pharmacy services (where relevant),
- substance misuse services, and
- flu vaccination by GP practices

NHS services that increase the demand for pharmaceutical services include:

- GP out of hours services (where a prescription is issued),
- walk-in centres and minor injury units (where a prescription is issued),
- GP extended access hubs,
- community nursing prescribing,
- dental services,
- end of life services, and
- services that have been moved into the primary care setting.

The number of items prescribed in the above services can be identified as described earlier in this chapter, although not for all of them as they will not have an organisation data code. For example:

- the level of dental prescribing is not available at health and wellbeing board level.
- the provision of pharmacy services to any prison in the health and wellbeing board's is unlikely to be part of pharmaceutical services and the number of items may not be available.

Where an organisation data code has not been issued and therefore the number of items prescribed is not available it is suggested that the pharmaceutical needs assessment notes that dentists, for example, will issue NHS prescriptions which are dispensed as part of pharmaceutical services, however the level of activity is unknown.

8. Maps

The pharmaceutical needs assessment must include a map that identifies the premises at which pharmaceutical services are provided within the area of the health and wellbeing board. This can be produced using the Department of Health and Social Care Office for Health Improvement and Disparities' SHAPE application (which has the premises pre-loaded) or other mapping software applications. This map must be kept up-to-date (without needing to republish the whole document or publish a supplementary statement – see chapter 8).

It is likely that, due to the size of the health and wellbeing board's area, the markers for some of the premises overlap and the map may therefore be of limited value. It is recommended that locality level maps are also included as they may be clearer.

There is no cap on the number of maps that may be included. Health and wellbeing boards may therefore wish to consider mapping the location of premises:

- against indicators such as population density and deprivation, and
- provision of each of the advanced and any enhanced services.

Mapping travel times to premises by private and public transport and on foot can help in the identification of any geographical gaps in provision and these maps can be produced using the Department of Health and Social Care Office for Health Improvement and Disparities' SHAPE application.

9. Choice with regard to obtaining pharmaceutical services

The 2013 regulations require the health and wellbeing board to have regard to whether there is sufficient choice with regard to obtaining pharmaceutical services.

Earlier in this chapter a suggested process for identifying where prescriptions are dispensed was described. This will allow the health and wellbeing board to identify the number of different pharmacies and dispensing appliance contractors that residents chose to use on either a regular or infrequent basis.

It should also be borne in mind that as of 30 June 2021 each resident had the choice of using any of the 379 distance selling premises in England, all of which are required to provide all of the essential services remotely to anyone anywhere in England who may request them.

Other pharmacies provide delivery services. Whilst these are not a pharmaceutical service, where provided they can improve the provision of, or access to, services,

particularly dispensing services, in the areas that the pharmacy delivers to. The health and wellbeing board however should note that this is a private service and can therefore be withdrawn at any time. It will therefore need to decide how much weight to place on such services.

In addition, all pharmacies are now required to facilitate, to a reasonable extent, remote access to the pharmaceutical services they provide, where people wish to access them remotely. This change was brought into the terms of service earlier in 2021 and will take time to become embedded. However, it is likely that this will be an attractive option for certain residents, but not all as there will be those who do not have access to the internet or who prefer to access services on a face-to-face basis.

Possible factors to be considered in terms of the benefits of sufficient choice are as follows.

1. what is the current level of access within the health and wellbeing board's area to pharmaceutical services?

what is the extent to which services already offer people a choice, which may be improved by the provision of additional facilities?

what is the extent to which current service provision is adequately responding to the changing needs of the community it serves?

is there a need for specialist or other services, which would improve the provision of, or access to, services such as for specific populations or vulnerable groups?

Taking into account the above, and by asking residents what influences their choice of pharmacy as part of the patient and public engagement questionnaire, will allow the health and wellbeing board to establish whether it considers that residents have sufficient choice with regard to obtaining pharmaceutical services.

Chapter 6: Identifying gaps and articulating needs/improvements/ better access

1. Background

In order to provide pharmaceutical services in England a person and the premises from which they will provide services must be included in the relevant pharmaceutical list. NHS England and NHS Improvement is responsible for preparing, maintaining and publishing pharmaceutical lists in respect of each health and wellbeing board's area. Applications for inclusion in one of these lists are submitted to Primary Care Support England and determined by NHS England and NHS Improvement.

The main purpose of the pharmaceutical needs assessment is to inform the submission of applications for inclusion in a pharmaceutical list, and the subsequent determination of such applications.

There are a number of different types of application which can be submitted where someone wishes to open new pharmacy or dispensing appliance contractor premises.

- to meet a current need identified in the relevant pharmaceutical needs assessment.
- to meet a future need identified in the relevant pharmaceutical needs assessment.
- to secure improvements or better access identified in the relevant pharmaceutical needs assessment.
- to secure future improvements or better access identified in the relevant pharmaceutical needs assessment.
- to secure improvements or better access that were not identified in the relevant pharmaceutical needs assessment.
- to open distance selling premises.

As can be seen the first four types of application are based on the pharmaceutical needs assessment for the area of the health and wellbeing board where the applicant wishes to provide services.

The regulations require pharmaceutical needs assessments to include statements of the pharmaceutical services that the health and wellbeing board has identified that are not provided within its area but which the board is satisfied:

- need to be provided in order to meet a current need,
- will need to be provided in specified circumstances in order to meet a future need,
- would, if they were provided, secure improvements or better access, or
- would, if they were provided in specified future circumstances, secure future improvements or better access.

The needs, improvements or better access could be for a particular service or for a range of services.

Where the health and wellbeing board does not identify any needs for, or improvements or better access to, pharmaceutical services within the pharmaceutical needs assessment the only types of application for new premises that could be submitted are those offering unforeseen benefits or for distance selling premises.

2. Identifying gaps in provision – current provision

The requirements of paragraphs 2(a) and 4(a) of Schedule 1 to the 2013 regulations are set out in the box below.

Necessary services: gaps in provision

2. A statement of the pharmaceutical services that the [health and wellbeing board] has identified (if it has) as services that are not provided in the area of the [health and wellbeing board] but which the [health and wellbeing board] is satisfied-

(a) need to be provided (whether or not they are located in the area of the [health and wellbeing board]) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;

Improvements and better access: gaps in provision

4. A statement of the pharmaceutical services that the [health and wellbeing board] has identified (if it has) as services that are not provided in the area of the [health and wellbeing board] but which the [health and wellbeing board] is satisfied-

(a) would, if they were provided (whether or not they were located in the area of the [health and wellbeing board]), secure improvements, or better access to pharmaceutical services, or pharmaceutical services of a specific type, in its area,

So far the pharmaceutical needs assessment will have:

- described the demographics of the area and any expected changes to these within the three-year lifetime of the document,
- identified the health needs of the population and which can be met by the provision of pharmaceutical services,
- described and mapped the provision of pharmaceutical services (both by those within the area and outside of it), and
- described the other NHS services that affect the need for pharmaceutical services.

The next step is to identify whether or not there are any gaps in the current provision of pharmaceutical services. Such gaps could be for:

- a pharmacy providing a specified range of services,
- a specific service, or
- a service, or services, to be provided at specified times.

The regulations are silent as to how the health and wellbeing board identifies any gaps. It is suggested that there are three levels where gaps may exist.

1. geographical gaps in the location of premises – are premises in the right locations? Are there any current gaps in the spread of premises?
2. geographical gaps in the provision of services
3. gaps in the times at which, or days on which, services are provided.

Once any gaps are identified they are to be articulated as needs for, or improvements or better access to, pharmaceutical services.

Care needs to be taken when articulating needs, improvements or better access as vague or incomplete statements could lead to applications either being:

- (a) granted inappropriately because:

- (i) the applicant is not offering the service that was required, or
 - (ii) the location of their premises is in the wrong place, or
 - (iii) their opening times are the same as, or similar to, the other pharmacies and they are offering no additional benefit; or
- (b) refused inappropriately because either NHS England and NHS Improvement or NHS Resolution was unclear as to what the need/improvement/better access is and therefore whether the applicant is offering to meet or secure it.

2.1 Current geographical gaps in the location of premises

In order to identify gaps in the location of premises it is recommended that a travel time standard is chosen and then access mapped against it. Information gained from the public engagement questionnaire will help inform the travel time standard used, along with information on how the public travels to pharmacies.

Using mapping software or the Department of Health and Social Care Office for Health Improvement and Disparities' SHAPE application will allow the health and wellbeing board to map travel times to the current premises within its area by public and private transport, on foot or by bicycle. Some mapping software will confirm the number of people who do not live within the travel time, but not all will. Where it does not, the use of freely available mapping applications will allow analysis of whether or not there is a resident population in the area or areas.

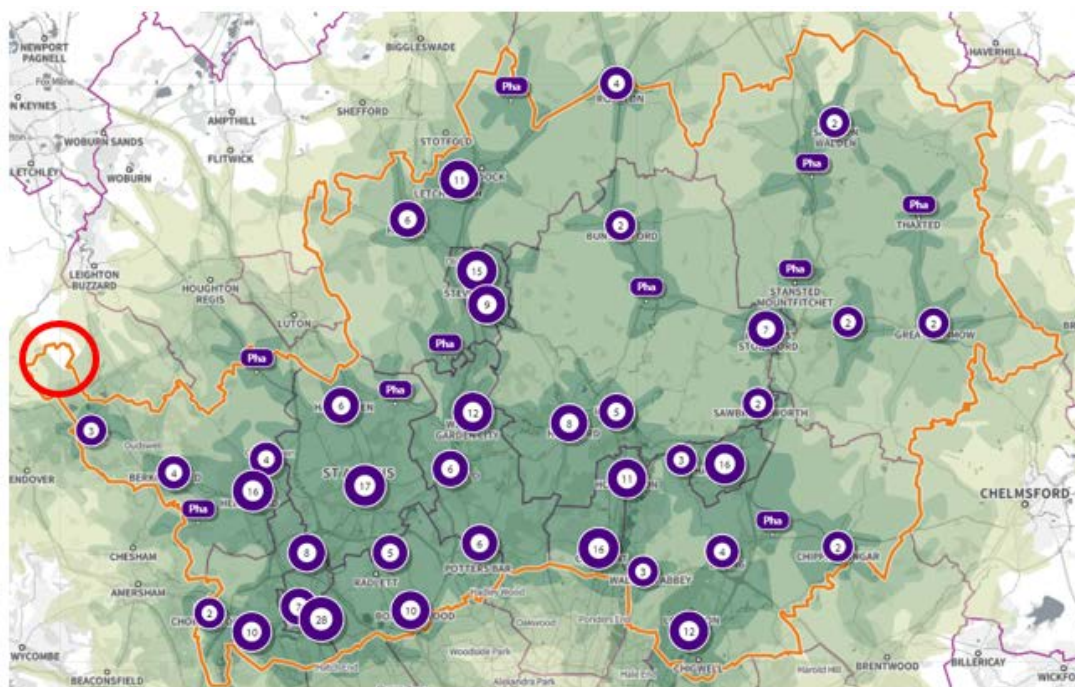
Having mapped access to the premises within the health and wellbeing board's area, those areas that are outside of the travel time need to be identified. These are likely to be on the edge of the board's area so it will be necessary to add on those pharmacies in the neighbouring area in order to avoid identifying gaps that do not actually exist.

For example, SHAPE shows that all but a small part of Hertfordshire is within 20 minutes of a pharmacy within the county by car (circled in red in the map below).

In the following maps the darker the colour the shorter the journey with the darkest green representing journey times of up to five minutes.

Google Maps reveals that the area is mostly open countryside with only a few scattered residences.

Figure 1: Map 1 – 20-minute travel time to Hertfordshire pharmacies

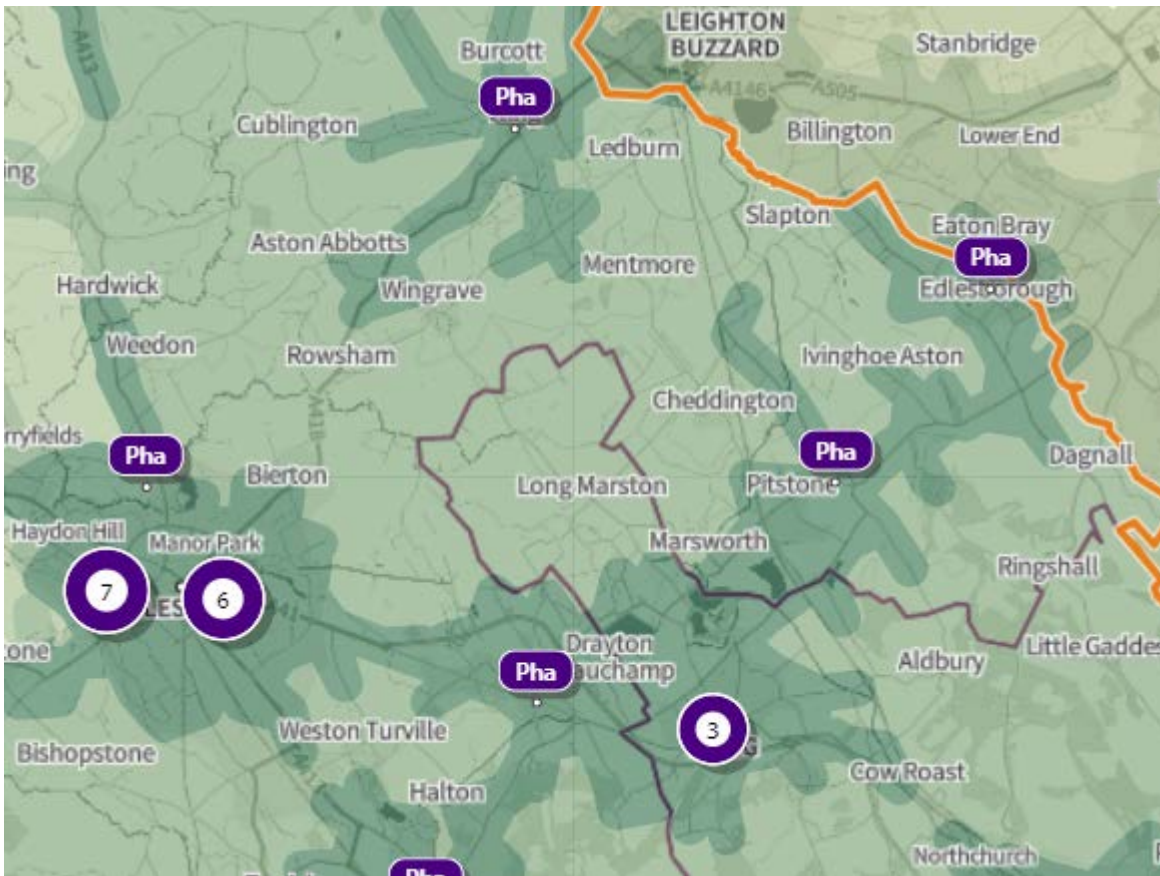


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Analysis of where prescriptions are dispensed (as described in chapter 5) will help map out of area providers and therefore whether it is appropriate to include pharmacies in neighbouring areas in the mapping of travel times. SHAPE can also be used to plot the GP practices and map where their prescriptions were dispensed in the most recently available month (usually three months in arrears).

For example, the data shows that prescriptions are dispensed in Buckinghamshire. When access to pharmacies in Buckinghamshire is mapped this area is now within a ten-minute drive of a pharmacy.

Figure 2: Map 2 – travel time to pharmacies within and outside of Hertfordshire



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In addition, GP practices may have branch surgeries that are outside of the health and wellbeing board's areas and this will need to be taken into account as it will affect where people access pharmaceutical services.

For example, one of the GP practices in Tring has a branch surgery in a village in Buckinghamshire. When analysing where that practice's prescriptions are dispensed SHAPE shows that a proportion are dispensed by the pharmacy in that village as can be seen from the map below.

Figure 3: Map 3 – mapping where practice prescriptions are dispensed

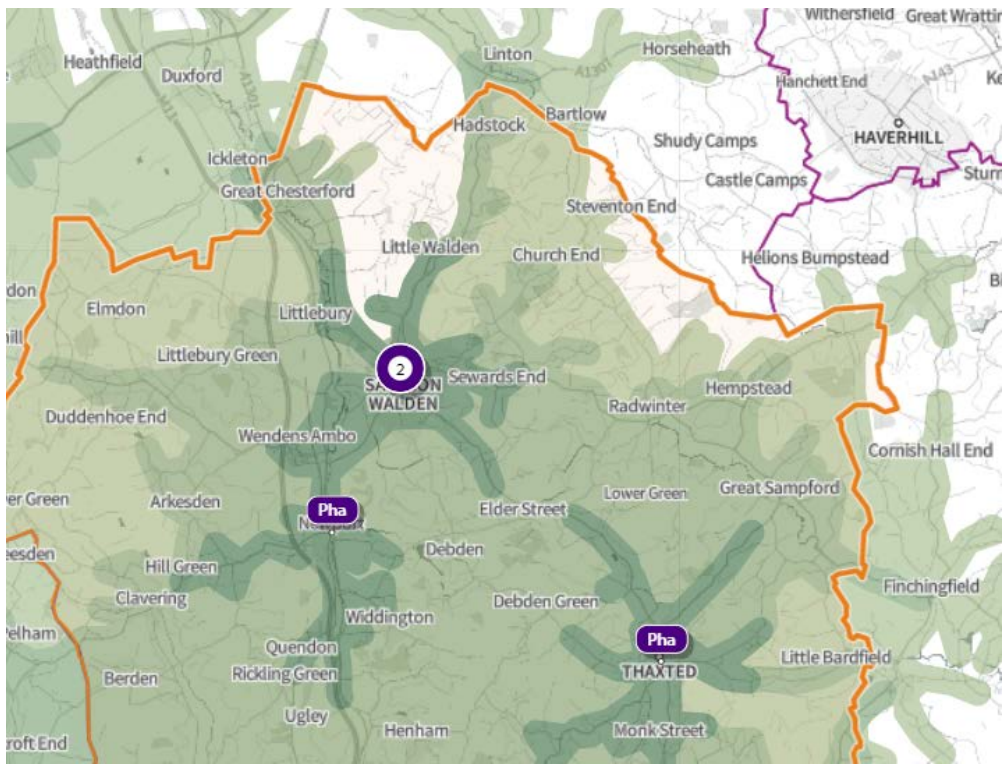


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Use of this data will provide evidence of where prescriptions are dispensed and help to validate the travel time standard chosen.

If a 15-minute drive time was chosen for Hertfordshire then other parts of the county would also fall outside of that standard, in particular to the north and north east of Saffron Walden as shown in the map below.

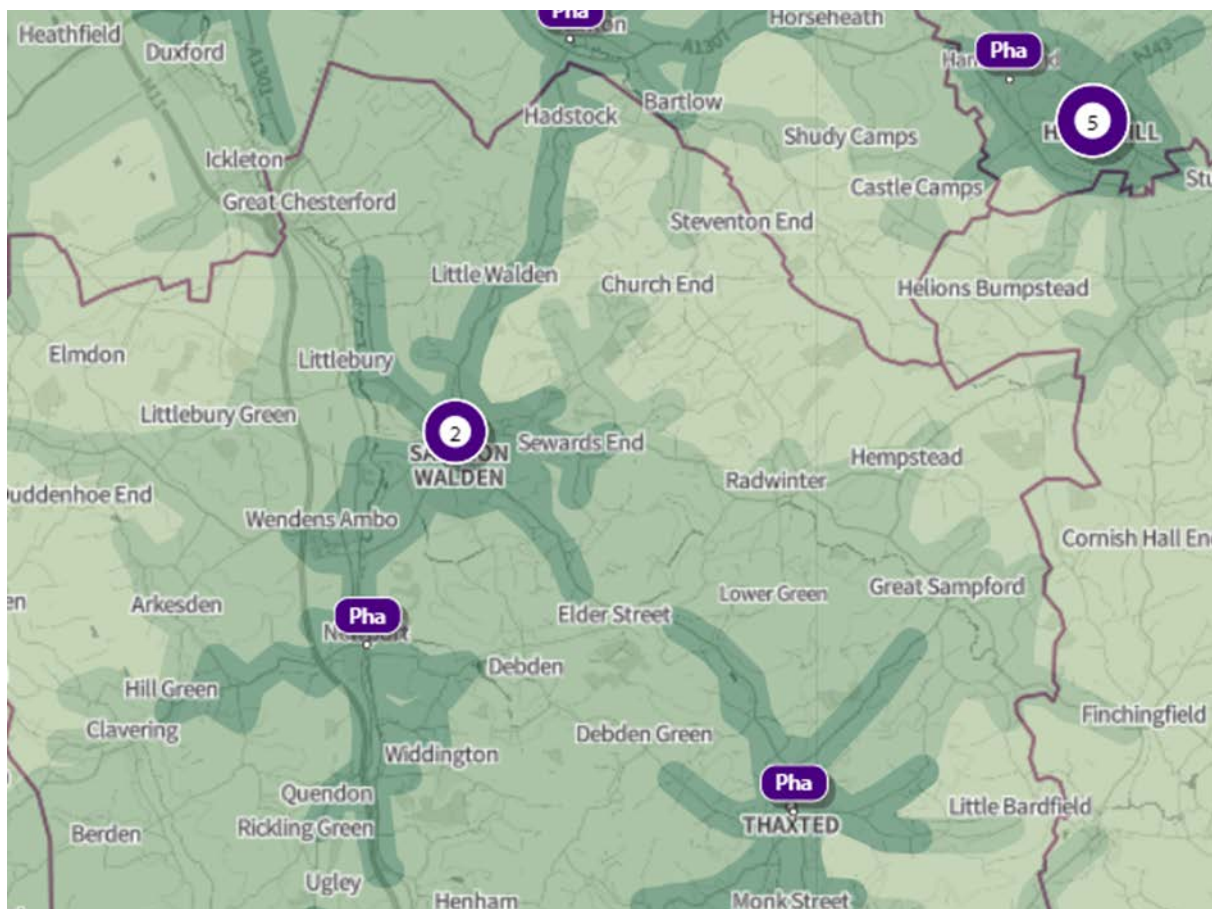
Figure 4: Map 4 – 15-minute travel time to Hertfordshire pharmacies



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However, when the pharmacies over the border in Cambridgeshire, Suffolk and Essex are taken into account, the areas are within a 15-minute drive of a pharmacy.

Figure 5: Map 5 – travel time to pharmacies within and outside of Hertfordshire



Depending on the geography of the health and wellbeing board's area it may be necessary to have two travel standards – one for rural areas and one for built-up areas. In rural areas the provision of a dispensing service by GP practices will need to be taken into account again so that gaps are not inappropriately identified.

2.2 Current geographical gaps in the provision of services

Provision of each of the advanced services and any enhanced services that are commissioned will then need to be mapped in order to establish any geographical gaps in provision. However, if all pharmacies provide a particular service this won't be necessary.

2.3 Current gaps in the times at which, or days on which, services are provided

Consideration will then need to be given as to whether there are any gaps in the times at which services are provided. This could be for a specific service e.g. the need for the provision of the community pharmacist consultation service at the weekend, or a range of services.

Health and wellbeing boards will need to decide how much weight is to be given to the provision of pharmaceutical services during supplementary opening hours, bearing in mind that these hours can be changed with at least three months' notice.

Access to services at certain times or on certain days may have been highlighted as part of the public engagement questionnaire and this should be taken into account in this consideration.

3. Articulating current needs

It is not enough just to identify a gap or gaps. The 2013 regulations require the health and wellbeing board to include a statement of the service that needs, or services that need, to be provided in order to meet a need for that service or services.

Health and wellbeing boards need to be as precise as possible in articulating any current need, clearly setting out what service is provided, at what times it needs to be provided, and where. Words such as 'may', 'might' or 'could' must be avoided in order to ensure that only applications that will meet the identified need are granted.

Including a statement such as "There might be a need for services in the area" is too vague and does not meet the requirements of the 2013 regulations. Is there a need or not? What are the services that are required? Where do they need to be provided?

A statement that better meets the requirements of the 2013 regulations would be as follows.

"Taking into account the above information, the health and wellbeing board is satisfied that there is a current need for the provision of the community pharmacist consultation service on Saturdays and Sundays between the hours of 09.00 and 19.00, in Anytown, to the north of the river."

It clearly sets out:

- (a) what service is required,
- (b) when it is to be provided, and
- (c) where it is to be provided.

If the current need for a pharmacy is identified, then the pharmaceutical needs assessment should state that. However, it should be noted that a pharmacy of itself is not a pharmaceutical service, therefore the need would be expressed as follows.

“There is a current need for a pharmacy providing the following services, Monday to Saturday:

- all essential services,
- the community pharmacist consultation service,
- the new medicine service, and
- flu vaccinations.”

Should an application then be submitted offering to meet that need, NHS England and NHS Improvement can clearly assess the application against the identified need and determine whether or not to grant it. In addition, NHS England and NHS Improvement can hold the applicant to providing the advanced services (the provision of the essential services is a given for all pharmacies included in a pharmaceutical list).

The health and wellbeing board could go on and specify the required opening hours, for example 09.00 to 19.00 Monday to Friday and 09.00 to 18.00 on Saturday. Whilst this would total more than 40 core opening hours per week an applicant could apply and offer these core opening hours and NHS England and NHS Improvement could grant the application partly on the basis of these core opening hours and then hold the applicant to them once the pharmacy opens.

4. Articulating current improvements or better access

Whilst current needs may be identified in relation to the lack of provision of a particular service or services, the health and wellbeing board may also identify improvements or better access to the existing provision of services. This is most likely to be in relation to the times at which the existing services are provided, although it could be in relation to reducing the travelling time or distance to access a service.

Health and wellbeing boards should note that opening hours of themselves are not pharmaceutical services. Therefore, they should avoid identifying a need for, or improvement or better access to, opening hours. If there is a gap in the provision of services of certain times this would be articulated as an improvement or better access to specified services at specified times.

Instead of saying “Extended opening hours on weekday evenings would lead to better access to services” it should be articulated as:

“Better access to the following services would be secured by their provision on weekday evenings between 17.00 and 19.30:

- all essential services,
- the community pharmacist consultation service, and
- the new medicine service.”

The pharmaceutical needs assessment would then go on to confirm where the better access is required, for example in X ward, or in A, B and C wards.

5. Identifying gaps in provision – future provision

The requirements of paragraphs 2(b) and 4(b) of Schedule 1 to the 2013 regulations are set out in the box below.

Necessary services: gaps in provision

2. A statement of the pharmaceutical services that the [health and wellbeing board] has identified (if it has) as services that are not provided in the area of the [health and wellbeing board] but which the [health and wellbeing board] is satisfied-

(b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the [health and wellbeing board]) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Improvements and better access: gaps in provision

4. A statement of the pharmaceutical services that the [health and wellbeing board] has identified (if it has) as services that are not provided in the area of the [health and wellbeing board] but which the [health and wellbeing board] is satisfied-

(b) would, if in specified future circumstances they were provided (whether or not they were located in the area of the [health and wellbeing board]), secure future improvements, or better access, to pharmaceutical services, or pharmaceutical services or a specified type, in its area.

The pharmaceutical needs assessment must also set out any needs for pharmaceutical services that may arise during the three-year lifetime of the document. Matters to have regard to here include:

- housing developments,
- regeneration projects,

- highways projects that will affect how services are accessed,
- creation of new retail and leisure facilities that will draw people to an area,
- changes in the provision of primary medical services for example the relocation of GP practices, mergers of GP practices, known closures of GP practices, and
- other changes to the demand for services e.g. increases in the range of services within primary care that increase the number of prescriptions that need to be dispensed, care or nursing home developments.

The health and wellbeing board would then go through the same process as it did to identify any gaps in the current provision of pharmaceutical services.

The services that pharmacies provide are subject to national negotiation, and it is therefore possible that during the lifetime of the pharmaceutical needs assessment new essential or advanced services will be rolled out. It is not possible for the health and wellbeing board to foresee what new advanced services may be launched (any new essential services would have to be provided by all pharmacies), so this would be something to consider as part of the ongoing duties with regard to producing new pharmaceutical needs assessments and/or publishing supplementary statements (see chapter 8).

6. Articulating future needs, improvements, or better access

Information that will be useful to inform the discussion on future needs, improvements or better access includes knowledge of the existing contractors' capacity (gathered as part of the contractor questionnaires) as it is not possible to assume a pharmacy that dispenses the highest number of items per month is at capacity and the pharmacy that dispenses the lowest has spare capacity. Contractors will have different operating and staffing models and may use a dispensing hub elsewhere in the country, and these will affect their ability to meet an increase in demand for their services.

In relation to new housing developments the health and wellbeing board will need to consider not just the contractors' capacity but also the ability of residents to access the nearest pharmacies. Information on those that will be amongst the first to move in is unlikely to be available, but the following information will assist:

- the type of housing that will be built during the three-year period,
- the estimated occupancy rate (this may vary depending on the type of housing being built),
- access to public transport,

- footpaths and cycle paths into and out of the area,
- the distance to the nearest pharmacies and/or dispensing doctors, and
- what other facilities are there or will be built during the three-year period for example GP practices, schools, retail and leisure facilities, and employment.

The pharmaceutical needs assessment will need to identify the demand for pharmaceutical services that will be generated, the ability for the existing contractors to meet that demand, and the ability for residents to access the existing contractors. It should be borne in mind that the residents will have access to all the distance selling premises in England who are required to provide all the essential services, and pharmacies will increasingly be offering remote access to services where this is appropriate. In addition some of the existing contractors will offer private delivery services.

If a pharmacy providing a specified range of services is identified as needed within a housing development, then consideration will need to be given as to the trigger for that need. Is it on:

- completion of a certain number of houses?
- occupation of a certain number of houses?
- completion of a certain phase of the development?
- completion of the whole development?
- completion of some or all of the other facilities?

Whatever the trigger is, it needs to be clearly articulated in the pharmaceutical needs assessment, and should be based on information that is measurable so that an accurate assessment can be made. For example:

“There is a future need for a pharmacy within the village centre of the development on occupation of 1,000 houses, that is open Monday to Friday between 09.00 and 19.00, and on Saturdays 09.00 to 17.30, providing the following services:

- all essential services, and
- the following advanced services:
 - community pharmacist consultation service,
 - flu vaccination, and

- hypertension case-finding service.”

If an application is then submitted to meet this future need NHS England and NHS Improvement could either:

- defer determination of it until 1,000 houses are occupied, or
- determine and grant the application subject to the condition that services are not provided until 1,000 houses are occupied.

The same applies to applications to secure future improvements or better access.

Chapter 7: Consultation

1. Regulatory requirements

Regulation 8 requires the health and wellbeing board to consult a specified range of organisations on a draft of the pharmaceutical needs assessment at least once during the process of drafting the document. They must be given a minimum period of 60 days to submit their response, beginning on the day by which they are 'served with a draft' of the document.

'Served with a draft' is defined within the 2013 regulations - a consultee is treated as served with a draft of the document when the health and wellbeing board notifies them of the website on which the document is available and will continue to be available for a period of at least 60 days.

Health and wellbeing boards should note that it is sufficient to send consultees the weblink to the document. However, if one of the consultees requests a hard copy of the document this must be provided as soon as practicable, and in any event within 14 days, free of charge.

2. Those to be consulted

The following organisations must be consulted:

- the local pharmaceutical committee,
- the local medical committee,
- pharmacy and dispensing appliance contractors included in the pharmaceutical list for the area of the health and wellbeing board,
- dispensing doctors included in the dispensing doctor list for the area of the health and wellbeing board, if any,
- any pharmacy contractor that holds a local pharmaceutical services contract with premises that are in the health and wellbeing board's area,
- Healthwatch, and any other patient, consumer, or community group in the area which the health and wellbeing board believes has an interest in the provision of pharmaceutical services,
- any NHS trust or NHS foundation trust in the health and wellbeing board's area,

- NHS England and NHS Improvement, and
- any neighbouring health and wellbeing board.

The health and wellbeing board is free to consult with any other organisation and/or members of the public if it so wishes, but is not obliged to do so. In light of the upcoming changes to the structure of the NHS, the health and wellbeing board may wish to consult the integrated care board and integrated care partnership for its area.

3. Suggested questions

The 2013 regulations do not specify what is asked as part of the consultation. It is suggested that views are sought on the following questions.

- (i) has the purpose of the pharmaceutical needs assessment been explained?
- (ii) does the pharmaceutical needs assessment reflect the current provision of pharmaceutical services within your area?
- (iii) are there any gaps in service provision i.e. when, where and which services are available that have not been identified in the pharmaceutical needs assessment?
- (iv) does the draft pharmaceutical needs assessment reflect the needs of your area's population?
- (v) has the pharmaceutical needs assessment provided information to inform market entry decisions i.e. decisions on applications for new pharmacies and dispensing appliance contractor premises?
- (vi) has the pharmaceutical needs assessment provided information to inform how pharmaceutical services may be commissioned in the future?
- (vii) has the pharmaceutical needs assessment provided enough information to inform future pharmaceutical services provision and plans for pharmacies and dispensing appliance contractors?
- (viii) are there any pharmaceutical services that could be provided in the community pharmacy setting in the future that have not been highlighted?
- (ix) do you agree with the conclusions of the pharmaceutical needs assessment?

(x) do you have any other comments?

4. Consultation report

The 2013 regulations require a report of the consultation to be included in the final version of the pharmaceutical needs assessment. This should include the responses to the consultation, any response to them by the health and wellbeing board and a list of any amendments or changes subsequently made to the pharmaceutical needs assessment.

It should be noted that if, as a result of the consultation, the health and wellbeing board identifies new needs for, or improvements or better access to, pharmaceutical services, then there will need to be a second period of consultation, although this does not have to be for 60 days. Health and wellbeing boards should therefore bear this in mind when agreeing the project timeline.

Chapter 8: Updating of PNAs and supplementary statements

1. What the legislation says

As at October 2021, the 2013 regulations require the next pharmaceutical needs assessment to be published by 1 April 2022 although this will be amended to 1 October 2022 as a result of the ongoing response to the Covid-19 pandemic. Health and wellbeing boards should note this is the latest date by which they must publish their next pharmaceutical needs assessment, although they are free to publish it sooner if they so wish.

Once the 2022 version is published, health and wellbeing boards will be required to publish their next pharmaceutical needs assessment within three years of the date on which the 2022 version was published.

However, there may be occasions where a health and wellbeing board will need to publish its next pharmaceutical needs assessment sooner. In addition, the health and wellbeing board may need to publish a supplementary statement or statements. Once the document is published, the health and wellbeing board will therefore need to establish a process to meet the regulatory requirements regarding publishing new versions and/or supplementary statements. A decision-making flowchart is included at appendix 2 to assist health and wellbeing boards with these requirements.

2. Subsequent pharmaceutical needs assessments

Once a pharmaceutical needs assessment is published, the 2013 regulations require the health and wellbeing board to produce a new one if it identifies changes to the need for pharmaceutical services, which are of a significant extent. This could be due to changes to:

- the number of people in the area who require pharmaceutical services,
- the demography of the area, or
- risks to the health or wellbeing of people in the area (both residents and visitors).

The only exception to this requirement is where the health and wellbeing board is satisfied that producing a new pharmaceutical needs assessment would be a disproportionate response to the changes.

The box below contains an example to illustrate this regulatory requirement.

Is a new pharmaceutical needs assessment required?

Whilst drafting its next pharmaceutical needs assessment, the health and wellbeing board notes that the regeneration of a steelworks plant is due to start in four years' time. As well as 15,000 houses there will also be a business park, retail area and extensive leisure and recreational facilities. It is anticipated that when finished the development will draw a considerable number of daily visitors.

Whilst groundworks will start in year three, building of the first phase of housing is not due to start until the following year. The health and wellbeing board is of the opinion that a pharmacy providing a specified range of pharmaceutical services seven days a week will be required in the future but decides not to include the project in the pharmaceutical needs assessment as it will not generate any need for pharmaceutical services within the three-year lifetime of the document.

Six months after the pharmaceutical needs assessment is published, it is announced that the project is being bought forward in order to stimulate the local economy and the first phase of housing will commence within the next six months.

Due to the location of the development on the edge of a town from which it is separated by a busy motorway, there is no easy access to the nearest pharmacies.

The health and wellbeing board is of the opinion that this represents a significant change to the need for pharmaceutical services and starts the process of producing its next pharmaceutical needs assessment.

The health and wellbeing board will therefore need to put a system in place that allows it to identify any changes to the need for pharmaceutical services that arise during the three-year lifetime of the pharmaceutical needs assessment.

3. Supplementary statements

The health and wellbeing board will also need to put in place a system which allows it to identify any changes to the availability of pharmaceutical services and then determine whether or not it needs to issue a supplementary statement. This responsibility could be delegated to a committee or sub-committee or could remain with the board.

Primary Care Support England is responsible for notifying a range of organisations when:

- a pharmacy or dispensing appliance contractor opens new premises or relocates to new premises, and
- a change of ownership application takes place.

NHS England and NHS Improvement is responsible for notifying a range of organisations when:

- core and/or supplementary opening hours change,
- pharmacy or dispensing appliance contractor premises close permanently, and
- when a dispensing practice ceases to dispense either to a particular area or completely¹⁷.

Health and wellbeing boards should ensure that both organisations are aware of who to send the notifications to¹⁸.

At the moment there is no mechanism for health and wellbeing boards to be automatically notified when a contractor signs up to provide a new advanced or enhanced service, or ceases to provide such a service. This will therefore need to be discussed with NHS England and NHS Improvement and a process agreed.

A supplementary statement is to be published to explain changes to the availability of pharmaceutical services where:

- (a) the changes are relevant to the granting of an application or applications for inclusion in the pharmaceutical list for the area of the health and wellbeing board's area; and
- (b) the health and wellbeing board is satisfied that producing a new pharmaceutical needs assessment would be a disproportionate response to those changes or it is already producing its next pharmaceutical needs assessment but is satisfied that it needs to immediately modify the existing document in order to prevent significant detriment to the provision of pharmaceutical services.

Supplementary statements are statements of fact; they do not make any assessment of the impact the change may have on the need for pharmaceutical services. Effectively, they are an update of what the pharmaceutical needs assessment says about the availability of

¹⁷ This responsibility may transfer to Primary Care Support England in the future.

¹⁸ [Primary Care Support England contact us](#) and [NHS England and NHS Improvement pharmacy contract teams](#)

pharmaceutical services. They are not a vehicle for updating what the pharmaceutical needs assessment says about the need for pharmaceutical services.

Once published the supplementary statement becomes part of the pharmaceutical needs assessment and will therefore be referred to by NHS England and NHS Improvement when it determines applications for inclusion in a pharmaceutical list. It will also be referred to by NHS Resolution when it determines an appeal. Supplementary statements are therefore to be published alongside the pharmaceutical needs assessment.

The box below contains an example to illustrate this regulatory requirement.

Does a supplementary statement need to be published?

The health and wellbeing board is notified that:

1. there has been a change of ownership of a pharmacy. This is not a change to the availability of pharmaceutical services and therefore no supplementary statement is to be issued.
2. a pharmacy has relocated three doors down the road. This is a very minor change to the availability of pharmaceutical services and is not relevant to the granting of an application for inclusion in the pharmaceutical list. No supplementary statement is therefore to be issued. The health and wellbeing board may need to update the map showing the premises at which pharmaceutical services are provided depending upon the scale of it. As the move is such a short distance it is likely that the marker representing the pharmacy is unlikely to move that far, or at all, on the map.
3. one of three pharmacies that are on the same road within 600 metres of each other reduces its supplementary opening hours on a Saturday and now closes at 13.00 instead of 17.00. The other two pharmacies open on Saturday afternoons, one until 22.00 as it is a 100 hour pharmacy. Whilst this is a change to the availability of pharmaceutical services is it relevant to the granting of an application for inclusion in the pharmaceutical list? Due to the close proximity of the two other pharmacies, one of which must stay open until 22.00, it is unlikely to be relevant and therefore a supplementary statement does not need to be issued.
4. the only pharmacy in a deprived part of a town closes. The next nearest pharmacy is two miles away. This is a change to the availability of pharmaceutical services so the health and wellbeing board would need to consider whether the change is relevant to the granting of an application for inclusion in the pharmaceutical list. One way of doing that is to consider whether, when the pharmaceutical needs assessment was written, if the pharmacy had not been there would it have been identified as a gap in the provision of pharmaceutical services? In making this decision the health and wellbeing board will need

to take into account travel times to the nearest pharmacy, the availability of private and public transport, the fact it is likely to be too far to walk for many people, and the availability of other NHS services such as GPs.

5. if the health and wellbeing board considers that if the pharmacy mentioned in paragraph 4 had not been open during the writing of the PNA that there would have been a gap in the provision of pharmaceutical services then it would need to publish a supplementary statement. However, if not, then a supplementary statement should not be published as it could lead to applications to meet a current need as the current need would be inferred by the publication of the supplementary statement. Following the closure of the pharmacy the health and wellbeing board must update the map showing the premises at which pharmaceutical services are provided.

6. the pharmaceutical needs assessment identifies the need for a new pharmacy. An application is subsequently received, granted and the pharmacy opens. This is a change to the availability of pharmaceutical services and is also relevant to the granting of further applications as the pharmaceutical needs assessment only identified the need for one pharmacy. A supplementary statement would therefore need to be published so as to avoid the submission of unnecessary applications. Following the opening of the pharmacy the health and wellbeing board must update the map showing the premises at which pharmaceutical services are provided.

7. an unforeseen benefits application for a pharmacy within a village is granted. This is a change to the availability of pharmaceutical services and is also relevant to the granting of further applications. A supplementary statement would therefore need to be published so as to avoid the submission of unnecessary applications.

Where the health and wellbeing board identifies changes to the availability of pharmaceutical services that are not relevant to the granting of applications and therefore does not issue a supplementary statement, it will need to keep a record of these changes so that they can be incorporated into the next version of the pharmaceutical needs assessment.

Examples of supplementary statements can be found in appendix 3.

4. Supplementary statements and pharmacy consolidations

Since 5 December 2016 pharmacies have been able to apply to NHS England and NHS Improvement to consolidate the provision of pharmaceutical services at two pharmacies onto one site, i.e. one set of premises closes. However, such applications:

- cannot involve distance selling premises,

- can only involve two pharmacies that are in the area of the same health and wellbeing boards,
- may be submitted where the applicant owns both pharmacies,
- may be submitted where the applicant owns one of the pharmacies and another contractor owns the other pharmacy.

NHS England and NHS Improvement is directed to refuse a consolidation application if it satisfied that to grant it would create a gap in pharmaceutical services provision that could be met by an application offering to:

- meet a current or future need for pharmaceutical services, or
- secure improvements or better access to pharmaceutical services.

Health and wellbeing boards will be notified of such applications and must make representations in writing which indicate whether or not granting the application would create such a gap. They will have 45 days to submit such representations and will receive a number of reminders of this statutory duty if they do not respond within the 45 days. Health and wellbeing boards must therefore put in place, if they have not already done so, a process by which a consideration can be made as to whether the closure of one of the pharmacies would result in such a gap.

If a consolidation application is granted the applicant will have six months within which to effect it (potentially extended to an overall total of nine months). When the pharmacy that is to close does so the health and wellbeing board will be notified of this by Primary Care Support England. At that point the health and wellbeing board is to issue a supplementary statement where it is of the opinion that the closing of one of the pharmacies does not create a gap that could be met by an application offering to meet a need for, or secure improvements or better access to, pharmaceutical services.

Such a supplementary statement remains in place and provides regulatory protection for the continuing pharmacy against an application offering to meet a need for, or secure improvements or better access to, pharmaceutical services for the remaining lifetime of the pharmaceutical needs assessment. Having granted a consolidation application NHS England and NHS Improvement must then refuse any further applications known as “unforeseen benefits applications” by other pharmacy contractors seeking inclusion in the pharmaceutical list, if the applicant is seeking to rely on the consolidation as evidence of a gap in provision. This would be the case at least until the next revision of the pharmaceutical needs assessment.

When the pharmaceutical needs assessment is then to be revised, the health and wellbeing board will need to consider again where there are any current geographical gaps in the location of premises – see chapter 6.1. The health and wellbeing board will be aware that the consolidation did not previously create a gap and a supplementary statement was published at the time to this effect. Unless there have been other changes in the locality, and these are then sufficient to have created a need for an additional pharmacy or the provision of a pharmaceutical service or services at certain times, there will continue to be no gap. It is recommended that within the pharmaceutical needs assessment that it is noted that a pharmacy previously closed as the result of a consolidation but that did not create a gap and the health and wellbeing board remains of that opinion. This will then ensure that the regulatory protection conferred by the consolidation will continue for the lifetime of the next pharmaceutical needs assessment. Health and wellbeing boards should, however, note that unforeseen benefits applications could still be submitted where the basis is for a different reason to the fact there used to be a pharmacy but it closed as a result of a consolidation application.

Health and wellbeing boards should note that if a consolidation application is refused the owner of the site that was to be closed can still give notice to NHS England and NHS Improvement that they intend to close the pharmacy. The health and wellbeing board would then need to consider whether it will need to provide a supplementary statement following this closure. If the refusal was because NHS England and NHS Improvement was satisfied that to grant the consolidation would create a gap in pharmaceutical services provision, then a supplementary statement would be required following the closure of the premises.

Appendix 1 – Suggested timeline

This appendix sets out suggested consecutive steps to be taken by health and wellbeing boards to support the development of the pharmaceutical needs assessment. [A separate spreadsheet is available that may be used by health and wellbeing boards to support planning of the process.](#)

Step 1: Governance:

- Invite stakeholders to join the steering group and set date of first meeting
- Steering group meetings to be scheduled in line with the group's wishes (suggested minimum meetings included)
- Board meetings (schedule board update reports as required)

Step 2: Health needs and priorities:

- Obtain reference documentation e.g. needs assessments
- Obtain information on known housing development, regeneration projects or transport developments that are current or will occur within the lifetime of the pharmaceutical needs assessment
- Obtain any additional data
- Agree localities to be used at first steering group meeting
- Analyse data

Step 3: Patient/public questionnaire:

- Agree patient/public questionnaire at first steering group meeting
- Upload questionnaire to online platform
- Promote questionnaire via the council's websites, communications channels and online presence, and via press release
- Questionnaire runs for four weeks
- Analysis of questionnaire responses

Step 4: Current pharmaceutical services provision:

- Contractor questionnaires to be agreed at first steering group meeting
- Upload contractor questionnaires to online platform
- Contractor questionnaires open for four weeks
- Analyse responses
- Obtain dispensing data and advanced and enhanced services activity data
- Analyse and map service provision data

Step 5: Synthesis and drafting:

- Draft overview, health needs, identified patient groups and patient/public engagement results sections of the pharmaceutical needs assessment
- Draft pharmaceutical services sections
- Undertake locality assessments
- Share first complete draft pharmaceutical needs assessment with the steering group
- Steering group to review the pharmaceutical needs assessment
- Steering group meeting to agree changes to the pharmaceutical needs assessment
- Incorporate comments from steering group
- Share final draft of consultation pharmaceutical needs assessment with steering group
- Submit consultation draft of PNAs to health and wellbeing board/committee/sub-committee for sign-off
- Pharmaceutical needs assessment signed off for consultation

Step 6: Consultation:

- Consultation questions agreed
- Consultation documents drafted
- Liaison with council's communications teams
- Consultations run for 60 days

- Review consultation responses and produce first draft of consultation reports
- Consultation report shared with steering group
- Steering group to agree response to the consultations
- Pharmaceutical needs assessment finalised
- Final pharmaceutical needs assessment submitted to the health and wellbeing board
- Final pharmaceutical needs assessment signed off by health and wellbeing board
- Pharmaceutical needs assessment published by 1 October 2022

Appendix 2 – Decision-making flowchart

Once the pharmaceutical needs assessment has been published, the health and wellbeing board will need to establish a process for publishing new versions and supplementary statements. This appendix sets out the decision-making process. A flowchart has also been provided that reflects the decision-making process set out below.

Decision-making process

If, as part of its regular review of the provision of pharmaceutical services in its area the health and wellbeing board identifies a change since the publication of the current pharmaceutical needs assessment then ask the question: is it relevant to the granting of market entry applications?

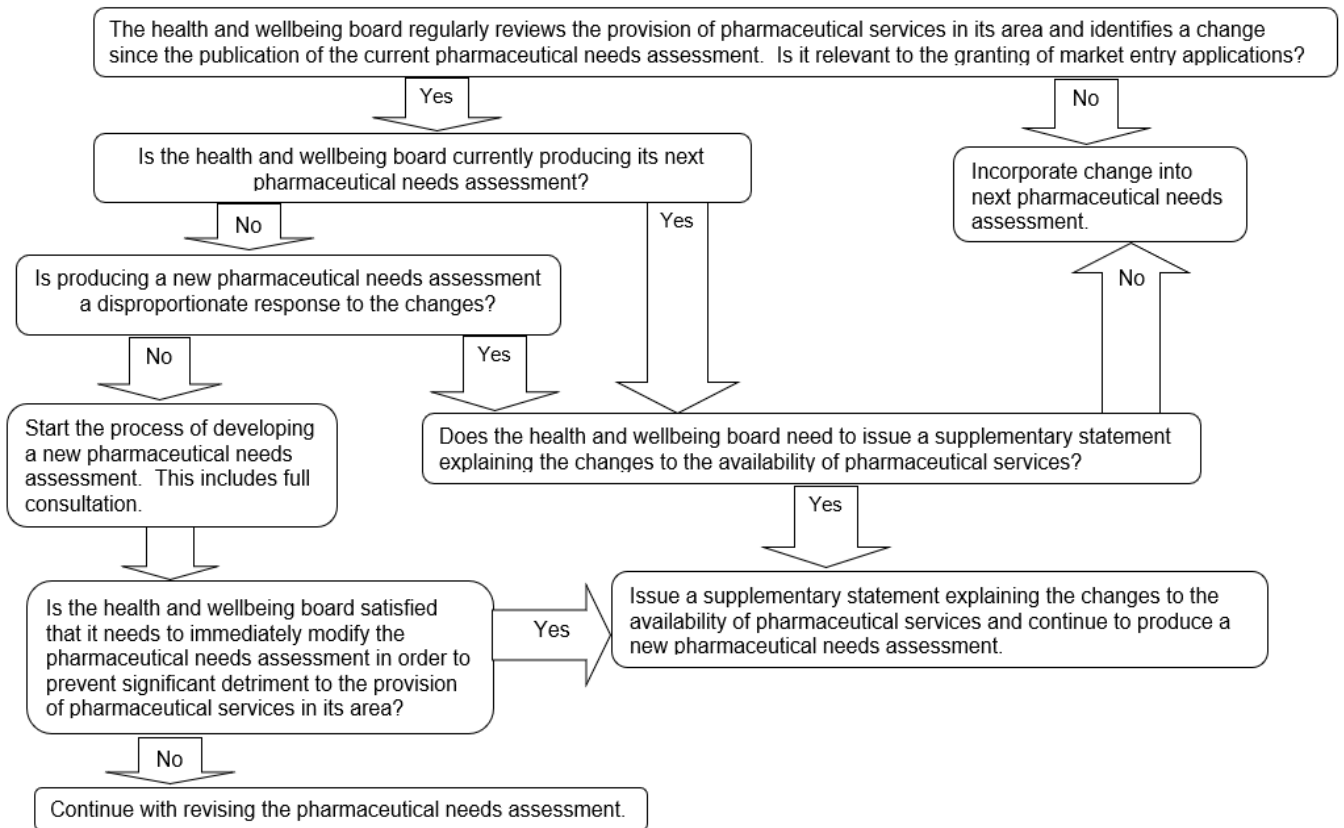
If the answer is no, then incorporate the change into next pharmaceutical needs assessment.

If the answer is yes, then ask the question: is the health and wellbeing board currently producing its next pharmaceutical needs assessment?

If the answer is no, then ask the question: Is producing a new pharmaceutical needs assessment a disproportionate response to the changes? If the answer is no, then start the process of developing a new pharmaceutical needs assessment. This includes full consultation. Then, ask the question: is the health and wellbeing board satisfied that it needs to immediately modify the pharmaceutical needs assessment in order to prevent significant detriment to the provision of pharmaceutical services in its area? If the answer is no, then continue with revising the pharmaceutical needs assessment. If the answer is yes, then issue a supplementary statement explaining the changes to the availability of pharmaceutical services and continue to produce a new pharmaceutical needs assessment.

If the answer is yes, then ask the question: does the health and wellbeing board need to issue a supplementary statement explaining the changes to the availability of pharmaceutical services? If the answer is no, then incorporate the change into next pharmaceutical needs assessment. If the answer is yes, then issue a supplementary statement explaining the changes to the availability of pharmaceutical services and continue to produce a new pharmaceutical needs assessment.

Decision-making flowchart



Appendix 3 – Template supplementary statements

1. Opening of a new pharmacy

Health and wellbeing board logo and address

Supplementary statement to the [insert name] pharmaceutical needs assessment

Date pharmaceutical needs assessment published –

Date supplementary statement issued –

The pharmaceutical needs assessment for the area of [insert name] Health and Wellbeing Board identified in section/chapter [X] a need for the following:

- [insert details of need(s) identified and the service(s) required to meet that need for the particular locality]

[NHS England and NHS Improvement/NHS Resolution] granted an application by [insert name of contractor] to open a pharmacy at [insert address] to provide the following pharmaceutical services:

- [insert all pharmaceutical services that the applicant is to provide]

These services will be provided at the following times:

- [insert core and supplementary hours as detailed in the application]

The pharmacy opened on [insert date of opening].

Supplementary statement issued by: ¹⁹

Post:

Date:

¹⁹ This should be the name of the person or panel/committee who has been authorised to issue supplementary statements.

2. Closing of a pharmacy

Health and wellbeing board logo and address

Supplementary statement to the [insert name] pharmaceutical needs assessment

Date pharmaceutical needs assessment published –

Date supplementary statement issued –

The following pharmacy has closed:

- [insert name and address of pharmacy]

The pharmacy provided the following pharmaceutical services:

- [insert all pharmaceutical services that the pharmacy provided]

These services were provided at the following times:

- [insert core and supplementary hours]

The pharmacy closed on [insert date of opening].

Supplementary statement issued by: ²⁰

Post:

Date:

3. Consolidation of two pharmacies

Health and wellbeing board logo and address

Supplementary statement to the [insert name] pharmaceutical needs assessment

Date pharmaceutical needs assessment published –

Date supplementary statement issued –

²⁰ This should be the name of the person or panel/committee who has been authorised to issue supplementary statements.

The following pharmacy has closed as a result of a successful consolidation application:

- [insert name and address of pharmacy]

The pharmacy provided the following pharmaceutical services:

- [insert all pharmaceutical services that the pharmacy provided]

These services were provided at the following times:

- [insert core and supplementary hours]

The pharmacy closed on [insert date of opening].

It is the opinion of [insert name] Health and Wellbeing board that the removal of this pharmacy from the pharmaceutical list does not create a gap in pharmaceutical services provision that could be met by a routine application:

- to meet a current or future need for pharmaceutical services, or
- to secure improvements, or better access, to pharmaceutical services.

Supplementary statement issued by²¹:

Post:

Date:

²¹ This should be the name of the person or panel/committee who has been authorised to issue supplementary statements

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