LPCs

October 2021

PSNC Briefing 045/21: Pharmaceutical Needs Assessments Guidance for LPCs

Contents

1 Introduction

Pharmaceutical needs assessments were first drafted by primary care trusts in 2005 following the introduction of the, then, new community pharmacy contractual framework. Guidance on how to write a pharmaceutical needs assessment was published, however their length and content varied considerably across the country and the degree to which they were used to inform commissioning decisions was mixed.

The 'Review of NHS pharmaceutical contractual arrangements' by Anne Galbraith [1] concluded that pharmaceutical needs assessments would fail to make any significant difference unless:

- They have consistency across primary care trusts (ensured via minimum standards set out in directions);
- They fully support a wider assessment of the health and wellbeing needs of the population for appropriate services from a range of accessible locations;

[1] Review of NHS pharmaceutical contractual arrangements, March 2007

- They set out a range of desired health outcomes which contractors are to meet;
- Their development is supported with sufficient capacity and skills at an appropriate level within the organisation; and
- They are 'live' documents which have been through a thorough process of consultation with patients, consumers and health professionals and are reviewed (and peer reviewed) regularly.

'Pharmacy in England. Building on strengths - delivering the future[2]' confirmed that the structure of, and data requirements for, pharmaceutical needs assessments required further review and strengthening to ensure that they are an effective and robust commissioning tool. Subsequently a Department of Health and Social Care advisory group[3] drafted regulations which set out the minimum information requirements for pharmaceutical needs assessments and the requirement for a statutory consultation on a draft of the documents.

Whilst primary care trusts were initially responsible for the drafting and publication of pharmaceutical needs assessments, this duty transferred to health and wellbeing boards with effect from 1 April 2013.

The requirements for pharmaceutical needs assessments are set out in Part 2 and Schedule 1 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended[4] (referred to in this document as the 2013 regulations).

This document aims to support local pharmaceutical committee representatives who sit on the steering groups established to support the drafting of pharmaceutical needs assessments. It provides an explanation of the requirements, tips in the writing of the documents and will help local pharmaceutical committees to support the production of robust documents that meet both the requirements of the regulations and the needs of the health and wellbeing board's population.

At the time of drafting (August 2021), NHS England and NHS Improvement is responsible for commissioning pharmaceutical services from pharmacies and dispensing appliance contractors. It is also responsible for the dispensing service provided by some GP practices. However, it is anticipated that this may change.

The Health and Care Bill 2021[5] is currently going through Parliament and as drafted takes forward measures that were contained within the NHS's "Recommendations to Government and Parliament"[6]. These include the establishment of integrated care boards and provisions to allow the delegation by NHS England and NHS Improvement of its national commissioning responsibilities to those boards.

In a letter dated 22 July 2021[7], NHS England and NHS Improvement set out its expectation that, subject to Parliament, integrated care boards will be able to take on delegated responsibility for pharmaceutical services (including provision by dispensing doctors and dispensing appliance contractors) from April 2022. By April 2023 it expects all integrated care boards will have taken on delegated responsibility for pharmaceutical services.

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[2] Pharmacy in England. Building on strengths - delivering the future. Department of Health and Social Care April 2008
[3] Advisory group on the NHS (Pharmaceutical Services) Regulations
[4] NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
[5] Health and Care Bill 2021
[6] The NHS's recommendations to Government and Parliament for an NHS Bill, September 2019
[7] NHS England and NHS Improvement's direct commissioning functions letter, July 2021

There is no mention within the Bill that pharmaceutical needs assessments will transfer from health and wellbeing boards to another organisation and therefore they should aim to produce their next documents by 1 October 2022[8].

With the anticipated move of commissioning responsibility for pharmaceutical services to integrated care boards, pharmaceutical needs assessments will need to reflect the fact that the boards may commission a wider range of enhanced services than NHS England and NHS Improvement currently commissions.

2 The role of the local pharmaceutical committee

Local pharmaceutical committees have a number of roles in the development of a pharmaceutical needs assessment.

- Member of the steering group.
- Inputting into the pharmacy contractor questionnaire to ensure only relevant information is requested, keeping the administrative burden on the contractors is kept to a minimum.
- Encouraging contractors to complete the contractor questionnaire in order that their views are taken into account and as complete a set of information is gathered as possible. (Some local pharmaceutical committees host the contractor questionnaire, but this is not a requirement. If a local pharmaceutical committee wishes to collect additional information for other purposes rather than have two separate questionnaires running at, or around, the same time it may be worth considering wrapping them up into one questionnaire which the local pharmaceutical committee hosts and promotes. Care will need to be taken to ensure that contractors are aware of how the data collected will be used.)
- Ensuring that all pharmaceutical service provision is taken into account and advising the steering group of the range of services that fall within that term. This may include explaining what the services entail.
- Representing contractors' interests when the steering group discusses what gaps in provision may exist and whether these are needs for, or improvements or better access to, pharmaceutical services.
- Commenting on drafts of the pharmaceutical needs assessment.
- Where the consultation version of the pharmaceutical needs assessment identifies the need for a service, or improvements or better access to an existing service, highlight this to affected contractors. They have a window of opportunity to meet that need or secure the improvements or better access themselves by signing up to provide the service, or amending opening hours. If a contractor provides an identified service then it is likely that the final version of the pharmaceutical needs assessment will be amended accordingly.

Whilst the local pharmaceutical committee is a member of the steering group, ultimately it will be for the health and wellbeing board to determine the final version of the pharmaceutical needs assessment. This may mean that needs, improvements or better access may be included that the local pharmaceutical committee does not agree with. It is for this reason that it is important that the local pharmaceutical committee is an active member of the steering group, formally responds to the consultation, and encourages contractors to do the same.

Local pharmaceutical committees will have a key role in advising the steering group of how things are "on the ground" as contractors deal with the implications of the:

- COVID-19 pandemic,

[8] It should be noted that whilst the regulations currently state that the next pharmaceutical needs assessments are to be published by 1 April 2022, the Department of Health and Social Care has confirmed that this date will be amended to 1 October 2022 due to the Covid-19 pandemic.

- previous funding cuts,
- the five-year flat cash funding deal (2019-2024)[9] agreed between the Department of Health and Social Care, NHS England and NHS Improvement, and PSNC, and
- the statement in the five-year deal that there are "… more pharmacies in some places than may be necessary to ensure good access to NHS pharmaceutical services.".

They will be able to provide context on whether, for example, the closure of a pharmacy does **not** create a gap in service provision.

Not all members of the steering group will not be aware of the reduction in funding in 2015/16 and the direction of travel set out in the five-year deal.

3 Overview of process

The regulations are silent as to the process to follow when drafting a pharmaceutical needs assessment, other than the need to consult with a list of certain persons at least once on a draft of the document for at least sixty days. There are, however, eight key stages in the process.

3.1 Governance

The health and wellbeing board will need to consider how it will discharge its pharmaceutical needs assessment duties and it is strongly recommended that a steering group is set up with representation from the key stakeholders (see section 4 – engagement). The health and wellbeing board may wish to consider delegating responsibility for signing off the consultation but must retain responsibility (sign off) for the final pharmaceutical needs assessment.

Where responsibility is delegated to the steering group it is recommended that the group reports back to the board at an agreed frequency.

A timeline should be developed for the group so that it can ensure that the key milestones are met and the health and wellbeing board can publish its next pharmaceutical needs assessment by the regulatory date.

3.2 Engagement

Whilst the steering group will have representation from the key stakeholders it will also be necessary to engage with individual contractors within the health and wellbeing board's area and the public. More information on this can be found in section 4 – engagement).

3.3 Population and health needs

The joint strategic health needs assessment documents are likely to be the main sources of demographic and health needs data, but other needs assessments and documents produced by the public health team may also be of use. The planning department will be able to advise of housing developments and regeneration projects that are currently in progress or will start during the lifetime of the pharmaceutical needs assessment. The highways department will be able to advise of any infrastructure projects that will or may change how people access services.

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[9] Community Pharmacy Contractual Framework: 2019 to 2024
https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024

3.4 Current provision of pharmaceutical services

More information on how to source this information can be found in section 5 – information.

3.5 Drafting

Whether the current pharmaceutical needs assessment is used as the basis for the next version or the steering group starts from scratch will depend on whether or not the current document meets the requirements of the regulations. As this will be the third document that the health and wellbeing board has written it may well be happy to use the existing document structure and update to reflect changes that have taken place since it was published, and the changes that are expected to occur within the three-year lifetime of the new document.

It is likely that an initial draft of the document will be presented to the steering group once all the data has been collated and engagement exercises have taken place, and then a discussion can take place as to whether there are any gaps in the provision of pharmaceutical services either now or in the future.

Once the gaps have been articulated as needs, improvements or better access the document will need to be signed off before the consultation starts.

3.6 Consultation

The health and wellbeing board must consult with the specified list of persons for at least sixty days. It may choose to run the consultation for a longer period of time, for example if it is due to run over the Christmas-New Year period but must not have a shorter period of consultation.

A report on the consultation is to be included in the final version of the pharmaceutical needs assessment which includes the health and wellbeing board's response to any points raised. Steering groups will need to bear in mind that just because one person has raised an issue that it doesn't necessarily require a change to be made to the pharmaceutical needs assessment. However, consideration should always be given to whether something has been missed or an error has been made.

3.7 Review and production of final version

Following the consultation the responses are reviewed and a decision made as to whether any parts of the pharmaceutical needs assessment need to be amended. A report on the consultation along the lines of "we asked, you said, and we've done" is to be produced and will sets out the changes that have been made to the document as a result of the consultation, if any. As a minimum, it is likely that there will have been some changes either to the provision of pharmaceutical services or to contractors between drafting and the end of the consultation and these could include:

- Changes of ownership,
- New premises opening,
- Relocation of existing premises, and
- Changes of opening hours.

A list of the changes that have been made between the consultation and final version of the document should be included in the document for transparency, and it is suggested that it could be added to the consultation report.

If any changes have occurred which materially change the document's conclusions, for example responses lead to the conclusion that there is a need for a new pharmacy in a particular area, then it may be necessary to have a second period of consultation specifically in relation to those changes. For this reason it is suggested that the consultation is timed to allow for a second period of consultation just in case. However, if stakeholder engagement is robust from the start, no surprises should come out of the consultation.

3.8 Sign off and publication

Once the final version of the document is available it will need to be signed off and then published. The health and wellbeing board is under a duty to ensure that NHS England and NHS Improvement has access to its pharmaceutical needs assessment, so it is recommended that once the document is published on the council's website the weblink is sent to the steering group so that duty is discharged and all stakeholders are able to access it.

3.9 Applications which are submitted whilst the pharmaceutical needs assessment is being drafted

Once the pharmaceutical needs assessment is out to consultation it may stimulate the submission of applications, for example to meet a need identified in the current pharmaceutical needs assessment that is not included in the next version, or to meet a need that is identified in the next version. Local pharmaceutical committees should be aware that the default position in the regulations is that NHS England and NHS Improvement is required to determine an application using the pharmaceutical needs assessment that is published on the day the application is to be determined. In this context, a pharmaceutical needs assessment is not "published" until it has been consulted upon for the required 60 days, the consultation report has been added to it, and the complete document has been signed off.

The scenarios in the following boxes illustrate how applications are dealt with in the transitional period from one pharmaceutical needs assessment to another.

Scenario 1 – application is submitted based on the contents of the next pharmaceutical needs assessment but is determined before it is published

The consultation on Anytown's new pharmaceutical needs assessment starts on Monday 7 February and ends on Friday 8 April 2022. It identifies the need for a new pharmacy in a housing development, offering a specified range of services, seven days a week. This need is not in the current, published, pharmaceutical needs assessment.

An application is submitted on Friday 15 April and is considered by the relevant NHS England and NHS Improvement pharmaceutical services regulations committee at its meeting on 11 August 2022. At that point in time the published pharmaceutical needs assessment is the one that was published in March 2018, as there has been a delay in publishing the new pharmaceutical needs assessment. The committee is therefore directed to determine the application against the 2018 pharmaceutical needs assessment and not the 2022 version. As the need that the applicant is offering to meet is not identified in the 2018 version it would be refused.

Scenario 2 – application is submitted during the 60-day consultation on the next pharmaceutical needs assessment and is determined after it is published

The consultation on Anytown's new pharmaceutical needs assessment starts on Monday 1 June and ends on Sunday 31 July 2022. It identifies the need for a new pharmacy in a

housing development, offering a specified range of services, seven days a week. This need is not in the current, published, pharmaceutical needs assessment.

An application is submitted on Monday 25 July 2022, during the 60-day consultation. It is notified to the interested parties on Monday 8 August 2022 with the 45-day notification period ending on 22 September 2022. The representations are circulated and final comments are due by Sunday 9 October 2022.

The new pharmaceutical needs assessment is published on 1 October 2022

The application is considered by the relevant NHS England and NHS Improvement pharmaceutical services regulations committee at its October 2022 meeting. The regulations direct the committee to determine the application against the 2022 pharmaceutical needs assessment, however the representations highlight the fact that the application was circulated when the 2018 pharmaceutical needs assessment was the published version and it did not identify the need that the applicant is offering.

NHS England and NHS Improvement's pharmacy manual states that where a new pharmaceutical needs assessment is published after the 45-day notification period but before the application is determined, the regional team will prepare a letter to be sent to the applicant and those persons who made representations asking for their views on the provisions within regulation 22(2) of the 2013 regulations, in particular whether the only way to determine the application justly is with regard to the 2018 pharmaceutical needs assessment.

The committee will take into account any representations received on this matter, and if it is satisfied that the application is to be determined against the 2022 version then a second 45-day notification period will commence for all interested parties.

In addition to the above, NHS Resolution is also directed to consider an appeal against the pharmaceutical needs assessment that is published on the date of the appeal hearing, unless it is of the opinion that the only way to justly determine the appeal is in relation to an earlier pharmaceutical needs assessment.

It is therefore important that local pharmaceutical committees respond when they are notified of an application in order that they have the opportunity to comment on any subsequent appeal.

4 Regulatory terms and definitions

In order to ensure that a pharmaceutical needs assessment, as a minimum, meets the requirements of the regulations it is important to understand the terms that are used. This chapter defines those that are most likely to be referred to in the drafting of a pharmaceutical needs assessment.

4.1 Pharmaceutical services

For the purposes of the pharmaceutical needs assessment, 'pharmaceutical services' is defined in regulation 3(2) of the 2013 regulations. In summary the term includes the provision of:

- Essential services that must be provided by pharmacies and dispensing appliance contractors that are included in a pharmaceutical list,
- Advanced services that pharmacies and dispensing appliance contractors may choose to provide,

- Enhanced services that NHS England and NHS Improvement (potentially integrated care boards in the future) may commission from pharmacies,
- Local pharmaceutical services, and
- The dispensing service provided by some GP practices.

The enhanced services that NHS England and NHS Improvement may commission are listed in The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 which can be found in Part VIC of the Drug Tariff[10]. Services that are commissioned from pharmacies by other commissioners, for example local authorities, are not enhanced services and do not fall within the definition of pharmaceutical services.

4.2 Controlled locality

A controlled locality is an area that has been determined by the NHS (as at October 2021 NHS England and NHS Improvement) or on appeal (currently by NHS Resolution) to be "rural in character".

Since 1 April 1983 there has been a regulatory requirement to publish maps of any areas that have been determined to be a controlled locality. However, before that date there was no such requirement and therefore maps may not be available for all of a health and wellbeing board's area.

The availability of controlled locality maps is variable across the country, as is their quality. Some will have been produced using mapping software and boundaries are easy to identify. Others may be maps that were produced by drawing lines on copies of Ordnance Survey maps, may be many years old and it is now difficult to identify the edge of a controlled locality around a town as it has expanded over the years, for example.

Whilst not directly an issue for the production of the pharmaceutical needs assessment, the availability and quality of controlled locality maps is of importance when applications are submitted, as NHS England and NHS Improvement will need to be able to clearly identify whether or not the premises are within a controlled locality so that the correct interested parties can be identified, and the relevant regulatory tests are considered.

Separate to pharmaceutical needs assessments, local pharmaceutical committees and local medical committees can ask NHS England and NHS Improvement to determine whether an area is, or areas are, still a controlled locality or part of one. Relevant factors should be considered before such an application is made.

The steering group may choose to include copies of the controlled locality maps in the pharmaceutical needs assessment but is not required to do so by the regulations. Careful consideration should be given as to whether or not they are included, and steering groups should be mindful that the only map within the pharmaceutical needs assessment that can be updated is the map that identifies the location of the premises at which pharmaceutical services are provided. There is therefore a risk that one or more controlled locality maps may be replaced or amended following a redetermination by NHS England and NHS Improvement but the previous version remains published in the pharmaceutical needs assessment.

4.3 Directed services

This is a collective term for the advanced and enhanced services that may be provided/commissioned which are identified in The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013.

4.4 Enhanced services

[10] The Drug Tariff, NHS Business Services Authority

The enhanced services that NHS England and NHS Improvement may commission from pharmacies are those listed in the Directions mentioned in section 4.3 above. Only those services that are commissioned by NHS England and NHS Improvement fall within this definition. Services that are commissioned from pharmacies by clinical commissioning groups or local authorities are not enhanced services and do not fall within the legal definition of pharmaceutical services.

However, if a clinical commissioning group or a local authority asked NHS England and NHS Improvement to commission a particular service on its behalf from pharmacies then, as long as the service is one of those listed in the Directions, then it becomes an enhanced service and so would be included in the pharmaceutical needs assessment.

4.5 Historic rights

Whilst not a term that appears in the regulations it is used to describe the arrangements that were in place before 1 April 1983 whereby a GP practice could dispense to eligible patients.

Before 1 April 1983 where it was determined by the NHS (or on appeal) that an area was "rural in character" a GP practice could dispense to its registered patients who lived in that area, as long as they also lived more than 1.6km from a pharmacy. There was no requirement for the practice to first apply to do so. This has become known as historic rights.

The term does not mean that a practice has historic rights to dispense to all of its area; simply those areas that it dispensed to before 1 April 1983.

4.6 Locally commissioned services

This term also doesn't appear in the regulations; however its use has been adopted to cover those services commissioned by commissioners other than NHS England and NHS Improvement and therefore fall outside the legal definition of pharmaceutical services. An example would be the public health services commissioned by local authorities from pharmacies.

4.7 Necessary services

These are the pharmaceutical services that are identified as services which are necessary to meet the need for pharmaceutical services. See chapter 6 for further information on this matter.

4.8 NHS services

NHS services are those services provided as part of the health service and include services that local authorities commission as part of public health services. They may include smoking cessation, emergency hormonal contraception and screening services. The term also includes services provided for, or arranged by, clinical commissioning groups[11], hospital trusts and NHS foundation trusts.

4.9 Other relevant services

These are pharmaceutical services that are identified as services which aren't necessary to meet the need for pharmaceutical services but have secured improvements or better access to them.

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[11] It should be borne in mind that clinical commissioning groups are likely to be replaced by integrated care boards with effect from 1 April 2022.

4.10 Outline consent

Since 1 April 1983, where a GP practice wishes to start dispensing to an area for the first time it has been required to apply for consent to do so. This is known as outline consent.

4.11 Premises approval

Premises approval was introduced into the regulations on 1 April 2005. Where a GP practice wishes to dispense to a new area it must first apply for outline consent for that area and also premises approval for the premises from which it wishes to dispense to the area.

Similarly, if a dispensing practice wishes to relocate to new premises it must apply to relocate the premises approval from its existing premises to its new premises. Or, if a practice wishes to dispense from additional premises it must apply for premises approval for those premises.

There are no standards for the premises and they are not required to be registered with any regulatory body. Rather, the regulations set out certain circumstances where premises approval must be refused, for example where they are within 1.6km of a pharmacy (other than a distance selling premises).

Shortly after the requirement was introduced, primary care trusts wrote to their dispensing practices and gave them premises approval for the premises at which they provided the dispensing service at that point in time.

4.12 Reserved locations

Reserved locations were introduced into the regulations with effect from 1 April 2005. Where an application to open new or additional pharmacy premises in a controlled locality (but not in connection with distance selling premises) is received, NHS England and NHS Improvement is required to determine whether the proposed premises are within a reserved location.

A count is undertaken when the application is received of the number of people who reside within 1.6km of the proposed premises and who are registered with a GP practice in England. If the total number of such people is less than 2,750 then it is a reserved location.

However, if NHS England and NHS Improvement is of the opinion that if pharmaceutical services were provided at the proposed premises, the use of those services would be similar to, or greater than, the use that would be expected if there were 2,750 or more people then it can determine that the proposed premises are not within a reserved location. Two appeal decisions on this matter may be useful background reading[12].

Reserved locations only take effect if the application is granted, and the pharmacy subsequently opens. Normally when a pharmacy opens in a controlled locality those people living within 1.6km of it can no longer be dispensed to by their GP practice. However, if a reserved location is determined then they remain as a dispensing patient and can choose to use either the dispensary or the pharmacy or both.

NHS England and NHS Improvement is required to publish a map of the reserved location and ensure the boundaries of it are clearly delineated. The steering group may choose to include such maps in the pharmaceutical needs assessment but is not required to do so by the regulations. Again caution should be

[12] Appeal SHA/18391 November 2016 and appeal SHA/18698 September 2017 NHS Resolution Primary Care Appeals

exercised as the applicant (or any subsequent owner of the pharmacy) can ask for the matter to be redetermined and it is therefore possible that within the lifetime of the pharmaceutical needs assessment the reserved location may cease to exist, however the map remains in the public domain.

4.13 Supplementary statements

A health and wellbeing board may publish a supplementary statement where it has identified changes to the availability of pharmaceutical services which are:

- Relevant to the granting of applications for inclusion in a pharmaceutical list, and
- The health and wellbeing board is satisfied that producing a new pharmaceutical needs assessment is a disproportionate response to the change or changes, or
- It is in the process of producing a new pharmaceutical needs assessment and is satisfied that the current one needs to be immediately modified in order to prevent significant detriment to the provision of pharmaceutical services.

Supplementary statements that are published in these circumstances are statements of fact, for example pharmacy A has closed. They are not assessments of need so a statement couldn't say that pharmacy A has closed and therefore there is a current need for a pharmacy in the same location. But the statement of fact/supplementary statement should only be published where it is relevant to the granting of applications. So, for example, if the closure of a pharmacy is not relevant to the granting of applications, because no gap in the provision of services is created by the closure, **no** supplementary statement should be published. The exception to this is consolidations.

Consolidation applications may only be granted where to do so would **not** create a gap that could be met by an application offering to meet a need or secure improvements or better access. Once a consolidation takes effect the health and wellbeing board is required to publish a supplementary statement explaining that, in its view, the removal of site 2 (the closing site) does **not** create a gap in the provision of pharmaceutical services. This is designed to discourage new applications that will not, or at least are unlikely, to be granted.

Once published supplementary statements become part of the pharmaceutical needs assessment and so are to be published alongside it.

Local pharmaceutical committees may find chapter 8 of the pharmaceutical needs assessment information pack[13] published by the Department of Health & Social Care on 14 October 2021 useful in relation to the issuing of supplementary statements and publication of subsequent pharmaceutical needs assessments.

5 Stakeholder engagement

The regulations require the health and wellbeing board to consult a list of specified persons on the contents of the pharmaceutical needs assessment and this must be done at least once. Those persons include:

- The local pharmaceutical committee,
- The local medical committee,
- Contractors included in the pharmaceutical list or lists for the area of the health and wellbeing board, and the dispensing doctor list,
- Any LPS contractor in the health and wellbeing board's area,

[13] Pharmaceutical needs assessments. Information pack for local authority health and wellbeing boards. Department of Health & Social Care October 2021

- Healthwatch and any other patient, consumer or community group in the health and wellbeing board's area which in the board's opinion has an interest in the provision of pharmaceutical services,
- Any NHS trust of NHS foundation trust in the health and wellbeing board's area,
- NHS England and NHS Improvement, and
- Any neighbouring health and wellbeing board.

However, it is strongly recommended, and has become good practice across England and Wales, to engage with stakeholders in other ways and in advance of the formal consultation.

5.1 Steering group

Forming a steering group with representation from the local representative committees, patients and the public, and NHS England and NHS Improvement must be a health and wellbeing board's first step. Including these stakeholders will ensure that those tasked with writing the document are supported by a range of people with a strong interest in the provision of pharmaceutical services and having a final document that is robust and well researched.

5.2 Contractor questionnaires

Whilst much of the information required to write a pharmaceutical needs assessment is in the public domain (see section 4) there will be some that can only be provided by the contractors and therefore contractor questionnaires should be undertaken. It is strongly recommended that the questionnaire be kept as short as possible and to only seek information that cannot be sourced from elsewhere.

Local pharmaceutical committees can help increase the completion rate by either promoting the questionnaire to their contractors and encouraging completion or hosting it themselves.

PSNC has produced two template pharmacy questionnaires[14] for this purpose.

One is more comprehensive and is designed to capture a wider range of information that will be of use to local pharmaceutical committees when discussing services that their pharmacies can or could provide for local commissioners, as well as update the information held on each pharmacy. It will also provide an evidence base for discussions with commissioners other than NHS England and NHS Improvement as to the opportunities they have to commission more services from pharmacies.

The second is a much shorter version which contains the minimum information that is required for the pharmaceutical needs assessments recognising that '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.[15]

Steering groups are likely to consider having similar questionnaires for any dispensing appliance contractors and dispensing doctors in the health and wellbeing board's area.

Some health and wellbeing boards have begun to include questions asking about contractors' capacity, for example asking whether, in light of growing demand for services, they:

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[14] PNA pharmacy questionnaire 2021, PSNC October 2021

[15] Department of Health & Social Care pharmaceutical needs assessments information pack for local authority health and wellbeing boards published October 2021, in particular Chapter 5 page 22

- Have capacity within their premises and staffing structure to manage such an increase,
- Don't have capacity but could make adjustments to do so, or
- Don't have capacity and are unable to make adjustments.

This allows the steering group to determine whether the existing estate has capacity to meet an increase in demand resulting things such as an ageing population, a growing population due to housing developments, an increased range of services being commissioned etc. This was considered a relevant factor in a determination of an appeal[16] following the refusal of an unforeseen benefits application for a pharmacy in a large regeneration project.

Should such questions be included, local pharmaceutical committees may wish to ensure their contractors understand the background to the question so that they don't leave themselves open to a successful unforeseen benefits application. However, it is likely many contractors can meet a demand where they have the confidence to invest in additional staffing and/or premises developments and there will be additional income, for example, through increased prescriptions and services from an increase in the population.

Unlike pharmacies, dispensing doctors' dispensaries do not have contracted opening hours. Therefore, it is recommended that the dispensing doctor questionnaire asks for the times when the dispensary is open.

5.3 Patient and the public questionnaire

As can be noted from the list of statutory consultees at the beginning of this chapter, individual members of the public do not have to be consulted on a draft of the pharmaceutical needs assessment. However, it would be difficult to draft a robust and well researched pharmaceutical needs assessment without seeking the views of the those using pharmaceutical services.

As with the contractor questionnaires it is recommended that only that information required for the pharmaceutical needs assessment is collected, unless it will be used for another purpose. Members of the public can be bombarded with surveys and may become frustrated if their views are sort on a matter but then not included in the output of the survey, or not taken into account.

It is suggested that patient and the public engagement questionnaire seeks views on the following.

- How they access pharmacies, dispensing practice premises and dispensing appliance contractor premises (although it should be noted that in relation to the latter, services are usually provided remotely), for example by car, on foot, by public transport, or remotely,
- How long it takes them to access those premises,
- Which day of the week they prefer to access services,
- Their preferred time of the day to access services,
- What influences their choice of pharmacy or dispensing appliance contractor premises (for example, close to home, close to their GP practice, close to work); and
- Whether they mostly use the same pharmacy, or different ones.

6 Information requirements (current services, identifying gaps and articulating needs)

Schedule 1 of the regulations sets out the minimum information that must be contained within the pharmaceutical needs assessment. It consists of a series of statements and an explanation of how the assessment was carried out.

[16] NHS Resolution Primary Care Appeals appeal SHA/18228 June 2016

6.1 Necessary services: current provision (paragraph 1, Schedule 1)

The steering group will need to decide which services are to be defined as 'necessary services' and then include a statement of those services ie what they are. These services may be provided within the health and wellbeing board's area or outside of it.

It is for the steering group to decide how to determine which of all the pharmaceutical services are 'necessary'. It is suggested that this is done by service type. For example, all of the essential services could be defined as 'necessary services' because, for example, if they weren't provided then members of the public would have difficulty in accessing their prescribed medication. Enhanced services, for example, that are also provided by other providers may not be considered to be 'necessary services'.

Once the necessary services are defined the pharmaceutical needs assessment will then need to identify where they are provided.

Identifying out of area providers – dispensing service

In order to identify out of area providers, it is recommended that a list is collated of all the services within the health board's area that generate prescriptions. This list will include the GP practices and other services such as:

- the GP out of hours service,
- community nursing services,
- GP extended hours access hubs,
- urgent care centres, and
- walk-in centres.

The clinical commissioning group will be able to provide this information to the steering group or alternatively it can be sourced from NHS Digital's organisation data service portal[17].

Once the list of prescribing services has been collated information on where all the prescriptions are dispensed can be sourced from the NHS Business Services Authority website[18]. Each month, a report (the "Practice prescribing dispensing data") is published which shows where all the prescriptions written in England are dispensed. By using the list of organisation data service or ODS codes for each practice and prescribing service it is possible to identify where all the prescriptions written in the health and wellbeing board's area are dispensed.

NHS England and NHS Improvement can provide a copy of the consolidated pharmaceutical list and this will then allow the pharmaceutical needs assessment to identify the number of items prescribed and:

- the number and percentage dispensed within the health and wellbeing board's area by pharmacy, dispensing appliance contractor (if any) and dispensing practice (if any), as well as the number and percentage of items personally administered by non-dispensing practices, and

[17] Organisation Data Service portal, NHS Digital
[18] Dispensing contractors' data, NHS Business Services Authority's Information Services

- the number and percentage dispensed outside of the health and wellbeing board's area and by whom.

If any of the advanced services are deemed to be 'necessary services' then the NHS Business Services Authority website can also provide information on their provision – the pharmacy and appliance contractor dispensing data reports which are produced monthly[19]. Details of the number of flu vaccinations provided are available via NHS Business Services Authority's public insight portal 'Catalyst'[20]. It is not possible to identify whether contractors who are outside of the health and wellbeing board's area will have provided any advanced services, but if prescriptions are being dispensed by out of area contractors, then it can be assumed that they may also have provided advanced services.

It should be noted that, depending on when the pharmaceutical needs assessment is being drafted there may be some advanced services that have only recently been launched and therefore activity data may be low or non-existent. In that case, NHS England and NHS Improvement will be able to provide the steering group with a list of those contractors that have signed up to provide the service or services.

If any enhanced services are deemed to be necessary services then NHS England and NHS Improvement will be able to provide information on them and who is commissioned to provide them.

6.2 Necessary services: gaps in provision (paragraph 2, schedule 1)

The regulations require the inclusion of a statement of the pharmaceutical services that the health and wellbeing board has identified, if any, that need to be provided in order to meet a current or future need for either a particular pharmaceutical service or a range of services. If a future need is identified, then the pharmaceutical needs assessment will need to specify the future circumstances that will trigger that need.

There are three levels at which gaps in the provision of necessary services can be identified.

- Geographical spread of premises – are the premises where they need to be?
- Opening hours – are they open when they need to be?
- Service provision – are services provided where they are needed?

The Covid-19 pandemic may have changed how a proportion of the population accesses pharmaceutical services, in particular the dispensing service. Analysis of where prescriptions are dispensed will reveal if there has been a substantial change in behaviour.

6.2.1 Geographical spread of premises

The starting point for any assessment is identifying whether or not the premises are currently located where they need to be. The location of each contractor's premises can be mapped using tools such as Public Health England's Strategic Health Asset Planning and Evaluation (or SHAPE[21]). This is a web enabled, evidence-based application which links national data sets, clinical analysis, public health, primary care and demographic data with information on the location of premises. It includes a fully integrated geographical information system mapping tool and supports travel time analysis.

[19] Dispensing contractors' data, NHS Business Services Authority's Information Services
[20] Advanced service flu report, NHS Business Services Authority's Information Services
[21] Public Health England's Strategic Health Asset Planning and Evaluation

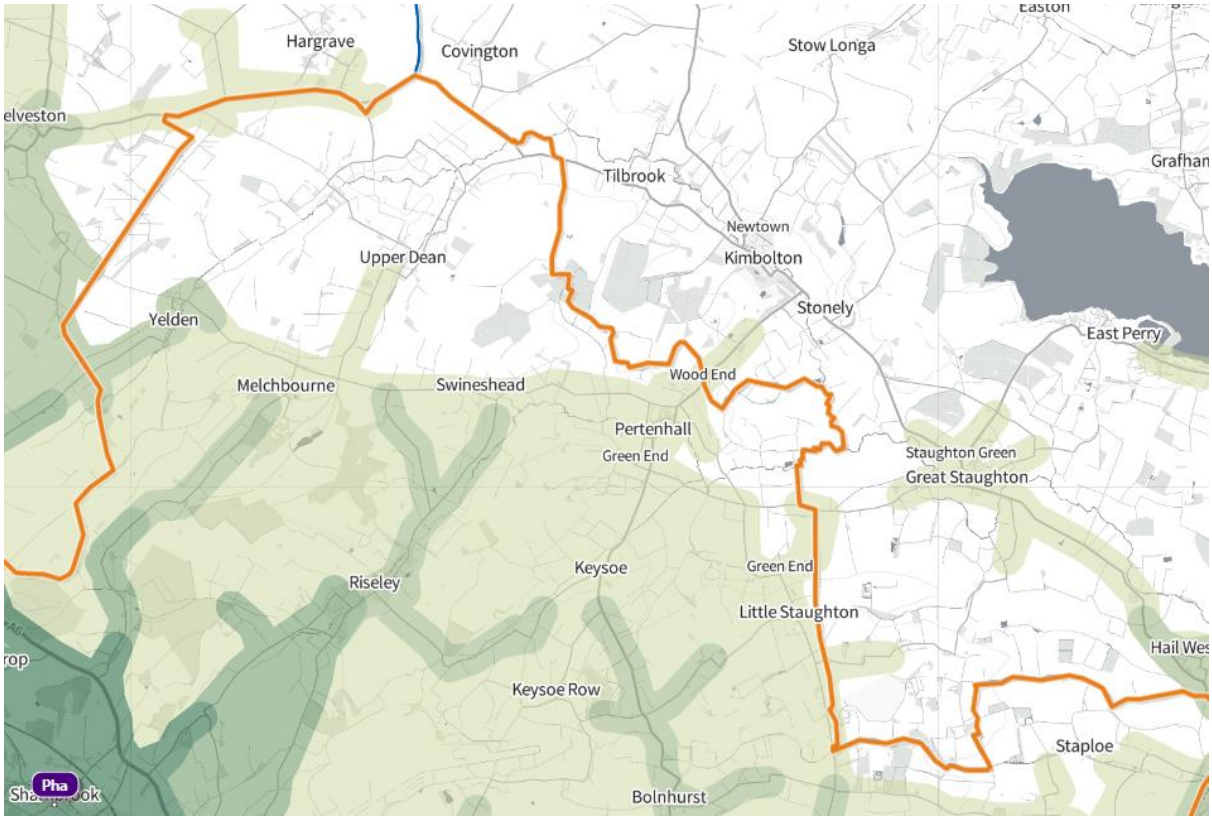
By mapping the travel times to the existing premises it is possible to identify whether there are any parts of the health and wellbeing board's area that do not fall within a certain travel time. It will then be necessary to see if there is a resident population or not in that area or those areas – if there isn't then this is not a gap. If there is, then this may be a gap and consideration will need to be given as to whether or not to identify this as a current need. It should be borne in mind that if the population is small then a pharmacy may not be viable, particularly if the area is in a controlled locality and a reserved location may be determined in connection with an application to open a pharmacy.

Travel times can be mapped for travelling on foot, by private transport and by public transport. Setting a reasonable travel time should be based upon the responses to the public engagement questionnaire.

Don't forget that those living on the edge of the health and wellbeing board's area may choose to access pharmaceutical services over the border in a neighbouring health and wellbeing board's area. The pharmaceutical needs assessment should first map travel times to those premises within the area and before identifying whether or not there are any geographical gaps it will then be necessary to map access to those premises just over the border.

An example of this is shown below. Figure 1 shows travel times to pharmacies in North Bedfordshire, with the darkest green being five minutes by car and the lightest green being 20 minutes by car. The map suggests that there is an area around Upper Dean that is not within 20 minutes of a pharmacy when travelling by car.

Figure 1 – access to pharmacies in North Bedfordshire[22]



However, when account is taken of the pharmacies over the border in Cambridgeshire the picture changes and this area is now within ten to 15 minutes of a pharmacy when travelling by car (figure 2).

22 Public Health England's Strategic Health Asset Planning and Evaluation

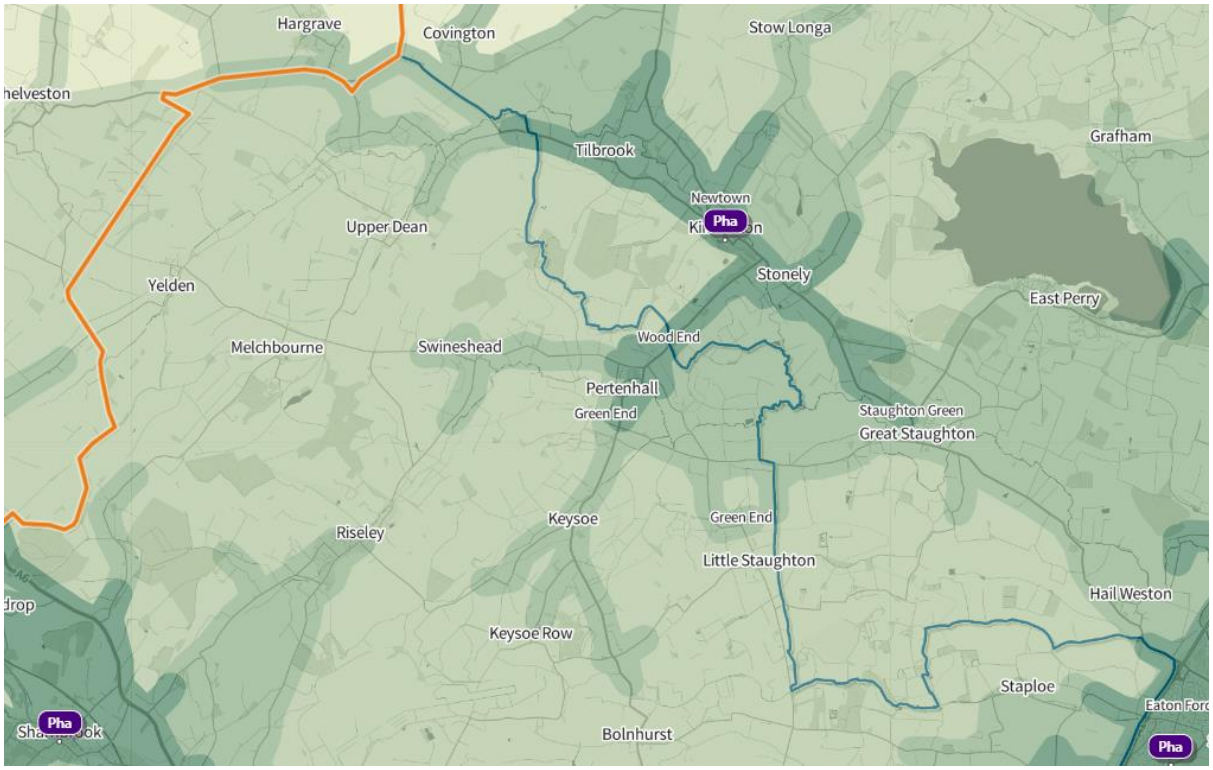


Figure 2 - access to pharmacies for North Bedfordshire residents[23]

Once the steering group has identified any current gaps in the location of premises it will then need to clearly articulate those as a current need. To do this the pharmaceutical needs assessment will need to state:

- What the required service is or services are,
- Where it is to be provided,
- When is required, and
- If it is a future need, the future circumstances when it will arise.

The regulations require a clear statement to be included so words such as 'may', 'might' and 'could' are to be avoided so as to avoid any confusion when it comes to determining applications to meet the need. An example of how to articulate a current need is shown in the box below.

Articulating a current need

Scenario - a housing development is being built on the edge of a town and the steering group has identified that there is a current need for a pharmacy in it.

Simply stating that there is a need for a pharmacy in the development is not sufficient to meet the requirements of the regulations. Instead the pharmaceutical needs assessment must identify the pharmaceutical services that are required.

[23] Public Health England's Strategic Health Asset Planning and Evaluation

"The health and wellbeing board has identified that there is a current need for the provision of the following pharmaceutical services to be provided at premises within the footprint of the New Village development:

- All essential services,
- The community pharmacist consultation service, and
- The new medicines service.

The current need is for these services to be provided Monday to Saturday, between 9am and 7pm Monday to Friday and 9am to 1pm on Saturdays, as a minimum."

Any applicant therefore looking to submit a current needs application can clearly understand what is required and NHS England and NHS Improvement will be able to clearly identify whether or not an application is offering to meet the need in full or in part and so can grant or refuse it accordingly.

Having identified whether there are any current gaps in the location of premises the steering group will then need to identify any that will arise during the three-year lifetime of the document. The planning department, local development plan and annual monitoring reports will all be useful in identifying where housing is due to be built, and the predicted number of houses that will be built during the three years. The planning department will also be able to advise on the average occupancy rate that is used to calculate the likely number of people moving into a development.

When considering whether or not there is a future need, or future needs, for new premises within housing developments, consideration will need to be given to the following:

- Can the existing contractors manage an increase in demand? The responses to the contractor questionnaire will be helpful here.
- Can those moving into the new housing access current pharmaceutical services provision?

It is unlikely that information on the needs of residents who have moved in or may move into the development will be available, or the level of car ownership, however it is likely that at some stage there will be a small group of people who do not have access to private transport for part of the day, there is no or limited public transport and it is too far to walk to the nearest pharmacy or pharmacies. Consideration will therefore need to be given as to how they could access pharmaceutical services, bearing in mind that they will have access to over 300 distance selling premises (as at August 2021) who must deliver to them, and that as of 1 January 2021 all pharmacies are required to facilitate remote access to the pharmaceutical services they provide where patients wish to access them in that way and where it is reasonable to facilitate such access.

If the steering group identifies that there will be a future need for a pharmacy providing a range of services it needs to both articulate what the need is and the circumstances when it will arise.

Articulating a future need for premises in a housing development

Scenario - The local development plan identifies that a brownfield site is to be regenerated and will lead to the creation of:

- 4,000 houses,
- A range of sports facilities and an abundance of open parkland, wildlife habitats and new lakes,
- Primary schools, nurseries and after school activities,
- A 100 acre business park with planning for office, manufacturing and warehousing uses creating approximately 2,000 out of circa 6,000 jobs,
- A local centre including a public house, retail, leisure and community facilities, and
- An integrated transport strategy that includes new road links, cycle routes, footpaths and bus services.

It is anticipated that up to half of the houses will have been built within the lifetime of the pharmaceutical needs assessment.

The steering group notes that the nearest pharmacy (1.6 kms by road) did not reply to the contractor questionnaire and it therefore does not know whether or not the contractor has capacity to manage the initial increase in demand from the development.

It is determined that there will be a need for a pharmacy in the development in the future.

"The health and wellbeing board has identified that there will be a future need on occupation of the thousandth house for the provision of the following pharmaceutical services to be provided at premises within the footprint of the local centre of New town development:

- All essential services,
- The community pharmacist consultation service, and
- The new medicines service.

The future need is for these services to be provided Monday to Saturday, between 9am and 7pm Monday to Friday and 9am to 1pm on Saturdays, as a minimum."

By setting the trigger for the future need as the occupation of the thousandth house rather than a specific date means that if the development speeds up or slows down the pharmaceutical needs assessment is still responsive to the anticipated demand for pharmaceutical services.

Information on any new premises that are to be built and from which NHS services will be provided will also need to be sourced from the clinical commissioning group. Consideration will need to be given as to whether known relocation of GP practices, or mergers of GP practices, will change the pattern of demand for pharmaceutical services or change how people will access such services.

6.2.2 Opening hours

Having established whether the premises are in the right place and identified needs where they are not, consideration will then be given as to whether or not they are open when they need to be. NHS England and NHS Improvement will be able to provide the steering group with the core and opening hours for each of the pharmacy and dispensing appliance contractor premises, and

Opening hours of themselves are not pharmaceutical services. Therefore, a pharmaceutical needs assessment shouldn't identify the need for opening hours at certain times. Instead, it should identify the necessary services that are required at specified times.

It should also identify where the need is for. Statements such as:

"In all localities there is a current need for extended opening hours before 9am on weekday mornings, after 7pm on weekday and Saturday evenings and on Sundays as this would be beneficial to the working population"

should be avoided as it is not clear exactly where the need is. Localities often cover quite a large area, and an application may be received in one part of a locality but it's not accessible for everyone living in the locality. Also, what would happen if two applications were received on opposite sides of the road which happened to be the boundary of the two localities. Potentially, they may both be granted, but is that what was really needed?

Therefore, if the steering group is of the opinion that services need to be provided in a certain geographical area in order to meet the needs of the population at a specified time, that should be specified.

Notable with regard to opening hours is that GP extended hours (provided either via individual practices or hubs) may vary from year to year subject to national negotiations. It will therefore be difficult to plan pharmacy services at a specified time and location in relation to these, during the lifetime of the pharmaceutical needs assessment.

6.2.3 Service provision

Having established whether or not the premises are in the right location and are open at times that meet the needs of the population the final stage is to identify whether or not there are any gaps in the provision of necessary services other than essential services (which will have been identified when looking at premises and times).

Mapping current providers of each of the advanced and enhanced services which have been defined as necessary services will help identify geographical gaps in provision. However, as there may be other providers of these services (see section 5.5) they will also need to be included in the mapping of provision so as not to inadvertently identify gaps that do not exist.

As before, if a gap in service provision is identified the need must be clearly stated and include:

- What the service is,
- Where it is required to be provided, and
- Any specific times at which, or days on which, it is to be provided.

6.3 Other relevant services: current provision (paragraph 3, Schedule 1)

Having dealt with those services that are deemed to be necessary service, the pharmaceutical needs assessment must then include a statement of those pharmaceutical services that are deemed to be "other relevant services". In summary these are those pharmaceutical services which aren't necessary to meet a need or needs, but which have secured improvements or better access to pharmaceutical services. They could be services that are provided within the health and wellbeing board's area or outside of it.

Section 5.1 provides links to websites where information on these services can be found. NHS England and NHS Improvement will be able to provide information on what enhanced services it commissions and who provides them.

6.4 Improvements or better access: gaps in provision (paragraph 4, Schedule 1)

Once the provision of "other relevant services" has been identified and mapped the steering group will need to identify gaps in provision. The guidance in section 5.2 above is equally relevant to this step and NHS Resolution has also issued guidance[24] on how to articulate improvements or better access which will also be of use when identifying needs.

Key points of NHS Resolution's guidance in identifying improvements or better access

Two step test

- Need to identify the pharmaceutical services that are not provided and also that the health and wellbeing board is satisfied that if they were provided they would secure improvements or better access.
- Just saying that there isn't a pharmacy open on a Sunday in a locality isn't enough. Need to go a step further and say that the provision of essential services at a specified location within a locality would secure improvements or better access to pharmaceutical services pursuant to paragraph 4(a) of Schedule 1 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

Wording – "potential improvements"

- Suggests a lack of certainty on the part of the health and wellbeing board as to whether the pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.

Wording – "potential gaps"

- Again suggests uncertainty.
- The regulations don't require the identification of gaps. They require statements as to the improvements or better access to pharmaceutical services that are required.

Wording – "small areas of a locality"

- This wording leaves the decision-maker having to try to decide whether where the applicant wishes to open will secure the identified improvements or better access that the health and wellbeing board has identified. It would be much better for the pharmaceutical needs assessment to identify the required location so that it is clear to the decision-maker.

Wording – "improvements could be made"

- "Could" can have different meanings in different contexts. Much better to use words such as "will", "would", "is" or "are".

"No need for a new pharmacy/contract"

- NHS Resolution has previously determined that this type of statement does not automatically mean the decision-maker has to refuse an application.

[24] Primary Care Appeals – Regulation 17 [improvements/better access] guidance note, NHS Resolution, February 2020

- The regulations do not require the health and wellbeing board to specify how any identified improvements or better access should be secured.
- If a pharmaceutical needs assessment sets out improvements or better access and the existing contractors and NHS England and NHS Improvement have done nothing to secure them or that, then the only way they can be secured is via the grant of a new application.

6.5 Other NHS services (paragraph 5, schedule 1)

As mentioned in section 5.2.2 above, there will be other providers of services that affect the need for pharmaceutical services, and a statement of these is to be included in the pharmaceutical needs assessment. Such services may be provided or arranged by:

- a local authority (i.e. the public health services that it commissions),
- NHS England and NHS Improvement,
- a clinical commissioning group,
- an NHS trust, or
- an NHS foundation trust.

Such services may either increase the need for pharmaceutical services or reduce them. Examples of services which increase the need for pharmaceutical services, in particular the dispensing and related services, include:

- provision of primary medical services by GP practices,
- GP out of hours services,
- GP extended access hubs,
- hospital services,
- drug and alcohol services,
- community nursing services,
- any service commissioned by a clinical commissioning group within the primary care setting which issues prescriptions,
- end of life services, and
- urgent treatment centres.

The work described in section 5.1 will allow the steering group to identify all the services with the health and wellbeing board's area which issue prescriptions.

Examples of services which reduce the need for pharmaceutical services include:

- hospital pharmacy departments – reduce the demand for the dispensing and related services,
- personal administration of items by GP practices - reduce the demand for the dispensing and related services,
- public health services commissioned by the local authority - remove the need for them to be commissioned as enhanced services by NHS England and NHS Improvement from pharmacies,
- prison pharmacy services – in general prescriptions written in prisons are not dispensed as part of pharmaceutical services, and are instead dispensed under a contract held by the prison,

- provision of services by GP practices which if they were commissioned from a pharmacy would fall within the definition of enhanced services e.g. stop smoking services and emergency hormonal contraception.

The provision of these services and the locations at which they are provided are to be included when identifying the current provision of pharmaceutical services with a view to identifying needs, improvements or better access.

6.6 How the assessment was carried out (paragraph 6, schedule 1)

6.6.1 Localities

The steering group will need to decide how to divide up the health and wellbeing board's area into localities in order to identify needs, improvements or better access at a lower level. Within the pharmaceutical needs assessment it is required to set out the methodology for deciding on the localities.

There is no standard way of identifying localities as it will depend on the geography of the health and wellbeing board's area. It is suggested that the availability of reliable data should inform how the area is divided up – there is little point in determining the localities and then discovering that health and demographic data is not available at that level.

6.6.2 Needs of the different localities

The pharmaceutical needs assessment needs to set out how it has taken into account the different needs of the different localities. It is therefore suggested that each locality has its own chapter which contains the relevant information for that area (be that demographic, health needs or service provision) so that needs and improvements or better access can be identified at locality level.

6.6.3 Needs of people who share a protected characteristic

An explanation of how the pharmaceutical needs assessment has taken account of the different needs of people who share a protected characteristic is also to be included. As of August 2021, the protected characteristics defined in the Equality Act 2010 are:

- age,
- disability,
- gender reassignment,
- marriage and civil partnership,
- pregnancy and maternity,
- race,
- religion or belief,
- sex, and
- sexual orientation.

It is recommended that the pharmaceutical needs assessment contains a chapter which identifies the different patient groups within the health and wellbeing board's area, not just those that share a protected characteristic, and their health needs. This may include:

- students,
- offenders and ex-offenders,
- homeless and rough sleepers,

- traveller and gypsy communities,
- refugees and asylum seekers,
- military veterans,
- visitors and tourists (both day-trippers and those staying for longer), and
- infrastructure projects which will draw in a workforce for a fixed period of time e.g. construction of the High Speed 2 rail-link or a nuclear power station.

Whilst the need for pharmaceutical services of this groups may be similar to those of the rest of the population it is recommended that they are identified so that they can be taken into account in the overall assessment of need.

6.6.4 Consultation report

Once the 60-day consultation has taken place a report on it will need to be included in the pharmaceutical needs assessment. It should take the format of "we asked, you said, and this is our response".

The steering group will need to consider all responses received as a result of the consultation and decide whether any changes to the document are required. The rationale for making, or not making, a change is to be set out in the consultation report.

6.7 Map of provision (paragraph 7, schedule 1)

The only map that must be included within the pharmaceutical needs assessment is one that identifies the premises at which pharmaceutical services are provided in the health and wellbeing board's area. This will include pharmacy, dispensing appliance contractor and dispensing practices' premises.

There will be considerable benefit in including other maps within the pharmaceutical needs assessment, not least because one map may not be able to clearly identify all the premises as individual sites due to the need to balance the scale of the map and being able to include in on a page.

Other maps that may be useful to include are those showing:

- travel times to premises,
- locations of providers of specific services, and
- travel times to premises open at the weekend or in the evening.

Maps can be very useful when identifying gaps in the current provision of services and can be a way of representing provision in an easy to understand way.

7 Top five things for local pharmaceutical committees to consider

1. Approach the public health team in your local authority, or authorities, to find out what the plans are for their next pharmaceutical needs assessment. Confirm that you are willing to participate in the steering group (or equivalent – some may call it a project group).
2. Remind contractors that health and well-being boards will be starting the process of writing their next pharmaceutical needs assessment in the Autumn and are likely to be requesting information. It is in their best interests to participate in the process and provide information when requested to do so.
3. Contact multiple contractors to see if they would prefer the contractor questionnaire to be completed at branch or head office level. Ask the regional managers to raise awareness of the questionnaire with their branches.

4. NHS England and NHS Improvement may not be able to attend steering group meetings – you may therefore be the only person with local knowledge of what services are provided and where.
5. It is likely that the starting point for the next pharmaceutical needs assessment will be the current version. Have a read through this and any supplementary statements so that you can highlight areas of concern and any changes at a steering group meeting.