



Department
of Health

Pharmaceutical needs assessments

Information Pack for local authority Health and
Wellbeing Boards

May 2013

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Pharmaceutical Needs Assessment

Information Pack for local authority Health and
Wellbeing Boards

**Prepared by Medicines, Pharmacy and Industry – Pharmacy Team with the assistance of
the Local Government Association and members of the National Learning Network for
HWBs**

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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 duty with regard to pharmaceutical needs assessments (PNAs)

Summary

- The Health and Social Care Act 2012 transfers responsibility for the developing and updating of PNAs to health and wellbeing boards (HWBs). Under the Act, the Department of Health has powers to make Regulations.
- The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 set out the legislative basis for developing and updating PNAs and can be found at: <http://www.dh.gov.uk/health/2013/02/pharmaceutical-services-regulations/>.
- This information pack is intended to support local authority HWBs in a practical way in understanding and implementing these requirements. The pack is set out as follows:
 - chapter 1 gives an introduction and legislative background;
 - chapter 2 outlines what the term “pharmaceutical services” includes in relation to PNAs;
 - chapter 3 outlines the minimum information that must be in PNAs;
 - chapter 4 expands on what the legislation says about the publication and updating of PNAs;
 - chapter 5 explains the consultation requirements; and
 - chapter 6 outlines matters to consider when making assessments.
- There are two appendices:
 - appendix 1 contains a glossary of terms and phrases used in regulation 2 of the 2013 Regulations; and
 - appendix 2 sets out some frequently asked questions and answers.

Chapter 1 – introduction and legislative background

Introduction

1. If a person (a pharmacist, a dispenser of appliances, or in some circumstances and normally in rural areas, GPs) wants to provide NHS pharmaceutical services, they are required to apply to the NHS to be included on a pharmaceutical list. Pharmaceutical lists are compiled and held by the NHS Commissioning Board, now known as NHS England. This is commonly known as the NHS “market entry” system.
2. Under the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations (“the 2013 Regulations”), a person who wishes to provide NHS pharmaceutical services must generally apply to NHS England to be included on a relevant list by proving they are able to meet a pharmaceutical need as set out in the relevant PNA. There are exceptions to this, such as applications for needs not foreseen in the PNA or to provide pharmaceutical services on a distance-selling (internet or mail order only) basis. The first PNAs were published by NHS primary care trusts (PCTs) and were required to be published by 1 February 2011.
3. From April 2013, Health and Well-being Boards (HWBs) will be developing PNAs for the first time. We therefore have limited examples of practice involving HWBs. However, we have included some examples of the ways in which PCTs developed their first PNAs. The examples are illustrative and provide HWBs with an indication of how they may wish to approach their work.

Legislative background

4. The Health and Social Care Act 2012 established HWBs. The Act also transferred responsibility to develop and update PNAs from PCTs to HWBs. Responsibility for using PNAs as the basis for determining market entry to a pharmaceutical list transferred from PCTs to NHS England from 1 April 2013.
5. The NHS Act (the “2006” Act), amended by the Health and Social Care Act 2012, sets out the requirements for HWBs to develop and update PNAs and gives the Department of Health (DH) powers to make Regulations.

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- (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.

Wider context

6. 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 HWBs in relation to Joint Strategic Health Assessments (JSNAs). The aim of JSNAs 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.

7. The preparation and consultation on the PNA should take account of the JSNA and other relevant strategies, such as children and young people’s plan, the local housing plan and the crime and disorder strategy in order to prevent duplication of work and multiple consultations with health groups, patients and the public. The development of PNAs is a separate duty to that of developing JSNAs as PNAs will inform commissioning decisions by local authorities (public health services from community pharmacies) and by NHS England and clinical commissioning groups (CCGs). HWBs may therefore wish to note that PNAs, as a separate statutory requirement, cannot be subsumed as part of these other documents but can be annexed to them.

Chapter 2: Pharmaceutical needs assessments

What the legislation says

1. Regulations 3-9 and Schedule 1 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 set out the requirements for PNAs.

Pharmaceutical services

2. Section 126 of the 2006 Act places an obligation on NHS England to put arrangements in place so that drugs, medicines and listed appliances ordered via NHS prescriptions can be supplied to persons. This section also makes provision for the types of healthcare professional who are authorised to order drugs, medicines and listed appliances on an NHS prescription.
3. “Pharmaceutical services” in relation to PNAs include:
 - “*essential services*” which every community pharmacy providing NHS pharmaceutical services must provide and is set out in their terms of service¹ – the dispensing of medicines, promotion of healthy lifestyles and support for self-care;
 - “*advanced services*” - services community pharmacy contractors and dispensing appliance contractors can provide subject to accreditation as necessary – these are Medicines Use Reviews and the New Medicines Service for community pharmacists and Appliance Use Reviews and the Stoma Customisation Service for dispensing appliance contractors; and
 - *locally commissioned services* (known as enhanced services) commissioned by NHS England.
4. The following are included in a pharmaceutical list. They are:
 - *pharmacy contractors* (healthcare professionals working for themselves or as employees who practice in pharmacy, the field of health sciences focusing on safe and effective medicines use); and
 - *dispensing appliance contractors* (appliance suppliers are a specific sub-set of NHS pharmaceutical contractors who supply, on prescription, appliances such as stoma and incontinence aids, dressings, bandages etc). They cannot supply medicines.

¹ The precise contractual requirements for providing NHS pharmaceutical services are set out in Schedules 4-6 of the Regulations.

5. In addition, there are two other types of pharmaceutical contractor - *dispensing doctors*, who are medical practitioners authorised to provide drugs and appliances in designated rural areas known as “controlled localities” (see Appendix 1) and *local pharmaceutical services (LPS) contractors* who provide a level of pharmaceutical services in some HWB areas.
6. A Local Pharmaceutical Service (LPS) contract allows NHS England to commission community pharmaceutical services tailored to specific local requirements. It provides flexibility to include within a single 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. All LPS contracts must, however, include an element of dispensing.
7. The definition of “pharmaceutical services” in relation to PNAs is set out in the following table:

Regulation	Explanation
<p>Regulation 3(2) – <i>the pharmaceutical services to which each pharmaceutical needs assessment must relate are all the pharmaceutical services that may be provided under arrangements made by the NHS CB for:</i></p> <p><i>(a) the provision of pharmaceutical services (including directed services) by a person on a pharmaceutical list.</i></p>	<p>There are three types of pharmaceutical service provided by pharmacy and dispensing appliance contractors as outlined in paragraph (3) above. Directed services are those services set out in Secretary of State Directions to NHS England, for example, medicines use reviews and NHS England commissioned enhanced pharmaceutical services, such as services to care homes, language access and patient group directions.</p>
<p><i>(b) the provision of local pharmaceutical services under an LPS scheme (but not LP services which are not local pharmaceutical services).</i></p>	<p>A Local Pharmaceutical Service (LPS) contract allows NHS England to commission community pharmaceutical services tailored to specific local requirements. “LP services” is a legal term. NHS England has powers to include in LPS contracts other NHS services or other wider services, such as services relating to the provision of education and training. However, including those other services in an LPS contract turns those services into “LP services” but it does not turn them into “local pharmaceutical services”.</p>
<p><i>(c) the dispensing of drugs and appliances by a person on a dispensing doctors list (but not other NHS services that may be provided under arrangements made by the NHS CB with a dispensing doctor).</i></p>	<p>For dispensing doctors, only the provision of those services set out in their pharmaceutical services terms of service (set out in the Schedules to the 2013 Regulations) is included within the definition of pharmaceutical services. Services such as GP enhanced services – either directed, such as childhood immunisation programmes or local, such as phlebotomy are not “pharmaceutical services”.</p>

3: Information to be contained in PNAs

What the legislation says

1. Regulation 4 and Schedule 1 of the 2013 Regulations outline the minimum requirements for PNAs.

Pharmaceutical needs

2. When assessing local need for pharmaceutical services, HWBs may wish to note that general health need is not the same as the need for pharmaceutical services. There will be differences within HWB areas between:
 - those health needs that may be met using pharmaceutical services commissioned by NHS England. For example, NHS England wishes to commission pharmaceutical services that help reduce the number of people in the HWB area who are being unnecessarily readmitted to hospital due to non-compliance with their medication. NHS England might therefore commission local community pharmacies to carry out medication use review services;
 - public health services commissioned by local authorities; and
 - those that cannot be met by pharmaceutical contractors, for example, minor surgery clinics.
3. Schedule 1 sets out the minimum information to be contained in pharmaceutical needs assessments. The following table provides the text of the Schedule as well as an explanation:

Regulation	Explanation
<p>Schedule 1, paragraph 1 – necessary services: current provision</p> <p>1. <i>A statement of the pharmaceutical services that the HWB has identified as services that are provided:</i></p> <p>(a) <i>in the area of the HWB and which are necessary to meet the need for pharmaceutical services in its area; and</i></p> <p>(b) <i>outside the area of the HWB but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the HWB has identified such services).</i></p>	<p>In order to assess the adequacy of provision of pharmaceutical services, current provision by all providers of such services needs to be mapped. This can be done, for example, by using NHS England's list of pharmaceutical services providers for the relevant area. This will need to include providers and premises within the HWB area, and also those that may lie outside in a neighbouring HWB area but who provide the services to the population within the HWB area.</p> <p>Examples of this type of service provider are pharmacies, distance-selling pharmacies (those who provide pharmaceutical services but not face to face on the premises, dispensing appliance contractors and dispensing doctors). Data from the Information Services Portal at the NHS Business Services Authority (NHS BSA)² can be used to assess the use of distance-selling pharmacies and dispensing appliance contractors by people residing within the HWB's area.</p> <p>The PNA includes a statement outlining this provision.</p>

² The Information Services Portal provides access to a variety of information reports on key prescribing areas. It is anticipated that all NHS Prescription Services reporting will be accessed via the Portal in the future. For more information, see: <http://www.nhsbsa.nhs.uk/PrescriptionServices/3607.aspx>.

<p>Schedule 1, paragraph 2 – necessary services: gaps in provision</p> <p>2. <i>A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied-</i></p> <p><i>(a) need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;</i></p> <p><i>(b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the HWB) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.</i></p>	<p>Having assessed local needs and the current provision of services, the PNA needs to identify any gaps that need to be filled. Such needs might comprise a pharmacy providing a minimum of “essential services” in a deprived area, or pharmaceutical services of a specified type. The PNA may also identify a gap in provision that will need to be provided in future circumstances, for example, a new housing development is being planned in the HWB area.</p> <p>Gaps in provision are not just gaps in pharmaceutical health needs but also gaps by service type. For example, a locality may have adequate provision of essential services to meet the needs of the population, but have a need for more specialist services, such as the management of a long-term condition. Examples of gaps that HWB’s may identify, include:</p> <ul style="list-style-type: none"> • inadequate provision of essential services at certain times of day or week leading to patients attending the GP-led health centres being unable to have their prescription dispensed; • opening hours that do not reflect the needs of the local population; • areas with little or no access to pharmaceutical services; and • adequate provision of dispensing services (by those GPs who dispense), but patients unable to access the wider range of essential services. <p>The PNA includes a statement outlining any gaps.</p>
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<p>Schedule 1, paragraph 3 – other relevant services: current provision</p> <p>3. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are provided-</p> <p>(a) in the area of the HWB and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access to pharmaceutical services in its area;</p> <p>(b) outside the area of the HWB and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;</p> <p>(c) in or outside the area of the HWB and, whilst not being services of the types described in sub-paragraph (a) or (b), or paragraph 1, they nevertheless affect the assessment by the HWB of the need for pharmaceutical services in its area.</p>	<p>This is related to the types of application that persons can make to be included on a pharmaceutical list or provide directed services. There are five types of market entry application (known as routine applications):</p> <ul style="list-style-type: none"> • current need; • future need; • improvements or better access; • future improvements or better access; and • unforeseen benefits (where the applicant provides evidence of a need that was not foreseen when the PNA was published). <p>The HWB will have identified those services that are necessary for the provision of adequate pharmaceutical services (See the section on Schedule 1, paragraph 1 above). There may, however, be pharmaceutical services that provide improvements to the provision or better access for the public whether at the current time or in the future.</p>
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<p>Schedule 1, paragraph 4 – improvements and better access: gaps in provision</p> <p>4. <i>A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied-</i></p> <p><i>(a) would, if they were provided (whether or not they were located in the area of the HWB), secure improvements, or better access to pharmaceutical services, or pharmaceutical services of a specific type, in its area,</i></p> <p><i>(b) would, if in specified future circumstances they were provided (whether or not they were located in the area of the HWB), secure future improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area.</i></p>	<p>It is important that PNAs identify services that are not currently being provided but which will be needed to secure future improvements to pharmaceutical services – common examples of this are major industrial, communications or housing developments, service redesign as set out in, for example, the Joint Health and Wellbeing Strategy, or re-provision. Provision may also change where significant economic downturn is expected, i.e. a large employer moves their operations to Europe or Asia.</p> <p>HWBs can also identify those services, which are currently not being commissioned by NHS England, local authorities or CCGs but may be services that could be commissioned in the future.</p> <p>It should be noted that if a HWB identifies a need or improvement and better access, NHS England does not have to meet the need – this is because NHS England may have other factors to take into account, i.e. other commissioning decisions.</p> <p>The PNA includes a statement outlining this provision.</p>
<p>Schedule 1, paragraph 5 – other services</p> <p>5. <i>A statement of any NHS services provided or arranged by the HWB, NHS CB, a CCG, an NHS trust or an NHS foundation trust to which the HWB has had regard in its assessment, which affect-</i></p> <p><i>(a) the need for pharmaceutical services, or pharmaceutical services of a specified type, in its</i></p>	<p>There may be services provided or arranged by the HWB, NHS England, a CCG, an NHS trust (including foundation trusts) which could, if they were included in a PNA, be provided by pharmaceutical services contractors. For example, a large health centre providing a stop smoking service or immunisation service at a community hospital. Only those NHS services which affect the need for pharmaceutical services or potential pharmaceutical services need to be included.</p>

<p>area; or</p> <p><i>(b) whether further provision of pharmaceutical services in its area would secure improvements, or better access to pharmaceutical services, or pharmaceutical services of a specific type in its area.</i></p>	<p>The PNA includes a statement outlining the services identified in the assessment which affect pharmaceutical needs.</p>
<p>Schedule 1, paragraph 6 – how the assessment was carried out</p> <p><i>6. An explanation of how the assessment has been carried out, in particular –</i></p> <p><i>(a) how it has determined what are the localities in its area;</i></p> <p><i>(b) how it has taken into account (where applicable)-</i></p> <p><i>(i) the different needs of different localities in its area, and</i></p> <p><i>(ii) the different needs of people in its area who share a protected characteristic; and</i></p> <p><i>(c) a report on the consultation that it has undertaken.</i></p>	<p>HWBs may wish to divide up their area to reflect different needs in different localities – for example, to identify needs for different segments of their populations. If so, HWBs may wish to designate any PNA localities to mirror JSNA localities.</p> <p>The PNA includes a statement setting out how the HWB has determined the localities; the different needs of different localities in its area including the needs of those people in the area sharing a protected characteristic, for example, a large travellers’ site; and a report on the consultation undertaken on the PNA.</p>

Maps

4. Paragraph 7 of Schedule 1 of the 2013 Regulations specifies that HWBs are required to include a map in their PNA identifying the premises at which pharmaceutical services are provided in the area of the HWB.
5. Regulation 4(2) requires HWBs to keep the above map up to date, in so far as is practicable (without the need to republish the whole of the assessment or publish a supplementary statement) – see Chapter 4 below.

Case study

Several PCTs worked with other agencies and organisations to produce pertinent maps. When Greater Manchester PCT wanted to determine the accessibility of their pharmacies by determining the hours they were open, they asked the Greater Manchester Passenger Transport Executive for their help in calculating this using a specific software package.

4: Publication and updating of PNAs

What the legislation says

1. Regulations 5 and 6 cover the date by which the HWB's first PNA must be published and the arrangements for revising the PNA.

Publication of first PNA

2. Regulation 5 states that the HWB's first PNA must be published by 1 April 2015. However, this does not preclude HWBs from publishing their first PNA earlier.

Updating and revising PNAs

Timelines for publication of first and revised assessments

- The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 come into force on 1 April 2013;
- HWBs will be required to produce **the first** assessment **by 1 April 2015**;
- HWBs will be required to publish a revised assessment within **three years** of publication of their first assessment; and
- HWBs will be required to publish a revised assessment as soon as is reasonably practical after identifying significant changes to the availability of pharmaceutical services since the publication of its PNA unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

6. The following box gives some examples of possible changes which may mean a revised assessment or supplementary statement is needed and the factors HWBs may want to consider:

Revised PNA or supplementary statement?

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

In this instance, the HWB may need to consider whether it is disproportionate to revise the assessment in year 2. The HWB may consider not issuing a Supplementary Statement as there have been no changes to the availability of pharmaceutical services.

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

The HWB may consider whether the making of a revised assessment is a proportionate response. Will the provision of services be continued for its population, i.e. are there alternative providers of services? Would closure of all or some of the outlets warrant a full-scale revision of the PNA or would that be disproportionate, taking into account all relevant circumstances? If the change in the availability of pharmaceutical services is likely to have an impact on the need for additional pharmaceutical services, the HWB may consider issuing a supplementary statement.

Example: within its PNA, the HWB has identified that a locality has over-provision of essential and advanced services. Subsequently, one pharmacy within that locality gives notice to NHS England that it intends to close.

Following that closure, the HWB may consider issuing a Supplementary Statement that stated pharmacy X had closed. The HWB may also consider issuing a Supplementary Statement if the change is relevant to whether or not there is a gap in the provision of pharmaceutical services.

5: Consultation

What the legislation says

1. Regulation 8 sets out the requirements for consultation on PNAs. The local authority duty to involve was first introduced in the Local Government and Public Involvement in Health Act 2007 and was updated and extended in the Local Democracy, Economic Development and Construction Act 2008.

Those to be consulted

2. The Regulations set out that:
 - HWBs must consult the bodies set out in Regulation 8 at least once during the process of developing the PNA. Any neighbouring HWBs who are consulted should ensure any LRC in the area which is different from the LRC for the original HWB's area is consulted;
 - there is a minimum period of 60 days for consultation responses; and
 - those being consulted can be directed to a website address containing the draft PNA but can, if they request, be sent an electronic or hard copy version.

6: Matters for consideration when making assessments

What the legislation says

1. Regulation 9 sets out the matters HWBs must have regard to when developing their PNAs as far as is practicable to do so.

Matters for consideration

2. The following are the matters for consideration by HWBs:
 - the demography of its area;
 - whether there is sufficient choice with regard to obtaining pharmaceutical services; (see box below);

Possible factors to be considered in terms of the benefits of sufficient “choice”

- What is the current level of access within the locality to NHS pharmaceutical services?
- What is the extent to which services in the locality already offer people a choice, which may be improved by the provision of additional facilities?
- What is the extent to which there is sufficient choice of providers in the locality, which may be improved, by additional providers?
- What is the extent to which current service provision in the locality 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?
- What is the HWB’s assessment of the overall impact on the locality in the longer-term?

- any different needs of different localities in its area;
- the pharmaceutical services provided in the area of any neighbouring HWB which affect the need for pharmaceutical services in its area, or whether further provision of pharmaceutical services in its area would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area;
- any other NHS services provided in or outside the area (not covered above) which affect the need for pharmaceutical services in its area, or whether further provision of pharmaceutical services in its area would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
- likely future needs (see box below).

Identifying known future needs

Are there:

- known firm plans for the development/expansion of new centres of population i.e. housing estates, or for changes in the pattern of population i.e. urban regeneration, local employers closing or relocating?
- known firm plans in and arising from local joint strategic needs assessments or joint health and wellbeing strategies?
- known firm plans for changes in the number and/or sources of prescriptions i.e. changes in providers of primary medical services, or the appointment of additional providers of primary medical services in the area?
- known firm plans for developments which would change the pattern of local social traffic and therefore access to services, i.e. shopping centres or significant shopping developments whether these are in town, on the edge of town or out of town developments?
- plans for the development of NHS services?
- plans for changing the commissioning of public health services by community pharmacists, for example, weight management clinics, lifechecks?
- introduction of special services commissioned by clinical commissioning groups?
- new strategy by social care/occupational health to provide aids/equipment through pharmacies or dispensing appliance contractors?

Appendix 1 – Glossary of terms and phrases defined in regulation 2 of the 2013 Regulations

Term or phrase	Definition as per regulation 2 of the 2012 Regulations	Explanation
Controlled localities/controlled locality	Means an area that is a controlled locality by virtue of regulation 36(1) or is determined to be so in accordance with regulation 36(2).	A controlled locality is an area which has been determined, either by NHS England, a primary care trust a predecessor organisation or on appeal by the NHS Litigation Authority (whose appeal unit handles appeals for pharmaceutical market entry and performance sanctions matters), to be “rural in character”. It should be noted that areas that have not been formally determined as rural in character and therefore <i>controlled localities</i> , are not <i>controlled localities</i> unless and until NHS England determines them to be. Such areas may be considered as rural because they consist open fields with few houses but they are not a <i>controlled locality</i> until they have been subject to a formal determination.

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Core opening hours	Is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 4 or paragraph 13(2) of Schedule 5, or both.	Pharmacies are required to be open for 40 hours per week, unless they were approved under Regulation 13(1)(b) of the 2005 Regulations in which case they are required to open for 100 hours per week. Dispensing appliance contractors (DACs) are required to be open for not less than 30 hours per week.
Directed services	Means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act.	These are advanced and enhanced services as set out in Directions.
Dispensing doctor(s)	Is to be construed in accordance with regulation 46(1).	These are providers of primary medical services who provide pharmaceutical services from medical practice premises in the area of NHS England; and general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in the area of the HWB.
Distance selling premises	Listed chemist premises, or potential pharmacy premises, at which essential services are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises.	These premises could have been approved under the 2005 Regulations in which case they could be pharmacies or DACs. Under the 2012 and 2013 Regulations only pharmacy contractors may apply to provide services from distance selling premises. Distance-selling contractors are in the main internet and some mail-order, but they all cannot provide “essential services” to persons face to face at their premises and must provide a service across England to anyone who requests it.

Enhanced services	Means the additional pharmaceutical services that are referred to in direction 4 of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013.	These are pharmaceutical services commissioned by NHS England, such as services to Care Homes, language access and patient group directions.
Essential services	Except in the context of the definition of “distance selling premises”, is to be construed in accordance with paragraph 3 of Schedule 4.	These are services which every community pharmacy providing NHS pharmaceutical services must provide and is set out in their terms of service – these include the dispensing of medicines, promotion of healthy styles and support for self-care. Distance-selling pharmacy contractors cannot provide essential services face to face at their premises.
Neighbouring HWB	In relation to a HWB (HWB1), means the HWB of an area that borders any part of HWB1.	Used when, for example, an HWB is consulting on their draft PNA and needs to inform the HWBs which border their HWB area.
NHS chemist	Means an NHS appliance contractor or an NHS pharmacist.	

Appendix 2 – Frequently asked questions

Q1: What are “pharmaceutical services”?

The NHS Act 2006³ sets out a wider definition for pharmaceutical services. Pharmaceutical services are generally provided by virtue of Part 7 of the Act. Under section 126(1) – (3), NHS England is required to secure, on the basis of Regulations made by the Secretary of State, the provision of services to people in their area of medicines and listed appliances and "such other services as may be prescribed" (*section 126(3)(e)*). Prescribed services must be set out in Regulations. Therefore, these prescribed services, and the dispensing services referred to in section 126(3)(a) to (d), constitute the core NHS pharmaceutical services. Section 127 also provides for “additional pharmaceutical services” to be set out in Directions to NHS England. This facility was originally introduced in the late 1990s to enable pharmacies to provide other types of service that did not fall within those core services as defined by Section 126(3). Directed services include advanced and enhanced services for pharmacy contractors and advanced services for dispensing appliance contractors.

Pharmaceutical services do not include any services commissioned directly from the above pharmaceutical contractors by local authorities, clinical commissioning groups etc.

Q2: Wouldn't it have been better if the Board produced and updated Pharmaceutical Needs Assessments as it is commissioning NHS pharmaceutical services?

No. Local authorities worked with PCTs (and are now working with NHS England) to produce Joint Strategic Needs Assessments. It was therefore a logical step for HWBs to take over PNAs from PCTs. These PNAs are designed to be an integral part of that wider strategic approach to commissioning. Alongside identifying strategic health needs through JSNAs, HWB PNAs will inform the commissioning of community pharmacy services by NHS England and local public health commissioning decisions.

³ http://www.opsi.gov.uk/acts/acts2006/ukpga_20060041_en_1

Q3: Is market entry the responsibility of the local authority since they will be more familiar with local health and wellbeing issues than NHS England?

No. Commissioning and market entry are inter-related and if local authorities took on responsibility for market entry, they would also need to be the commissioners of pharmaceutical services. This would divorce pharmaceutical services from the rest of primary care and would create new burdens and costs for local authorities who would need to acquire specialist knowledge to implement legislation with which they were unfamiliar.

Added to that, if a local authority came to the conclusion that there was, for example, a gap in pharmaceutical services, it would have to bear the consequences in terms of more costs to itself of any increased capacity that the local authority had concluded in its pharmaceutical needs assessment was necessary.

Q4: Will Health and Wellbeing Boards be obliged to consult pharmacists about local PNAs?

Yes. The NHS Act 2006 already requires the Department to set out in Regulations various matters about pharmaceutical needs assessments. The 2013 Regulations stipulate minimum consultation requirements, including a need to consult local contractors.

Q5: If the PNA identifies a need for pharmaceutical services, then shouldn't NHS England be required to address that need?

NHS England will be acting under an annual mandate from Secretary of State. Beyond that, NHS England should therefore be free to decide how best to meet its responsibilities for commissioning services according to the needs of the local population. We expect NHS England to weigh all the evidence carefully – taking account of pharmaceutical needs alongside other relevant factors. Placing an obligation on NHS England to fill a gap would hamper the Board's ability to make such robust commissioning decisions.