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1 Introduction

Key messages

From 1 April 2013, every health and wellbeing board (HWB) in England has a statutory responsibility to publish and keep up to date a statement of the needs for pharmaceutical services for the population in its area, referred to as a pharmaceutical needs assessment (PNA).

The PNA will help in the commissioning of pharmaceutical services in the context of local priorities and will be used by NHS England and NHS Improvement (NHSE/I) when making decisions on applications to open new pharmacies. As these decisions may be appealed and challenged via the courts, it is important that PNAs comply with regulations and that mechanisms are established to keep the PNA up to date. In accordance with these regulations, the pan-Lancashire PNA will be updated every three years. However, due to the Covid-19 pandemic in 2020 and 2021, the requirement to publish a PNA was suspended until October 2022.

This PNA describes current provision and what may be needed for the population of Blackburn with Darwen Council, Blackpool Council and Lancashire County Council (pan-Lancashire area), and includes information on

- pharmacies in the region and the services they currently provide, including dispensing, providing advice on health, medicines reviews and local public health services such as stop smoking, sexual health and support for drug users
- relevant maps of the pan-Lancashire area and providers of pharmaceutical services in the area
- pharmaceutical contractors in neighbouring HWB areas that might affect the need for services in pan-Lancashire
- potential gaps in provision and likely future needs for the population of the pan-Lancashire area
- potential opportunities relating to needs of the population

1.1 What is a pharmaceutical needs assessment?

The PNA is a structured approach to identifying unmet pharmaceutical need. It can be an effective tool to enable HWBs to identify the current and future commissioning of services required from pharmaceutical service providers. The Department of Health and Social Care (DHSC) published an information pack to help HWBs undertake PNAs.ⁱ

1.2 What is the purpose of the PNA?

This PNA will serve several key purposes.ⁱⁱ

- It will be used by NHSE/I when making decisions on applications to open new pharmacies and dispensing appliance contractor premises, or applications from current pharmaceutical providers to change their existing regulatory requirements. When applications are received regarding the Pharmaceutical List the Primary Care Contracting Pharmacy Sub-Group considers the PNA alongside the quality of the

application, the legislative framework and the relevant test criteria. This group feeds into the Primary Care Contracting Group and both these groups are part of the ICB.

- It will help the HWB to work with providers to target services in areas where they are needed and limit duplication of services in areas where provision is sufficient.
- It will inform interested parties of the pharmaceutical needs across pan-Lancashire and enable work to plan, develop and deliver pharmaceutical services for the population.
- It will inform commissioning decisions by local commissioning bodies including local authorities (public health services from community pharmacies), NHSE/I and clinical commissioning groups (CCGs).

1.3 Legislative background

Section 126 of the NHS Act 2006 placed 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 of the act also described the types of healthcare professionals who are authorised to order drugs, medicines and listed appliances on an NHS prescription.

In 2012, the Health and Social Care Act was produced and superseded the NHS Act 2006. The 2012 act established HWBs and transferred the responsibility to publish and keep up-to-date a statement of the needs for pharmaceutical services of the population in its area, with effect from 1 April 2013. The requirements on how to develop and update PNAs are set out in regulations 3-9 schedule 1 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013.ⁱⁱⁱ

The 2012 act also amended the Local Government and Public Involvement in Health Act 2007 to introduce duties and powers for HWBs in relation to joint strategic needs assessments (JSNAs). The preparation and consultation on the PNA should take account of the JSNA and other relevant local strategies 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 a separate statutory requirement, PNAs cannot be subsumed as part of these other documents but can be annexed to them.

The PNA must be published by the HWB by October 2022 and will have a maximum lifetime of three years. Due to the Covid-19 pandemic in 2020 and 2021, the requirement to publish a PNA was suspended to October 2022. As part of developing the PNA, HWBs must undertake a consultation for a minimum of 60 days. The 2013 regulations list those persons and organisations that the HWB must consult. This list includes

- any relevant local pharmaceutical committee (LPC) for the HWB area
- any local medical committee (LMC) for the HWB area
- any persons on the pharmaceutical lists and any dispensing GP practices in the HWB area
- any local Healthwatch organisation for the HWB area, and any other patient, consumer and community group that, in the opinion of the HWB, has an interest in the provision of pharmaceutical services in its area
- any NHS trust or NHS foundation trust in the HWB area
- NHSE/I
- any neighbouring HWB

The Health and Social Care Act 2012 also transferred responsibility for using PNAs as the basis for determining market entry to a pharmaceutical list from primary care trusts (PCTs) to NHSE/I. The PNA will be used by NHSE/I when making decisions on applications to open new pharmacies and dispensing appliance contractor premises, or applications from current pharmaceutical providers to change their existing regulatory requirements. Such decisions are appealable to the NHS Resolution Primary Care Appeals, and decisions made on appeal can be challenged through the courts. PNAs will also inform the commissioning of enhanced services from pharmacies by NHSE/I, and the commissioning of services from pharmacies by the local authority and other local commissioners, for example CCGs. It is extremely important that PNAs comply with the requirements of the regulations and are kept up to date by submitting supplementary statements when deemed necessary.

Failure to comply with the regulatory duties may lead to a legal challenge, for example where a party believes that they have been disadvantaged following refusal by NHSE/I of their application to open new premises.

HWBs will also be required to publish a revised assessment when significant changes to the need for pharmaceutical services are identified, unless this is considered a disproportionate response. HWBs therefore need to establish systems that allow them toⁱⁱ

- identify changes to the need for pharmaceutical services within their area
- assess whether the changes are significant
- decide whether producing a new PNA is a disproportionate response

The PNA steering group plans to meet twice a year to assess the need for supplementary statements, these will be published on the PNA webpages. This will include the ongoing assessment of sufficient provision including drive/walk time analysis, analysis of pharmacies per head of population and examination of population density and demographic profiling.

HWBs need to ensure they are aware of any other changes to the NHS contract, changes to the commissioning of public health services by the local authority and the commissioning of services by CCGs as these may affect the need for pharmaceutical services. HWBs also need to ensure that NHSE/I and its area offices have access to their PNAs.

1.4 What are NHS pharmaceutical services?

Pharmaceutical services as defined in the National Health Service Act 2006 and the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013, as amended include the following.

The services that a pharmaceutical needs assessment must include are defined within both the National Health Service Act 2006 and the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended. Pharmaceutical services may be provided by

- a pharmacy contractor who is included in the pharmaceutical list for the area of the HWB
- a pharmacy contractor who is included in the local pharmaceutical services list for the area of the HWB
- a dispensing appliance contractor (DAC) who is included in the pharmaceutical list held for the area of the HWB and

- a doctor or GP practice that is included in the dispensing doctor list held for the area of the HWB

NHS England and NHS Improvement is responsible for preparing, maintaining and publishing these lists. As at 1 February 2022

- Blackburn with Darwen had 46 pharmacies, 0 dispensing doctors and 0 DACs
- Blackpool had 39 pharmacies, 0 dispensing doctors and 0 DACs
- Lancashire had 267 pharmacies, 8 dispensing doctors and 4 DACs

Pharmacy contractors may operate as either a sole trader, partnership or a body corporate and The Medicines Act 1968 governs who can be a pharmacy contractor.

1.4.1 Pharmaceutical services provided by pharmacy contractors

Unlike for GPs, dentists and optometrists, NHSE/I does not hold contracts with the majority of pharmacy contractors. Instead, they provide services under a contractual framework, sometimes referred to as the community pharmacy contractual framework, details of which (the terms of service) are set out in schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, and also in the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. Pharmacy contractors provide three types of service that fall within the definition of pharmaceutical services and the community pharmacy contractual framework. They are

- Essential services – all pharmacies must provide these services
 - o dispensing of medicines
 - o dispensing of appliances
 - o repeat dispensing
 - o disposal of unwanted drugs
 - o public health (promotion of healthy lifestyles) via being a Healthy Living Pharmacy
 - o signposting
 - o support for self-care
 - o since 15 February 2021, the discharge medicines service
 - o clinical governance
- Advanced services – pharmacies may choose whether to provide these services or not. If they choose to provide one or more of the advanced services, they must meet certain requirements and must be fully compliant with the essential services and clinical governance and promotion of healthy living requirements
 - o new medicine service
 - o stoma appliance customisation
 - o appliance use review
 - o seasonal influenza adult vaccination service
 - o community pharmacist consultation service
 - o Hepatitis C antibody testing service

- o home delivery service (during a declared pandemic only)
 - o community pharmacy Covid-19 lateral flow device distribution service
 - o hypertension case finding service
 - o pandemic delivery service
 - o smoking cessation service – as of 15 February 2022 not yet launched
- Enhanced services – service specifications for this type of service are developed by NHSE/I and then commissioned to meet specific health needs

Underpinning the provision of all of these services is the requirement on each pharmacy contractor to participate in a system of clinical governance and promotion of healthy living. This system is set out within the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended and includes

- a patient and public involvement programme
- an audit programme
- a risk management programme
- a clinical effectiveness programme
- a staffing and staff management programme
- an information governance programme and
- a premises standards programme

Pharmacies are required to open for 40 hours per week, and these are referred to as core opening hours, but many choose to open for longer and these additional hours are referred to as supplementary opening hours. Between April 2005 and August 2012, some contractors successfully applied to open new premises on the basis of being open for 100 core opening hours per week (referred to as 100 hour pharmacies), which means that they are required to be open for 100 core hours per week, 52 weeks of the year (with the exception of weeks which contain a bank or public holiday, or Easter Sunday). It continues to be a condition that these 100 hour pharmacies remain open for 100 core hours per week, and they may open for longer hours.

The proposed opening hours for each pharmacy are set out in the initial application, and if the application is granted and the pharmacy subsequently opens, then these form the pharmacy's contracted opening hours. The contractor can subsequently apply to change their core opening hours and NHSE/I will assess the application against the needs of the population of the HWB area as set out in the pharmaceutical needs assessment to determine whether to agree to the change in core opening hours or not. If a pharmacy contractor wishes to change their supplementary opening hours, they simply notify NHSE/I of the change, giving at least three months' notice.

Whilst the majority of pharmacies provide services on a face-to-face basis, eg people attend the pharmacy to ask for a prescription to be dispensed, or to receive health advice, there is one type of pharmacy that is restricted from providing services in this way. They are referred to in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, as distance selling premises (sometimes called mail order or internet pharmacies).

Distance selling premises are required to provide essential services and participate in the system of clinical governance and promotion of healthy living in the same way as other pharmacies; however, they must provide these services remotely. For example, a patient asks for their prescription to be sent to a distance selling premises via the electronic prescription service and the contractor dispenses the item and then delivers it to the patient's preferred

address. Distance selling premises therefore interact with their customers via the telephone, email or a website. Such pharmacies are required to provide services to people who request them wherever they may live in England and delivery of dispensed items is free of charge.

1.4.2 *Pharmaceutical services provided by dispensing appliance contractors*

As with pharmacy contractors, NHSE/I does not hold contracts with dispensing appliance contractors. Their terms of service are set out in schedule 5 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended and in the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. Dispensing appliance contractors provide the following services for appliances (not drugs), for example catheters and colostomy bags, which fall within the definition of pharmaceutical services

- dispensing of prescriptions (both electronic and non-electronic), including urgent supply without a prescription
- dispensing of repeatable prescriptions
- home delivery service for some items
- supply of appropriate supplementary items (eg disposable wipes and disposal bags)
- provision of expert clinical advice regarding the appliances and
- signposting

They may also choose to provide advanced services. If they do choose to provide them then they must meet certain requirements and must be fully compliant with their terms of service and the clinical governance requirements. The two advanced services that they may provide are:

- stoma appliance customisation
- appliance use review

As with pharmacies, dispensing appliance contractors are required to participate in a system of clinical governance. This system is set out within the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended and includes

- a patient and public involvement programme
- a clinical audit programme
- a risk management programme
- a clinical effectiveness programme
- a staffing and staff programme and
- an information governance programme

Dispensing appliance contractors are required to open at least 30 hours per week, and these are referred to as core opening hours. They may choose to open for longer and these additional hours are referred to as supplementary opening hours. The proposed opening hours for each dispensing appliance contractor are set out in the initial application, and if the application is granted and the dispensing appliance contractor subsequently opens then these form the dispensing appliance contractor's contracted opening hours. The contractor can subsequently apply to change their core opening hours. NHSE/I will assess the application against the needs of the population of the HWB area as set out in the PNA to determine whether to agree to the change in core opening hours or not. If a dispensing appliance contractor wishes to change their supplementary opening hours, they simply notify NHSE/I of the change, giving at least three months' notice.

1.4.3 Pharmaceutical services provided by doctors

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, allow doctors to dispense to eligible patients in certain circumstances. The regulations are complicated on this matter but, in summary

- patients must live in a 'controlled locality' (an area which has been determined by NHSE/I or a preceding organisation as rural in character), more than 1.6km (measured in a straight line) from a pharmacy (excluding distance selling premises), and
- their practice must have premises approval and consent to dispense to that area

There are some exceptions to this, for example patients who have satisfied NHSE/I that they would have serious difficulty in accessing a pharmacy by reason of distance or inadequacy of means of communication.

1.4.4 Local Pharmaceutical services

Local pharmaceutical services contracts allow NHSE/I to commission services, from a pharmacy, which are tailored to specific local requirements. Local pharmaceutical services complement the national contractual arrangements described above but they are an important local commissioning tool in their own right. Local pharmaceutical services provide flexibility to include within a contract a broader or narrower range of services (including services not traditionally associated with pharmacies) than is possible under the national contractual arrangements. For the purposes of the PNA the definition of pharmaceutical services includes local pharmaceutical services. There are two local pharmaceutical services contracts: one in Blackpool and one in Lancashire.

1.5 Local pharmacy services

Local pharmacy services are services which are commissioned locally and fall outside of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013. The 2013 regulations set out the enhanced services that may be commissioned from pharmacy contractors. It is important to note that the definition of enhanced services has changed, and the current commissioning arrangements can now be seen as more complex since pharmacy services previously commissioned by one organisation (PCTs) can now be commissioned by at least three different organisations (CCGs, local authorities and NHSE/I) and the responsibility for commissioning some services continues to evolve or is subject to review. Enhanced services and local improvement services are currently commissioned directly by NHSE/I and CCGs. These could include seasonal flu vaccination service, minor ailment services, palliative care and the pharmacy led Covid-19 vaccination service.

1.5.1 Public health services

Local authorities are responsible for commissioning a wide range of services, including most public health services and social care services. The local authority can commission pharmacies to provide public health services such as

- supervised consumption
- needle and syringe exchange
- NHS Health checks
- emergency hormonal contraception services
- sexual health services such as chlamydia screening, testing and treatment

- stop smoking
- weight management programmes
- alcohol screening and brief interventions

1.5.2 NHSE/I

NHSE/I currently commissions the pharmacy core contract (including advanced services). Currently, NHSE/I does not fully commission any enhanced services. However, this position may change according to the future developments in commissioning integration, the role of pharmacies and the needs of local populations. NHSE/I commissioned and continue to commission the pharmacy led Covid-19 vaccination Service.

1.5.3 Clinical commissioning groups (CCGs)

CCGs have a role to commission NHS services locally. These services include planned hospital care, rehabilitative care, urgent and emergency care (including out-of-hours and accident and emergency services), most community health services, maternity services, mental health and learning disability services.

CCGs also commission local pharmacy services. Through thorough engagement, CCGs are able to ensure locally commissioned pharmacy services are responsive to local needs, such as minor ailments services, palliative care schemes and other medicines optimisation services.

1.6 What are pharmaceutical lists?

If a person (a pharmacist, a dispenser of appliances or in some circumstances and, normally in rural areas, a GP) 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 by NHSE/I. This is commonly known as the NHS 'market entry' system.

Under the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013, a person who wishes to provide NHS pharmaceutical services must apply to NHSE/I to be included on a relevant list by generally proving they are able to meet a pharmaceutical need as set out in the relevant PNA. There are exceptions to the applications to meet a need, such as applications for needs not foreseen in the PNA or to provide pharmaceutical service on a distance-selling (internet or mail-order only) basis. The following are included in a pharmaceutical list.

- Pharmacy contractors: a person or body corporate who provides NHS pharmaceutical services under the direct supervision of a pharmacist registered with the General Pharmaceutical Council.
- Dispensing appliance contractors: appliance suppliers are a subset of NHS pharmaceutical contractors who supply, on prescription, appliances such as stoma and incontinence aids, dressings and bandages. They cannot supply medicines.
- Dispensing doctors: medical practitioners authorised to provide drugs and appliances in designated rural areas known as 'controlled localities'.
- Local pharmaceutical services (LPS) contractors also provide pharmaceutical services in some HWB areas.

1.7 What information will this PNA contain?

The information to be contained in the PNA is set out in schedule 1 of The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013. This PNA includes information as of February 2022

- pharmacies across pan-Lancashire and the services they currently provide, including dispensing, providing advice on health, medicines reviews and local public health services, such as stop smoking, sexual health and support for drug users
- relevant maps relating to pan-Lancashire area and providers of pharmaceutical services in the area
- services in neighbouring HWB areas that might affect the need for services in the pan-Lancashire area
- potential gaps in provision and likely future needs for the population across pan-Lancashire
- potential overprovision of services

References

ⁱ Department of Health and Social Care. 'Pharmaceutical needs assessments: Information Pack for local authority Health and Wellbeing Boards.' October 2021.

<https://www.gov.uk/government/publications/pharmaceutical-needs-assessments-information-pack>

ⁱⁱ Primary Care Commissioning. 'Pharmaceutical needs assessments. March 2013'. <http://www.pcc-cic.org.uk/>

ⁱⁱⁱ The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. <http://www.legislation.gov.uk/ukxi/2013/349/made>