

## What is a Pharmaceutical Needs Assessment?

The Pharmaceutical Needs Assessment is a structured approach to identifying unmet pharmaceutical need. It can be an effective tool to enable Health and Wellbeing Boards to identify the current and future commissioning of services required from pharmaceutical service providers. The Department of Health (DH) published an Information Pack to help Health and Wellbeing Boards undertake Pharmaceutical Needs Assessments.<sup>1</sup>

## What is the purpose of the Pharmaceutical Needs Assessment?

This PNA will serve several key purposes:<sup>2</sup>

- It will be used by NHS England 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.
- It will help the Health and Wellbeing Board to work with providers to target services to the areas where they are needed and limit duplication of services in areas where provision is adequate.
- It will inform interested parties of the pharmaceutical needs in Blackpool 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), NHS England and Clinical Commissioning Groups (CCGs).

## Legislative background

Section 126 of the NHS Act 2006 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 of the Act also describes the types of healthcare professionals who are authorised to order drugs, medicines and listed appliances on an NHS prescription. The first PNAs were published by NHS Primary Care Trusts (PCTs) according to the requirements in the 2006 Act. NHS Blackpool published their first PNA in 2011.

The Health and Social Care Act 2012 amended the NHS Act 2006. The 2012 Act established Health and Wellbeing Board and transferred to them 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

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<sup>1</sup> Department of Health. 'Pharmaceutical needs assessments: Information Pack for local authority Health and Wellbeing Boards.' May 2013.

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/197634/Pharmaceutical\\_Needs\\_Assessment\\_Information\\_Pack.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/197634/Pharmaceutical_Needs_Assessment_Information_Pack.pdf)

<sup>2</sup> Primary Care Commissioning. 'Pharmaceutical needs assessments.' March 2013. <http://www.pcc-cic.org.uk/>

Regulations 3-9 Schedule 1 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013.<sup>3</sup>

The 2012 Act also amended the Local Government and Public Involvement in Health Act 2007 to introduce duties and powers for Health and Wellbeing Boards in relation to Joint Strategic Needs Assessments (JSNAs). The preparation and consultation on the Pharmaceutical Needs Assessment should take account of the Joint Strategic Needs Assessment ( 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 Pharmaceutical Needs Assessments is a separate duty to that of developing Joint Strategic Needs Assessments. As a separate statutory requirement, Pharmaceutical Needs Assessments cannot be subsumed as part of these other documents but can be annexed to them.

The Pharmaceutical Needs Assessment must be published by the HWB by April 2015, and will have a maximum lifetime of three years. As part of developing their first Pharmaceutical Needs Assessment, Health and Wellbeing Boards must undertake a consultation for a minimum of 60 days. The 2013 Regulations list those persons and organisations that the Health and Wellbeing Board must consult. This list includes:

- Any relevant local pharmaceutical committee (LPC) for the Health and Wellbeing Board area.
- Any local medical committee (LMC) for the Health and Wellbeing Board area.
- Any persons on the pharmaceutical lists and any dispensing GP practices in the Health and Wellbeing Board area.
- Any local Healthwatch organisation for the Health and Wellbeing Board area, and any other patient, consumer and community group which in the opinion of the Health and Wellbeing Board has an interest in the provision of pharmaceutical services in its area.
- Any NHS trust or NHS foundation trust in the Health and Wellbeing Board area.
- NHS England.
- Any neighbouring Health and Wellbeing Board.

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 PCTs to NHS England. The PNA will be used by NHS England 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 Litigation Authority's Family Health Services Appeal Unit (FHSAU), and decisions made on appeal can be challenged through the courts. Pharmaceutical Needs Assessments will also inform the commissioning of enhanced services from pharmacies by NHS England, and the commissioning of services from pharmacies by the local authority and other local commissioners e.g. CCGs.

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<sup>3</sup> The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.  
<http://www.legislation.gov.uk/ukxi/2013/349/made>

The use of Pharmaceutical Needs Assessments for determining applications for new premises is relatively recent. It is expected that some decisions made by NHS England may be appealed and that eventually there will be judicial reviews of decisions made by the FHSAU. It is therefore important that PNAs comply with the requirements of the regulations, that due process is followed in their development, and that they are kept up-to-date.

Primary Care Commissioning (PCC) has highlighted that 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 NHS England of their application to open new premises.<sup>4</sup>

Health and Wellbeing Boards 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. Health and Wellbeing Boards therefore need to establish systems that allow them to:

- Identify changes to the need for pharmaceutical services within their area.
- Assess whether the changes are significant.
- Decide whether producing a new Assessment is a disproportionate response.

HWBs need to ensure they are aware of any 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 NHS England and its Area Teams have access to their Pharmaceutical Needs Assessments.

## **What are NHS pharmaceutical services?**

Pharmaceutical services as defined in the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 include:

- Essential services which every community pharmacy providing NHS pharmaceutical services must provide (as described in Schedule 4, Part 2 of the Regulations) which includes the dispensing of medicines, promotion of healthy lifestyles and support for self-care.
- Advanced services which community pharmacy contractors and dispensing appliance contracts can provide subject to accreditation. These are currently Medicines Use Reviews (MUR) and the New Medicines Service from community pharmacists and Appliance Use Reviews and the Stoma Customisation Service which can be provided by dispensing appliance contracts and community pharmacies.
- Enhanced services are commissioned directly by NHS England. These could include anti-coagulation monitoring, the provision of advice and support to residents and staff in care homes in connection with drugs and appliances, on demand availability of specialist drugs, and out-of-hours services.

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<sup>4</sup> Pharmaceutical Needs Assessments: Right Service in the Right Place. 25 March 2013. <http://www.pcc-cic.org.uk/article/pharmaceutical-needs-assessments-right-service-right-place>

## 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. Local pharmacy services do not impact on the commissioning of new pharmacy contracts.

The 2013 regulations set out the enhanced services which may be commissioned from pharmacy contractors. It is important to note that the definition of 'Enhanced services' have 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 NHS England) and the responsibility for commissioning some services is yet to be resolved.

- **Public Health Services and Enhanced services**

The changes to enhanced services are summarised in the following excerpt from PCC:<sup>5</sup>

- **Public Health Services**

The commissioning of the following enhanced services which were listed in the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2012 transferred from PCTs to local authorities with effect from 1 April 2013:

- Needle and syringe exchange
- Screening services such as chlamydia screening
- Stop smoking
- Supervised administration service
- Emergency hormonal contraception services through patient group directions

Where such services are commissioned by local authorities they no longer fall within the definition of enhanced services or pharmaceutical services as set out in legislation and therefore should not be referred to as enhanced services.

However, the 2013 directions do make provision for NHS England to commission the above services from pharmacy contractors where asked to do so by a local authority. Where this is the case they are treated as enhanced services and fall within the definition of pharmaceutical services.

- **Enhanced Services**

The following enhanced services may be commissioned by NHS England from 1 April 2013 in line with pharmaceutical needs assessments produced by PCTs up to 31 March 2013 and by Health and Wellbeing Boards thereafter:

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<sup>5</sup> Primary Care Commissioning. Pharmacy Enhanced Services from 1 April 2013: <http://www.pcc-cic.org.uk/article/pharmacy-enhanced-services-1-april-2013>

- Anticoagulation monitoring
  - Care home service
  - Disease specific medicines management service
  - Gluten free food supply service
  - Independent prescribing service
  - Home delivery service
  - Language access service
  - Medication review service
  - Medicines assessment and compliance support
  - Minor ailment service
  - On demand availability of specialist drugs
  - Out of hours service
  - Patient group direction service (not related to public health services)
  - Prescriber support service
  - Schools service
  - Supplementary prescribing service
- **Clinical Commissioning Groups**

CCGs now have the role to commission most NHS services locally, aside from those commissioned by NHS England such as GP core contracts and specialised commissioned services. CCGs involve clinicians in their area to ensure commissioned services are responsive to local needs. CCGs will be able to commission services from pharmacies but similar to public health services these services will be known as local services and then fall outside the definition of enhanced services, and so have no bearing on pharmacy applications.

## **What are pharmaceutical lists?**

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 by NHS England. 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 NHS England 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 Councils.
- Dispensing appliance contractors: appliance suppliers are a sub-set of NHS pharmaceutical contractors who supply, on prescription, appliances such as stoma and incontinence aids, dressings, bandages etc. 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.

### **What information will this Pharmaceutical Needs Assessment contain?**

The information to be contained in the Pharmaceutical Needs Assessment is set out in Schedule 1 of The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013. Briefly, this Pharmaceutical Needs Assessment includes information on:

- Pharmacies in Blackpool 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 Blackpool and providers of pharmaceutical services in the area.
- Services in neighbouring Health and Wellbeing Board areas that might affect the need for services in Blackpool.
- Potential gaps in provision that could be met by providing more pharmacy services, or through opening more pharmacies, and likely future needs.

The Pharmaceutical Needs Assessment is aligned with the Joint Strategic Needs Assessment and Health and Wellbeing Board Strategy for Blackpool.