Bristol Clinical Commissioning Group

Bristol Health & Wellbeing Board

P H A R M A C E U T I C A L N E E D S A S S E S S M E N T (P N A)	
Author, including organisation	Kelechi Nnoaham, Bristol City Council
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Report for Decision	

1. Purpose of this Paper

1.1 To provide information regarding the duty placed on Health and Wellbeing Boards to ensure the production of Pharmaceutical Needs Assessments (PNAs).

1.2 To propose practical processes that need to be put in place now in order to fulfil this duty.

2. Context

2.1 A Pharmaceutical Needs Assessment (PNA) is a document which records the assessment of the need for pharmaceutical services within a specific area. As such, it sets out a statement of the pharmaceutical services which are currently provided, together with when and where these are available to a given population.

2.2 The Health and Social Care Act 2012 transferred the statutory responsibility for the development and updating of PNAs from NHS Primary Care Trusts (PCTs) to Health and Wellbeing Boards, with effect from 1 April 2013. At the same time, NHS England became responsible for maintaining NHS Pharmaceutical Lists and 'market entry' decisions. *This is the term used to describe the process by which applications*

for new premises are made, processed and determined for new contractors.

2.3 The Health & Wellbeing Board (HWB) must publish its first PNA by April 2015.

2.4 The HWB responsibilities, in relation to PNAs, require the establishment of robust processes and governance arrangements to ensure that these are discharged effectively and in accordance with the statutory framework.

2.5 The size of the task with respect to developing and maintaining the PNA is significant and will require dedicated resource and specialist subject matter expertise to inform decision making.

3. PURPOSES AND USES OF THE PNA

3.1 The purpose of a PNA is fundamentally two-fold: to guide 'market-entry' for new contractors and to guide commissioning services from pharmacies.

The PNA will be used by:

- Potential contractors – to apply to open new premises
- Existing contractors – to identify new services which they could provide
- NHS England Area Teams to make decisions on applications for new contractor premises or services, make decisions on applications to relocate existing premises and commissioning of enhanced services
- Health and Wellbeing Boards – to guide commissioning of pharmacy-led Public Health services to address health inequalities and improve the health of their population

3.2 This paper sets out the relevant background and responsibilities of Health and Wellbeing Boards in relation to PNAs and makes recommendations on how the Bristol Health and Wellbeing Board may wish to discharge its responsibilities.

4. Health and Wellbeing Board Responsibilities in relation to PNAs

4.1 The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 set out the legislative basis and the full HWB requirements for developing and updating PNAs (and the responsibility of NHS England in relation to market entry).

4.2 In summary, the HWB responsibilities are to:

- **Publish its first PNA by 1 April 2015**
  The Regulations set out the minimum information which must be included within the PNA; the matters which must be considered when making the assessment; and the process to be followed (including a formal consultation with specified stakeholders for a minimum of 60 days) in the preparation of the PNA. In the interim period, the PNA published by a HWB's former PCT(s) will be used, by NHS England, to inform market entry decisions.

- **Maintain and keep the PNA up-to-date**
  In response to changes in the availability of pharmaceutical services, there is a requirement for the HWB to determine whether or not it needs to revise the PNA or, where this is thought to be a disproportionate response, to issue a supplementary statement setting out the change(s). As a minimum, a new PNA must be published every 3 years.

- In addition, the HWB is required to keep up-to-date a map of provision of NHS Pharmaceutical Services within its area.

By way of example:
If a change in pharmaceutical services is sufficient to impact upon the granting of an application (eg closure of the only pharmacy in a deprived area) by NHS England, then the HWB may determine that it should revise its PNA and issue a supplementary statement. If, however, the change is relatively minor, eg relocation of an existing premise from one side of a street to another, the HWB may determine that it would be disproportionate to revise the PNA and just issue a Supplementary statement.

Where a change generally does not have a material impact upon the granting of applications eg a change in the trading name of a pharmacy, then the HWB is under no obligation to issue a

supplementary statement. However, it may choose to do so as this provides a useful mechanism to keep local stakeholders up-to-date with such changes.

The HWB should update the map of pharmaceutical premises for all the above changes.

Bristol's current PNA is available at : http://www.bristol.nhs.uk/about-us/publications/pharmaceutical-needs-pna.aspx.

5. Who needs to be involved?

- Health and Wellbeing Boards: Governance: absolute duty lies with HWB. Responsibility to develop, maintain and use the PNA; opportunity to use needs assessment approach to identify opportunities for PH community pharmacy services

- NHS Area Teams (ATs) : ATs hold the contracts. ATs know the regulations. ATs have a vested interest in the PNA being as accurate and fit for purpose as possible.

- LPCs: Local Pharmaceutical Committees who know their contractors

6. What the HWB needs to do now with respect to existing (inherited) PNA

- HWB MUST (duty) ensure that NHS England AT has access to:
  - The PNA(s) that it inherited from a Primary Care Trust (PCT)
  - Any supplementary statement that it publishes in relation to a PCT's PNA

- Must also ensure that other HWBs and potential applicants have access to the PCT's PNA it holds

- Must be regularly reviewing the current PNA (and, in the future, its successors), identifying changes and acting according to the regulation statement:

    - To do this there may be a backlog of information from the NHS England Area Team to be collected
    - HWB must develop a process for identifying changes to the need for pharmaceutical services
    - Decide whether these are of a *significant* extent
    - Decide whether revision is necessary
    - Decide who makes these decisions (HWB, Steering Group; an officer?)
    - Default position is a complete re-write of the PNA unless to do so is considered a "disproportionate response"

- Consider risk assessing current PNA against the regulations

7. Governance and Process

7.1 It is recognised that a new PNA will take at least 12 months to develop. Putting in place arrangements for its development needs to start now.

It is recommended that the Health and Wellbeing Board:

(i) Appoints a Board member who is responsible and has overall accountability for ensuring it meets all the duties. This needs to happen straight away. This person would also have responsibility for PNA maintenance. It is envisaged that a framework will set out the tasks which the nominated officer will undertake without referring back to the HWB for decision. This would also involve deciding whether a supplementary statement is to be issued and who signs it. Many other local authorities have placed this role with the Director of Public Health.

(ii) Establishes a PNA Steering Group to co-ordinate the production of the PNA (See below).

(iii) Seeks assurance that resources are available to fund this process. Most recent advice puts this cost at approximately £60,000.

(iv) Identifies the required capacity to progress this work

(v) Adds the development of the PNA to the appropriate risk register

7.2 PNA Steering Group – Proposed membership

A steering group would require representation from the following organisations.

- Local pharmaceutical committee (LPC)
- Local medical committee (LMC) (particularly if dispensing doctors are involved; but even if not, LMC is a consultee under legislation)
- Medicines management (Clinical Commissioning Group)
- Contracting and commissioning (NHS England Area Teams)
- Public health (particularly to address: needs assessment; PH community pharmacy service commissioning)
- Community pharmacy adviser (someone who knows pharmacies – could be LPM member)
- Lay representation/Patient and Public Involvement Lead
- CCG (as they commission some of the services)

7.3 Terms of Reference for the Steering Group need to be prepared (bearing in mind this sub-committee has responsibility for a) producing the PNA and b) its constant review) and a programme of dates created. An outline project timeline will need to be produced. Reporting arrangements to the Health and Wellbeing Board need to be agreed. Details of this delegated activity need to be formally minuted by the Health and Wellbeing Board.

8. Options for delivering the PNA work programme

8.1 Based on the experience of previous production of a PNA, it is known that the size of the task with respect to developing and maintaining the PNA is significant and will require

dedicated resource and specialist subject matter expertise to inform decision making.

8.2 External consultants

The whole process could be outsourced to a commercial company (contractor). This would NOT include determining local health needs and priorities which must be locally owned.

Experience of using such companies has been mixed. Costs for such a service to develop a PNA was quoted to be around £50,000. (The DH estimate of cost to the organisation is £61,000)

If this option was favoured, the need to **maintain** the PNA with in-house resource would remain.

8.3 Dedicated project manager

This would need to be someone with demonstrable large-scale project skills and could either be identified from the current workforce or a dedicated, time-limited, post created. Again, the need to maintain the PNA would still be required beyond the time span of a dedicated time-limited post.

8.4 A BNSSG Approach (Bristol, North Somerset, South Gloucestershire)

Colleagues in neighbouring authorities are exploring the possibility of collaboration in a framework approach to the PNA. There are strengths and weaknesses with this approach as it has the potential to slow the process down but would benefit from a consistent approach and possible economies of scale.

NHS England Area Team may not have the capacity to collaborate with four individual project managers and would potentially favour a collaborative approach.

9. Key risks and Opportunities

Risks

There are certain risks attached to the PNA process which need managing and mitigating against. These include:

Failure to:

– keep the PNA under review
– follow a fair, unbiased process
– have regard to the relevant information
– include required information
– consult

Possible legal challenges

There is potential for legal challenges associated with the PNA. These include direct challenge to the local authority (as the legal entity) for failure to meet duties by:

– those consulted on a draft of the PNA
– contractors who believe they are affected by what the PNA does or does not say

If NHS England refuses an application, the applicant can appeal to the Family Health Services Appeal Unit (FHSAU). Grounds for the appeal cannot challenge the legality or reasonableness of the PNA or the fairness of the process by which it was produced. The only option would be to take the matter through the courts – and if the FHSAU found the PNA to be deficient (including the current one), the HWB is liable (currently untested in law).

10. Recommendations

That the Director of Public Health is delegated by the Health and Wellbeing Board to put in place appropriate governance for the development of the PNA.

The exact details of the governance and approach will be dependent on discussions with colleagues in the BNSSG area and

with the NHS Area Team. Discussions will take place very quickly to establish the most appropriate way forward.

The DPH to report back to the Health and Wellbeing Board when the governance is established and agreement on the approach has been made.

11. Appendices

Appendix A: Overview of Regulatory Framework

Appendix B: Timeline

APPENDIX (10) A

Overview of the Regulatory Framework

The provision of NHS Pharmaceutical Services is a controlled market. Any pharmacist, dispenser of appliances or, in some circumstances (eg rural areas) a GP who wishes to provide NHS Pharmaceutical Services must be on an NHS pharmaceutical list.

The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Amend-ment) Regulations 2010 placed each PCT under a duty to prepare and publish a PNA by 1 February 2011. The Regulations also required PCTs to maintain and update the document, to reflect changes in the availability of pharmaceutical services. This was either through a system of issuing supplementary statements or full review, depending on the nature of the changes. This requirement, originally placed upon PCTs, was introduced in preparation for a planned change in the arrangements for managing the NHS Pharmaceutical services market.

In September 2012, the NHS (Pharmaceutical Services) Regulations 2012 came into effect. These regulations set out the new system of market entry (which replaced the old control of entry system), whereby applications to open new pharmacies, move existing premises or to provide additional pharmaceutical services must be considered against the PNA for the area in which the application relates. Under these Regulations, PCTs were responsible for both the PNA and market entry decisions.

The Health and Social Care Act 2012 transferred the statutory responsibility for the development and updating of Pharmaceutical Needs Assessments (PNAs), from NHS Primary Care Trusts (PCTs), to Health and Wellbeing Boards with effect from the 1 April 2013. At the same time, the National Commissioning Board (now referred to as NHS England) became responsible for maintaining NHS Pharmaceutical Lists and market entry decisions.

‘Pharmaceutical services’ are defined within the National Health Service Act 2006; only NHS England can commission pharmaceutical services. For the purposes of the PNA they are:

- Essential services – all pharmacies must provide these. This includes dispensing medicines and appliances, providing prescription-linked healthy lifestyle advice, disposal of unwanted medicines, support for self-care and signposting. This also includes Public Health campaigns. NHS England must participate in six per year, negotiated with Public Health.
- Advanced services – pharmacies can choose to provide all or some upon accreditation. These include targeted Medicine Use Reviews (MURs), Appliance Use Reviews (AURs) and the New Medicine Service (NMS) to support patients with long-term conditions who are prescribed new medicines, and the provision of stoma and medical equipment.

- Enhanced services: such as services to care homes, disease-specific medicines management and minor ailment services. Only NHS England can commission these; should councils decide to commission similar services from community pharmacies, they will need to contract directly with the pharmacy. Public health services commissioned by councils will not be part of NHS pharmaceutical services but will require council contracts with their own monitoring and governance arrangements, as for other providers.

APPENDIX (10) B

Timeline

The timetable of meeting dates for 2014/15 Municipal Year have not yet been set. This timeline is therefore provisional, based on the current year.

December 2013	Discussion within sub region on options for collaboration
December – January 2014	Establishment of Steering Group
January 2014	Agreement on approach to be taken and arrangements put in place to progress the work
February 2014	Report back on arrangements to the Health and Wellbeing Board
October – December 2014	Formal 60 day consultation period
February 2015	Approval of the PNA