Appendix 1: Legal requirements for PNAs

This section contains an extract from The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Please note that the HWB takes no responsibility for the accuracy of the extract. The full text of the Regulations is available at: http://www.legislation.gov.uk/uksi/2013/349/contents/made

1. These regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and came into force on 1st April 2013.

2. Interpretation *(long – see website)*

3. Pharmaceutical needs assessment

(1) The statement of the needs for pharmaceutical services which each HWB is required to publish by virtue of section 128A of the 2006 Act(1) (pharmaceutical needs assessments), whether it is the statement of its first assessment or of any revised assessment, is referred to in these Regulations as a "pharmaceutical needs assessment".

(2) The pharmaceutical services the PNA must cover are all the pharmaceutical services that may be provided under arrangements made by the NHSCB for:

a. the provision of pharmaceutical services (including directed services) by a person on a pharmaceutical list;
b. the provision of local pharmaceutical services under an LPS scheme (but not LP services which are not local pharmaceutical services); or
c. the dispensing of drugs and appliances by a person on a dispensing doctors list (but not other NSH services that may be provided under arrangements made by the NHSCB with a dispensing doctor)

4. Information to be contained in PNA

(1) Each pharmaceutical needs assessment must contain the information set out in Schedule 1.
(2) Each HWB must, in so far as is practicable, keep up to date the map which it includes in its pharmaceutical needs assessment pursuant to paragraph 7 of Schedule 1 (without needing to republish the whole of the assessment or publish a supplementary statement)

5. Date by which the first HWB PNAs are to be published

Each HWB must publish its first PNA by 1st April 2015.

6. Subsequent assessments

(1) After it has published its first PNA, each HWB must publish a statement of its revised assessment within three years of its previous publication of a pharmaceutical needs assessment.
(2) A HWB must make a revised assessment as soon as is reasonably practicable after identifying changes since the previous assessment, which are of a significant extent, to the need for pharmaceutical services in its area, having regard in particular changes to –
a) the number of people in its area who require pharmaceutical services;
b) the demography of its area; and
c) the risks to the health or wellbeing of people in its area,
unless it is satisfied that making a revised assessment would be a disproportionate response.

(3) *Pending the publication of a statement or a revised assessment, a HWB may publish a supplementary statement explaining changes to the availability of pharmaceutical services (..) where –*

a) *the changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or(ii) of the 2006 Act; and*

b) *the HWB –*

(i) *is satisfied that making its first or revised assessment would be a disproportionate response to those changes, or*

(ii) *is in the course of making its first or revised assessment and is satisfied that immediate notification of its PNA is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.*

7. Temporary extension of PCT PNAs and access by the NHSCB and HWBs to PNAs

Before the publication by an HWB of the first PNA that it prepares for its area, the PNA that relates to any locality within that area is the PNA that relates to that locality of the PCT for that locality immediately before the appointed day, read with

a) *any supplementary statement published by the PCT (..)*
b) *any supplementary statement published by the HWB (..)*

Each HWB must ensure that the NHSCB has access to –

a) *the HWB's PNA (including any supplementary statements) (..)*
b) *any supplementary statement that the HWB publishes (..)*
c) *any PNA of a PCT that it holds, which is sufficient to enable the NHSCB to carry out its functions under these Regulations*

Each HWB must ensure that, as necessary, other HWBs have access to any PNAs of any PCT that it holds, which is sufficient to enable the other HWBs to carry out their functions under these Regulations.

8. Consultation on PNAs

(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each HWB (HWB1) must consult the following about the contents of the assessment it is making—

(a) any Local Pharmaceutical Committee for its area (including any Local Pharmaceutical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);

(b) any Local Medical Committee for its area (including any Local Medical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);

(c) any persons on the pharmaceutical lists and any dispensing doctors list for its area;

(d) any LPS chemist in its area with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services;

(e) any Local Healthwatch organisation for its area, and any other patient, consumer or community group in its area which in the opinion of HWB1 has an interest in the provision of pharmaceutical services in its area; and

(f) any NHS trust or NHS foundation trust in its area;

(g) the NHSCB; and

(h) any neighbouring HWB.

(2) The persons mentioned in paragraph (1) must together be consulted at least once during the process of making the assessment on a draft of the proposed pharmaceutical needs assessment.

(3) Where a HWB is consulted on a draft under paragraph (2), if there is a Local Pharmaceutical Committee or Local Medical Committee for its area or part of its area that is different to a Local Pharmaceutical Committee or Local Medical Committee consulted under paragraph (1)(a) or (b), that HWB—

(a) must consult that Committee before making its response to the consultation; and

(b) must have regard to any representations received from the Committee when making its response to the consultation.

(4) The persons consulted on the draft under paragraph (2) must be given a minimum period of 60 days for making their response to the consultation, beginning with the day by which all those persons have been served with the draft.

(5) For the purposes of paragraph (4), a person is to be treated as served with a draft if that person is notified by HWB1 of the address of a website on which the draft is available and is to remain available (except due to accident or unforeseen circumstances) throughout the period for making responses to the consultation.

(6) If a person consulted on a draft under paragraph (2)—

(a) is treated as served with the draft by virtue of paragraph (5); or

(b) has been served with copy of the draft in an electronic form, but requests a copy of the draft in hard copy form, HWB1 must as soon as is practicable and in any event within 14 days supply a hard copy of the draft to that person (free of charge).

9. Matters for consideration when making assessments

(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each HWB must have regard, in so far as it is practicable to do so, to the following matters—

(a) the demography of its area;

(b) whether in its area there is sufficient choice with regard to obtaining pharmaceutical services;

(c) any different needs of different localities within its area;

(d) the pharmaceutical services provided in the area of any neighbouring HWB which affect—

> *(i) the need for pharmaceutical services in its area, or*
>
> *(ii) 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*

(e) any other NHS services provided in or outside its area (which are not covered by subparagraph

(d)) which affect—

> *(i) the need for pharmaceutical services in its area, or*

(ii) 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.

(2) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each HWB must take account of likely future needs—

(a) to the extent necessary to make a proper assessment of the matters mentioned in paragraphs 2 and 4 of Schedule 1; and

(b) having regard to likely changes to—

(i) the number of people in its area who require pharmaceutical services,

(ii) the demography of its area, and

(iii) the risks to the health or wellbeing of people in its area.

SCHEDULE 1 Regulation 4(1)

Information to be contained in pharmaceutical needs assessments

Necessary services: current provision

1. *A statement of the pharmaceutical services that the HWB has identified as services that are provided—*

(a) in the area of the HWB and which are necessary to meet the need for pharmaceutical services in its area; and

(b) 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).

Necessary services: gaps in provision

2. *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—*

(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;

(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.

Other relevant services: current provision

3. *A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are provided—*

(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;

(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;

(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.

Improvements and better access: gaps in provision

4. *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—*

(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 specified type, in its area,

(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.

Other NHS services

5. *A statement of any NHS services provided or arranged by a local authority, the NHSCB, a CCG, an NHS trust or an NHS foundation trust to which the HWB has had regard in its assessment, which affect—*

(a) the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area; or

(b) 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.

How the assessment was carried out

6. *An explanation of how the assessment has been carried out, and in particular—*

(a) how it has determined what are the localities in its area;

(b) how it has taken into account (where applicable)—

(i) the different needs of different localities in its area, and

(ii) the different needs of people in its area who share a protected characteristic; and

(c) a report on the consultation that it has undertaken.

Map of provision

7. *A map that identifies the premises at which pharmaceutical services are provided in the area of the HWB.*