
STATUTORY INSTRUMENTS

2013 No. 349

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

PART 2

Pharmaceutical needs assessments

Pharmaceutical needs assessments

3.—(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 ^{M1} (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 to which each pharmaceutical needs assessment must relate 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 NHS services that may be provided under arrangements made by the NHSCB with a dispensing doctor).

Marginal Citations

M1 Inserted by the [Health Act 2009 \(c. 21\), section 25](#).

Information to be contained in pharmaceutical needs assessments

4.—(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).

Date by which the first HWB pharmaceutical needs assessments are to be published

5. Each HWB must publish its first pharmaceutical needs assessment by 1st April 2015.

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Subsequent assessments [^{F1}and later first assessments]

6.—^{F2}(A1) [^{F3}Subject to paragraph (A3),] any HWB that has not published a pharmaceutical needs assessment before 1st July 2020 must publish its first pharmaceutical needs assessment by ^{F4}1st October] 2022.

(A2) Any HWB that has published a pharmaceutical needs assessment before 1st July 2020 must publish a revised assessment by ^{F5}1st October] 2022 (but it is not required to publish a revised assessment before that date).]

^{F6}(A3) Any HWB established on or after 1st January 2022 must publish its first pharmaceutical needs assessment no later than twelve months after it is established.]

(1) ^{F7}Subject to paragraph (2), after it has published its first assessment as required by paragraph (A1) or (A3), or a revised assessment as required by paragraph (A2) or (2),] each HWB must publish a statement of its revised assessment within 3 years of its previous publication of a pharmaceutical needs assessment.

(2) ^{F8}Each HWB that has published a pharmaceutical needs assessment] 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 to 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 well-being of people in its area,

unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

(3) Pending the publication of a statement of a revised assessment, a HWB may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its or a Primary Care Trust's pharmaceutical needs assessment (and any such supplementary statement becomes part of that assessment), 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 a revised assessment would be a disproportionate response to those changes, or
 - (ii) is in the course of making its first or a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.

^{F9}(3A) Pending the publication of a first pharmaceutical needs assessment under paragraph (A1) or (A3), a HWB (“HWB1”) may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of a pharmaceutical needs assessment by another HWB (“HWB2”) prior to the establishment of HWB1, 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 in respect of premises in a locality in the area of HWB1 that was, prior to HWB1’s establishment, in the area of HWB2; and
- (b) HWB1 is in the course of making its first pharmaceutical needs assessment and is satisfied that immediate modification of HWB2’s assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in that locality in the area of HWB1.]

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

[^{F10}(4) Where chemist premises are removed from a pharmaceutical list as a consequence of the grant of a consolidation application, if in the opinion of the relevant HWB the removal does not create a gap in pharmaceutical services provision that could be met by a routine application—

- (a) to meet a current or future need for pharmaceutical services; or
- (b) to secure improvements, or better access, to pharmaceutical services,

the relevant HWB must publish a supplementary statement explaining that, in its view, the removal does not create such a gap, and any such statement becomes part of its pharmaceutical needs assessment.]

F1	Words in reg. 6 heading inserted (14.9.2020) by The National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/885), regs. 1(2), 4(2)
F2	Reg. 6(A1)(A2) inserted (14.9.2020) by The National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/885), regs. 1(2), 4(2)(a)
F3	Words in reg. 6(A1) inserted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(2)(a)
F4	Words in reg. 6(A1) substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(2)(b)
F5	Words in reg. 6(A2) substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(3)
F6	Reg. 6(A3) inserted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(4)
F7	Words in reg. 6(1) substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(5)
F8	Words in reg. 6(2) substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(6)
F9	Reg. 6(3A) inserted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 3(7)
F10	Reg. 6(4) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), 3

Temporary extension of [^{F11}earlier] pharmaceutical needs assessments and access by the NHSCB and HWBs to pharmaceutical needs assessments

7.—^{F12}(1)

[^{F13}(1A) Prior to the publication by a HWB (“HWB1”) of the first pharmaceutical needs assessment that it prepares for its area, as required by regulation 6(A1) or (A3), the pharmaceutical needs assessment that relates to any locality within its area is the pharmaceutical needs assessment of the HWB (“HWB2”) for that locality prior to the establishment of HWB1, read with—

- (a) any supplementary statement relating to that assessment published by HWB2 under regulation 6(3) (which has become part of that assessment); and

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- (b) any supplementary statement relating to that assessment published by HWB1 under regulation 6(3A).]
- (2) Each HWB must ensure that the NHSCB has access to—
- (a) the HWB's pharmaceutical needs assessment (including any supplementary statement that it publishes, in accordance with regulation 6(3), that becomes part of that assessment);
 - (b) any supplementary statement that the HWB publishes, in accordance with regulation [F14]6(3A), in relation to another HWB's] pharmaceutical needs assessment; and
 - (c) any pharmaceutical needs assessment of a Primary Care Trust that it holds,
- which is sufficient to enable the NHSCB to carry out its functions under these Regulations.
- (3) Each HWB must ensure that, as necessary, other HWBs have access to any pharmaceutical needs assessment of a Primary Care Trust that it holds, which is sufficient to enable the other HWBs to carry out their functions under these Regulations.

- | | |
|------------|---|
| F11 | Word in reg. 7 heading substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346) , regs. 1(2)(b), 4(2) |
| F12 | Reg. 7(1) omitted (1.1.2022) by virtue of The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346) , regs. 1(2)(b), 4(3) |
| F13 | Reg. 7(1A) inserted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346) , regs. 1(2)(b), 4(4) |
| F14 | Words in reg. 7(2)(b) substituted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346) , regs. 1(2)(b), 4(5) |

Consultation on pharmaceutical needs assessments

8.—(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).

Matters for consideration when making assessments

9.—(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 sub-paragraph (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,

Changes to legislation: *There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)*

- (ii) the demography of its area, and
- (iii) the risks to the health or well-being of people in its area.

Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

- blanket amendment words substituted by [S.I. 2023/1071 Sch. para. 1](#)