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STATUTORY INSTRUMENTS

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**2012 No. 1909**

**The National Health Service  
(Pharmaceutical Services) Regulations 2012**

**PART 2**

**Pharmaceutical needs assessments**

**Pharmaceutical needs assessments**

**3.**—(1) The statement of the needs for pharmaceutical services which each Primary Care Trust is required to publish by virtue of section 128A of the 2006 Act<sup>(1)</sup> (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 a Primary Care Trust 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 a Primary Care Trust with a dispensing doctor).

**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 Primary Care Trust 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 pharmaceutical needs assessment is to be published**

**5.** Each Primary Care Trust established—

- (a) on or after the appointed day; or
- (b) on a day that is less than 10 months before the appointed day,

must publish its first pharmaceutical needs assessment within 10 months of the date on which its PCT order comes into force (if it has not already done so).

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(1) Inserted by the Health Act 2009 (c. 21), section 25.

### Subsequent assessments

6.—(1) After it has published its first pharmaceutical needs assessment, each Primary Care Trust must publish a statement of its revised assessment—

- (a) within 10 months of the coming into force of any order under section 18 of the 2006 Act (Primary Care Trusts) varying its area that—
  - (i) comes into force on or after the appointed day, or
  - (ii) came into force on a day that is less than 10 months before the appointed day (if it has not already done so); or
- (b) within 3 years of its previous publication of a pharmaceutical needs assessment (whether under these Regulations or the 2005 Regulations).

(2) A Primary Care Trust must make a revised assessment as soon as is reasonably practicable after identifying changes since the publication of its pharmaceutical needs assessment which are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act<sup>(2)</sup> (regulations as to pharmaceutical services), 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 Primary Care Trust may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its 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 Primary Care Trust—
  - (i) is satisfied that making a revised assessment would be a disproportionate response to those changes, or
  - (ii) is in the course of making 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.

### Temporary extension of pharmaceutical needs assessments

7. As regards any locality, if—

- (a) the Primary Care Trust for that locality—
  - (i) has changed as a result of the coming into force of a PCT order (whether that Order establishes a new Primary Care Trust or varies the area of a Primary Care Trust), and
  - (ii) has not published a pharmaceutical needs assessment that relates to that locality; and
- (b) a pharmaceutical needs assessment which relates to that locality was published by a Primary Care Trust that was the Primary Care Trust for that locality before the coming into force of that PCT order,

pending the publication of a pharmaceutical needs assessment that relates to that locality by its (new) Primary Care Trust, the pharmaceutical needs assessment that relates to that locality is the pharmaceutical needs assessment mentioned in paragraph (b) (read with any supplementary statement relating to that assessment published under regulation 6(3)).

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(2) Section 129(2) has been amended by the Health Act 2009 (c. 21), section 26(2).

### **Consultation on pharmaceutical needs assessments**

8.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Primary Care Trust (PCT1) must consult the following about the contents of the assessment it is making—

- (a) any Local Pharmaceutical Committee for its area (including a Local Pharmaceutical Committee for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including a Local Medical Committee for its area and that of one or more other Primary Care Trusts);
- (c) the persons on its pharmaceutical lists and its dispensing doctors list (if it has one);
- (d) any LPS chemist with whom PCT1 has made arrangements for the provision of any local pharmaceutical services;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has an interest in the provision of pharmaceutical services in its area;
- (f) any local authority with which PCT1 is or has been a partner PCT;
- (g) any NHS trust or NHS foundation trust in its area; and
- (h) any neighbouring Primary Care Trust.

(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 Primary Care Trust is consulted on a draft under paragraph (2), if there is a Local Pharmaceutical Committee or Local Medical Committee for its area that is different to the Local Pharmaceutical Committee or Local Medical Committee consulted under paragraph (1)(a) or (b), the Primary Care Trust—

- (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 PCT1 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, PCT1 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 Primary Care Trust must have regard, in so far as it is practicable to do so, to the following matters—

- (a) any assessment or further assessment of relevant needs prepared under section 116 of the Local Government and Public Involvement in Health Act 2007<sup>(3)</sup> (health and social care: joint strategic needs assessments)—
    - (i) in the preparation of which the Primary Care Trust—
      - (aa) was a partner PCT, or
      - (bb) was not a partner PCT but the assessment nevertheless related to its area, and
    - (ii) which has not been superseded by a further assessment under that section;
  - (b) the outcome, in relation to the making of the assessment, of its compliance with its duties under Chapter 1 of Part 11 of the Equality Act 2010<sup>(4)</sup> (public sector equality duty);
  - (c) the demography of its area;
  - (d) the benefits from having a reasonable choice with regard to obtaining pharmaceutical services;
  - (e) any different needs of different localities within its area;
  - (f) the pharmaceutical services provided under arrangements with any neighbouring Primary Care Trust 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 to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area; and
  - (g) any other NHS services provided in or outside its area (which are not covered by subparagraph (f)) 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 to 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 Primary Care Trust 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 with regard to the people who share a protected characteristic, and
    - (iii) the risks to the health or well-being of people in its area, including particular risks to the health or well-being of people in its area who share a protected characteristic.

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<sup>(3)</sup> 2007 c.28.

<sup>(4)</sup> 2010 c. 15.