

2010 No. 914

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical Services and
Local Pharmaceutical Services) (Amendment) Regulations 2010**

<i>Made</i>	- - - -	<i>21st March 2010</i>
<i>Laid before Parliament</i>		<i>26th March 2010</i>
<i>Coming into force</i>	- -	<i>24th May 2010</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 128A, 272(7) and (8) and 275(1) of the National Health Service Act 2006(a).

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010 and come into force on 24th May 2010.

Amendment of the National Health Service (Pharmaceutical Services) Regulations 2005

2. The National Health Service (Pharmaceutical Services) Regulations 2005(b) are amended in accordance with regulations 3 to 10.

Amendment of regulation 2

3. In regulation 2(c) (interpretation), in paragraph (1)—

- (a) in the definition of “FHSAA”, after “the Act” insert “and abolished on 18th January 2010 by article 3 of the Transfer of Tribunal Functions Order 2010(d) (abolition of tribunals)”;
- (b) in sub-paragraph (c) of the definition of “national disqualification”, for “is treated” substitute “was, before 18th January 2010, treated”;
- (c) for the definition of “pharmaceutical services” substitute the following definition—
 - ““pharmaceutical services” means—
 - (a) except in the context of Part 1A and Schedule 3A, pharmaceutical services other than directed services;
 - (b) in the context of Part 1A and Schedule 3A, the pharmaceutical services to which a pharmaceutical needs assessment must relate by virtue of regulation 3A(2);”;

(a) 2006 c.41; section 128A was inserted by the Health Act 2009 (c. 21), section 25. By virtue of section 271 of the 2006 Act, the powers conferred by section 128A are exercisable by the Secretary of State only in relation to England. Section 275(1) is cited for the definitions of “prescribed” and “regulations”.

(b) S.I. 2005/641.

(c) Amended by S.I. 2005/1501 and 3491, 2006/552, 562, 913, 1501 and 3373, 2007/289 and 674, 2008/528 and 2009/2205.

(d) S.I. 2010/22.

(d) insert the following definitions at the appropriate places—

““partner PCT” has the meaning given in section 116(9) of the Local Government and Public Involvement in Health Act 2007^(a) (health and social care: joint strategic needs assessments);” and

““pharmaceutical needs assessment” is to be construed in accordance with regulation 3A(1);”.

New Part 1A of the National Health Service (Pharmaceutical Services) Regulations 2005

4. After Part 1, insert the following Part—

“PART 1A

Pharmaceutical Needs Assessments

Pharmaceutical needs assessments

3A.—(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, 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) with 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 with 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

3B.—(1) Each pharmaceutical needs assessment must contain the information set out in Schedule 3A.

(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 8 of Schedule 3A (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

3C.—(1) Each Primary Care Trust established on or before 1st April 2010 must publish its first pharmaceutical needs assessment on or before 1st February 2011.

(2) Each Primary Care Trust established after 1st April 2010 must publish its first pharmaceutical needs assessment within 10 months of the date on which its PCT order comes into force.

(a) 2007 c.28.

Subsequent assessments

3D.—(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 varying its area; or
- (b) within 3 years of its previous publication of a pharmaceutical needs assessment.

(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, 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 detriment to the provision of pharmaceutical services in its area.

Temporary extension of pharmaceutical needs assessments

3E. 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 3D(3)).

Consultation

3F.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Primary Care Trust 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 formed 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 formed 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 the Primary Care Trust has made arrangements for the provision of any local pharmaceutical services;
- (e) any person with whom the Primary Care Trust has made arrangements for the provision of dispensing services;
- (f) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of the Primary Care Trust has an interest in the provision of pharmaceutical services in its area;
- (g) any local authority with which the Primary Care Trust is or has been a partner PCT;
- (h) any NHS trust or NHS foundation trust in its area; and
- (i) 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) 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.

(4) Where a Primary Care Trust is consulted under paragraph (2) on a draft of a proposed pharmaceutical needs assessment, 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.

Matters for consideration when making assessments

3G.—(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 (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 different needs of members of different groups in its area who share a common attribute in respect of any of the following matters—
 - (i) age,
 - (ii) disability,
 - (iii) gender,
 - (iv) proposed, commenced or completed reassignment of gender,
 - (v) race,
 - (vi) religion or belief, and
 - (vii) sexual orientation,

and the different needs of members of different groups that share a common attribute in respect of more than one of the matters specified in paragraphs (i) to (vii);

- (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 dispensing services or other NHS services provided in or outside its area (which are not covered by sub-paragraph (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 3A; and
- (b) having regard to likely changes to—
 - (i) the number of people in its area who will require pharmaceutical services,
 - (ii) the membership of the different groups in its area who share a common attribute in respect of one, or more than one, of the matters specified in paragraph (1)(b)(i) to (vii), and
 - (iii) the risks to the health or well-being of people in its area, or to particular risks to the health or well-being of members of different groups in its area who share a common attribute in respect of one, or more than one, of the matters specified in paragraph (1)(b)(i) to (vii).”.

Amendment of regulation 18 and its heading

5.—(1) In regulation 18(a) (which relates to refusal of outline consent and premises approval), in paragraph (1)(a), for from “locality and” to “reserved location;” substitute “locality;”.

(2) In the heading of regulation 18, omit “but not in a reserved location”.

Amendment of regulation 30

6. In regulation 30(b) (appeals against imposition of conditions and related decisions), in paragraph (3), for “FHSAA” substitute “First-tier Tribunal”.

Amendment of Schedule 1

7. In Schedule 1 (terms of service of pharmacists)—

(a) Amended, and its heading substituted, by S.I. 2005/1501.

(b) Amended by S.I. 2010/22.

- (a) in paragraph 34(a) (information to be supplied), in sub-paragraph (3A), for “4 to 7” substitute “4 to 8”; and
- (b) in paragraph 36(b) (charges for drugs and refunds), in sub-paragraph (4), for “on form FP57 0405 or FP57 0403” substitute “in such form and manner as the Secretary of State has determined for an application for such a repayment under regulation 10(2)(b) of the Charges Regulations(c)”.

Amendment of Schedule 3

8. In Schedule 3 (terms of service of suppliers of appliances)—

- (a) the paragraph 13A inserted by regulation 20 of the National Health Service (Pharmaceutical Services) (Appliances) (Amendment) Regulations 2009(d) (which relates to clinical governance) is renumbered as paragraph 13AA; and
- (b) in paragraph 21(e) (information to be supplied), in sub-paragraph (3A), for “4 to 7” substitute “4 to 8”.

New Schedule 3A

9. After Schedule 3, insert the following Schedule—

“SCHEDULE 3A

Information to be contained in pharmaceutical needs assessments

Necessary services: current provision

1. A statement of the pharmaceutical services that the Primary Care Trust has identified as services that are provided—

- (a) in the area of the Primary Care Trust and which are necessary to meet the need for pharmaceutical services in its area; and
- (b) outside the area of the Primary Care Trust but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the Primary Care Trust has identified such services).

Necessary services: gaps in provision

2. A statement of the pharmaceutical services that the Primary Care Trust has identified (if it has) as services that are not provided in the area of the Primary Care Trust but which the Primary Care Trust is satisfied—

- (a) need to be provided (whether or not they are located in the area of the Primary Care Trust) 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 Primary Care Trust) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

(a) Amended by S.I. 2006/3373 and 2009/2205.
 (b) Amended by S.I. 2005/1501.
 (c) Regulation 10 of those Regulations has been amended by S.I. 2000/3189, 2002/2352 and 2004/696.
 (d) S.I. 2009/3340.
 (e) Amended by S.I. 2006/3373 and 2009/2205.

Other relevant services: current provision

3. A statement of the pharmaceutical services that the Primary Care Trust has identified (if it has) as services that are provided—

- (a) in the area of the Primary Care Trust and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements to, or better access to, pharmaceutical services in its area;
- (b) outside the area of the Primary Care Trust and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements to, or better access to, pharmaceutical services in its area;
- (c) in or outside the area of the Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust has identified (if it has) as services that are not provided in the area of the Primary Care Trust but which the Primary Care Trust is satisfied—

- (a) would, if they were provided (whether or not they were located in the area of the Primary Care Trust), secure improvements to, 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 Primary Care Trust), secure future improvements to, or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Dispensing services

5. A statement of any dispensing services to which the Primary Care Trust 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 to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Other NHS services

6. A statement of any NHS services provided by the Primary Care Trust, another Primary Care Trust, an NHS trust or an NHS foundation trust to which the Primary Care Trust 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 to or better access to, pharmaceutical services, or pharmaceutical services of a specified type, in its area.

How the assessment was carried out

7. 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 members of different groups in its area that share a common attribute in respect of one, or more than one, of the matters specified in regulation 3G(1)(b)(i) to (vii); and
- (c) a report on the consultation that it has undertaken.

Map of provision

8. A map that identifies the premises at which pharmaceutical services and dispensing services are provided in the area of the PCT.”.

Amendment of Schedule 4

10. In Part 3 of Schedule 4(a) (information and undertakings to be given by an applicant in connection with an application for inclusion (or temporary inclusion) in a pharmaceutical list), in paragraph 8, for “name and address” substitute “name, address, date of birth and (where applicable) professional registration number”.

Amendments to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006

11. In the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(b)—
- (a) in regulation 2(c) (interpretation), in paragraph (1)—
 - (i) in the definition of “FHSAA”, after “Appeal Authority” insert “and abolished on 18th January 2010 by article 3 of the Transfer of Tribunal Functions Order 2010(d) (abolition of tribunals)”, and
 - (ii) in the definition of “national disqualification”, for “is treated” substitute “was, before 18th January 2010, treated”;
 - (b) in regulation 4(e) (designation of priority neighbourhoods or premises)—
 - (i) in paragraph (3), for “must designate” substitute “may designate”, and
 - (ii) in paragraph (4), for “A designation” substitute “Any designation made”; and
 - (c) in Schedule 2 (contract terms), in paragraph 18 (charges for drugs and refunds), for “on form FP57 0405 or FP57 0403” substitute “in such form and manner as the Secretary of State has determined for an application for such a repayment under regulation 10(2)(b) of the Charges Regulations”.

Signed by authority of the Secretary of State for Health

21st March 2010

Mike O'Brien
Minister of State,
Department of Health

(a) There are no relevant amending instruments.
 (b) S.I. 2006/552.
 (c) Amended by S.I. 2006/913 and 3373, 2007/674 and 2008/528 and 1700.
 (d) S.I. 2010/22.
 (e) Amended by S.I. 2008/528.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations insert into the National Health Service (Pharmaceutical Services) Regulations 2005 (“the 2005 Regulations”) new requirements relating to pharmaceutical needs assessments (“PNAs”). A PNA is a statement of the assessment each Primary Care Trust (“PCT”) must make, under section 128A(1) of the National Health Service Act 2006, of the needs in its area for pharmaceutical services provided as part of the National Health Service (“NHS”). In due course, PNAs will form the basis for decisions to grant applications for inclusion in a pharmaceutical list (listing is a prerequisite for a pharmacy business being allowed to provide services under the 2005 Regulations), and applications to change the pharmaceutical services that a listed pharmacy business provides or to change the premises from which a listed pharmacy business is allowed to provide them.

These Regulations also make some unrelated, minor amendments to the 2005 Regulations – and to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (“the 2006 Regulations”).

Regulation 3(b) and (c) inserts definitions into the 2005 Regulations that relate to the new PNA provisions, and regulation 4 inserts a new Part 1A into the 2005 Regulations. The new regulations in Part 1A include: a clarification of the services that are to be covered by PNAs (new regulation 3A); an obligation upon current PCTs to publish their first PNAs on or before 1st February 2011, and for new PCTs to publish their first PNAs within 10 months of establishment (new regulation 3C); and obligations relating to subsequent assessments, including provision for supplementary statements, in limited circumstances, pending full revision of a PNA (new regulation 3D). Because, in due course, every locality will need to be covered by a PNA in order for certain decisions relating to pharmaceutical list entries to be made, where a PCT is dissolved or its boundaries are changed and this means that a locality is no longer covered by a PNA produced by its PCT, provision is made so that the PNA produced by the previous PCT for the locality continues to have effect pending the production of a new or revised PNA by the locality’s new PCT (new regulation 3E). There are also consultation requirements that have to be fulfilled before each PNA is published (new regulation 3F) and provisions relating to a number of matters to which PCTs must have regard when producing their PNAs (new regulation 3G).

Regulation 9 inserts a new Schedule 3A into the 2005 Regulations, which sets out the information that must be included in PNAs. This includes statements of current provision and statements identifying both unmet needs in the PCT’s area for pharmaceutical services and gaps in current provision which, if filled, would secure improvements to, or better access to, pharmaceutical services. The PNA must also include an explanation of how the assessment was carried out – and a map identifying the premises at which pharmaceutical services and dispensing services (services similar to pharmaceutical services that are provided under contractual arrangements with GP practices) are provided in the area of the PCT. There is also provision for that map to be kept up to date (the new regulation 3B, which also introduces the new Schedule 3A).

The unrelated minor amendments are as follows. Regulations 3(a) and (b), 6 and 11(a) make modifications to the 2005 and 2006 Regulations which are consequential upon the abolition, on 18th January 2010, of the Family Health Service Appeals Authority. Regulation 5 amends the 2005 Regulations so that, as regards applications from doctors for outline consent or premises approval, the grounds for refusal given in regulation 18(2) of those Regulations apply in relation to all applications relating to controlled localities. Regulations 7(a), 8(b) and 10 amend the requirements relating to application forms and notification of information so that when details identifying directors and superintendents of bodies corporate need to be supplied, the information to be provided includes dates of birth and any professional registration numbers. Regulations 7(b) and 11(c) remove references from the 2005 and 2006 Regulations to two forms which are no longer in use but which were for claims for repayment of NHS charges. Regulation 8(a) corrects a numbering error in Schedule 1 to the 2005 Regulations. Regulation 11(b) amends regulation 4 of the 2006 Regulations, which is about the designation of priority neighbourhoods and premises, to make it clear that the scheme for designations under that regulation does not require a designation

to be in place in respect of all pharmacy premises from which local pharmaceutical services are, or are to be, provided.

An Impact Assessment has been prepared and can be obtained from www.dh.gov.uk. Copies are also available from the Department of Health, Skipton House, 80 London Road, London SE1 8LH.

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STATUTORY INSTRUMENTS

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The National Health Service (Pharmaceutical Services and
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£5.50