

2002 No. 888

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Local Pharmaceutical Services
and Pharmaceutical Services) Regulations 2002**

<i>Made</i> - - - -	<i>14th May 2002</i>
<i>Laid before Parliament</i>	<i>15th May 2002</i>
<i>Coming into force</i>	<i>5th June 2002</i>

The Secretary of State for Health, in exercise of the powers conferred on him by sections 41, 42 and 126(4) of the National Health Service Act 1977(a), and sections 28(8), 30, 34 and 65(1) of, and paragraph 1(2)(b) of Schedule 2 to, the Health and Social Care Act 2001(b), and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002 and shall come into force on 5th June 2002.

(2) These Regulations extend to England only(c).

(3) In these Regulations—

“the Act” means the Health and Social Care Act 2001;

“the approved pilot scheme” has the meaning given to it in regulation 8(2)(b);

“designation” means a designation made by a Health Authority under regulation 3(1);

“the principal Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992(d);

“the relevant date” has the meaning given to it in regulation 8(6); and

“the relevant pilot scheme” has the meaning given to it in regulation 3(3).

(4) In these Regulations—

(a) 1977 c.49; see section 128(1), as amended by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 26(2)(g) and (i); and by the Health Act 1999 (c.8) (“the 1999 Act”), Schedule 4, paragraph 38(2), for the definitions of “prescribed” and “regulations”. Section 41 was substituted by the Health and Social Care Act 2001 (c.15) (“the Act”), section 42(1). Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1); extended by the Health and Medicines Act 1988 (c.49), section 17; and amended by S.I. 1987/2202, article 4; by the 1990 Act, section 12(3); by the Health Authorities Act 1995 (c.17) (“the 1995 Act”), Schedule 1, paragraph 30; and by the Act, section 43(2), (3) and (4). Section 126(4) was amended by the 1990 Act, section 65(2); and by the 1999 Act, Schedule 4, paragraph 37(6).

(b) 2001 c.15.

(c) As regards Wales, the functions of the Secretary of State under sections 41 and 42 of the National Health Service Act 1977 (“the 1977 Act”) were transferred to the National Assembly for Wales under S.I. 1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66.

(d) S.I. 1992/662; the relevant amending instrument is S.I. 1998/681.

- (a) a reference to the approval of a pilot scheme^(a) is a reference to the approval of proposals for a pilot scheme by the Secretary of State under paragraph 3(1)(a) or (b) of Schedule 2 to the Act, and “approve” shall be construed accordingly;
- (b) a reference to the rejection of a pilot scheme is a reference to the rejection of proposals for a pilot scheme by the Secretary of State under paragraph 3(1)(c) or 4(3)(c) of Schedule 2 to the Act, and “reject” shall be construed accordingly;
- (c) a reference to a pilot scheme which has been varied is a reference to proposals for a pilot scheme which have been approved by the Secretary of State but subsequently varied (prior to implementation) with the agreement of the Secretary of State or, as the case may be, in a manner authorised by directions given by the Secretary of State under paragraph 7(3) of Schedule 2 to the Act;
- (d) a reference to the implementation of a pilot scheme is a reference to the implementation of proposals for a pilot scheme by a Health Authority in accordance with paragraph 7 of Schedule 2 to the Act (making a scheme), and “implement” shall be construed accordingly; and
- (e) (unless the context otherwise requires) any reference to a numbered regulation is a reference to the regulation bearing that number in these Regulations, and any reference in a regulation to a numbered paragraph is a reference to the paragraph bearing that number in that regulation.

Local pharmaceutical services

2. “Local pharmaceutical services” means services of a kind which may be provided under section 41 of the National Health Service Act 1977 or by virtue of section 41A^(b) of that Act, other than practitioner dispensing services^(c), and which are provided under a pilot scheme.

Designation of priority neighbourhoods or premises

3.—(1) Subject to the following provisions of this regulation, for the purposes of section 30 of the Act, a Health Authority may designate neighbourhoods, premises, or descriptions of premises.

- (2) Subject to regulation 6(4), a Health Authority may make a designation if it is—
 - (a) preparing proposals for a pilot scheme (whether for approval or for preliminary approval) or considering whether to prepare such proposals;
 - (b) awaiting the decision of the Secretary of State regarding proposals for a pilot scheme which it has submitted (whether for approval or for preliminary approval); or
 - (c) preparing to implement a pilot scheme which has been approved.

(3) A designation must designate the neighbourhood in which, or the premises or description of premises at which, piloted services^(d) are to be provided under proposals for a pilot scheme, or under a pilot scheme which has been approved; and such a pilot scheme is referred to below in these Regulations as “the relevant pilot scheme”.

- (4) A designation must—
 - (a) be made in writing and dated;
 - (b) include a map showing the location of the neighbourhood or premises that have been designated; and
 - (c) specify the relevant pilot scheme.
- (5) A Health Authority must give notice of a designation which it has made to—
 - (a) any Local Pharmaceutical Committee^(e) formed for the area of that Health Authority or of an affected Health Authority;

(a) “Pilot scheme” is defined in section 28(2) of the Act.

(b) Section 41A was inserted by the National Health Service (Primary Care) Act 1997 (c.46), section 27(1), and amended by the Act, section 43(1).

(c) “Practitioner dispensing services” are defined in section 28(9) of the Act.

(d) “Piloted services” are defined in section 28(5) of the Act.

(e) See section 44(1) of the 1977 Act, amended by the 1990 Act, section 12; the 1995 Act, section 2, Schedule 1, paragraphs 1 and 32; the 1999 Act, sections 11 and 65 and Schedule 5; the Health and Social Security Act 1984 (c.48), section 24 and Schedule 8; and the Act, section 43(6).

- (b) any Local Medical Committee^(a) formed for the area of that Health Authority or of an affected Health Authority;
 - (c) any person whose name is included in the pharmaceutical list of that Health Authority or of an affected Health Authority who, in the opinion of the Health Authority, might be affected by the designation;
 - (d) any person whose name is included in the dispensing doctor list of that Health Authority or of an affected Health Authority who, in the opinion of the Health Authority, might be affected by the designation; and
 - (e) any Community Health Council^(b) serving the area of that Health Authority or of an affected Health Authority.
- (6) A Health Authority must make available for inspection at its offices copies of all designations which it has made, including any variations of such designations.
- (7) In this regulation—
- (a) “preliminary approval” means approval by the Secretary of State under paragraph 4(3)(a) or (b) of Schedule 2 to the Act (preliminary approval of proposals);
 - (b) “affected Health Authority” means a Health Authority which must be consulted under paragraph 5(3) of Schedule 2 to the Act (effect of proposals on existing services);
 - (c) “pharmaceutical list” shall be construed in accordance with regulation 4 of the principal Regulations (pharmaceutical lists); and
 - (d) “dispensing doctor list” shall be construed in accordance with regulation 21B^(c) of the principal Regulations (dispensing doctor lists).

Variation of designations

- 4.—(1) A Health Authority may vary a designation which it has made if—
- (a) where the designation relates to a neighbourhood, the piloted services to be provided under the relevant pilot scheme are to be provided from a part only of that neighbourhood;
 - (b) where the designation relates to premises, the piloted services to be provided under the relevant pilot scheme are to be provided from a part only of that premises; or
 - (c) where the designation relates to a description of premises, the piloted services to be provided under the relevant pilot scheme are to be provided from certain only of the premises described.
- (2) A designation as varied must designate the neighbourhood, premises or description of premises as so changed, and must satisfy the conditions specified in regulation 3(4).
- (3) A Health Authority must give notice of a variation of a designation to those persons listed in regulation 3(5).

Reviews of designations

- 5.—(1) A Health Authority must regularly review a designation which it has made.
- (2) A Health Authority must conduct a review of a designation before the end of the period of six months beginning with the date of that designation or (as the case may be) the date of the last review of that designation.
- (3) When conducting a review of a designation, a Health Authority must take into account representations received from any person notified under regulation 3(5).
- (4) A Health Authority must notify those persons listed in regulation 3(5) of the outcome of a review of a designation.

Cancellation of designations

- 6.—(1) A Health Authority may at any time cancel a designation which it has made.
- (2) A Health Authority must cancel a designation which it has made—

(a) See section 44(A1) of the 1977 Act, inserted by the 1999 Act, section 11.

(b) See section 20 of the 1977 Act, amended by the 1995 Act, section 2 and Schedule 1, paragraphs 1 and 11.

(c) Regulation 21B was inserted by S.I. 1998/681.

- (a) if required to do so by a direction given by the Secretary of State under section 30(2)(d)(i) of the Act;
- (b) if, within a period of twelve months beginning with the date of a designation, proposals for the relevant pilot scheme have not been submitted to the Secretary of State for approval;
- (c) if the relevant pilot scheme has been rejected;
- (d) if there is a change to the neighbourhood in which, or the premises from which, piloted services are to be provided under the relevant pilot scheme, other than a change specified in regulation 4(1);
- (e) if, within a period of twelve months beginning with the date of the approval of the relevant pilot scheme, that scheme (or that scheme as varied) has not been implemented; or
- (f) upon implementation of the relevant pilot scheme (or that scheme as varied).

(3) A Health Authority must give notice of a cancellation of a designation to those persons listed in regulation 3(5).

(4) Where a Health Authority has cancelled a designation, it may not designate the same neighbourhood, premises or description of premises within a period of six months beginning with the date of the cancellation of the designation, except where the reason for the cancellation of the designation was the rejection of the relevant pilot scheme.

Requests to Health Authorities for preparation of proposals

7.—(1) A person who wishes to make a request must do so on the form supplied for that purpose by the Health Authority to which the request is to be made.

- (2) A Health Authority must, if asked to do so by any person who wishes to make a request—
 - (a) provide that person with a copy of any directions given by the Secretary of State under paragraph 2(3) and (5)(b) of Schedule 2 to the Act (directions as to proposals and recommendations); and
 - (b) specify the matters with which the request must deal and the information which it must include.

(3) Paragraph (4) applies in relation to a Health Authority only where the Secretary of State has, in directions, specified a date (or a number of dates) by which any proposals for a pilot scheme by that Health Authority are to be submitted to him under paragraph 2(1) of Schedule 2 to the Act (submission of proposals for pilot schemes).

(4) The Health Authority must, if asked to do so by any person who wishes to make a request, inform that person of all dates specified as mentioned in paragraph (3) which have not passed at the time the Health Authority is asked for the information.

(5) In this regulation, “request” means a request to a Health Authority under paragraph 1(1)(b) of Schedule 2 to the Act (request by a person wishing to participate in a pilot scheme).

Provision of financial assistance

8.—(1) A Health Authority may make payments of financial assistance for preparatory work within the meaning of section 34(2) of the Act.

(2) Subject to the provisions of this regulation, such payments may be made only following receipt by the Health Authority of a written application from a person (“the applicant”), who—

- (a) where the financial assistance is requested for preparatory work falling within section 34(2)(a) of the Act, wishes to provide piloted services; or
- (b) where the financial assistance is requested for preparatory work falling within section 34(2)(b) of the Act, is named as a proposed provider of piloted services in a pilot scheme which has been approved, or in that scheme as varied, and such a pilot scheme is referred to below in this regulation as “the approved pilot scheme”.

(3) Payments of financial assistance may be made under paragraph (1) only if the following conditions are all satisfied—

- (a) the applicant’s application specifies the purposes for which he intends to use the payment of financial assistance for which he has applied;
- (b) the Health Authority has notified the applicant in writing that it is willing to make a payment of financial assistance to him for the purposes so specified, and of the maximum amount of the payment which it is willing to make; and
- (c) the applicant has satisfied the Health Authority that—
 - (i) he has incurred costs which are not less than the amount of the payment of financial assistance for which he has applied, and
 - (ii) those costs were incurred before the relevant date, for the purposes specified in his application.

(4) Where two or more persons have together applied for financial assistance, payment may be made to any one of them on behalf of them all; but otherwise in such a case “the applicant” means all of them together.

(5) In relation to applications made by persons referred to in paragraph (2)(b), subject to any directions given by the Secretary of State under paragraph 7(1) of Schedule 2 to the Act as to implementation of proposals—

- (a) if the approved pilot scheme does not specify the date by which it is to be implemented, a Health Authority may give notification to an applicant under paragraph (3)(b) only if it has agreed with him the date by which it is to be implemented; but
- (b) where a Health Authority and the applicant have agreed a date by which the approved pilot scheme is to be implemented, they may, at any time before that date, agree a different date as the date by which it is to be implemented, in substitution for that date.

(6) In paragraph (3)(c)(ii) and in regulation 9(1), “the relevant date” means—

- (a) in relation to applications made by persons referred to in paragraph (2)(a), the date on which the Health Authority submits the proposals in question to the Secretary of State or, as the case may be, the date on which the Health Authority notifies the applicant that it does not intend to submit the proposals in question to the Secretary of State; or
- (b) in relation to applications made by persons referred to in paragraph (2)(b), whichever of the dates mentioned in heads (i) to (iii) occurs first—
 - (i) the date on which the approved pilot scheme is implemented,
 - (ii) the date on which the Health Authority receives notification from an applicant to whom it has given notification under paragraph (3)(b) in respect of the approved pilot scheme that he wishes to withdraw before that scheme is implemented^(a), or
 - (iii) the date specified in the approved pilot scheme or, as the case may be, for the time being agreed under paragraph (5) as the date by which the scheme is to be implemented.

Conditions on payment of financial assistance

9.—(1) Notwithstanding that the applicant has satisfied the Health Authority as mentioned in regulation 8(3)(c), the Health Authority must upon making a payment of financial assistance under regulation 8(1) also require all the costs in respect of which the payment is made to have been incurred before the relevant date and for the purposes specified in the application for that payment.

(2) An applicant receiving such a payment must comply with any conditions which the Health Authority may impose in writing in connection with that requirement.

(3) Where a Health Authority, despite having been satisfied as mentioned in regulation 8(3)(c), subsequently discovers that the applicant has not complied with any conditions imposed

(a) See paragraph 7(2) of Schedule 2 to the Act as to withdrawal by a proposed participant in a pilot scheme.

under paragraph (2) it may demand repayment of any part of the payment that was not properly incurred and the applicant shall forthwith repay the sum demanded.

Amendment of the principal Regulations

10.—(1) The principal Regulations are amended as follows.

(2) In regulation 4 (pharmaceutical lists)—

- (a) in paragraph (3), after “granted by the FHSA, subject,” insert “in a case falling within sub-paragraph (a) above, to regulation 6A, and”;
- (b) in paragraph (4), at the beginning insert “Subject to regulation 6A,”; and
- (c) in paragraph (10), after “the FHSA is satisfied that the change is a minor relocation, it may” insert “, subject to regulation 6A,”.

(3) In regulation 5 (notification of applications), in paragraph (1), at the beginning insert “Subject to regulation 6A,”.

(4) In regulation 6 (determination of applications), at the beginning of paragraphs (1), (2) and (7), insert “Subject to regulation 6A,”.

(5) After regulation 6 (determination of applications), insert—

“6A Deferral of consideration of certain applications

(1) Subject to paragraph (2), this regulation applies to—

- (a) an application under regulation 4(2);
- (b) an application under regulation 4(2) where the applicant has previously been granted preliminary consent, but where regulation 15(2) applies;
- (c) an application for preliminary consent under regulation 14; or
- (d) a notification under regulation 4(10),

relating to the provision of pharmaceutical services from premises (in the case of a notification under sub-paragraph (d) above, the changed premises) which are specified or described in a designation, or located within a neighbourhood specified in a designation.

(2) This regulation does not apply to—

- (a) an application under regulation 4(2) and to which regulation 4(3)(b) applies;
- (b) an application under regulation 4(2) where the applicant has previously been granted preliminary consent, and where all the conditions specified in regulation 15(1) are satisfied;
- (c) an application under regulation 14 and to which, by virtue of regulation 14(4), regulation 4(3)(b) applies;
- (d) an application or notification in respect of which a determination by the Health Authority has been made, where that determination is the subject of an appeal under regulation 8 or 13; or
- (e) an application or notification which was received by the Health Authority more than thirty days before the date of the designation mentioned in paragraph (1).

(3) A Health Authority may defer consideration or determination of an application or notification to which this regulation applies; but may no longer do so when the designation mentioned in paragraph (1) is cancelled (or varied in such a way that it no longer specifies or includes the premises in question).

(4) A Health Authority must, as soon as is practicable, notify the applicant of a decision to defer consideration or determination of his application or notification, and send him a copy of the designation mentioned in paragraph (1).

(5) In this regulation, “designation” means a designation made by a Health Authority under regulation 3(1) of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(a).”

(a) S.I. 2002/888.

(6) In regulation 11 (applications for inclusion in pharmaceutical lists in respect of controlled localities)—

- (a) in paragraph (2), after “Subject to paragraph (4)” insert “and regulation 6A”; and
- (b) in paragraph (3), at the beginning insert “Subject to regulation 6A,”.

(7) In regulation 12 (determination of applications in respect of controlled localities)—

- (a) at the beginning of paragraphs (1), (2), (2A), (5), (12) and (13), insert “Subject to regulation 6A,”; and
- (b) in paragraph (14), after “regulation 4(4)” insert “and regulation 6A”.

(8) In regulation 15 (effect of preliminary consent), in paragraph (1), after “Subject to” insert “regulation 6A and”.

Signed by authority of the Secretary of State for Health

14th May 2002

Hazel Blears
Parliamentary Under Secretary of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in connection with the establishment of pilot schemes for the provision of local pharmaceutical services under Chapter 1 of Part 2 of the Health and Social Care Act 2001.

Regulation 2 defines “local pharmaceutical services”. Regulation 3 allows a Health Authority to designate a neighbourhood or premises at which local pharmaceutical services are to be provided under a pilot scheme, and that regulation, together with regulations 4, 5 and 6, provides for the circumstances in which designations may or must be made, varied, reviewed or cancelled.

Regulation 10 amends the National Health Service (Pharmaceutical Services) Regulations 1992 to allow a Health Authority to defer consideration of certain applications to be included in a pharmaceutical list where the pharmaceutical services are to be provided from premises which are the subject of a designation.

Regulation 7 makes provision regarding the supply of information in connection with requests to a Health Authority by persons wishing to participate in a pilot scheme.

Regulation 8 allows a Health Authority to make a payment of financial assistance to a person who wishes to participate in a pilot scheme. Payments may be made in respect of work reasonably undertaken in connection with preparing proposals for a pilot scheme or, as the case may be, preparing for the provision of piloted services. An application for either type of financial assistance must specify the purposes for which the applicant intends to use the payment and payments may be made only in respect of costs which have been incurred for those purposes by the relevant date. Regulation 9 provides that a Health Authority may impose conditions designed to require a person who is given financial assistance to return all or part of the payment made, if it is subsequently discovered that costs were not in fact incurred by the relevant date or for the purposes specified in the application.

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