

**2002 No. 2016**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Local Pharmaceutical Services  
and Pharmaceutical Services) (No. 2) Regulations 2002**

<i>Made</i> - - - -	<i>31st July 2002</i>
<i>Laid before Parliament</i>	<i>31st July 2002</i>
<i>Coming into force</i>	<i>20th August 2002</i>

The Secretary of State for Health, in exercise of the powers conferred on him by sections 41, 42, 43 and 126(4) of the National Health Service Act 1977(a), and sections 33(3)(a), (7) and (9), 37(b), 41 and 65(1) of 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) (No. 2) Regulations 2002 and shall come into force on 20th August 2002.

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

(3) In these Regulations—

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

“local pharmaceutical services” have the meaning given in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(d);

“member”, in relation to a PHS body(e)—

(a) where the relevant pilot scheme(f) has not yet been implemented, means a person proposing to provide piloted services(g) under that scheme, and

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(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 43 was amended by the 1995 Act, Schedule 1, paragraph 31; by the Health Services Act 1980 (c.53); section 21(2); by the National Health Service (Primary Care) Act 1997 (c.46), section 29(1) and Schedule 2, paragraph 14; by the 1990 Act, Schedule 9, paragraph 18(2); and by the Act, section 42(2) and 43(5). 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, 42 and 43 of the National Health Service Act 1977 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. 2002/888.

(e) “PHS body” has the meaning given in section 33(5) and (6) of the Act.

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

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

(b) where the relevant pilot scheme has been implemented, is to be construed in accordance with section 33(7) of the Act;

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

“relevant Health Authority” means the Health Authority which is or is to be, a party to the relevant pilot scheme; and

“relevant pilot scheme” means the pilot scheme under which—

(a) those making an application to become a PHS body are to provide, or are providing, piloted services, or

(b) the members of the PHS body are to provide, or are providing, piloted services, as the case may be.

### **Applications to become a PHS body**

2.—(1) An application must be made in writing, and must include the name and address of each applicant.

(2) A copy of an application must be sent to the relevant Health Authority.

(3) The grant of an application does not affect the nature of, or any rights or liabilities arising under, any contract entered into by an applicant before the date on which the application comes into effect.

(4) In this regulation, “application” means an application under section 33 of the Act to become a PHS body in respect of a pilot scheme under which local pharmaceutical services are, or are to be, provided.

### **Ceasing to be a PHS body**

3.—(1) Subject to paragraphs (3) and (4), a PHS body shall cease to be such a body if all the members of the PHS body withdraw from the relevant pilot scheme before it has been implemented.

(2) Subject to paragraphs (3) and (4), where the relevant pilot scheme has been implemented, a PHS body shall cease to be such a body if—

(a) the relevant pilot scheme comes to an end (in circumstances other than those specified in sub-paragraph (b));

(b) the Secretary of State gives directions under section 32(3) of the Act relating to the relevant pilot scheme; or

(c) all the members of the PHS body agree in writing that that body is to cease to be such a body on a specified date, and they give notice in writing of their decision to the Secretary of State and the relevant Health Authority.

(3) Subject to paragraph (4), the date on which a PHS body ceases to be such a body is—

(a) in a case falling within paragraph (1), the date on which the last member of the PHS body withdraws from the relevant pilot scheme;

(b) in a case falling within paragraph (2)(a), the date on which the relevant pilot scheme comes to an end;

(c) in a case falling within paragraph (2)(b), the date on which the directions are given; and

(d) in a case falling within paragraph (2)(c), the date specified by the members of the PHS body.

(4) Where a PHS body ceases to be such a body under this regulation, it ceases to be such a body for all purposes except that of being a party to an NHS contract entered into on a date before

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(a) S.I. 1992/662; relevant amending instruments are S.I. 1996/698, 1998/681 and 1999/696.

that on which the PHS body ceases to be such a body (for which purpose it ceases to be such a body on the determination of that NHS contract).

(5) Where, by virtue of paragraph (4), a PHS body remains such a body for the purpose of being a party to an NHS contract—

- (a) if (on the date the PHS body ceases to be such a body for other purposes under this regulation) the relevant pilot scheme has been implemented, that body is to be treated as consisting of those who provided piloted services under that scheme on the date on which that body ceased (for all other purposes) to be a PHS body; and
- (b) if (on the date the PHS body ceases to be such a body for other purposes under this regulation) the relevant pilot scheme has not been implemented, that body is to be treated as consisting of those who proposed to provide piloted services under that scheme on the date on which that NHS contract was entered into.

(6) In this regulation, “NHS contract” has the meaning assigned by section 4(1) of the National Health Service and Community Care Act 1990(a).

### **Right of return to pharmaceutical lists**

4.—(1) Before the Secretary of State approves a pilot scheme under paragraph 3(1)(a) or (b) of Schedule 2 to the Act, he must determine whether a pilot scheme provider is to be given a right of return under regulation 8A of the principal Regulations if he makes an application for his name to be included in a Health Authority’s pharmaceutical list after ceasing to provide local pharmaceutical services under the scheme.

(2) Before a pilot scheme is varied so as to permit a new pilot scheme provider to provide local pharmaceutical services under the scheme, the Secretary of State must make a determination under this regulation in relation to the new pilot scheme provider.

(3) Before a pilot scheme is varied so as to permit the provision of local pharmaceutical services from different, or additional, premises, the Secretary of State must consider how such a change affects (if at all) a determination under this regulation, and may make a further determination varying a determination in consequence of such a change.

(4) The Secretary of State may at any time make a determination under this regulation varying a determination about a pilot scheme provider if he is asked to do so by the pilot scheme provider concerned.

(5) A determination under this regulation that a pilot scheme provider is to be given a right of return as described in paragraph (1) may be made subject to specified conditions.

(6) Before making any determination under this regulation, the Secretary of State must publish the principles by reference to which he will make it.

(7) Those principles may be—

- (a) principles applying generally to all determinations;
- (b) principles applying only to the pilot scheme in question; or
- (c) a mixture of both.

(8) The Secretary of State must notify the Health Authority and the pilot scheme provider or providers concerned in writing of any determination made by him under this regulation.

(9) Different determinations may be made with respect to different pilot scheme providers providing local pharmaceutical services under the same pilot scheme.

(10) A determination may identify the pilot scheme provider or providers to which it applies by name or in any other way.

(11) In this regulation—

“pharmaceutical list” shall be construed in accordance with regulation 4(b) of the principal Regulations (pharmaceutical lists); and

“pilot scheme provider” means a person providing, or proposing to provide, piloted services under a pilot scheme.

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(a) 1990 c.19.

(b) Regulation 4 was amended by S.I. 2002/888.

## **Amendment of the principal Regulations**

- 5.—(1) The principal Regulations are amended as follows.
- (2) In regulation 2 (interpretation), in the appropriate alphabetical position, insert—
- ““the 2001 Act” means the Health and Social Care Act 2001(a);”,
- ““local pharmaceutical services” have the meaning given in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(b);”, and
- ““pharmacy pilot scheme” has the same meaning as the term “pilot scheme” in section 28(2) of the 2001 Act”.
- (3) After regulation 8 (appeals), insert—

### **“Right of return to pharmaceutical lists**

**8A.**—(1) This regulation applies if the Secretary of State makes a determination under regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(c) that a person is to be given a right of return to a Health Authority’s pharmaceutical list on making an application for his name to be included in that list after ceasing to provide local pharmaceutical services under a pharmacy pilot scheme, and the conditions mentioned in paragraph (2) are satisfied.

- (2) The conditions are that—
- (a) the period of time between the cessation of provision of local pharmaceutical services by the applicant and the commencement of provision of pharmaceutical services by the applicant will be such that the provision of such services will be continuous (except for such period as the Health Authority may for good cause allow); and
- (b) the determination or determinations relevant to the application have not been invalidated by any subsequent determination, and that any conditions specified in the determination or determinations are satisfied.
- (3) A person making an application under this regulation for inclusion of his name in a pharmaceutical list must apply to the Health Authority in the form set out in Part I of Schedule 3 while he is still providing local pharmaceutical services under a pharmacy pilot scheme, and in addition he must—
- (a) make clear that the application is made by virtue of this regulation; and
- (b) attach copies of all determinations relevant to the application.
- (4) If a person has made an application in the manner described in paragraph (3) to a Health Authority for his name to be included in their pharmaceutical list, the Health Authority must grant the application.
- (5) Any conditions imposed by a Health Authority under regulation 9(7) or 12(15) (or by the Secretary of State under regulation 10(10)(b) or 13(13)(b)) which are still in force by virtue of regulation 12(15A)(d) shall be unaffected by the grant of an application under this regulation.
- (6) A Health Authority must, as soon as is practicable, give notice in writing of its decision on an application under this regulation to those persons or bodies listed in regulation 7(1)(a).
- (7) Where a Health Authority grants an application under this regulation, the applicant must be included in the relevant pharmaceutical list or lists only if, not less than 14 days before the expiry of six months after the date on which the grant was notified to him by the Health Authority in accordance with paragraph (6), he notifies the Health Authority, in the form set out in Part II of Schedule 3, that he will, within the next 14 days, commence the provision of the services in respect of which the application was made at the premises to which the application related.

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(a) 2001 c.15.

(b) S.I. 2002/888.

(c) S.I. 2002/2016.

(d) Paragraph (15A) of regulation 12 was inserted by S.I. 2002/2016.

(8) Where, at any time after making an application under this regulation, but before the expiry of the six months referred to in paragraph (7), the applicant notifies the Health Authority that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the Health Authority is satisfied that the change is a minor relocation, it may amend the premises named in the original application.

(9) For the purposes of paragraph (7), the date of the notification of a grant of an application is the day after the expiry of the period of 30 days beginning on the date on which notice of that decision is given under paragraph (6).

(10) For the avoidance of doubt, regulations 4 (except paragraph (1)), 5, 6, 7, 8, 11, 12, 13, 14 and 15 do not apply to an application under this regulation.”.

(4) In regulation 12 (determination of applications in respect of controlled localities), after paragraph (15) insert—

“(15A) Where a Health Authority has imposed any conditions under regulation 9(7) or paragraph (15), or the Secretary of State has imposed any conditions under regulation 10(10)(b) or 13(13)(b), those conditions shall be unaffected by the commencement or continuation of a pharmacy pilot scheme for the provision of local pharmaceutical services by the person whose application was granted subject to such conditions (or by a successor to that person who likewise provides local pharmaceutical services under that scheme).”.

(5) In regulation 17 (removal from pharmaceutical lists), after paragraph (1) insert—

“(1A) Where a chemist provides local pharmaceutical services under a pharmacy pilot scheme, and no longer provides pharmaceutical services, the Health Authority must remove his name from the pharmaceutical list.”.

(6) In Part I of Schedule 3 (application for inclusion in a pharmaceutical list or inclusion in a list in respect of different services or premises), in paragraph 7, after “*pharmaceutical services listed in paragraph 6 are already provided*”, insert “, or those applying for a right of return to a pharmaceutical list under regulation 8A”.

Signed by authority of the Secretary of State for Health

31st July 2002

*David Lammy*  
Parliamentary Under Secretary of State  
Department of Health

## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations make further 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 makes provision in relation to applications to become a health service body for the purposes of section 4 of the National Health Service and Community Care Act 1990 (in the Regulations called a “PHS body”). The effect of such an application being granted is that the contracts entered into between the Health Authority and the PHS body will be NHS contracts within the meaning of that Act, rather than legal contracts. Regulation 3 makes provision concerning the circumstances in which a PHS body ceases to be such a body. Regulations 2 and 3 also make special provision in connection with contracts to clarify that the grant or loss of PHS body status does not affect the status of pre-existing contracts.

Regulation 4 provides that the Secretary of State, before approving a pilot scheme or a variation to such a scheme, must make a determination as to whether a person who is to provide services under the scheme is to be given a right of return to a Health Authority’s pharmaceutical list if he applies for his name to be included in that list after ceasing to provide services under the pilot scheme. Regulation 4 makes further provision about such determinations.

Regulation 5 amends the National Health Service (Pharmaceutical Services) Regulations 1992 to provide for applications to join a Health Authority’s pharmaceutical list where a valid determination has been made in relation to the applicant, as long as the provision of services is continuous. If such an application is made in the manner specified, the Health Authority must grant the application.

Regulation 5 also provides that any conditions imposed on the grant of an application to provide pharmaceutical services in connection with the provision of pharmaceutical services by a doctor are not affected by the transition to a pilot scheme; and where a person no longer provides pharmaceutical services (but provides services under a pilot scheme), the Health Authority must remove his name from the pharmaceutical list.



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