

2005 No. 1501

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical Services)
(Amendment No. 2) Regulations 2005**

<i>Made</i> - - - -	<i>6th June 2005</i>
<i>Laid before Parliament</i>	<i>7th June 2005</i>
<i>Coming into force</i> - -	<i>5th July 2005</i>

The Secretary of State, in exercise of the powers conferred upon her by sections 16B, 41, 42, 43, 49I, 49Q and 126(4) of the National Health Service Act 1977(a) hereby makes the following Regulations:

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Amendment No. 2) Regulations 2005, and shall come into force on 5th July 2005.

(2) These Regulations shall apply in relation to England only(b).

(3) The National Health Service (Pharmaceutical Services) Regulations 2005(c) are amended in accordance with the provisions of these Regulations.

Amendment of regulation 2

2. In regulation 2(1) (interpretation)—

(a) after the definition of “health care professional” insert—

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- (a) 1977 c.49; section 16B was inserted by the Health Act 1999 (c. 8) (“the 1999 Act”), section 2(1) and was amended by the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”), section 1(3) and 6(2) and Schedule 1, Part 1, paragraphs 1 and 4(a) and (b) and Schedule 5, paragraphs 4 and 6. Section 41 was substituted by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), section 42(1) and was amended by the 2002 Act, Schedule 2, Part 1, paragraphs 1 and 13, by the Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590) article 3, Schedule, Part 1, paragraph 3 and by the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771) article 8. Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1), and was extended by the Health and Medicines Act 1988 (c.49), section 17, and was amended by S.I. 1987/2202, article 4, by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 12(3), by the Health Authorities Act 1995 (c.17) (“the 1995 Act”), Schedule 1, paragraph 30, by the Pharmacists (Fitness to Practice) Act 1997 (c.19), Schedule, paragraph 6, by the 2001 Act, sections 20(6), 43(2), (3) and (4) and by Schedule 6 Part 1 and by the 2002 Act, Schedule 2, paragraph 16. 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) (“the 1997 Act”), section 29(1) and Schedule 2, paragraphs 3 and 14, by the 1990 Act, Schedule 9, paragraph 18(2), by the 2001 Act, sections 20(7), 42(2) and 43(5) and by the 2002 Act, Schedule 2, paragraph 17. Sections 49I and 49Q were inserted by the 2001 Act, section 25 and were amended by the 2002 Act, Schedule 2, paragraphs 1, 21 and 23 to 28. Section 126(4) was amended by the 1999 Act, section 65(1) and Schedule 4, paragraphs 3 and 37. See section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of “prescribed” and “regulations”.
- (b) As regards Wales, the functions of the Secretary of State under sections 41, 42, 43, 49I and 49Q and 126(4) of 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(5) and as read with section 40(1) of the 2002 Act.
- (c) S.I. 2005/641 as amended by S.I. 2005/1015.

““home Primary Care Trust” means the Primary Care Trust in which the registered office of a chemist which is a body corporate is located;”; and

(b) in the definition of “supplementary prescriber”—

(i) in paragraph (a)(iii), for “. or”, substitute “,”,

(ii) in paragraph (a)(iv), for “; and”, substitute—

“, or

(v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989; and”, and

(iii) in paragraph (b), after “annotation” insert “or entry”.

Amendment of regulation 5

3.—(1) In regulation 5(1) (applications for inclusion in or amendment to a pharmaceutical list), for “Subject to paragraph (4),” substitute “Subject to paragraph (5),”.

(2) In regulation 5(2), insert “Subject to regulation 69A,” at the beginning.

Amendment of regulation 6

4.—(1) In regulation 6(1) (applications involving a minor relocation within a Primary Care Trust’s area) insert “Subject to paragraphs (1A) and (1B),” at the beginning.

(2) After regulation 6(1) insert—

“(1A) Where the application for the existing premises was exempt from regulation 12 by reason of regulation 13(1)(a) (being premises within an approved retail area), regulation 6(1) and (2) to (9) shall not apply to the current application unless the new premises are within the same approved retail area.

(1B) Where—

(a) a relocation to new premises has taken place pursuant to paragraph (1A); and

(b) a further application is made to relocate from those premises,

regulation 6(1) and (2) to (9) shall not apply to the current application unless the new premises are within the same approved retail area.”.

Amendment of regulation 7

5.—(1) In regulation 7(1) (applications involving a minor relocation between neighbouring Primary Care Trusts) insert “Subject to paragraphs (1A) and (1B),” at the beginning.

(2) After regulation 7(1) insert—

“(1A) Where the application for the existing premises was exempt from regulation 12 by reason of regulation 13(1)(a) (being premises within an approved retail area), regulation 7(1) and (2) to (9) shall not apply to the current application unless the new premises are within the same approved retail area.

(1B) Where—

(a) a relocation to new premises has taken place pursuant to paragraph (1A); and

(b) a further application is made to relocate from those premises,

regulation 7(1) and (2) to (9) shall not apply to the current application unless the new premises are within the same approved retail area.”.

Amendment of regulation 10

6. In regulation 10(4) insert “Subject to regulation 69A,” at the beginning.

Amendment of regulation 16

7. For regulation 16(2)(b) (new one-stop primary care centres) substitute—

“(b) at which there is, or will be, one or more providers of primary medical services with a patient list which comprises, or patient lists which together comprise, at least 18,000 patients; and”.

New Regulation 18ZA

8. After regulation 17 insert—

“Refusal: premises which are in a controlled locality but not in a reserved location

18ZA.—(1) Paragraph (2) applies where—

- (a) the application is made by a registered pharmacist, a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968^(a) or a supplier of appliances, in respect of premises in a controlled locality; and
- (b) either—
 - (i) the Primary Care Trust has determined under regulation 35, or
 - (ii) on appeal it is determined,that the premises from which the applicant wishes to provide pharmaceutical services are not in a reserved location.

(2) Subject to regulations 25 and 26, the Primary Care Trust—

- (a) shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality; and
- (b) may refuse an application in a case to which regulation 36(9) applies (notwithstanding that it would, if determining that application in isolation, grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.”.

Amendment of regulation 18

9.—(1) For regulation 18(1) (refusal: premises which are in a controlled locality but not in a reserved location) substitute—

“(1) Paragraph (2) applies where—

- (a) the application for outline consent is in relation to an area which is a controlled locality and—
 - (i) the Primary Care Trust has determined under regulation 35, or
 - (ii) on appeal it is determined,that the area to which the applicant wishes to provide pharmaceutical services is not in a reserved location; or
- (b) the application for premises approval is for premises from which the applicant wishes to be authorised to dispense to patients living in the area referred to in subparagraph (a).”.

(a) 1968 c.67. Section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50).

(2) In regulation 18(2), for the words “regulations 25 and 26” substitute “regulations 25, 26 and 65(4)”.

(3) The heading immediately preceding regulation 18 accordingly becomes “**Refusal: outline consent and premises approval where patients are in a controlled locality but not in a reserved location**”.

Amendment of regulation 28

10. In regulation 28(1) (notifications by Primary Care Trusts to other persons), after “shall notify” insert “within seven days of that decision”.

Amendment of regulation 31

11. In regulation 31(2) (determination that an area is a controlled locality), for “paragraphs (7) and (8)(b) and (c)”, substitute “paragraphs (7), (8) and (9)(b) and (c)”.

Amendment of regulation 33

12. In regulation 33(4) (notification of an application in respect of premises in a controlled locality), for “within 30 days” substitute “within 45 days”.

Amendment of regulation 34

13.—(1) In regulation 34(1)(c) (decision not to consider an application in respect of premises in a controlled locality), for “regulation 18(2)” substitute “regulation 18ZA(2)”.

(2) Omit regulation 34(1)(d)(ii).

Amendment of regulation 35

14. In regulation 35(3) (pharmaceutical services in reserved locations), for “paragraph (1)(a)”, substitute “paragraph (2)(a)”.

Amendment of regulation 47

15. In regulation 47(2) (cases where the Primary Care Trust must remove a chemist), after “director” insert “or superintendent” in all places where it occurs.

Amendment of regulation 50

16.—(1) In regulation 50(1) (procedure on suspension)—

(a) omit sub-paragraph (c); and

(b) in sub-paragraph (d), for “if he so requests within the 28 day period mentioned in sub-paragraph (c)” substitute “on a specified day, provided that at least 24 hours notice of the hearing is given.”.

(2) For regulation 50(2) substitute—

“(2) If the chemist does not wish to have an oral hearing or does not attend the oral hearing, the Primary Care Trust may suspend the chemist with immediate effect.

(2A) If an oral hearing does take place, the Primary Care Trust shall take into account any representations made by the chemist before it reaches its decision.”.

(3) In regulation 50(3), for “once it has reached a decision to suspend him” substitute “following the hearing”.

(4) In regulation 50(4), at the end insert “within seven days of making that decision”.

(5) After regulation 50(5) insert—

“(6) The Primary Care Trust may at any time revoke the suspension and notify the chemist of its decision.”.

Amendment of regulation 54

17. In regulation 54(3)(e) (temporary provision of services during a period of suspension) insert “subject to regulation 69A,” at the beginning.

Amendment of regulation 56

18. In regulation 56 (standards of, and payments for, drugs and appliances), after paragraph (1) insert—

“(1A) The Primary Care Trust shall make payments, calculated in the manner provided by the Drug Tariff or in accordance with any determination made by virtue of paragraph (2) (subject to any deduction required to be made by regulations made under section 77 of the Act) to chemists in respect of drugs and appliances, containers, medicines measures and dispensing fees and other fees and allowances.”.

New regulation 69A

19. In Part 6 (Miscellaneous), before regulation 70 insert—

“Home Primary Care Trusts

69A.—(1) Where an applicant which is a body corporate with a registered office in England, is required to provide to a Primary Care Trust any information under Part 3 of Schedule 4 such information may be provided to the applicant’s home Primary Care Trust instead of to the Primary Care Trust to whom it is making the application.

(2) Where an applicant has already provided that information to the home Primary Care Trust in relation to a previous application, it does not need to provide it again in relation to the current application.

(3) Where paragraph (1) or (2) applies, the applicant shall inform the Primary Care Trust to which the application is made that his home Primary Care Trust already has the information.

(4) Where paragraph (2) applies, the applicant shall in addition either—

(a) confirm that information is up to date; or

(b) update the information by sending it to his home Primary Care Trust.

(5) The home Primary Care Trust shall consider the information as if it were considering an application in accordance with regulation 19 and shall prepare a recommendation as to whether the application should be refused under regulation 19.

(6) recommendation shall set out all relevant facts and shall be fully reasoned.

(7) The home Primary Care Trust shall pass any information it has received from the applicant and its recommendation to any Primary Care Trust to which an application has been made by the applicant within 28 days of being requested to do so by that other Primary Care Trust.”.

Amendment of regulation 73

20.—(1) For regulation 73(3) (transitional provisions) substitute—

“(3) The procedure after grant of application for any application granted under the 1992 Regulations (whether or not pursuant to paragraph (1) or (2)) shall be that in regulations 4(9) to (11) of the 1992 Regulations.”.

(2) Omit regulation 73(4).

(3) After regulation 73(5), insert—

“(5A) Where paragraph (5) applies, regulation 41(1)(a) shall be read as if the words “within the period referred to in regulation 40(4)” were “within the period referred to in regulation 14(5) of the 1992 Regulations.”.

Amendment of Schedule 1

21.—(1) For paragraph 31 (home Primary Care Trusts of bodies corporate) substitute—

“Home Primary Care Trusts of bodies corporate

31.—(1) Where a pharmacist is a body corporate with a registered office in England, the information to be provided under paragraphs 29 and 30 may be provided instead to the home Primary Care Trust, if the pharmacist also provides the home Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included.

(2) The home Primary Care Trust shall consider such information and decide whether this raises any questions about the pharmacist’s fitness to practise.

(3) If the home Primary Care Trust is of the opinion that the information does raise a question about the pharmacist’s fitness to practise, it shall make a recommendation about the appropriate action to be taken (if any) in relation to the pharmacist.

(4) A recommendation shall set out all the relevant facts and shall be fully reasoned.

(5) The home Primary Care Trust shall pass any of the information provided by the pharmacist and any recommendation it has made under paragraph (3) to any other Primary Care Trust—

(a) in whose pharmaceutical list the pharmacist is included; or

(b) to whom the pharmacist has made or makes an application to be included in its pharmaceutical list,

that requests it, within 28 days of receiving such a request.”

(2) In paragraph 36(4) (charges for drugs and refunds) of Schedule 1, after “or form FP57 0403” insert “in relation to a claim for repayment of a payment made in England, or the equivalent form issued in Scotland in relation to a claim for repayment of a payment made in Scotland”.

Amendment of Schedule 2

22. In paragraph 10(2)(b) for the words “Local Pharmaceutical Committee” substitute “Local Medical Committee”.

Amendment of Schedule 3

23. For paragraph 18 (home Primary Care Trust of bodies corporate) substitute—

“Home Primary Care Trusts of bodies corporate

18.—(1) Where a supplier of appliances is a body corporate with a registered office in England, the information to be provided under paragraphs 16 and 17 may be provided instead to the home Primary Care Trust, if the supplier of appliances also provides the home Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included.

(2) The home Primary Care Trust shall consider such information and make a decision about the fitness to practise of the supplier of appliances.

(3) If the home Primary Care Trust is of the opinion that the information does raise any questions about the fitness to practise of the supplier of appliances, it shall make a recommendation about the appropriate action to be taken (if any) in relation to the supplier of appliances.

(4) A recommendation shall set out all the relevant facts and shall be fully reasoned.

(5) The home Primary Care Trust shall pass any of the information provided by the supplier of appliances and any recommendation it has made under paragraph (3) to any other Primary Care Trust—

(a) in whose pharmaceutical list the supplier of appliances is included; or

(b) to whom the supplier of appliances has made or makes an application to be included in its pharmaceutical list,

that requests it, within 28 days of receiving such a request.”.

6th June 2005

Jane Kennedy
Minister of State for Quality and Patient Safety,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make changes to the National Health Service (Pharmaceutical Services) Regulations 2005 (“the Principal Regulations”).

The definition of supplementary prescriber is amended to include trained optometrists who are now authorised to prescribe (regulation 2).

The Principal Regulations provided for a body corporate to provide fitness to practise information under paragraph 29 or 30 of Schedule 1, or paragraph 18 of Schedule 3, to the Principal Regulations only to the Primary Care Trust in which its registered office is located (and not all Primary Care Trusts in which its name is included in the pharmaceutical list). This principle is extended so that a body corporate that wishes to be included in a pharmaceutical list (or another pharmaceutical list) need only provide information to its home Primary Care Trust. The home Primary Care Trust is required to consider the information provided and make a recommendation. It is then required, if requested to do so, to pass the recommendation (and the related information) on to the Primary Care Trust or Trusts on whose list the body corporate has applied for inclusion (regulations 3(2), 6, 17, 19, 21 and 23).

The minor relocation procedure no longer applies to a chemist who has taken advantage of the exemption provision relating to an approved retail area and who then wishes to relocate out of that retail area (regulations 4 and 5).

The grounds for refusing applications concerning controlled localities from chemists and dispensing doctors are now dealt with separately (regulations 8, 9 and 13(1)).

Amendments are made to regulation 50 concerning the procedure for suspension of a chemist, the main purpose of which is to enable a Primary Care Trust to suspend a chemist much more quickly in appropriate cases (regulation 16).

Other minor changes are—

- (a) the clarification that one or more providers of primary medical services may work together within a one stop primary care centre (regulation 7);
- (b) Primary Care Trusts must notify decisions to certain persons within a specific timescale (regulation 10);
- (c) extending the timescale for giving notification of applications in controlled localities (regulation 12); and
- (d) extending regulation 47(2) to superintendents (regulation 15).

Further amendments are required to correct errors in the Principal Regulations (regulations 3(1), 11, 13(2), 14, 18, 20, 21(2) and 22).

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