
STATUTORY INSTRUMENTS

2006 No. 3373

The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006

PART 3

Amendment of the Pharmaceutical Services Regulations

Amendment of the Pharmaceutical Services Regulations

8. The National Health Service (Pharmaceutical Services) Regulations 2005⁽¹⁾ are amended in accordance with the provisions of this Part.

Amendment of regulation 2 of the Pharmaceutical Services Regulations

9. In paragraph (1) of regulation 2 **(2)** (interpretation)—

(a) in the definition of “independent nurse prescriber”, in sub-paragraph (b) omit “, medicines”; and

(b) in the definition of “pharmacist independent prescriber”,—

(i) in sub-paragraph (b), for “drugs, medicines and appliances as a pharmacist independent prescriber;” substitute “drugs and appliances as a pharmacist independent prescriber; and “ and

(ii) after sub-paragraph (b) add the following sub-paragraph—

“(c) who is—

(i) included in a pharmaceutical list, and with whom the Primary Care Trust has made an arrangement for the provision of a directed service which is an Independent Prescribing Service;

(ii) employed or engaged by a person who is included in a pharmaceutical list, and the Primary Care Trust has made an arrangement with that person for the provision of a directed service which is an Independent Prescribing Service;

(iii) employed or engaged by a GMS contractor, a PMS contractor, an APMS contractor or a PCTMS practice to provide services equivalent to a directed service which is an Independent Prescribing Service;

(iv) a relevant GMS contractor, a relevant PMS contractor, or a relevant APMS contractor contracted to provide services equivalent to a directed service which is an Independent Prescribing Service;

⁽¹⁾ S.I. 2005/641, as amended by S.I. 2005/1015, 1501 and 3315, and 2006/913 and 1501.

⁽²⁾ The relevant amending instruments are S.I. 2005/1501 and 3315, and 2006/552, 913 and 1501.

- (v) employed or engaged by a relevant GMS contractor, a relevant PMS contractor, or a relevant APMS contractor to provide services equivalent to a directed service which is an Independent Prescribing Service; or
- (vi) employed or engaged by a Primary Care Trust or an LPS chemist to provide services equivalent to a directed service which is an Independent Prescribing Service; or
- (vii) employed or engaged by a NHS trust or NHS foundation trust to provide NHS services and is prescribing in that capacity;”.

Amendment of regulation 6 of the Pharmaceutical Services Regulations

10. In regulation 6(3) (applications involving a minor relocation within a Primary Care Trust’s area)—

- (a) in paragraph (1), for “regulation 9(2)” substitute “regulation 9”; and
- (b) in paragraph (8), omit “in writing”.

Amendment of regulation 7 of the Pharmaceutical Services Regulations

11. In regulation 7(4) (applications involving a minor relocation between neighbouring Primary Care Trusts)—

- (a) in paragraph (1), for “regulations 9(2)” substitute “regulations 9”; and
- (b) in paragraph (8), omit “in writing”.

Amendment of regulation 10 of the Pharmaceutical Services Regulations

12. In paragraph (9) of regulation 10(5) (right of return to pharmaceutical lists), omit “in writing”.

Amendment of regulation 14 of the Pharmaceutical Services Regulations

13. In regulation 14 (variation of directed services in respect of exempted premises)—

- (a) in paragraph (6), omit “in writing” in both places that it occurs; and
- (b) in paragraph (10), omit “in writing”.

Amendment of regulation 19 of the Pharmaceutical Services Regulations

14. In paragraph (4)(f) of regulation 19 (6)(refusal: fitness to practise grounds), for “Part 1” substitute “Part 2”.

Amendment of regulation 21 of the Pharmaceutical Services Regulations

15. In paragraph (4) of regulation 21 (conditional inclusion relating to fitness to practise matters), for “in writing as soon as is practicable of any” substitute “within seven days of the date of a decision to impose any conditions of the”.

(3) The relevant amending instrument is [S.I. 2005/1501](#).

(4) The relevant amending instrument is [S.I. 2005/1501](#).

(5) The relevant amending instruments are [S.I. 2005/1501](#) and [2006/552](#).

(6) The relevant amending instrument is [S.I. 2006/552](#).

Amendment of regulation 23 of the Pharmaceutical Services Regulations

16. In regulation 23 (notification of applications)—
- (a) in paragraph (2), omit “in writing” at the first place where it occurs; and
 - (b) in paragraph (3), omit “in writing” at the first place where it occurs.

Amendment of regulation 24 of the Pharmaceutical Services Regulations

17. In sub-paragraph (a) of paragraph (2) of regulation 24 (7)(determination of applications), before “check as far” insert “ensure that it has sight of all relevant documents and”.

Amendment of regulation 26 of the Pharmaceutical Services Regulations

18. In paragraph (3) of regulation 26(8) (deferral of consideration of applications on fitness to practise grounds), omit “in writing”.

Amendment of regulation 27 of the Pharmaceutical Services Regulations

19. In regulation 27 (notification of decision)—
- (a) in paragraph (1)—
 - (i) omit “in writing”,
 - (ii) before sub-paragraph (a), insert the following sub-paragraph—
 - “(za) in the case of an application to which regulation 6(1) or 7(1) applies, to—
 - (i) the applicant, and
 - (ii) any person who has made representations to the Primary Care Trust in accordance with regulation 23(2) or 23(3);”, and
 - (iii) in sub-paragraph (a), for “regulation 6,7,” substitute “regulation 6(3),7(3),”;
 - (b) in paragraph (2), after “involves” insert “either a minor relocation within a Primary Care Trust’s area or between neighbouring Primary Care Trusts that falls to be dealt with under regulation 6(3), or 7(3) as appropriate or”; and
 - (c) in paragraph (3), omit “in writing”.

Amendment of regulation 28 of the Pharmaceutical Services Regulations

20. In paragraph (4)(b) of regulation 28(9) (notifications by Primary Care Trusts to other persons), for “the name and registered office” substitute “the name, registration number, registered office and telephone number relating to that office of the body corporate together with the name and address of any director or superintendent”.

Amendment of regulation 29 of the Pharmaceutical Services Regulations

21. In regulation 29 (appeals)—
- (a) after paragraph (1) insert—
 - “(1A) Where a Primary Care Trust has determined an application to which regulation 6(1) or 7(1) applied, the persons who may appeal to the Secretary of State are—

(7) The relevant amending instrument is [2006/552](#).

(8) The relevant amending instrument is [2006/552](#).

(9) The relevant amending instruments are [S.I. 2005/1501](#) and [2006/552](#).

- (a) the applicant; and
- (b) any person who—
 - (i) was given notice of the application under regulation 23(2)(c) or (d) or regulation 23(3)(c) or (d), and
 - (ii) made representations to the Primary Care Trust in accordance with regulation 23(2) or 23(3).”;
- (b) in paragraph (2)(a), for “regulation 6(1), 7(1),” substitute “regulation 6(3), 7(3),”;
- (c) in paragraph (7), for “paragraph (2)” substitute “paragraph (1A), (2)”;
- (d) in paragraph (11), before sub-paragraph (a) insert—
 - “(za) in the case of an appeal to which paragraph (1A) relates, to the persons mentioned in regulation 27(1)(za);”;
- (e) in paragraph (19), omit “in writing”.

Amendment of regulation 31 of the Pharmaceutical Services Regulations

22. In paragraph (12) of regulation 31(10) (determination that an area is a controlled locality), omit “in writing”.

Amendment of regulation 32 of the Pharmaceutical Services Regulations

23. In paragraph (11) of regulation 32 (appeals relating to rurality of an area), omit “in writing”.

Amendment of regulation 34 of the Pharmaceutical Services Regulations

24. In paragraph (1)(b) of regulation 34(11) (decision not to consider an application in respect of premises in a controlled locality)—

- (a) after “any application to which” insert “regulation 12 or”; and
- (b) for “pharmacist” substitute “chemist”.

Amendment of regulation 36 of the Pharmaceutical Services Regulations

25. In regulation 36(12) (determination of applications in respect of controlled localities),—

- (a) in paragraph (1), for “regulations 25 and 26” substitute “regulations 18ZA, 25 and 26”; and
- (b) in paragraph (3)(a), before “check as far” insert “ensure that it has sight of all relevant documents and”.

Amendment of regulation 37 of the Pharmaceutical Services Regulations

26. In regulation 37 (notification of decision in respect of applications in controlled localities)—

- (a) in paragraph (1)—
 - (i) omit “in writing”, and
 - (ii) for sub-paragraph (b) substitute—
 - “(b) of the rights of appeal arising under regulation 38.”;
- (b) in paragraph (2), after “application” insert “under regulation 6(3), 7(3) or”; and

(10) The relevant amending instrument is [S.I. 2005/1501](#).

(11) The relevant amending instrument is [S.I. 2005/1501](#).

(12) The relevant amending instrument is [S.I. 2006/552](#).

- (c) in paragraph (3), omit “in writing”.

Amendment of regulation 38 of the Pharmaceutical Services Regulations

27.—(1) Before paragraph (2) of regulation 38(13) (appeals in connection with determinations in respect of controlled localities etc) insert the following paragraphs—

“(1A) Where a Primary Care Trust has determined an application to which regulations 33 to 36 applied, and regulation 6(1) or 7(1) also applied to that application, the persons who may appeal to the Secretary of State are—

- (a) the applicant; and
- (b) any person who—
 - (i) was given notice of the application under regulation 33(2)(c) or (d) or regulation 33(3)(c) or (d), and
 - (ii) made representations to the Primary Care Trust in accordance with regulation 33(4).

(1B) Where a Primary Care Trust has determined an application to which regulations 33 to 36 applied, and regulation 6(3), 7(3), 8, 9, or 10 also applied to that application, or the Primary Care Trust has made a decision under regulation 39(8) in relation to that application, the persons who may appeal to the Secretary of State are—

- (a) the applicant; and
- (b) any person who was given notice of the decision under regulation 37(1)(a)(iv) or (v) or regulation 37(3)(c) or (d).

(1C) Where a Primary Care Trust has determined an application to which regulations 33 to 36 applied, and regulation 12 also applied to that application or would have applied but for an exemption under regulation 13, the persons who may appeal to the Secretary of State are—

- (a) the applicant; and
- (b) except in the case of an application to which regulation 13(1) applies, any person who—
 - (i) was given notice of the application under regulation 33(2)(c) or (d) or regulation 33(3)(c) or (d), and
 - (ii) made representations to the Primary Care Trust in accordance with regulation 33(4).

(1D) Paragraphs (1A), (1B) and (1C) do not apply to determinations of applications under regulation 18ZA or 36(2).”.

(2) For sub-paragraph (a) of paragraph (2) of regulation 38, substitute—

“(a) has determined an application that does not fall within paragraph (1A), (1B) or (1C) or a question raised by an application (but not the application itself) to which regulations 33 to 36 applied;”.

(3) In paragraph (3) of regulation 38—

- (a) in sub-paragraph (a)(ii)(aa), for “regulation 33(2)(f), (h) or (i)” substitute “regulation 33(2)(f), (i) or (j)”; and
- (b) in sub-paragraph (a)(ii)(bb), for “regulation 33(2)(f), (h) or (i)” substitute “regulation 33(2)(f), (i) or (j)”.

Amendment of regulation 39 of the Pharmaceutical Services Regulations

- 28.** In regulation 39 (procedure after grant of application)—
- (a) in paragraph (3), omit “written”; and
 - (b) for sub-paragraph (a) of paragraph (10), substitute—
 - “(a) where notice of the Primary Care Trust’s decision is given under regulation 27(1) or (as the case may be) regulation 37(1), the day after the expiry of—
 - (i) 30 days beginning on the date on which notice of the decision is given, or
 - (ii) such lesser number of days as may be specified by the Primary Care Trust if it considers that there is good cause to reduce the number of days; or”.

Amendment of regulation 45 of the Pharmaceutical Services Regulations

- 29.** In paragraph (11) of regulation 45(14) (removal from pharmaceutical lists), omit “in writing”.

Amendment of regulation 46 of the Pharmaceutical Services Regulations

- 30.** In paragraph (2)(f) of regulation 46 (criteria for decisions on removal), for “Part 1” substitute “Part 2”.

Amendment of regulation 48 of the Pharmaceutical Services Regulations

- 31.** In regulation 48 (procedure on removal)—
- (a) in paragraph (2)(a), omit “in writing”; and
 - (b) in paragraph (4), for “inform” substitute “notify”.

Amendment of regulation 50 of the Pharmaceutical Services Regulations

- 32.** In regulation 50(15) (procedure on suspension)—
- (a) in paragraph (1)(a), omit “in writing”; and
 - (b) in paragraph (4), for “inform” substitute “notify”.

Amendment of regulation 51 of the Pharmaceutical Services Regulations

- 33.** In regulation 51 (procedure on review of Primary Care Trust decision)—
- (a) in paragraph (1)(a), omit “in writing”; and
 - (b) in paragraph (3), for “inform” substitute “notify”.

Amendment of regulation 54 of the Pharmaceutical Services Regulations

- 34.** In regulation 54(16) (temporary provision of services during a period of suspension)—
- (a) in paragraph (7)(a), insert at the beginning “ensured that it has had sight of all relevant documents and”;
 - (b) in paragraph (13)(c), omit “in writing”;
 - (c) in paragraph (14), omit “in writing”;

(14) The relevant amending instrument is [S.I. 2006/552](#).

(15) The relevant amending instrument is [S.I. 2005/1501](#).

(16) The relevant amending instruments are [S.I. 2005/1501](#) and [2006/552](#).

- (d) in paragraph (17), for “notify” substitute “inform”;
- (e) in paragraph (19), omit “in writing”; and
- (f) in paragraph (21)(d), omit “in writing”.

Amendment of regulation 55 of the Pharmaceutical Services Regulations

35. In paragraph (1) of regulation 55 (notifications),—

- (a) after “it shall notify” insert “,within 7 days of the date of the decision to remove, contingently remove or suspend,”; and
- (b) after “shall additionally notify” insert “within 7 days of the request in writing”.

Amendment of regulation 58 of the Pharmaceutical Services Regulations

36. After paragraph (4) of regulation 58 (payments to suspended chemists) add the following paragraphs—

“(5) If a payment is made in accordance with a determination under paragraph (2), but the payee was not entitled to receive all or any part of it, if the amount to which he was not entitled has not been recovered by other means, it may be recovered by the Primary Care Trust as a civil debt.

(6) If a chemist is dissatisfied with a decision of a Primary Care Trust (“the original decision”)—

- (a) to refuse to make a payment to, or in respect of, him in accordance with a determination under paragraph (2);
- (b) to make a payment to, or in respect of, him in accordance with a determination under paragraph (2), but at a lower level than the level which he considers to be correct; or
- (c) in respect of recovery of what the Primary Care Trust considers to be an overpayment,

he may ask the Primary Care Trust in writing to review the original decision and, if he does so, the Primary Care Trust shall reconsider that decision, and once it has done so, it must notify the chemist of the decision that is the outcome of its reconsideration of its original decision (“the reconsidered decision”), and give him notice of the reasons for its reconsidered decision.

(7) If the chemist remains dissatisfied (whether on the same or different grounds), he may appeal to the Secretary of State by giving him a notice of appeal within a period of 28 days beginning on the day that the Primary Care Trust notified him of the reconsidered decision.

(8) A notice of appeal under paragraph (7) shall include—

- (a) the names and addresses of the parties to the disputed decision;
- (b) a copy of the reconsidered decision; and
- (c) a brief statement of the grounds for appeal.

(9) The Secretary of State shall then send a written request to the parties to make, in writing and within a specified period, any representations they may wish to make about the matter (and the request to the Primary Care Trust shall include a copy of the chemist’s brief statement of the grounds for appeal).

(10) Once the period specified pursuant to paragraph (9) has elapsed, the Secretary of State shall—

- (a) give a copy of the representations received from a party to the other party; and

- (b) request in writing a party to whom a copy of representations is given to make within a specified period any written observations which he or it wishes to make on those representations.

(11) Once the period specified pursuant to paragraph (10)(b) has elapsed, the Secretary of State shall, as soon as is reasonably practicable, having taken into account any such representations or observations as are referred to in paragraphs (9) and (10) (if submitted within the specified periods) and such other evidence as he sees fit to consider—

- (a) determine the appeal, and shall give notice of the determination (including a record of the reasons for it) to both parties; and
- (b) give the Primary Care Trust such directions in writing, if any, on the matter as he thinks fit.”.

Amendment of regulation 60 of the Pharmaceutical Services Regulations

37. In regulation 60(17) (arrangement for provision of pharmaceutical services by doctors)—

- (a) in paragraph (4)(b), omit “in writing”; and
- (b) in paragraph (15), omit “in writing”.

Amendment of regulation 61 of the Pharmaceutical Services Regulations

38. In regulation 61 (outline consent and premises approval)—

- (a) in paragraph (1)(b), for “because there has been a practice amalgamation” substitute “because a practice amalgamation has taken place or will be taking place”; and
- (b) in paragraph (2), for “33 to 38” substitute “33, 34, 36 to 38”.

Amendment of regulation 65 of the Pharmaceutical Services Regulations

39. In regulation 65 (premises approval: additional and new premises after outline consent has taken effect)—

- (a) in paragraph (1)(b)(ii), for “34 to 36(1)” substitute “34, 36(1)”;
- (b) in paragraph (4)(a)(ii), for “dispensing services in” substitute “dispensing services to”;
- (c) in paragraph (5), for “The Primary Care Trust” substitute “The relevant Primary Care Trust”;
- (d) in paragraph (6), for “the Primary Care Trust” substitute “the relevant Primary Care Trust”;
- (e) in paragraph (7)(a), for “the Primary Care Trust” substitute “the relevant Primary Care Trust”;
- (f) in paragraph (8)—
 - (i) in sub-paragraph (b), for “authority” substitute “approval”, and
 - (ii) for “the Primary Care Trust” substitute “the relevant Primary Care Trust”; and
- (g) in paragraph (9)—
 - (i) for “The Primary Care Trust” substitute “The relevant Primary Care Trust”; and
 - (ii) for the words “temporary authority granted” substitute “temporary approval granted”.

(17) The relevant amending instrument is [S.I. 2005/1015](#).

Amendment of regulation 66 of the Pharmaceutical Services Regulations

- 40.** In paragraph (3) of regulation 66 (premises approval: practice amalgamations)—
- (a) for “of the new practice are, or will be,” substitute “of the new amalgamating practice had been” ; and
 - (b) after “a doctor who” insert “is a party to the practice amalgamation and who”.

Amendment of Schedule 1 to the Pharmaceutical Services Regulations

41.—(1) Schedule 1(18) (terms of service of pharmacists) is amended in accordance with this regulation.

(2) In sub-paragraph (1)(a) of paragraph 22 (pharmacy opening hours: general), omit “not less than”.

(3) In paragraph 24 (determination of pharmacy opening hours instigated by the Primary Care Trust)—

- (a) in sub-paragraph (3)(c), omit “not less than”;
- (b) in sub-paragraph (6), omit “in writing”; and
- (c) in sub-paragraph (9), omit “in writing”.

(4) In paragraph 25 (determination of pharmacy opening hours instigated by the pharmacist)—

- (a) in sub-paragraph (4), omit “not less than”;
- (b) in sub-paragraph (8), omit “in writing”;
- (c) in sub-paragraph (11), omit “in writing”.

(5) In sub-paragraph (4) of paragraph 29 (duty to provide information about fitness to practise matters: pharmacists on pharmaceutical lists on 1st April 2005), for “of the of the Police Act” substitute “of the Police Act”.

(6) In sub-paragraph (1) of paragraph 34 (information to be supplied), for paragraph (c) substitute—

- “(c) in the case of a pharmacist that is a body corporate, any change to the name, registration number, registered office, telephone number relating to that office of the body corporate or the name and address of any director or superintendent of the body corporate;”.

Amendment of Schedule 2 to the Pharmaceutical Services Regulations

42. In sub-paragraph (4)(b) of paragraph 7 of Schedule 2(19) (terms of service of dispensing doctors – refusal to provide drugs or appliances ordered), for “has altered” substitute “has not altered”.

Amendment of Schedule 3 to the Pharmaceutical Services Regulations

43.—(1) Schedule 3(20) (suppliers of appliances) is amended in accordance with this regulation.

(2) In paragraph 12 (determination of opening hours instigated by the Primary Care Trust)—

- (a) in sub-paragraph (6), omit “in writing”; and
- (b) in sub-paragraph (9), omit “in writing”;

(18) The relevant amending instruments are [S.I. 2005/1501](#) and [2006/552](#).

(19) The relevant amending instrument is [S.I. 2005/1501](#).

(20) The relevant amending instrument is [S.I. 2005/1501](#).

- (3) In paragraph 13 (determination of opening hours instigated by the supplier of appliances)—
- (a) in sub-paragraph (8), omit “in writing”; and
 - (b) in sub-paragraph (11), omit “in writing”.
- (4) In sub-paragraph (4) of paragraph 16 (duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1st April 2005), for “of the of the Police Act” substitute “of the Police Act”.
- (5) In sub-paragraph (1) of paragraph 21 (information to be supplied), for paragraph (c) substitute—
- “(c) in the case of a supplier of appliances that is a body corporate, any change to the name, registration number, registered office, telephone number relating to that office of the body corporate or the name and address of any director of the body corporate;”.