

2009 No. 2205

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Miscellaneous Amendments
Relating to Community Pharmaceutical Services and
Optometrist Prescribing) Regulations 2009**

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The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 89, 94, 126, 129, 132, 272(7) and (8) and 275(1) of, and paragraphs 2 and 3 of Schedule 12 to, the National Health Service Act 2006(a).

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009 and come into force on 17th September 2009.

(2) These Regulations apply in relation to England.

PART 1

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

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 this Part.

(a) 2006 c.41. By virtue of section 271 of the Act, the powers conferred by these sections 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.

Amendment of regulation 2

3. In regulation 2(a) (interpretation)—

- (a) in paragraph (1)—
 - (i) omit the definition of “Community Health Council”,
 - (ii) after the definition of “Nursing and Midwifery Register” insert the following definition—

““optometrist independent prescriber” means a person—

 - (a) who is an optometrist registered in the relevant register; and
 - (b) against whose name in the relevant register is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;”,
 - (iii) in the definition of “prescriber”, for “or a supplementary prescriber” substitute “, a supplementary prescriber or an optometrist independent prescriber”, and
 - (iv) in the definition of “relevant register”—
 - (aa) omit the “and” at the end of sub-paragraph (a), and
 - (bb) after sub-paragraph (b) insert the following sub-paragraph—

“(c) in relation to an optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989(b);”; and
- (b) after paragraph (4) insert the following paragraphs—

“(5) For the purposes of these Regulations, “emergency requiring the flexible provision of pharmaceutical services” means an emergency declared by means of a direction to Primary Care Trusts under section 8(1) of the 2006 Act to the effect that, as a result of the threatened damage to human welfare caused or which may be caused by the illness designated in the direction, Primary Care Trusts must for a specified period—

 - (a) exercise, or
 - (b) where a discretion is conferred, consider exercising,

one or more of their functions under regulation 7A, 60(8A) or 65A, paragraph 25A of Schedule 1 or paragraph 13A of Schedule 3, subject to any conditions or limitations set out in the direction.

(6) Where—

 - (a) a direction of the type mentioned in paragraph (5) is given; and
 - (b) the Secretary of State issues a further direction changing the specified period of the emergency,

the duration of the emergency is to be construed in accordance with the specified period as so changed.”.

New regulation 7A

4. After regulation 7, insert the following regulation—

“Temporary relocations and additional premises during an emergency requiring the flexible provision of pharmaceutical services

7A.—(1) Regulations 5(1)(b)(i) and (ii) and (c), 6, 7, 12 and 22(1) shall not apply to an application for a temporary amendment to a pharmaceutical list which the Primary Care Trust is satisfied is necessary or expedient because of an emergency requiring the flexible provision of pharmaceutical services.

(a) Amended by S.I. 2005/1501 and 3491, 2006/552, 562, 913, 1501 and 3373, 2007/289 and 674, and 2008/528.
(b) 1989 c.44; section 7(a) was substituted by S.I. 2005/848.

(2) In the circumstances described in paragraph (1), the Primary Care Trust may make a temporary amendment to an entry in the pharmaceutical list, but—

- (a) only for a specified period (which shall not be longer than the specified period of the emergency given by the Secretary of State) which the Primary Care Trust may extend or curtail in appropriate circumstances; and
- (b) the applicant may revert to the applicant's overridden entry in the pharmaceutical list before the end of the period specified by the Primary Care Trust, on giving the Primary Care Trust at least 24 hours notice.

(3) There is no right of appeal under these Regulations in respect of a decision to make or not to make, or to curtail the duration of, a temporary amendment to a pharmaceutical list made under this regulation.”.

Amendment of regulation 12 and its heading

5. In regulation 12(a) (necessary or desirable test)—

- (a) in paragraph (1), in both places where the term appears, for “desirable”, substitute “expedient”;
- (b) in paragraph (2), for “desirable” substitute “expedient”; and
- (c) in paragraph (3), for “desirable” substitute “expedient”,

and in the heading of that regulation, for “desirable” substitute “expedient”.

Amendment of the heading of regulation 13

6. In the heading of regulation 13 (exemption from the necessary or desirable test), for “desirable” substitute “expedient”.

New regulation 17A

7. After regulation 17, insert the following regulation—

“Refusal: same or adjacent premises

17A. A Primary Care Trust shall not grant an application to which regulation 5(1)(a) or (b)(i) or (ii) applies if—

- (a) a person on a pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services (“the existing services”) from—
 - (i) the premises to which the application relates, or
 - (ii) adjacent premises; and
- (b) the Primary Care Trust is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed premises should be considered as one site).”.

Amendment of regulation 23

8. In regulation 23(b) (notification of applications), in paragraph (3), omit sub-paragraph (e).

(a) Amended by S.I. 2005/1015.

(b) Amended by S.I. 2006/3373 and 2008/528.

Amendment of regulation 27

9. In regulation 27(a) (notification of decision), in paragraph (3)(e), for “Community Health Council notified under regulation 23(3)(e)” substitute “relevant local involvement network notified under regulation 23(3)(ee)”.

Amendment of regulation 28

10. In regulation 28(b) (notifications by Primary Care Trusts to other persons), in paragraph (4)(b)—

- (a) before “registration number,” insert “company”; and
- (b) for “name and address” substitute “name, address, date of birth and (where applicable) professional registration number”.

Amendment of regulation 33

11. In regulation 33(c) (notification of an application in respect of premises in a controlled locality), in paragraph (3), omit sub-paragraph (f).

Amendment of regulation 37

12. In regulation 37(d) (notification of decision in respect of applications in controlled localities), in paragraph (3)—

- (a) omit “and” at the end of sub-paragraph (d);
- (b) insert “; and” at the end of sub-paragraph (e); and
- (c) after sub-paragraph (e) insert the following sub-paragraph—
“(f) any relevant local involvement network notified under regulation 33(2)(g).”.

Amendment of regulation 53

13. In regulation 53 (withdrawals from the list), after paragraph (5), insert the following paragraphs—

“(6) Paragraph (7) applies where—

- (a) a Primary Care Trust—
 - (i) is carrying out an investigation of a chemist (“C”) for one of the reasons given in paragraph (2),
 - (ii) has decided—
 - (aa) to remove C from its pharmaceutical list under section 151 or 152(3) of the 2006 Act,
 - (bb) to remove C contingently from its pharmaceutical list under section 152(1) of the 2006 Act, or
 - (cc) to remove C from its pharmaceutical list for a breach of a condition imposed on inclusion under regulation 44,
- but has not yet given effect to its decision, or
- (iii) has suspended C under section 154(1)(b) of the 2006 Act;

(a) Amended by S.I. 2006/3373 and 2008/528.
(b) Amended by S.I. 2005/1501 and 2006/552 and 3373.
(c) Amended by S.I. 2005/1501 and 2008/528.
(d) Amended by S.I. 2006/3373.

- (b) an application is made, pursuant to regulation 8, to change the ownership of any listed premises from which C has undertaken to provide pharmaceutical services in the Primary Care Trust's area; and
- (c) if that application were granted, C would need to be removed from the pharmaceutical list.

(7) Where this paragraph applies, the Primary Care Trust shall determine the application, and if it grants the application—

- (a) it may include the new owner of the premises on the pharmaceutical list; but
- (b) it shall not, without the consent of the Secretary of State, remove C's name from the pharmaceutical list until the investigation or the proceedings referred to in paragraph (6)(a) have been concluded.

(8) If C's name is maintained on a pharmaceutical list pursuant to paragraph (7)—

- (a) a Primary Care Trust may exercise its functions under Part 3 as regards C; but
- (b) for all other purposes, C shall be treated as though C's name had been removed from the pharmaceutical list following the granting of the change of ownership application.”.

Amendment of regulation 60

14. In regulation 60(a) (arrangements for the provision of pharmaceutical services by doctors), after paragraph (8) insert the following paragraphs—

“(8A) Notwithstanding the preceding provisions of this regulation, a Primary Care Trust may also require a doctor who already provides pharmaceutical services to patients on a relevant patient list to provide pharmaceutical services to patients who are not on that list (“temporary services”)—

- (a) during an emergency requiring the flexible provision of pharmaceutical services;
- (b) where, as a result of the temporary closure of premises from which medicines, drugs or appliances are normally dispensed in the area of the Primary Care Trust, the Primary Care Trust considers that, in order to secure continuing adequate provision of pharmaceutical services in its area during the emergency, it is necessary for it to require provision of those temporary services; and
- (c) for a specified period (which shall not be longer than the specified period of the emergency given by the Secretary of State) which the Primary Care Trust may extend or curtail in appropriate circumstances.

(8B) Where a doctor is required to provide temporary services by virtue of paragraph (8A), any services provided to a patient as a result of that requirement are to be treated as services provided as part of the arrangements under which the doctor provides primary medical services to patients on the relevant patient list.

(8C) There is no right of appeal under these Regulations in respect of a decision—

- (a) to require, or not to require, a doctor to provide temporary services; or
- (b) to extend or curtail the duration of any requirement imposed by virtue of paragraph (8A),

but the requirement must be curtailed if the doctor notifies the Primary Care Trust in writing that the doctor is unwilling to provide pharmaceutical services to patients who are not on the relevant patient list during the emergency (and so wishes to revert to the doctor's overridden arrangements for the provision of pharmaceutical services).

(8D) Nothing in paragraph (8A) shall be taken as requiring a doctor (or a GMS, PMS or APMS contractor or PCTMS practice) to provide pharmaceutical services to patients at

(a) Amended by S.I. 2005/1015 and 2006/3373.

times when, or from premises at which, the doctor (or contractor or practice) is not also providing pharmaceutical services to patients on a relevant patient list.”.

New regulation 65A

15. After regulation 65, insert the following regulation—

“Temporary new or additional premises during an emergency requiring the flexible provision of pharmaceutical services

65A.—(1) Regulation 65 shall not apply to an application by a doctor of the type mentioned in regulation 65(1)(a) or (b) for—

- (a) temporary premises approval in relation to premises in addition to those in respect of which premises approval has already been given under this Part; or
- (b) temporary premises approval in relation to new premises where the doctor wishes to dispense instead of listed premises,

requiring a temporary amendment to a dispensing doctor list which a Primary Care Trust is satisfied is necessary or expedient because of an emergency requiring the flexible provision of pharmaceutical services.

(2) In the circumstances described in paragraph (1), the Primary Care Trust may grant the application, but—

- (a) only for a specified period (which shall not be longer than the specified period of the emergency given by the Secretary of State) which the Primary Care Trust may extend or curtail in appropriate circumstances; and
- (b) the applicant may revert to the overridden premises approval before the end of the period specified by the Primary Care Trust, on giving the Primary Care Trust at least 24 hours notice.

(3) There is no right of appeal under these Regulations in respect of a decision—

- (a) to grant or refuse an application under paragraph (1); or
- (b) to extend or curtail, or not to extend or curtail, temporary premises approval under paragraph (2)(a).”.

New regulation 69B

16. After regulation 69A(a), insert the following regulation—

“Proceedings with regard to overridden arrangements during an emergency requiring the flexible provision of pharmaceutical services

69B. Where, during an emergency requiring the flexible provision of pharmaceutical services, arrangements for the provision of pharmaceutical services are overridden by temporary arrangements—

- (a) any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed during the emergency for other reasons); and
- (b) if as a result of those proceedings, the overridden arrangements require amendment before the end of the temporary arrangements, when the emergency ends, the reversion to the overridden arrangements shall be to the overridden arrangements as amended as a result of those proceedings.”.

(a) Inserted by S.I. 2005/1501.

Amendment of paragraph 22 of Schedule 1

17. In paragraph 22 of Schedule 1 (terms of service of pharmacists – pharmacy opening hours: general)—

- (a) after sub-paragraph (1) insert the following sub-paragraph—

“(1A) A pharmacist shall also notify the Primary Care Trust of other hours during which the premises from which the pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to as “supplementary opening hours”).”;
- (b) in sub-paragraph (5)(a), for “the days on which or times at which pharmaceutical services are to be provided at” substitute “the supplementary opening hours of”; and
- (c) in sub-paragraph (6)(b) after “the Primary Care Trust”, insert “, unless the Primary Care Trust agrees otherwise”; and
- (d) in sub-paragraph (11), after “Good Friday” insert “, Easter Sunday”.

Amendment of paragraph 25 of Schedule 1

18. In paragraph 25 of Schedule 1 (terms of service of pharmacists – determination of pharmacy opening hours instigated by the pharmacist)—

- (a) in sub-paragraph (1)(a), after “each week” insert “(but not any condition imposed by virtue of regulation 13(2)(a))”; and
- (b) in sub-paragraph (4), for “paragraph 22(1)(a), the pharmacy will need to be open for 40 hours each week”, substitute “whichever of paragraph 22(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week”.

New paragraph 25A of Schedule 1

19. After paragraph 25 of Schedule 1, insert the following paragraph—

“Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

25A.—(1) Notwithstanding the provisions of this Part, during an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may, on application from a pharmacist (“P”), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at the premises from which P has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) P gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by P for the request are, in the opinion of the Primary Care Trust, adequate reasons.

(2) The Primary Care Trust need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that P’s reasons are not, in its opinion, adequate reasons, then the days on which or times at which P is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to P.”.

Amendment of paragraph 28 of Schedule 1

20. In paragraph 28(a) of Schedule 1 (terms of service of pharmacists – inducements etc.)—

(a) Amended by S.I. 2008/683.

- (a) in sub-paragraph (1)—
 - (i) for “A pharmacist or his staff shall not give” substitute “Neither a pharmacist nor any person employed or engaged by a pharmacist shall give”,
 - (ii) omit “or” at the end of paragraph (a),
 - (iii) at the end of paragraph (b), insert “; or”, and
 - (iv) after paragraph (b), insert the following paragraph—
 - “(c) receiving from the pharmacist any directed services.”
- (b) after sub-paragraph (2), insert the following sub-paragraphs—
 - “(3) Nothing in sub-paragraph (1) shall prohibit a pharmacist, or a person employed or engaged by a pharmacist, from providing to a patient to whom the pharmacist is providing any directed services any gift which—
 - (a) is supplied as part of the provision of any directed service to that patient;
 - (b) is directly related to that directed service;
 - (c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient’s family of a healthy lifestyle; and
 - (d) in the case of a gift which—
 - (i) is not a medicine, has a monetary value not exceeding £10, or
 - (ii) is a medicine, is supplied as part of the provision of a minor ailments service.
 - (4) Neither a pharmacist nor any person employed or engaged by a pharmacist shall give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of the pharmacist’s business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—
 - (a) present to the pharmacist an order for drugs or appliances on a prescription form or repeatable prescription;
 - (b) nominate the pharmacist as their dispensing contractor (or one of them) on their NHS Care Record; or
 - (c) ask the pharmacist to provide them with any directed service.
 - (5) For the purpose of sub-paragraph (4), “relevant person” means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—
 - (a) any NHS body, GMS contractor, PMS contractor or APMS contractor; and
 - (b) any person employed or engaged by any of the persons mentioned in paragraph (a).”.

Amendment of paragraph 31 of Schedule 1

21. In paragraph 31(a) of Schedule 1 (terms of service of pharmacists – Home Primary Care Trust of bodies corporate), in sub-paragraph (1), for “and 30”, substitute “, 30 and 34(3A) and (3B)”.

Amendment of paragraph 34 of Schedule 1

22. In paragraph 34(b) of Schedule 1 (terms of service of pharmacists – information to be supplied)—

- (a) in paragraph (1)(a), for “notified to him” substitute “notified to the Primary Care Trust”; and

(a) Substituted by S.I. 2005/1501.
 (b) Amended by S.I. 2006/3373.

- (b) after sub paragraph (3), insert the following sub paragraphs—

“(3A) Subject to sub-paragraph (7), where a pharmacist that is a body corporate appoints a superintendent or director who was not listed on that body corporate’s application for inclusion on a pharmaceutical list, that pharmacist shall, within 28 days of the person’s appointment, supply to the Primary Care Trust the information mentioned in paragraphs 4 to 7 of Part 3 of Schedule 4 about that person.

(3B) Subject to sub-paragraph (7), where—

- (a) a pharmacist that is a body corporate appointed a superintendent or director before 17th September 2009 who, on 17th September 2009, is still in post; and
- (b) before that date, the pharmacist had not supplied to the Primary Care Trust the information mentioned in paragraphs 4 to 7 of Part 3 of Schedule 4 about that person,

it must supply that information to the Primary Care Trust before 17th March 2010.”.

Amendment of paragraph 8 of Schedule 2

23. In paragraph 8 of Schedule 2(a) (terms of service of dispensing doctors – fees and charges), for sub-paragraph (2) substitute the following sub-paragraph—

“(2) Where a dispensing doctor provides a drug, appliance or additional service as part of the terms of service of the dispensing doctor, if—

- (a) a GMS contractor had provided that drug, appliance or service under a GMS contract, the contractor would have been entitled to a payment for that drug, appliance or service by virtue of directions under section 87 of the 2006 Act; and
- (b) the drug, appliance or service has been provided in accordance with the terms of service of the dispensing doctor (even if, by virtue of conditions imposed by the GMS Regulations, a GMS contractor could not have had equivalent terms of service),

the Primary Care Trust shall credit the dispensing doctor with that payment.”.

Amendment of paragraph 10 of Schedule 3

24. In paragraph 10 of Schedule 3 (terms of service of suppliers of appliances – opening hours: general)—

- (a) in sub-paragraph (1), omit sub-paragraph (b); and
- (b) in sub-paragraph (9) after “Good Friday” insert “, Easter Sunday”.

New paragraph 13A of Schedule 3

25. After paragraph 13 of Schedule 3, insert the following paragraph—

“Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

13A.—(1) Notwithstanding the provisions of paragraphs 10 to 13, during an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may, on application from a supplier of appliances (“S”), permit S a temporary change to the days on which or times at which S is obliged to provide pharmaceutical services at the premises from which S has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) S gives at least 24 hours notice of the change or closure; and

(a) Amended by S.I. 2006/1501.

- (b) the reasons given by S for the request are, in the opinion of the Primary Care Trust, adequate reasons.

(2) The Primary Care Trust need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that S's reasons are not, in its opinion, adequate reasons, then the days on which or times at which S is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to S."

Amendment of paragraph 18 of Schedule 3

26. In paragraph 18(a) of Schedule 3 (terms of service of suppliers of appliances – Home Primary Care Trusts of bodies corporate), in sub-paragraph (1), for "and 17", substitute ", 17 and 21(3A) and (3B)".

Amendment of paragraph 21 of Schedule 3

27. In paragraph 21(b) of Schedule 3 (terms of service of suppliers of appliances – information to be supplied)—

- (a) in paragraph (1)(a), for "notified to him" substitute "notified to the Primary Care Trust";
- (b) after sub-paragraph (3), insert the following sub-paragraphs—

"(3A) Subject to sub-paragraph (7), where a supplier of appliances that is a body corporate appoints a director who was not listed on that body corporate's application for inclusion on a pharmaceutical list, that supplier of appliances shall, within 28 days of the person's appointment, supply to the Primary Care Trust the information mentioned in paragraphs 4 to 7 of Part 3 of Schedule 4 about that person.

(3B) Subject to sub-paragraph (7), where—

- (a) a supplier of appliances that is a body corporate appointed a director before 17th September 2009 who, on 17th September 2009, is still in post; and
- (b) before that date, the supplier of appliances had not supplied to the Primary Care Trust the information mentioned in paragraphs 4 to 7 of Part 3 of Schedule 4 about that person,

it must supply that information to the Primary Care Trust before 17th March 2010."

Amendment of paragraph 5 of Schedule 4 and that paragraph's heading

28. In Part 1 of Schedule 4 (information to be included in an application for inclusion in a pharmaceutical list or inclusion in a list in respect of different services or premises)—

- (a) in the heading to paragraph 5, for "desirable" substitute "expedient"; and
- (b) in paragraph 5, for "desirable", substitute "expedient".

(a) Substituted by S.I. 2005/1501.
(b) Amended by S.I. 2006/3373.

PART 2

Amendment of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006

Amendment of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006

29. The National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(a) are amended in accordance with the provisions of this Part.

Amendment of regulation 2

30. In regulation 2(b) (interpretation), in paragraph (1)—

- (a) insert at the appropriate place—
 - ““emergency requiring the flexible provision of pharmaceutical services” has the meaning given in regulation 2(5) of the Pharmaceutical Services Regulations;”;
 - and
 - ““optometrist independent prescriber” means a person—
 - (a) who is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989; and
 - (b) against whose name is recorded in that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;”;
- (b) in the definition of “prescriber”, for “or a supplementary prescriber” substitute “, a supplementary prescriber or an optometrist independent prescriber”.

Amendment of regulation 15

31. In regulation 15(c) (right of return to pharmaceutical lists), after paragraph (6) insert the following paragraphs—

“(7) Nothing in this regulation prevents a Primary Care Trust from making a temporary amendment to an LPS Scheme which the Primary Care Trust is satisfied is necessary or expedient because of an emergency requiring the flexible provision of pharmaceutical services.

(8) In the circumstances described in paragraph (7), the Primary Care Trust may make a temporary variation to a determination about a contractor, but—

- (a) only for a specified period (which shall not be longer than the specified period of the emergency given by the Secretary of State) which the Primary Care Trust may extend or curtail in appropriate circumstances; and
- (b) the contractor may revert to the contractor’s overridden determination before the end of the period specified by the Primary Care Trust, on giving the Primary Care Trust at least 24 hours notice.

(9) There is no right of appeal under these Regulations in respect of a decision to make or not to make, or to curtail the duration of, a temporary variation to an LPS scheme made under paragraph (8).”.

Amendment of regulation 16

32. In regulation 16 (sharing of information received)—

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- (a) S.I. 2006/552.
 - (b) Amended by S.I. 2006/913 and 3373, 2007/674 and 2008/528 and 1700.
 - (c) Amended by S.I. 2006/3373 and 2008/528.

- (a) after paragraph (1) insert the following paragraph—
 - “(1A) Where a Primary Care Trust—
 - (a) terminates an LPS scheme on any ground specified in paragraphs 29 to 31 of Schedule 2, it must consider whether its reasons for doing so raise any question about—
 - (i) the contractor’s suitability to be a contractor, or
 - (ii) the fitness to practise of a pharmacist employed by the contractor; or
 - (b) is entitled to or has served a notice on a contractor under paragraphs 29 to 31 of Schedule 2 but the contractor’s LPS scheme is terminated on other grounds, the Primary Care Trust must consider whether the reasons why it served or was entitled to serve a notice under those paragraphs raise any question about—
 - (i) the contractor’s suitability to be a contractor, or
 - (ii) the fitness to practise of a pharmacist employed by the contractor.”; and
- (b) in paragraph (2) for “the information does raise such a question, it must pass the information it has received” substitute “a question referred to in paragraph (1) or (1A) is raised, it must pass on its concerns and any relevant supporting evidence”.

New regulation 16A

33. After regulation 16, insert the following regulation—

“Proceedings with regard to overridden arrangements during an emergency requiring the flexible provision of pharmaceutical services

16A. Where, during an emergency requiring the flexible provision of pharmaceutical services, arrangements for the provision of local pharmaceutical services are overridden by temporary arrangements—

- (a) any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed during the emergency for other reasons); and
- (b) if as a result of those proceedings, the overridden arrangements require amendment before the end of the temporary arrangements, when the emergency ends, the reversion to the overridden arrangements shall be to the overridden arrangements as amended as a result of those proceedings.”.

Amendment of Schedule 2

34.—(1) Schedule 2 (contract terms) is amended in accordance with the provisions of this regulation.

(2) In paragraph 15 (inducements etc.)—

- (a) in paragraph (1), for “A contractor or his staff must not give” substitute “Neither a contractor nor any person employed or engaged by a contractor shall give”;
- (b) after sub-paragraph (2), insert the following sub-paragraphs—
 - “(3) Neither a contractor nor any person employed or engaged by a contractor shall give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of the contractor’s business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—
 - (a) present to the contractor an order for drugs or appliances on a prescription form or repeatable prescription; or
 - (b) nominate the contractor as their dispensing contractor (or one of them) on their NHS Care Record.

(4) For the purpose of sub-paragraph (3), “relevant person” means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

- (a) any NHS body or any person (including a partnership) with a contract to provide a Primary Care Trust with primary medical services; and
- (b) any person employed or engaged by any of the persons mentioned in paragraph (a).”.

(3) After paragraph 26, insert the following paragraph—

“Temporary arrangements during an emergency requiring the flexible provision of pharmaceutical services

26A.—(1) Paragraph 26 shall not apply to an amendment of or variation to the LPS scheme that is made in accordance with this paragraph.

(2) During an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may, on application from a contractor (“C”)—

- (a) permit C a temporary change to the days on which or times at which C is obliged to provide local pharmaceutical services at the premises from which C has undertaken to provide local pharmaceutical services, or permit temporary closure of those premises, if—
 - (i) C gives at least 24 hours notice of the change or closure, and
 - (ii) the reasons given by C for the request are, in the opinion of the Primary Care Trust, adequate reasons; or
- (b) permit C any other temporary variation to C’s LPS scheme that, in the opinion of the Primary Care Trust, will facilitate continuity of the provision of services of a kind that may be provided under section 126, or by virtue of section 127, of the National Health Service Act 2006 during the emergency.

(3) The Primary Care Trust need not approve the request referred to in sub-paragraph (2)(a)(ii) in advance of the change or closure, and if it does not do so but decides subsequently that C’s reasons are not, in its opinion, adequate reasons, then the days on which or times at which C is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to C.”.

PART 3

Amendment of other Regulations

Amendment of the National Health Service (General Medical Services Contracts) Regulations 2004

35. In regulation 2 of the National Health Service (General Medical Services Contracts) Regulations 2004(a) (interpretation), in paragraph (1)—

- (a) after the definition of “open” insert the following definition—
 - ““optometrist independent prescriber” means a person—
 - (a) who is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989; and

(a) S.I. 2004/291; amended by S.I. 2004/2694, 2005/893, 3315 and 3491, 2006/1501, 2007/289 and 3491, and 2008/528 and 1700.

- (b) against whose name is recorded in that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;” and
- (b) in the definition of “prescriber”, after sub-paragraph (aa), insert the following sub-paragraph—
 - “(ab) an optometrist independent prescriber;”.

Amendment of the National Health Service (Personal Medical Services Agreements) Regulations 2004

36. In regulation 2 of the National Health Service (Personal Medical Services Agreements) Regulations 2004(a) (interpretation), in paragraph (1)—

- (a) after the definition of “open” insert the following definition—
 - ““optometrist independent prescriber” means a person—
 - (a) who is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989; and
 - (b) against whose name is recorded in that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;” and
- (b) in the definition of “prescriber”, after sub-paragraph (aa), insert the following sub-paragraph—
 - “(ab) an optometrist independent prescriber;”.

Signed by authority of the Secretary of State for Health.

Ann Keen
Parliamentary Under Secretary of State,
Department of Health

14th August 2009

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the National Health Service (General Medical Services Regulations 2004 (“the GMS Regulations”), the National Health Service (Personal Medical Services) Regulations 2004 (“the PMS Regulations”), the National Health Service (Pharmaceutical Services) Regulations 2005 (“the PS Regulations”) and the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (“the LPS Regulations”). The amendments relate to the statutory arrangements governing the provision of NHS community pharmaceutical services and optometrist prescribing.

Regulations 3(a)(i), 9 and 12 remove from the PS Regulations references to Community Health Councils, which have been abolished, and replace those references where appropriate with references to Local Improvement Networks.

Regulations 3(a)(ii) to (iv), 30, 35 and 36 contain measures which amend the PS Regulations, the LPS Regulations, the GMS Regulations and the PMS Regulations to allow retail pharmacies and dispensing doctors that are entitled to dispense against NHS prescriptions to dispense against prescriptions issued by an optometrist who is qualified to order drugs, medicines and appliances as an optometrist independent prescriber.

Regulations 3(b), 4, 14, 15, 16, 19, 23, 25, 31, 33 and 34(3) contain measures enabling temporary emergency changes to the arrangements for the provision of pharmaceutical services and local pharmaceutical services in England in the event of an emergency arising out of a threat to human

(a) S.I. 2004/627; amended by S.I.2004/2694, 2005/893, 3315 and 3491, 2006/1501, 2007/289 and 3491, and 2008/528 and 1700.

welfare which is caused or which may be caused by human illness (for example, pandemic influenza). In the case of such an emergency, arrangements are put in place to enable retail pharmacies and dispensing doctors to relocate temporarily or take on additional premises without needing to go through the normal applications process – and to enable dispensing doctors to provide pharmaceutical services to patients who are not on their normal patient list. Retail pharmacies included in a pharmaceutical list, whose opening hours are subject to detailed provisions in the PS Regulations, are given additional flexibilities to allow them to make emergency changes to their opening hours and to close premises, where it is reasonable to do so. Retail pharmacies and dispensing doctors will revert to their normal arrangements with their Primary Care Trust after the emergency, unless these have been changed in the mean time via the normal applications process.

Regulations 5, 6 and 28 replace the word “desirable” with the word “expedient” in a number of places in the PS Regulations. This is to reflect the replacement of the word “desirable” with the word “expedient” in the enabling primary legislation.

Regulations 7, 8, 10 and 11 make minor changes to the applications process relating to the lists of providers of pharmaceutical services kept by Primary Care Trusts. These changes amend the notification requirements in relation to applications, change some of the information to be provided, and prevent Primary Care Trusts from granting applications from retail pharmacies to open up adjoining premises as new premises, unless they are satisfied that it would be unreasonable to treat the two premises as one site.

Regulation 13 contains new arrangements for dealing with change of ownership applications in respect of pharmacy premises where the pharmacist who is currently entitled to provide pharmaceutical services from those premises is subject to an investigation by the relevant Primary Care Trust. Essentially, it becomes possible to grant the change of ownership application but continue with the proceedings against the pharmacist, even if the pharmacist no longer has any premises in the Primary Care Trust’s area.

Regulations 17 and 18 amend the PS Regulations to clarify the circumstances in which retail pharmacists on a pharmaceutical list may vary their opening hours without the prior authorisation of their Primary Care Trust – and the circumstances in which an application for a change of opening hours may be made in respect of a pharmacy which must be open for at least 100 hours per week. Also, Easter Sunday is added to the list of days on which a pharmacy is deemed to have been open for the purpose of calculating a pharmacy’s opening hours – and regulation 24 also makes this computation change in respect of the opening hours of dispensing appliance contractors.

Regulations 20 and 34(2) amend the PS Regulations and the LPS Regulations to extend the scope of the restrictions on a retail pharmacist – and the people working for them – providing inducements to customers in consideration for receiving services from the pharmacist. The restrictions now also cover additional services such as the provision of healthy eating advice or smoking cessation advice. However, there are exceptions allowing pharmacists to provide a low value gift to a patient if certain specified conditions are met. Pharmacists are also now prohibited from providing inducements to NHS bodies, or people employed or engaged by them, for them to recommend the pharmacist to potential customers.

Regulations 21, 22, 26 and 27 amend the PS Regulations to provide that where a pharmacist or appliance dispensing contractor which is a body corporate appoints a new superintendent or director, it must supply certain details in respect of that person to the relevant Primary Care Trust.

Regulation 32 amends the LPS Regulations to extend the information sharing obligations of Primary Care Trusts where they have concerns relating to their current and former contractors. In certain circumstances, they are under a duty to inform other Primary Care Trusts and the Royal Pharmaceutical Society of Great Britain of their concerns.

STATUTORY INSTRUMENTS

2009 No. 2205

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Miscellaneous Amendments
Relating to Community Pharmaceutical Services and
Optometrist Prescribing) Regulations 2009

£5.50