STATUTORY INSTRUMENTS

2005 No. 3315

The National Health Service (Primary Medical Services) (Miscellaneous Amendments) (No. 2) Regulations 2005

PART 3

AMENDMENT OF THE PMS AGREEMENTS REGULATIONS

Amendment of regulation 2 of the PMS Agreements Regulations

8.—(1) Regulation 2 (interpretation) of the PMS Agreements Regulations shall be amended as provided in the following paragraphs.

(2) In the definition of "batch issue", for "specified in Part 2 of Schedule 1", substitute "set out in respect of form FP10SS batch issue in the document issued by the Prescription Pricing Authority entitled "Prescription Form Overprint Specifications – GP System Prescription Overprint Specification", version 1 dated June 2004 (**1**)".

(3) In the definition of "immediate family member", after "spouse" insert "or civil partner".

(4) In the definition of "repeatable prescription", for "specified in Part 1 of Schedule 1", substitute "set out in respect of form FP10SS repeatable prescription (authorising form) in the document issued by the Prescription Pricing Authority entitled "Prescription Form Overprint Specifications – GP System Prescription Overprint Specification", version 1 dated June 2004".

(5) In the definition of "supplementary prescriber"—

(a) in paragraph (b)(iii), omit "or";

(b) in paragraph (b)(iv), for "and", in the second place where it occurs, substitute "or";

(c) after paragraph (b)(iv), insert—

"(v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(**2**), and"; and

(d) in paragraph (c), after "an annotation", insert, "or entry".

Amendment of regulation 5 of the PMS Agreements Regulations

9. In regulation 5(3) (general condition relating to all agreements) of the PMS Agreements Regulations, in sub-paragraph (j), before "he has been", insert, "within the period of five years prior to signing the agreement or commencement of the agreement, whichever is the earlier,".

Amendment of regulation 13 of the PMS Agreements Regulations

10. In regulation 13 (finance) of the PMS Agreements Regulations, in paragraph (1), for "the relevant body to make payments to the contractor", substitute, "payments to be made".

(**1**) The overprint specification can be found at www.ppa.org.uk/ppa/prescform_overspec.htm#gpss.
(**2**) 1989 c. 44, as amended by S.I. 2005/848.

Amendment of regulation 18 of the PMS Agreements Regulations

11. In regulation 18 (other contractual terms), in paragraphs (1) and (2), after "35(5) to (17)" insert "47(2) and (4), 47A(6) (in so far as it relates to a determination by the Secretary of State of an appeal) and (15) (in so far as it relates to an appeal to the Secretary of State), 47C(4), 47D (in so far as this paragraph relates to a Primary Care Trust which is not a party to the agreement or an appeal to the Secretary of State), 48A(8),".

Omission of Schedule 1 to the PMS Agreements Regulations

12. Schedule 1 (repeat dispensing forms) to the PMS Agreements Regulations shall be omitted.

Amendment of Schedule 5 to the PMS Agreements Regulations

13.—(1) Schedule 5 (other contractual terms) to the PMS Agreements Regulations shall be amended as provided in the following paragraphs.

(2) In paragraph 44 (excessive prescribing), in sub-paragraph (2), for the word "shall" substitute the words "may, if the contractor consents,".

(3) In paragraph 45 (dispensing services: general), for "Paragraphs 46 to 48" substitute "Paragraphs 46 to 48A".

(4) For paragraphs 46 (provision of dispensing services by contractors other than Primary Care Trusts) to 49 (provision of dispensing services by Primary Care Trusts) substitute—

"**Provision of dispensing services by contractors other than Primary Care Trusts**

46.—(1) Without prejudice to any separate right one or more medical practitioners may have under regulation 60 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors), a contractor may provide dispensing services to its registered patients under the agreement only if it is authorised or required to do so by the Primary Care Trust in accordance with the following provisions of this paragraph or paragraph 48.

(2) A Primary Care Trust may authorise or require a contractor to provide dispensing services to a registered patient only if that patient—

(a) satisfies one of the conditions in sub-paragraph (3); and

(b) has requested the contractor in writing to provide him with dispensing services.

(3) The conditions referred to in sub-paragraph (2)(a) are that the patient—

(a) satisfies the Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication;

(b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy (other than a distance selling chemist), and all of the conditions in sub-paragraph (4) are satisfied in his case;

(c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives—

(i) has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination, or

(ii) is a distance selling chemist,

and all of the conditions in sub-paragraph (4) are satisfied in his case; or

(d) is one to whom paragraph (a) or (b) applies and at the time of the request the patient is living as a member of the household, other than as a temporary resident, of another person in respect of whom a contractor has residual premises approval.

(4) The conditions referred to in sub-paragraphs (3)(b) and (c) are that—

(a) the contractor has been granted consent to dispense under paragraph 47 in respect of—

(i) the area in which the patient resides, and

(ii) the agreement under which the patient receives primary medical services;

(b) there is in effect premises approval in relation to the premises from which the contractor will dispense to the patient; and

(c) any conditions imposed in connection with that grant under regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(4) are such as to permit dispensing services to be provided under this paragraph by that contractor to the patient.

(5) If a contractor which has been requested to provide dispensing services by a patient who satisfies one of the conditions in sub-paragraph (3)—

(a) applies to the Primary Care Trust for the right to provide dispensing services to that patient, and sends with its application the patient's request to the contractor, the Primary Care Trust shall grant its application; or

(b) does not so apply, within the period of 30 days beginning with the date on which the patient made that request, the Primary Care Trust may, subject to sub-paragraph (7), require the contractor to provide dispensing services to that patient at listed premises in the case of a patient falling within sub-paragraph (3)(b) or (c), or practice premises in the case of a patient falling within sub-paragraph (3)(a), and shall give the contractor notice in writing to that effect.

(6) An application granted by the Primary Care Trust under sub-paragraph (5)(a) shall, with effect from the date of the patient's request to the contractor, enable that contractor to provide dispensing services at listed premises in the case of a patient falling within sub-paragraph (3)(b) or (c), or practice premises in the case of a patient falling within sub-paragraph (3)(a) to that patient, so long as the agreement remains in effect.

(7) A Primary Care Trust shall not, under sub-paragraph (5)(b), require a contractor to provide dispensing services at listed premises or practice premises to a patient if the contractor satisfies the Primary Care Trust that—

(a) it does not normally provide dispensing services under the agreement; or

(b) in the case of a patient to whom sub-paragraph (3)(b), (c) or (d) applies, the patient would not have serious difficulty by reason of distance or inadequacy of means of communication in obtaining drugs, medicines or appliances from a pharmacy.

(8) A Primary Care Trust shall give the contractor reasonable notice—

(a) that it requires it to provide dispensing services to a registered patient in accordance with the agreement; or

(b) that, subject to sub-paragraph (9), where a patient no longer satisfies the requirements of sub-paragraph (3), the contractor shall discontinue the provision of dispensing services to that patient.

(9) A notice under sub-paragraph (8)(b)—

(a) shall be subject to any postponement or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions imposed

under regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(4); and

(b) shall not be given—

(i) pending the outcome of the resolution of any dispute concerning the decision by a Primary Care Trust to postpone the making or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions referred to in paragraph (a); or

(ii) during the period for bringing an appeal, or pending the determination of any appeal, referred to in regulation 31(9) of the Pharmaceutical Regulations (determination of whether an area is a controlled locality).

(10) A contractor which has been granted the right under this paragraph to provide dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom that contractor has accepted as a temporary resident.

(11) In this paragraph and in paragraphs 47 to 51 "controlled locality", "distance selling chemist", "pharmacy", "practice premises", "premises approval", "reserved location" and "residual premises approval" have the same meanings as in the Pharmaceutical Regulations, and "listed premises" means the premises specified in relation to the contractor in the dispensing contractors list.

Consent to dispense and premises approval

47.—(1) A contractor which wishes to be granted the right under paragraph 46 to secure the provision of dispensing services to some or all of its registered patients may apply to the Primary Care Trust in writing for—

(a) consent to dispense, specifying—

(i) the area, and

(ii) the agreement,

in relation to which it wishes the consent to dispense to be granted; and

(b) premises approval, specifying—

(i) the premises for which it wishes to be granted premises approval and whether those premises are listed premises in relation to a different area, and

(ii) whether the application arises because there has been a practice amalgamation and, if so, the names of the contractors participating in the amalgamation.

(2) An application under sub-paragraph (1) shall be determined in accordance with paragraph 47A and regulations 18, 20(2), 33, 34 and 36 to 38 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraph (4)), as though it were an application for outline consent or premises approval under regulation 61 of those Regulations.

(3) The Primary Care Trust may refuse an application in respect of some of the premises for which approval is sought (notwithstanding that it would, if determining the application for those premises in isolation, grant it) where the number of applications for premises approval are such, or the circumstances in which they are made are such, that to grant all or some of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.

(4) Regulations 18, 20(2), 33, 34 and 36 to 38 of the Pharmaceutical Regulations shall apply as if—

(a) in regulations 18(1), 34(1), 38(2)(e), for the references to "outline consent" there were substituted references to "consent to dispense";

(b) in regulation 18(2), for the reference to provisions being "subject to regulations 25, 26 and 65(4)" there were substituted a reference to provisions being, "subject to paragraph 47D(4)";

(c) in regulations 18(2)(b) and (c), 33(2)(j) and 34(1)(a) for the references to "regulation 61" there were substituted references to this paragraph;

(d) in regulations 33(2) and 36(1) and (9), the references to provisions being "subject to regulations 25 and 26" were omitted;

(e) for regulation 33(3) there were substituted—

"(3) Where the Primary Care Trust has sent a copy of an application under paragraph (2)(f) to another Primary Care Trust or Local Health Board it shall also, as soon as practicable, send a copy to—

(a) the Local Pharmaceutical Committee for the locality of that other Primary Care Trust or Local Health Board (if any);

(b) the Local Medical Committee for the locality of that other Primary Care Trust or Local Health Board (if any);

(c) any person whose name is included in the pharmaceutical list of that other Primary Care Trust or Local Health Board, and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(d) any LPS chemist in the locality of that other Primary Care Trust or Local Health Board whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(e) any person (except that other Primary Care Trust or Local Health Board) who is a provider of primary medical services or whose name is included in the dispensing contractors list, or dispensing doctor list maintained in accordance with regulation 68 of the Pharmaceutical Regulations, of that other Primary Care Trust or Local Health Board who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(f) any Patients' Forum or Community Health Council serving the area of that other Primary Care Trust or Local Health Board; and

(g) any other patient, consumer or community group in the area of that other Primary Care Trust or Local Health Board that the Primary Care Trust considers has an interest in the provision of dispensing services in the neighbourhood.";

(f) in regulation 38(2)(c), for the references to "regulation 60" there were substituted a reference to paragraph 46;

(g) in regulation 38(2)(e)(i), for the reference to "regulation 62(8)" there were substituted a reference to paragraph 47A(8);

(h) in regulation 38(2)(e)(ii) for "paragraph (13)(a) of that regulation" there were substituted " paragraph 47A(13)(a);"; and

(i) in regulation 38(2)(e)(iii), for "paragraph (13)(b) of that regulation" there were substituted "paragraph 47A(13)(b)",

(5) Any reference in paragraphs 47A, 47C, 47D or 48A to regulations 18, 20(2), 33, 34 and 36 to 38 shall apply as modified by sub-paragraph (4).

Taking effect of consent to dispense and premises approval

47A.—(1) When granting consent to dispense, the Primary Care Trust shall determine in accordance with sub-paragraph (2) when the consent to dispense is to take effect.

(2) The consent to dispense shall take effect—

(a) in relation to premises to which sub-paragraph (3) applies, on the date on which consent to dispense is finally granted; and

(b) in relation to premises to which sub-paragraph (4) applies, in accordance with sub-paragraphs (11) to (13).

(3) This sub-paragraph applies to premises for which consent to dispense is sought and—

(a) which were, on the date of receipt of the application by the Primary Care Trust—

(i) practice premises, or

(ii) in a reserved location; or

(b) in relation to which, on the day before the date on which the application for consent to dispense is granted, there are no outstanding applications.

(4) This sub-paragraph applies where, on the day before the date on which the application for outline consent is granted, there are outstanding applications.

(5) For the purposes of sub-paragraphs (3), (4), (6), (9) and (10) and paragraphs 47C and 47D, an "outstanding application" means an application by a pharmacist under regulation 5 or 40 of the Pharmaceutical Regulations which—

(a) is in relation to premises which are within 1.6 kilometres of the premises for which premises approval has been sought; and

(b) which—

(i) has been made, but not determined (including on appeal), or

(ii) has been granted but the provision of pharmaceutical services from those premises has not commenced.

(6) Where sub-paragraph (2)(b) applies, notification of the determination of the application for consent to dispense by the Primary Care Trust or, on appeal, by the Secretary of State, shall give details of—

(a) the outstanding applications; and

(b) the earliest date on which an application can be made under sub-paragraph (11) to the Primary Care Trust for a determination that the consent to dispense should come into effect ("provisional date").

(7) The provisional date is the day after the end of a period of one year beginning with the date of—

(a) the determination of the application for consent to dispense; or

(b) where that determination is the subject of an appeal, the determination of that appeal.

(8) The Primary Care Trust may, at any time before the provisional date, for good cause determine that the provisional date shall be extended for a period not exceeding three months beginning with the date specified in sub-paragraph (7)(a) or (b), and any reference in this paragraph or in paragraph 47C to the provisional date shall include a reference to the provisional date as extended under this sub-paragraph.

(9) The Primary Care Trust shall—

(a) ensure that any notifications required to be given by the Primary Care Trust or the Secretary of State in relation to any outstanding applications are also given to the contractor who made the application under paragraph 47;

(b) notify that contractor if any outstanding application is withdrawn; and

(c) where it extends the provisional date under sub-paragraph (8), notify that contractor of the new provisional date.

(10) The consent to dispense shall lapse if, before the provisional date, pharmaceutical services are provided from premises which were the subject of an outstanding application which has been granted.

(11) On, or as soon as reasonably practicable after, the provisional date, the Primary Care Trust shall notify the contractor who made the application under paragraph 47 and—

(a) it may within three months of the provisional date require the Primary Care Trust in writing to determine whether the consent to dispense should come into effect; and

(b) the Primary Care Trust shall determine the request as soon as practicable and in accordance with sub-paragraphs (12) and (13).

(12) Where, on the date of the determination under sub-paragraph (11), the premises are practice premises, the Primary Care Trust shall determine that the consent to dispense and premises approval in respect of those premises shall come into effect on that date.

(13) Where, on the date of the determination under sub-paragraph (11), the premises are not practice premises—

(a) the application for consent to dispense shall be refused as regards premises approval for those premises; or

(b) where none of the premises for which premises approval has been granted are practice premises, the consent to dispense shall lapse.

(14) The Primary Care Trust shall notify its determination under sub-paragraph (11) to the contractor and those persons to whom notice of the application under paragraph 47 was required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations.

(15) Where the Primary Care Trust has determined that—

(a) the provisional date shall be extended under sub-paragraph (8);

(b) the application for consent to dispense shall be refused under sub-paragraph (13)(a); or

(c) consent to dispense shall lapse under sub-paragraph (13)(b),

the contractor may appeal to the Secretary of State against any such determination by giving notice of appeal in accordance with regulation 38(5) of the Pharmaceutical Regulations, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations

(16) Premises approval shall take effect when the related consent to dispense takes effect.

Lapse of consent to dispense and premises approval

47B.—(1) A consent to dispense shall cease to have effect—

(a) where no arrangement under paragraph 46 has been made pursuant to it within 12 months from its taking effect;

(b) where more than 12 months have elapsed since the last provision of drugs and appliances under an arrangement made pursuant to paragraph 46;

(c) in accordance with paragraph 47A(10) or (13);

(d) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval; or

(e) where the agreement has terminated(**3**).

(2) Premises approval shall cease to have effect in relation to—

(a) listed premises which have permanently ceased to be practice premises;

(b) listed premises which have not been used for dispensing by the contractor for six months or such longer period as the Primary Care Trust may for good cause allow;

(c) listed premises which were granted premises approval under paragraph 47E(3), where no practice amalgamation takes place within the period specified in paragraph 47E(7).

(3) Premises approval shall cease to have effect where the related consent to dispense ceases to have effect.

Premises approval: change of premises before consent to dispense takes effect

47C.—(1) Where—

(a) consent to dispense has been granted but has not yet taken effect under paragraph 47A; and

(b) before the provisional date, the contractor intends to change the premises from which he wishes to dispense,

the contractor may apply to the Primary Care Trust in writing for the Primary Care Trust to determine whether premises approval should be given in relation to the new premises, and the Primary Care Trust shall make the determination in accordance with sub-paragraph (2).

(2) If the Primary Care Trust is satisfied that the change of premises is a minor relocation it may grant premises approval for those premises, but if it is not so satisfied the application for the premises approval to be given in relation to the new premises shall be refused.

(3) The Primary Care Trust shall notify those persons to whom notice of the application under paragraph 47 was required to be given and applicants in relation to the outstanding applications, of its determination under sub-paragraph (2).

(4) The determination by the Primary Care Trust under sub-paragraph (2) may be appealed to the Secretary of State by the contractor, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations.

Premises approval: additional and new premises after consent to dispense has taken effect

47D.—(1) A contractor who has been granted consent to dispense which has taken effect and who wishes to be granted premises approval in relation to premises in addition to those in respect of which premises approval has been given ("additional premises") may apply to all the appropriate Primary Care Trusts and—

(a) the application shall be determined by the relevant Primary Care Trust, and

(b) this paragraph and paragraph 47 and regulations 18, 20(2), 34, 36(1) and (3) to (9), 37 and 38 of the Pharmaceutical Regulations shall apply to such an application as they apply to an application for consent to dispense under paragraph 47.

(2) For the purposes of this paragraph—

(a) the "appropriate Primary Care Trusts" are those who hold dispensing contractor lists on which the contractor making the application is included; and

(**3**) Paragraph 49 of the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291, as amended by S.I. 2004/906 and 2694 and 2005/28 and 893) makes provision in relation to consent to dispense and premises approval where a contractor moves from a personal medical services agreement to a general medical services contract.

(b) the "relevant Primary Care Trust" is the Primary Care Trust in whose area the additional premises are situated.

(3) A contractor wishing to be granted premises approval in relation to premises ("new premises") where it wishes to dispense instead of listed premises may apply to all the appropriate Primary Care Trusts and the application shall be determined by the relevant Primary Care Trust in accordance with sub-paragraph (4).

(4) The relevant Primary Care Trust shall—

(a) grant the application made in accordance with sub-paragraph (3) where—

(i) the new premises are less than 500 metres by the most practicable route on foot from the listed premises which they are to replace, or

(ii) the Primary Care Trust is otherwise satisfied that granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services in any part of a controlled locality,

provided that no further applications shall be granted under this sub-paragraph for a period of 12 months beginning with the date on which the contractor commenced providing services from the new premises unless the Primary Care Trust shall for good cause allow; and

(b) in any other case determine the application in accordance with sub-paragraph (1) as if the references to additional premises were to new premises.

(5) The relevant Primary Care Trust shall notify its determination under sub-paragraph (4)(a) to the persons to whom the notice is required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations and to the appropriate Primary Care Trusts.

(6) A determination by the relevant Primary Care Trust may be appealed to the Secretary of State by the contractor and any of the persons notified under sub-paragraph (5) apart from any Local Pharmaceutical Committee or any Local Medical Committee, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations.

(7) Subject to sub-paragraph (8), when granted in relation to new or additional premises, the premises approval shall take effect from the date of notification of the grant and for this purpose the date of the notification of a grant of any application shall be—

(a) where no appeal is made under sub-paragraph (6) against the decision of the relevant Primary Care Trust, the date after the expiry of the period of 30 days beginning with the date on which notice of that decision is given under sub-paragraph (5); or

(b) where such an appeal is made, the date on which the Secretary of State gives notice of his decision under regulation 38 of the Pharmaceutical Regulations.

(8) Where—

(a) the premises approval is granted in relation to additional premises; and

(b) in relation to the premises for which the approval is granted there was, at the date of the grant, an outstanding application,

the premises approval shall provisionally take effect on the date which is the day after the end of a period of one year, or such longer period (not exceeding three months) as the relevant Primary Care Trust may for good cause allow before the expiration of that year, from the final resolution of any outstanding application.

(9) The relevant Primary Care Trust may grant temporary premises approval to a contractor who has consent to dispense and premises approval in relation to additional or new premises where it considers it desirable to do so to secure the adequate provision of dispensing services

in the area served by the premises, and renew any such temporary approval granted, to secure such adequate provision, and where it does so it shall—

(a) notify those persons to whom notice of the application under paragraph 47 was required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations and applicants in relation to outstanding applications;

(b) state the period during which the temporary premises approval is to apply; and

(c) include those premises in the dispensing contractors list in relation to that contractor.

(10) Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding three months.

Premises approval: practice amalgamations

47E.—(1) "A practice amalgamation" occurs where two or more providers of primary medical services merge as a result of which two or more patient lists are combined and the agreement is varied.

(2) If, following a practice amalgamation, all the practice premises of the new practice are premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, then consent to dispense and premises approval shall continue to have effect.

(3) Where there is, or will be, a practice amalgamation and none or not all of the practice premises of the contractor are, or will be, premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, the contractor if it has been granted consent to dispense and premises approval which is in effect either immediately before the practice amalgamation or the date of the application under this sub-paragraph, may make an application for premises approval, and it shall be determined as provided in paragraph 47D as if it were an application from a contractor with premises approval to have the right to dispense from—

(a) additional premises where the premises approval is required for additional premises as defined in paragraph 47D(1); or

(b) new premises where the premises approval is required for new premises as defined in paragraph 47D(3),

and the Primary Care Trust may grant temporary premises approval under paragraph 47D(9).

(4) An application mentioned in sub-paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

(a) any premises approval in effect at the date of the practice amalgamation shall have effect from the date of the amalgamation as if it were a temporary approval under paragraph 47D(9) for a period stated by the Primary Care Trust not exceeding one year; and

(b) the contractor shall have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Primary Care Trust not exceeding one year.

(5) When the practice amalgamation takes effect the contractor shall notify all Primary Care Trusts in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to sub-paragraph (7), where an application made under sub-paragraph (3) was granted before the practice amalgamation takes place, premises approval shall take effect from the date of the practice amalgamation.

(7) Where an application was made under sub-paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted under that sub-paragraph, that grant shall lapse.

(8) Where an application under sub-paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the contractor if it had premises approval prior to making the application, shall have residual premises approval.

(9) For the purposes of this paragraph "residual premises approval" means approval to dispense—

(a) from premises in respect of which the contractor had premises approval at the time of the application in relation to the practice amalgamation; and

(b) to—

(i) a patient for whom the contractor making the application is authorised to provide dispensing services on the date the application was refused, but excluding any such patient who ceases to be a patient mentioned in paragraph 46(3)(b) or (c); or

(ii) a patient who is not mentioned in sub-paragraph (i) but who is mentioned in paragraph 46(3)(a) or (d) and for whom the contractor making the application is authorised to provide dispensing services on the date the application was refused.

(10) For the purposes of sub-paragraph (9), paragraph 46(3)(b) or (c) shall be read as if the words "and all of the conditions in sub-paragraph (4) are satisfied in his case" were omitted.

Contractors who previously provided dispensing services under a general medical services contract

48.—(1) This paragraph applies where the contractor was, immediately before the commencement of the agreement, providing primary medical services in the area of the Primary Care Trust under a general medical services contract and—

(a) the contractor was, immediately before the commencement of the agreement, providing dispensing services to some or all of its patients in accordance with the general medical services contract; and

(b) the contractor has notified the Primary Care Trust before entering into the agreement that it intends to provide dispensing services under it.

(2) In a case to which this paragraph applies the contractor shall be regarded as—

(a) being authorised or required under paragraph 46 to provide dispensing services under the agreement to any patient—

(i) to whom, immediately before commencement of the agreement, it provided dispensing services under a general medical services contract, and

(ii) who wishes the contractor to continue to provide him with such services; and

(b) having been granted consent to dispense in relation to the agreement under paragraph 47 in relation to the area for which it had such consent under the general medical service contract; and

(c) having been granted premises approval in relation to the agreement under paragraph 47 for those premises from which it had, immediately before the commencement of the agreement, authority to provide dispensing services under the general medical services contract.

Transitional provisions

48A.—(1) This paragraph applies where the contractor has been granted, prior to 6th January 2006, consent to dispense in accordance with paragraph 47 and that consent is in effect on 6th January 2006.

(2) For the purposes of this paragraph, "relevant premises" means—

(a) premises from which, at the date of notification under sub-paragraph (5), the contractor is providing primary medical services; or

(b) premises in addition to or in place of the premises specified in paragraph (a) where, immediately before 6th January 2006, the contractor intended to dispense.

(3) The Primary Care Trust shall determine whether or not to grant premises approval to relevant premises in accordance with sub-paragraphs (4) to (6).

(4) Before 5th February 2006 the Primary Care Trust shall notify the contractor that—

(a) the Primary Care Trust is required to make a determination under sub-paragraph (3) as to whether or not to grant premises approval in respect of the relevant premises; and

(b) it may make written representations to the Primary Care Trust in relation to such a determination within the period of 30 days beginning with the date of the Primary Care Trust's notification or such longer period as the Primary Care Trust may for good cause allow.

(5) The Primary Care Trust shall—

(a) also notify the Local Medical Committee (if any) and the Local Pharmaceutical Committee (if any) which were required to be sent a copy of the application under regulations 33(2) and (3) of the Pharmaceutical Regulations and inform them that they may make written representations within the period of 30 days beginning with the Primary Care Trust's notification;

(b) consider any representations received from the Committees mentioned in paragraph (a) and the contractor;

(c) determine that the contractor has premises approval for premises which are, or are part of, relevant premises; and

(d) notify its decision to the contractor, the Committees mentioned in paragraph (a), any person providing pharmaceutical services or dispensing services in the Primary Care Trust's area whose interests might, in the opinion of the Primary Care Trust, be affected and all Patients' Forums in that area.

(6) The Primary Care Trust shall grant premises approval under sub-paragraph (3) where it is satisfied that the relevant premises were, prior to 6th January 2006, being routinely used to provide dispensing services.

(7) The Primary Care Trust shall not refuse to grant premises approval under sub-paragraph (3) by reason of the relevant premises being within 1.6 kilometres of any pharmacy.

(8) The Primary Care Trust's determination under sub-paragraph (5)(c) may be appealed to the Secretary of State by a person notified of the determination under sub-paragraph (5)(d) except the Committees mentioned in sub-paragraph (5)(a), and regulations 38(5) to (15) of the Pharmaceutical Regulations shall apply to such appeals except that, for this purpose, regulation 38 shall be read as if—

(a) in paragraph (7), for "those persons mentioned in paragraph (3)(a)" to the end, there were substituted "those persons notified under sub-paragraph (5)(d)";

(b) in paragraph (12), the list of persons to whom notice of the hearing should be sent were a reference to the persons notified under sub-paragraph (5)(d); and

(c) in paragraph (14), sub-paragraphs (b), (c) and (d) were omitted.

(9) Until—

(a) the date of the determination of the Primary Care Trust under sub-paragraph (3); or

(b) the date that any appeal under sub-paragraph (8) is decided,

whichever is the later, a contractor shall be deemed to have been granted premises approval for the relevant premises, but it may not make any application to which paragraph 47C or 47D applies.

Provision of dispensing services by Primary Care Trusts

49.—(1) A Primary Care Trust may provide dispensing services under the agreement to its registered patients with the consent of the Strategic Health Authority.

(2) A Primary Care Trust may provide dispensing services to a registered patient only if that patient—

(a) satisfies one of the conditions in sub-paragraph (3); and

(b) has requested the Primary Care Trust in writing to provide him with dispensing services.

(3) The conditions referred to in sub-paragraph (2)(a) are that the patient—

(a) satisfies the Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication;

(b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy (other than a distance selling chemist);

(c) is resident in a controlled locality, and any pharmacy within a distance of 1.6 kilometres from where the patient lives—

(i) has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of further determination, or

(ii) is a distance selling chemist; or

(d) is one to whom paragraph (a) or (b) applies and at the time of the request the patient is living as a member of the household, other than as a temporary resident, of another person in respect of whom the Primary Care Trust has consent to dispense.

(4) A Primary Care Trust which provides dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom it has accepted as a temporary resident.”.

(5) In paragraph 50 (terms relating to the provision of dispensing services), after sub-paragraph (8) insert—

“(8A) A contractor providing dispensing services shall comply with paragraphs 7(1), (3) and (4) of Schedule 2 (terms of service of dispensing doctors) to the Pharmaceutical Regulations, with all references to “a dispensing doctor” or “the dispensing doctor” being read as references to the contractor providing dispensing services.”.

(6) In paragraph 51(dispensing contractor list)—

(a) for sub-paragraph (1) substitute—

“(1) Where the contractor is authorised or required by the Primary Care Trust under paragraph 46 or 48 to provide dispensing services to its patients and is actually doing so the Primary Care Trust in whose area most of the patients reside shall—

(a) include the contractor’s name;

(b) include the address of the contractor's premises from which it is authorised or required to dispense;

(c) include that the contractor is a contractor providing services under an agreement;

(d) include the premises in relation to which the contractor has premises approval;

(e) state in relation to each premises included—

(i) if premises approval is deemed, temporary or residual, that this is the case, and

(ii) the date on which premises approval took effect or where it has not taken effect, the date that it was finally granted;

(f) state the area in relation to which there is consent to dispense and premises approval; and

(g) include and identify separately, any premises in relation to which the contractor has undetermined applications for premises approval,

in its dispensing contractors list which it prepares and maintains under paragraph 51 of Schedule 6 to the General Medical Services Contracts Regulations (dispensing contractor list).”; and

(b) in sub-paragraph (2)(a), for the words “pursuant to paragraph 48(3)” substitute the words “ in accordance with paragraph 47B(1)”.

(7) For paragraph 66 (signing of documents), substitute—

“**66.**—(1) In addition to any other requirements relating to such documents whether in these regulations or otherwise, the contractor shall ensure—

(a) that the documents specified in sub-paragraph (2) include—

(i) the clinical profession of the health care professional who signed the document; and

(ii) the name of the contractor on whose behalf it is signed; and

(b) that the documents specified in sub-paragraph (3) include the clinical profession of the health care professional who signed the document.

(2) The documents referred to in sub-paragraph (1)(a) are—

(a) certificates issued in accordance with regulation 12, unless regulations relating to particular certificates provide otherwise; and

(b) any other clinical documents, apart from those specified in sub-paragraph (3).

(3) The documents referred to in sub-paragraph (1)(b) are batch issues, prescription forms and repeatable prescriptions.”.

(8) In paragraph 70 (patient records), in sub-paragraph (5)(c), for ““Good Practice Guidelines for General Practice Electronic Patient Records” published on 26th September 2003”, substitute, ““Good Practice Guidelines for General Practice Electronic Patient Records (Version 3.1)” published on 29th July 2005(**4**)”.

(9) In paragraph 117 (gifts), in sub-paragraph (2)(e), after “spouse”, insert, “or civil partner”.

(**4**) This document is available on the following website address: www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/PrimaryCareComputing.