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STATUTORY INSTRUMENTS

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**2012 No. 1909**

**The National Health Service  
(Pharmaceutical Services) Regulations 2012**

**PART 8**

**Dispensing doctors**

**Dispensing doctor lists**

**46.**—(1) Each Primary Care Trust must prepare and publish a list (a “dispensing doctor list”) of the names any “dispensing doctors” in the area of the Primary Care Trust, that is to say—

- (a) providers of primary medical services who provide pharmaceutical services from medical practice premises in the area of the Primary Care Trust; and
  - (b) general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in the area of the Primary Care Trust (not including general practitioners who are listed as part of the listing of a provider by virtue of paragraph (6)(b)).
- (2) Each dispensing doctor list must be available for public inspection and must include—
- (a) the address of any premises in the area of the Primary Care Trust for which a listed dispensing doctor has premises approval (“the listed dispensing premises”) and any other medical practice premises of the dispensing doctor in that area; and
  - (b) any area in relation to which the dispensing doctor has outline consent.
- (3) A Primary Care Trust must remove a dispensing doctor from its dispensing doctor list if—
- (a) in the case of a listed provider of primary medical services, that person or partnership ceases to be a provider of primary medical services or ceases to be a provider of those services to the Primary Care Trust;
  - (b) in the case of a listed general practitioner, that person is no longer on a medical performers list or no longer performs primary medical services within the area of the Primary Care Trust; or
  - (c) all the arrangements that the dispensing doctor has with the Primary Care Trust to perform or provide pharmaceutical services have been discontinued, or the permissions that the dispensing doctor requires in order to have such arrangements have lapsed, in accordance with this Part.
- (4) If—
- (a) a general practitioner who is the only partner or shareholder in a provider of primary medical services who is a dispensing doctor so elects; or
  - (b) all the general practitioners who are the members of a provider of primary medical services who are dispensing doctors so elect,

they may request that their Primary Care Trust lists that provider instead of them as the dispensing doctor (or doctors) on the Primary Care Trust’s dispensing doctors list.

- (5) In the circumstances described in paragraph (4)—
  - (a) the Primary Care Trust must agree to that request;
  - (b) the arrangements that the Primary Care Trust had with the individual dispensing doctor or doctors become arrangements with the provider of primary medical services; and
  - (c) the premises approvals and related outline consents of those general practitioners become the premises approvals and outline consents of the provider of primary medical services.
- (6) Where a provider of primary medical services is listed in a dispensing doctors list—
  - (a) the provider must notify the Primary Care Trust—
    - (i) of any general practitioner who performs primary medical services on behalf of the provider who the provider anticipates will provide pharmaceutical services on behalf of the provider, and
    - (ii) if a general practitioner who has been so notified, when the provider no longer anticipates that the general practitioner will provide pharmaceutical services on behalf of the provider; and
  - (b) as part of the listing of the provider in its dispensing doctors list, the Primary Care Trust must include the names of any general practitioner notified under sub-paragraph (a)(i), unless the Primary Care Trust has received a further notification in respect of that general practitioner under sub-paragraph (a)(ii).

#### **Terms of service of dispensing doctors: general**

47.—(1) The arrangements under which a dispensing doctor undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights and obligations that—

- (a) are included in these Regulations, including—
    - (i) the terms of service set out in Schedule 6 (which accordingly has effect), and
    - (ii) any obligation that is only applicable in prescribed cases, if the dispensing doctor is a person to whom the obligation is applicable;
  - (b) were imposed, in relation to the dispensing doctor's ability to provide pharmaceutical services, by virtue of regulation 20(2) of the 2005 Regulations<sup>(1)</sup> (imposition of conditions);
  - (c) are included in the arrangements for remuneration for services provided by dispensing doctors that give effect to regulation 92, in so far as those rights and obligations are applicable in the case of the dispensing doctor; and
  - (d) are included in regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008<sup>(2)</sup> (duty of services-providers to allow entry by local involvement networks), in so far as it applies to dispensing doctors.
- (2) The Primary Care Trust must ensure that those terms of service—
- (a) if the dispensing doctor has arrangements with the Primary Care Trust for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services, are conditions of and so are enforceable under those arrangements; or
  - (b) if the dispensing doctor has no such arrangements—

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<sup>(1)</sup> Prior to its repeal, regulation 20 was amended by S.I. 2006/552.

<sup>(2)</sup> S.I. 2008/915.

- (i) are terms of service of, and so are enforceable under, the arrangements that the Primary Care Trust has with a provider of primary medical services for the provision of primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services, or
- (ii) are terms of service of the arrangements under which a PCTMS practice provides primary medical services to the patients to whom the dispensing doctor provides pharmaceutical services.

### **Arrangements for the provision of pharmaceutical services by doctors: applications by patients**

**48.**—(1) A patient (P) may at any time request in writing that a dispensing doctor (D) provides P with pharmaceutical services if—

- (a) one or more of the Conditions specified in paragraphs (2) to (4) is satisfied in relation to P; and
- (b) P is on either D's patient list or the patient list of a provider of primary medical services or PCTMS practice (E) by whom D is employed or engaged.

(2) Condition 1 is that P satisfies the Primary Care Trust (PCT1) by which P is recorded as being on D or E's patient list that P would have serious difficulty in obtaining any necessary drugs or appliances from pharmacy premises by reason of distance or inadequacy of means of communication.

(3) Condition 2 is that P is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy premises, other than distance selling premises, and—

- (a) there is in effect—
  - (i) an outline consent that has been granted to D, and
  - (ii) a related premises approval for the premises from which D (or another general practitioner within the practice) would dispense to P; or
- (b) the following—
  - (i) immediately before these Regulations came into force, there was a right (other than outline consent) in effect under the 2005 Regulations for D, E or another general practitioner employed or engaged by E to provide drugs or appliances to patients on D or E's patient list (a right which continues in effect under these Regulations, subject to regulation 60),
  - (ii) P either—
    - (aa) has not previously been included in a patient list in the area of that Primary Care Trust,
    - (bb) has been so included but changed address from that last notified to the Primary Care Trust, or
    - (cc) has been so included and has not changed address, but immediately before P's acceptance by D or E onto their patient list, P was being provided with pharmaceutical services by another general practitioner or provider of primary medical services under arrangements with the Primary Care Trust, and
  - (iii) there is in effect premises approval in relation to the premises from which D would dispense to P.

(4) Condition 3 is that P is resident in a controlled locality and within a distance of 1.6 kilometres from pharmacy premises that are not distance selling premises, but—

- (a) P is resident in a reserved location; and
  - (b) either paragraph (3)(a) or (b) is satisfied in relation to P.
- (5) If D—
- (a) in response to the request, applies in writing to PCT1, enclosing P’s request, PCT1 must make arrangements with D for the provision of pharmaceutical services to P—
    - (i) in a case to which Condition 1 applies, from D’s medical practice premises, or
    - (ii) in a case to which Condition 2 or 3 applies, from D’s listed dispensing premises; or
  - (b) does not respond to the request as mentioned in sub-paragraph (a) within 30 days, PCT1 may, subject to paragraph (7), require D to undertake to provide pharmaceutical services to P—
    - (i) in a case to which Condition 1 applies, from D’s medical practice premises, or
    - (ii) in a case to which Condition 2 or 3 applies, from D’s listed dispensing premises,by a notification to that effect which gives D reasonable notice of when the requirement is to take effect.
- (6) PCT1 must not, under paragraph (5)(b), require D to undertake to provide services to P, if D satisfies PCT1 that—
- (a) D does not normally provide pharmaceutical services; or
  - (b) P would not have serious difficulty in obtaining any necessary drugs or appliances from pharmacy premises by reason of distance or inadequacy of means of communication.
- (7) Where arrangements have been made between D and PCT1 for the provision of pharmaceutical services, those arrangements take effect—
- (a) in a case to which paragraph (5)(a) applies, from the date of the patient’s request in writing; or
  - (b) in a case to which paragraph (5)(b) applies, from the date which PCT1 specifies in the notice under that paragraph as the date on which the arrangements are to take effect, or if D appeals the decision under paragraph (5)(b), the date on which that appeal reaches its final outcome.
- (8) Under those arrangements, at or from the relevant medical practice premises or listed dispensing premises for those arrangements, the following may provide pharmaceutical services to the patient, for as long as the arrangements remain in effect—
- (a) if the arrangements are with a provider of primary medical services (including an individual who is such a provider), any general practitioner performing primary medical services on behalf of that provider; or
  - (b) if the arrangements are with an individual general practitioner who performs primary medical services on behalf of a provider of primary medical services or a PCTMS practice, the general practitioner or any other general practitioner who performs primary medical services on behalf of that provider or practice.
- (9) To be valid, a notification under paragraph (5)(b) by the Primary Care Trust must include an explanation of—
- (a) the reasons for the imposition of the requirement; and
  - (b) D’s right of appeal under regulation 63(1)(a).

### **Necessary services for temporary patients**

**49.** A dispensing doctor who provides pharmaceutical services to patients on a patient list may provide necessary pharmaceutical services to a person who has been accepted by the dispensing doctor as a temporary patient.

### **Discontinuation of arrangements for the provision of pharmaceutical services by doctors**

**50.—(1)** In circumstances where a Primary Care Trust has arrangements (whether they were made under these Regulations or were made under or continued by virtue of the 2005 Regulations) with a dispensing doctor (D) to provide pharmaceutical services to a person (P), if—

- (a) pharmaceutical services have been provided to P because of the circumstances described in Condition 1 in regulation 48(2), but the Primary Care Trust determines that Condition 1 no longer applies in relation to P;
- (b) the area in which P is resident was but ceases to be a controlled locality, and the provision of pharmaceutical services to P arose out of P's residence in a controlled locality;
- (c) P was resident in but has moved out of a controlled locality, and the provision of pharmaceutical services to P arose out of P's residence in that controlled locality;
- (d) P is resident in a controlled locality but is not (any longer) resident at a distance of more than 1.6 kilometres from any pharmacy premises, other than distance selling premises, at or from which pharmaceutical services are being provided, and—
  - (i) the Primary Care Trust determines that Condition 3 in regulation 48(4) does not apply in respect of P, or
  - (ii) the Primary Care Trust determines that Condition 3 in regulation 48(4) does apply in respect of P, but P informs the Primary Care Trust that P wishes to be provided with pharmaceutical services by a person on its pharmaceutical list rather than by D (other than as permitted by paragraph 7 of Schedule 6);
- (e) P is resident in a reserved location, and—
  - (i) had previously informed the Primary Care Trust that P wished to be provided with pharmaceutical services by D, but
  - (ii) P has since informed the Primary Care Trust that P wishes instead to be provided with pharmaceutical services by a person on a pharmaceutical list rather than by D (other than as permitted by paragraph 7 of Schedule 6); or
- (f) P is resident in a location that ceases to be or be part of a reserved location as a consequence of a determination referred to in regulation 42 as D2,

D must terminate the provision of pharmaceutical services to P, subject to any postponement of the discontinuation by the Primary Care Trust in accordance with paragraphs (2) to (6).

- (2) A Primary Care Trust may postpone the discontinuation—
  - (a) until any proceedings relating to the discontinuation, including proceedings arising out of the grant of a routine or excepted application that has led to the discontinuation, have reached their final outcome; or
  - (b) where paragraph (3) or (4) applies.
- (3) This paragraph applies where—
  - (a) a Primary Care Trust grants a routine or excepted application, the result of which is the inclusion in its pharmaceutical list of pharmacy premises that are not already listed in relation to an NHS pharmacist;
  - (b) the pharmacy premises to which that application relates are not distance selling premises but—

- (i) are in a controlled locality, or
  - (ii) are within 1.6 kilometres of a part of a controlled locality in which patients of a dispensing doctor reside and those patients are being provided with pharmaceutical services by that dispensing doctor; and
  - (c) granting the routine or excepted application, in the opinion of the Primary Care Trust, results in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on a dispensing doctor list) or local pharmaceutical services in any part of a controlled locality.
- (4) This paragraph applies where a Primary Care Trust is required to terminate the provision of pharmaceutical services pursuant to paragraph (1)(f) but the Primary Care Trust is satisfied that the determination that led to the decision to terminate has adversely affected D.
- (5) Where paragraph (3) or (4) applies, the Primary Care Trust may postpone the discontinuation for such period as it thinks fit.
- (6) The Primary Care Trust must postpone the discontinuation—
- (a) while it is forming the opinion mentioned in paragraph (3)(c); or
  - (b) for such period as the Primary Care Trust considers necessary in order to give the doctor reasonable notice (in any case to which paragraph (1) applies) of the discontinuation.
- (7) The Primary Care Trust must notify any decision under this regulation to terminate arrangements to provide pharmaceutical services, subject to any postponement of the discontinuation, to—
- (a) D;
  - (b) if there is any postponement of the discontinuation, the NHS pharmacist listed in relation to any pharmacy premises, the presence of which, or the choice of a patient to obtain services from which, led to the determination of the Primary Care Trust;
  - (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts); and
  - (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
- (8) Each notification under paragraph (7) must include—
- (a) a statement of the reasons for the decision; and
  - (b) if the person notified is a person with rights of appeal under regulation 63(1)(b), an explanation of how those rights may be exercised.

### **Outline consent and premises approval: applications by doctors**

**51.—**(1) A person or partnership with a patient list, or a person who performs services on behalf of a provider of primary medical services or a PCTMS practice, who wishes to be granted the right to provide pharmaceutical services to patients on their own list or the provider's or practice's list (if the patients apply under regulation 48(1) on the basis of Condition 2 or 3) may apply in writing to the Primary Care Trust in whose area the premises from which the person or partnership making the application (D) wishes to dispense are located for—

- (a) consent (“outline consent”) to the provision of pharmaceutical services to patients who request those services and who reside in the area specified in the application;
- (b) approval of any medical practice premises from which D wishes to dispense (“premises approval”).

(2) Where D has outline consent that has taken effect and wishes to apply for premises approval in relation to—

- (a) additional medical practice premises from which to provide pharmaceutical services to patients who reside in the area for which D has an outline consent; or
- (b) medical practice premises from which D wishes to relocate to provide pharmaceutical services to patients who reside in the area for which D has an outline consent, but the move to new medical practice premises is not a relocation of the type provided for in regulation 55(2),

the premises approval application need not have a related outline consent application (even if the relevant outline consent was granted by a different Primary Care Trust) but in all other cases a premises approval application under paragraph (1)(b) must have a related outline consent application.

(3) An application for premises approval must include details of the address of the premises and whether those premises are already listed in relation to a different area.

(4) Except in so far as these Regulations provide to the contrary, a Primary Care Trust is to determine applications for outline consent and premises approval in such manner (including with regard to procedures) as it sees fit.

(5) A Primary Care Trust must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) for premises approval if the premises in respect of which approval is sought are within 1.6 kilometres of pharmacy premises that are not distance selling premises.

(6) A Primary Care Trust must refuse an application for outline consent to the extent that any part of the area specified in the application—

- (a) is not, or is not part of, a controlled locality; or
- (b) is within 1.6 kilometres of pharmacy premises that are not distance selling premises.

(7) Where a Primary Care Trust is minded to refuse an application for outline consent pursuant to paragraph (6)(a), it may defer that decision in order to make a determination under regulation 36(2).

(8) Subject to paragraph (9), a Primary Care Trust must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) if granting it would, in its opinion, prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust.

(9) If a Primary Care Trust determines that an application for outline consent would, if it had been made for a smaller area within the area specified in the application, not prejudice the proper provision of relevant NHS services in its area or in the area of a neighbouring Primary Care Trust, it may grant the application in respect of that smaller area.

(10) A Primary Care Trust must refuse an application (A1) under paragraph (1)—

- (a) for outline consent to the extent that any part of the area specified in A1 is the same as the area or any part of the area specified in an application for outline consent which was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made; or
- (b) for premises approval (but not under regulation 54, 55 or 58) if the premises specified in A1 were specified in an application for premises approval, or relate to an application for outline consent where any part of the area specified in that application is the same as the area or any part of the area specified in an earlier application for outline consent, which was refused—
  - (i) under this regulation, or
  - (ii) by virtue of regulation 18(2) of the 2005 Regulations<sup>(3)</sup> (refusal: outline consent and premises approval where patients are in a controlled locality),

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(3) Prior to its repeal, regulation 18(2) was amended by [S.I. 2005/1501](#) and [2010/914](#).

within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made, unless the Primary Care Trust is satisfied that there has been a substantial and relevant change of circumstances affecting the controlled locality to which the application relates since those proceedings reached their final outcome.

### **Notification of applications for outline consent and premises approval**

**52.**—(1) Where a Primary Care Trust (PCT1) receives an application for outline consent or premises approval (including an application for premises approval to which regulation 54 or 55 applies), as soon as is practicable, it must give notice of that application to—

- (a) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (c) any person—
  - (i) included in its pharmaceutical list, or
  - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included, whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (d) any LPS chemist—
  - (i) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
  - (ii) whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (f) any provider of primary medical services, or any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services), who in the opinion of PCT1 has a significant interest in the outcome of the application; and
- (g) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the proposed listed dispensing premises to which the application relates.

(2) PCT1 may also give notice of the application to any other person who, in the opinion of PCT1, has a significant interest in the outcome of the application;

(3) A Primary Care Trust notified under paragraph (1)(g) (PCT2) must, within 14 days of receiving the notification—

- (a) give notice of the application to—
  - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
  - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
  - (iii) any person—
    - (aa) included in its pharmaceutical list, or



- (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included, whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
  - (iv) any LPS chemist—
    - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and
    - (bb) whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
  - (v) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT2, has a significant interest in the outcome of the application, and
  - (vi) any provider of primary medical services, or any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services), who in the opinion of PCT2 has a significant interest in the outcome of the application; and
- (b) notify PCT1 of the action that it has taken under sub-paragraph (a).
- (4) A person (P) notified under paragraphs (1) to (3)(a) may make representations in writing about the application that is the subject of the notification to PCT1 to whom the application was made, provided P does so—
- (a) within 45 days of the date on which notice of the application was given to them; or
  - (b) in the case of notifications under paragraph (2) or (3), within such longer period as PCT1 may specify.
- (5) If PCT1 is considering, as a consequence of an application for outline consent or premises approval, making (including revising) a determination as to whether or not an area is or is not to be part of controlled locality, it must give notice under paragraph (1) at the same time that it gives notice under regulation 38(1).
- (6) A person (P) notified under paragraphs (1) to (3)(a)—
- (a) must be informed of P’s right to make representations under paragraph (4); and
  - (b) need not be given the same information as other persons notified under paragraphs (1) to (3)(a) but, subject to sub-paragraphs (7) to (9), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P’s interest in the matter.
- (7) P need not be provided with any information that is published as part of PCT1’s pharmaceutical needs assessment.
- (8) P must not be provided with any private addresses, private telephone numbers or dates of birth supplied by the applicant (A).
- (9) If A advises the Primary Care Trust that—
- (a) information supplied by A is considered by A to be confidential to A; and
  - (b) A does not consent to the information being disclosed as part of the notification,
- the Primary Care Trust must withhold that information from P if it considers that the full disclosure principle does not require it to provide that information to P.

(10) The “full disclosure principle” is that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application, unless it is fair and proper for that information to be withheld from that individual.

(11) If information is being withheld from P under paragraph (9), P must be informed of the nature of the information that is being withheld from P.

### **Decisions on outline consent and premises approval applications and the taking effect of grants**

**53.**—(1) Once a Primary Care Trust (PCT1) has determined an application for outline consent or premises approval, as soon as is practicable, it must give notice of that decision to—

- (a) the applicant; and
- (b) any person notified by it under regulation 52(1) or (2) in relation to the application.

(2) A Primary Care Trust notified under paragraph (1) must give notice of the decision to any person notified in relation to the application by it under regulation 52(3)(a).

(3) Each notification under paragraph (1) or (2) must include a statement of the reasons for the decision and, if the person notified is a person with rights of appeal in relation to the decision under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.

(4) When outline consent is granted, subject to paragraphs (12) and (14)(b), PCT1 must determine when the outline consent is to take effect.

(5) Subject to regulation 54, premises approval takes effect, if the application for it had a related outline consent application, when the related outline consent takes effect (but otherwise it does so in accordance with regulation 56).

(6) Outline consent takes effect on the day the proceedings relating to the grant of it have reached their final outcome, unless on the day before that day within 1.6 kilometres of the relevant practice premises there are premises which are the subject of an outstanding pharmacy application.

(7) For the purposes of this regulation, the “relevant practice premises” are the premises—

- (a) which are the subject of a related premises approval application; or
- (b) if there is no related premises approval application, that are the medical practice premises of the dispensing doctor from which the dispensing doctor wishes to dispense to patients in the area in relation to which outline consent is sought.

(8) In these Regulations, “outstanding pharmacy application” means—

- (a) an application which has not yet reached its final outcome—
  - (i) for inclusion in a pharmaceutical list (not necessarily that of PCT1), or
  - (ii) from a person included in a pharmaceutical list—
    - (aa) to relocate to different premises in the area of the Primary Care Trust whose list it is, or
    - (bb) to open, within the area of that Primary Care Trust, additional premises from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises other than distance selling premises; or

- (b) circumstances where an application of the type mentioned in paragraph (a) has been granted, and—
  - (i) the provision of pharmaceutical services from the premises for which listing was sought has not yet commenced, and
  - (ii) the grant has not yet lapsed.

(9) In a case where outline consent is not to take effect on the date on which it is granted, PCT1 must give the dispensing doctor to whom outline consent was granted (D) written details of—

- (a) the outstanding pharmacy application; and
- (b) the earliest date (referred to in this Part as the “provisional date”) on which an application can be made by D for a determination of when the outline consent is to come into effect.

(10) That provisional date, subject to paragraph (11), is the day after the end of the period of one year beginning on the day of—

- (a) the determination by PCT1 of D’s application of outline consent; or
- (b) where that determination is the subject of an appeal, the day on which the appeal reaches its final outcome.

(11) PCT1 may at any time before the provisional date determine that the provisional date be changed to a later date, but only to a date which is not more than 3 months after the date originally determined in accordance with paragraph (9).

(12) Outline consent lapses if, before the provisional date, pharmaceutical services are provided at the pharmacy premises to which the outstanding pharmacy application relates.

(13) On or as soon as is reasonably practicable after the provisional date, PCT1 must notify D that D may within 3 months of the provisional date request in writing that PCT1 determine whether the outline consent is to come into effect.

(14) Where PCT1 receives a request under paragraph (13), it must, as soon as is reasonably practicable determine—

- (a) unless paragraph (b) applies, that the outline consent is to come into immediate effect; or
- (b) that the outline consent has lapsed—
  - (i) where on the date of the determination (which must be a day from Monday to Friday, except Good Friday, Christmas Day or a bank holiday) primary medical services are not being provided at the relevant practice premises, or
  - (ii) by virtue of paragraph (12),

and it must inform D accordingly.

(15) A Primary Care Trust must notify the applicant for outline consent of its determination under paragraph (11) or (14) and must include with the notification of its determination an explanation of—

- (a) the reasons for the determination; and
- (b) the applicant’s rights of appeal in relation to it under regulation 63(1)(e).

**Premises approval: relocations of practice premises which are not significant before outline consent takes effect**

54.—(1) If outline consent has been granted but has not yet taken effect, before the provisional date the person or partnership (D) to whom it was granted may apply to the Primary Care Trust that granted it to change the premises from which D wishes to dispense.

(2) The Primary Care Trust may agree to the change (and so, where appropriate, grant premises approval to the new premises) if it is satisfied that the relocation is of the type provided for in regulation 55(2).

(3) Where a Primary Care Trust agrees to a change pursuant to paragraph (2), the premises approval takes effect when the related outline consent takes effect or, if later, on the date on which the change is agreed by the Primary Care Trust.

(4) The Primary Care Trust must notify its decision in relation to the application under paragraph (1) to the persons to whom it notified the application who made representations in relation

to it under regulation 52(4), and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision; and
- (b) if the person notified is a person with rights of appeal under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.

**Premises approval: relocations of practice premises which are not significant after outline consent has taken effect**

55.—(1) A dispensing doctor (D) who—

- (a) is providing pharmaceutical services from listed dispensing premises; and
- (b) wishes to relocate and dispense from new medical practice premises in relation to the area for which D has outline consent,

may apply in writing to the Primary Care Trust in whose area the new medical practice premises are located (whether or not it is the same Primary Care Trust as the Primary Care Trust that granted D outline consent) for premises approval for the new medical practice premises from which D wishes to dispense.

(2) Subject to paragraph (3), the Primary Care Trust must grant that application if it is of the type described in this paragraph, that is to say if the Primary Care Trust is satisfied that—

- (a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (b) granting the application would not result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on a dispensing doctor list) or of local pharmaceutical services—
  - (i) in any part of its area, or
  - (ii) in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate; and
- (c) the Primary Care Trust is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area.

(3) A Primary Care Trust must, unless it has good cause not to do so, refuse an application under paragraph (1) if an application under that paragraph or regulation 65(4)(a) of the 2005 Regulations<sup>(4)</sup> (premises approval: additional and new premises after outline consent has taken effect) has been granted to D during the 12 months before the application was submitted under paragraph (1).

(4) The Primary Care Trust must notify its decision in relation to the application under paragraph (1) to the persons to whom it notified the application who made representations in relation to it under regulation 52(4), and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision; and
- (b) if the person notified is a person with rights of appeal under regulation 63(1)(c) or (d), an explanation of how those rights may be exercised.

**Taking effect of premises approval where there is no related application for outline consent**

56.—(1) Where—

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(4) Prior to its repeal, regulation 65 was amended by [S.I. 2006/3373](#).

(a) premises approval is granted in relation to additional medical practice premises, or in relation to medical practice premises to which a dispensing doctor (D) is relocating; and  
(b) the application for premises approval had no related application for outline consent,  
paragraph (2) applies.

(2) In the circumstances described in paragraph (1), the approval takes effect—

- (a) on the date the determination of the application takes effect, and that date is—
- (i) if no appeal is made against the decision within the period for bringing an appeal, the date on which that period expires, or
  - (ii) if the decision is appealed within that period, the date on which the appeal reaches its final outcome; or
- (b) if on the day before that day within 1.6 kilometres of the relevant medical practice premises there are premises which are the subject of an outstanding pharmacy application, on the date which is—
- (i) the day after the end of a period of one year from the date on which that outstanding pharmacy application reaches its final outcome, or
  - (ii) such longer period (not exceeding 3 months) as the Primary Care Trust may for good cause allow before the expiry of that year.

(3) Premises approval to which paragraph (1) applies lapses if before the date on which it would otherwise take effect by virtue of paragraph (2), pharmaceutical services are provided at the pharmacy premises to which the outstanding pharmacy application relates.

### **Gradual introduction of premises approval**

**57.**—(1) Where a dispensing doctor (D) has outline consent but PCT1 considers that the provision of pharmaceutical services by any NHS pharmacist, or of LP services by any LPS chemist, is likely to be adversely affected if D provides pharmaceutical services from medical practice premises which have been subject to a related application for premises approval (whether under regulation 51, 54 or 55), PCT1 may by conditions—

- (a) postpone the taking effect of the related premises approval for such period as it thinks fit; or
- (b) limit the patients to whom D (or any successor to D) is able to provide pharmaceutical services from the medical practice premises in such manner, and for such periods, as it thinks fit.

(2) The Primary Care Trust must decide whether or not to impose conditions under paragraph (1)

- (a) if there was a delay in the related outline consent taking effect because of an outstanding pharmacy application, when it determines that the outline consent is to come into effect; or
- (b) in any other case, when it determines the application for premises approval.

(3) The Primary Care Trust must notify any decision to impose, or not to impose, conditions under paragraph (1) to—

- (a) D;
- (b) any person with third party appeal rights in relation to the related application for premises approval;
- (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),

- (4) A notification under paragraph (3) must include—
  - (a) a statement of the reasons for the decision; and
  - (b) if the person notified is a person with rights of appeal under regulation 63(1)(f), an explanation of how those rights may be exercised.

**Temporary provision in cases of relocations or additional premises where premises approval has not taken effect**

**58.**—(1) In the circumstances described in regulation 56(1), if the premises approval has not taken effect because of an outstanding pharmacy application which has not lapsed, the Primary Care Trust may grant the applicant (D) temporary premises approval—

- (a) if it considers it is desirable to do so in order to secure the adequate provision of pharmaceutical services in the area for which D has outline consent;
- (b) for a period of not exceeding 12 months, but which may be renewed for a further period not exceeding 3 months (and if the first period granted is less than 12 months, it may be renewed more than once for up to a total aggregate period of 15 months).

(2) If a Primary Care Trust grants temporary premises approval under paragraph (1), it must notify—

- (a) D;
- (b) the applicant who made the outstanding pharmacy application;
- (c) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (d) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),

(3) A notification under paragraph (2) must include—

- (a) a statement of the reasons for the decision; and
- (b) a statement of the duration of the temporary premises approval and any circumstances in which it might be extended; and

(4) If a Primary Care Trust refuses an application to grant temporary premises approval under paragraph (1), the Primary Care Trust must notify that decision to the applicant and include with that notification—

- (a) a statement of the reasons for the decision; and
- (b) an explanation of how D’s rights of appeal under regulation 63(1)(c)(iii) may be exercised.

**Practice amalgamations**

**59.**—(1) A “practice amalgamation” occurs where 2 or more patient lists are combined as a result of the coming together, as a single provider of primary medical services (SP), of 2 or more dispensing doctors.

(2) If, following a practice amalgamation, the medical practice premises of SP are all premises that immediately prior to the amalgamation were listed dispensing premises, the premises approvals for those premises and the related outline consents become the premises approvals and outline consents of SP.

(3) If, following practice amalgamation, paragraph (2) does not apply but one or more of the dispensing doctors coming together as SP had, immediately prior to amalgamation, listed dispensing premises—

- (a) if any listed dispensing premises become medical practice premises of SP—

- (i) the premises approvals for those premises, and the related outline consents, become approvals and consents of SP, and
  - (ii) any applications for premises approval in respect of other medical practice premises of SP are to be treated under this Part as applications for additional premises;
- (b) if none of the listed dispensing premises become medical practice premises of SP—
- (i) SP may nominate one of its medical practice premises as premises in respect of which it may apply for premises approval and have that application treated as a relocation from listed dispensing premises of a dispensing doctor who was part of the coming together to form SP, and
  - (ii) any applications for premises approval in respect of other medical practice premises of SP are to be treated under this Part as applications for additional premises.
- (4) Where a practice amalgamation is proposed, a dispensing doctor who intends to be part of the practice amalgamation may make an application on the basis of paragraph (3)(b) in anticipation of circumstances that are expected to arise following the practice amalgamation, and if the dispensing doctor does so—
- (a) any premises approval granted as a consequence becomes, when the practice amalgamates, a premises approval granted to SP; or
  - (b) if the proposed amalgamation does not take place, or if the dispensing doctor who makes the application does not become party to a practice amalgamation that does take place, any premises approval granted on the basis of that application lapses.
- (5) If an application for premises approval arises because a practice amalgamation has taken or is due to take place, it must include the names of all the medical practitioners and any other providers of primary medical services who are participating in the amalgamation.

### **Lapse of outline consent and premises approval**

- 60.**—(1) Outline consent lapses (in addition to as mentioned in regulation 53(12) and (14)(b)) if—
- (a) no arrangement has been made under regulation 48 with a patient pursuant to that outline consent within 6 months of the date on which it takes effect;
  - (b) 6 months have elapsed since any drug or appliance was dispensed under the arrangements made pursuant to that outline consent; or
  - (c) following a practice amalgamation, the amalgamated practice has no medical practice premises with premises approval and there are no outstanding applications to which regulation 59(3)(b) applies in respect of premises approval from the amalgamated practice.
- (2) If an area, or part of an area, for which a dispensing doctor (D) has outline consent becomes a location in relation to which it is no longer possible for D to provide pharmaceutical services to patients on a patient list, D ceases to have outline consent in relation to that location.
- (3) Premises approval lapses (in addition to as mentioned in regulation 56(3) and 59(4)(b)) if—
- (a) the premises are no longer medical practice premises of a dispensing doctor with outline consent;
  - (b) 6 months have elapsed, or such longer period as the Primary Care Trust may for good cause allow, since any drug or appliance was dispensed under the arrangements made pursuant to regulation 48 at those premises;
  - (c) the provider of primary medical services whose premises, or (if different) the dispensing doctor in relation to whom they are listed, notifies the Primary Care Trust on whose dispensing doctors list the premises are listed that all the medical practitioners with authority to dispense from those premises have ceased to do so;

- (d) the dispensing doctor in relation to whom the premises are listed in the dispensing doctors list is no longer listed in that list; or
  - (e) the related outline consent lapses.
- (4) A right which continues in effect by virtue of regulation 48(3)(b)(i) is to be treated as outline consent for the purposes of paragraphs (1) and (3).
- (5) For the purposes of—
- (a) paragraph (1)(a), no account is to be taken of a period when D is unable to make arrangements to provide pharmaceutical services, or
  - (b) paragraph (1)(b) or (3)(b), no account is to be taken of a period when D is unable to provide pharmaceutical services,
- because of a condition imposed by virtue of regulation 20(2) of the 2005 Regulations<sup>(5)</sup> (imposition of conditions) or by virtue of regulation 57.

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

**61.**—(1) During an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may require a dispensing doctor on its dispensing doctor list to provide pharmaceutical services (“temporary services”) to patients to whom the dispensing doctor is not otherwise entitled to provide pharmaceutical services—

- (a) where, as a result of the temporary closure of pharmacy premises in its area, 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
  - (b) for a specified period (which must 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.
- (2) The Primary Care Trust must terminate arrangements to provide temporary services if the doctor notifies it that the doctor is unwilling to provide those services (and so wishes to revert to the doctor’s overridden arrangements for the provision of pharmaceutical services).
- (3) A Primary Care Trust may grant temporary premises approval—
- (a) in relation to additional premises that are not listed dispensing premises; or
  - (b) to premises to which a doctor wishes to relocate temporarily from listed dispensing premises,

if it is satisfied that it is necessary or desirable to do so because of an emergency requiring the flexible provision of pharmaceutical services.

- (4) In the circumstances described in paragraph (3)—
- (a) the temporary premises approval must be for a specified period (which must 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 dispensing doctor 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.
- (5) There is no right of appeal under these Regulations in respect of a decision under this regulation—

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<sup>(5)</sup> Prior to its repeal, regulation 20 was amended by [S.I. 2006/552](#).



- (a) to require, or not to require, a dispensing doctor to provide temporary services;
- (b) to extend or curtail the duration of any requirement to provide temporary services;
- (c) to grant or refuse an application for temporary premises approval; or
- (d) to extend or curtail, or not to extend or curtail, temporary premises approval.

### **Persons barred from taking part in decision making with regard to applications for outline consent or premises approval**

**62.**—(1) No person is to take part in determining any application for outline consent (including determining when it is to come into effect), premises approval or temporary premises approval, or in taking decisions under regulation 50, 53 or 57, who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider or a PCTMS practice; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining any application, or taking any decision, referred to in paragraph (1) if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

### **Appeals against decisions under Part 8**

**63.**—(1) A person with appeal rights (as provided for in this regulation) may appeal to the Secretary of State against the following decisions by a Primary Care Trust (PCT1)—

- (a) a decision under regulation 48(5)(b) to require a dispensing doctor to undertake to provide pharmaceutical services, in respect of which the only person with appeal rights is the dispensing doctor;
- (b) a decision under regulation 50, requiring the termination of arrangements to provide pharmaceutical services, subject to any postponement of the discontinuation, in respect of which the only people with appeal rights are—
  - (i) the dispensing doctor who is being required to terminate arrangements, subject to any postponement of the discontinuation, and
  - (ii) if there is any postponement of the discontinuation, the NHS pharmacist listed in relation to any pharmacy premises, the presence of which, or the choice of a patient to obtain services from which, led to the determination of PCT1;
- (c) a decision to refuse an application for—
  - (i) outline consent under regulation 51,
  - (ii) premises approval under regulation 51, 54 or 55, or
  - (iii) temporary premises approval under regulation 58,

- in respect of which the only person with appeal rights is the applicant;
- (d) a decision to grant an application for—
  - (i) outline consent under regulation 51, or
  - (ii) premises approval under regulation 51, 54 or 55,
 in respect of which the only person with appeal rights is a person who has third party appeal rights;
- (e) a determination of—
  - (i) a change to a provisional date under regulation 53(11), or
  - (ii) whether outline consent is to come into effect under regulation 53(14),
 in respect of which the only person with appeal rights is the person to whom the relevant outline consent was granted; and
- (f) a decision to impose, or a failure to impose, conditions under regulation 57, in respect of which the only people with appeal rights are—
  - (i) the dispensing doctor, and
  - (ii) an NHS pharmacist or LPS chemist who has third party appeal rights in relation to the related application for premises approval,

provided they notify the Secretary of State with a valid notice of appeal within 30 days of the date on which the person bringing the appeal was notified of the decision that is being appealed.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

- (3) For the purposes of paragraph (1)(d) or (f), a person (P1) has third party appeal rights if—
- (a) P1 was a person whom PCT1 was required to notify about the relevant application for outline consent or premises approval by virtue of P1 being—
    - (i) included in its pharmaceutical list,
    - (ii) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but not (yet) included,
    - (iii) an LPS chemist with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, or
    - (iv) (except in relation to paragraph (1)(f)), a provider of primary medical services, or any other person on PCT1's dispensing doctors list if it has one (being a performer but not a provider of primary medical services),
 and a person whose interests might, in the opinion of PCT1, be significantly affected by the decision;
  - (b) P1 made representations in writing about the application under regulation 52(4); and
  - (c) subject to sub-paragraph (5), PCT1 is satisfied, having regard to those representations in writing and any oral representations made at any oral hearing, that P1—
    - (i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and
    - (ii) has grounds for opposing the application, which—
      - (aa) do not amount to a challenge to the legality or reasonableness of PCT1's pharmaceutical needs assessment, or to the fairness of the process by which PCT1 undertook that assessment, and
      - (bb) are not vexatious or frivolous.

(4) If PCT1 considers that a person notified under regulation 52(1) to (3)(a) is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of a decision (D1) in respect of which that person may be able to exercise those rights.

(5) A person to whom paragraph (3)(a) and (b) applies (P2) who is not notified by the Primary Care Trust that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D2) by the Primary Care Trust that it is not satisfied as mentioned in subparagraph (3)(c), provided that P2—

- (a) notifies the Secretary of State within 30 days of the date on which that person was notified of PCT1's decision that P2 wishes to appeal against both D1 and D2; and
- (b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

and if the appeal against D2 is successful, P2 is a person with third party appeal rights in relation to D1 for the purposes of this regulation.

(6) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 7, 10 and 12 and Schedule 2).