STATUTORY INSTRUMENTS

2013 No. 349

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

PART 8

Dispensing doctors

Dispensing doctor lists

46.—(1) In respect of the area of each HWB, the NHSCB must prepare and publish a list (a "dispensing doctor list") of the names of any "dispensing doctors" in that area, that is to say—

(a) providers of primary medical services who provide pharmaceutical services from medical practice premises in that area; and

(b) general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in that area (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 include—

(a) the address of any premises in the area of the relevant HWB 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 (which may be in the area of a neighbouring HWB).

(3) The NHSCB must remove a dispensing doctor from a 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 at or from (what were) the relevant listed dispensing premises;

(b) in the case of a listed general practitioner, that person is no longer on the medical performers list or no longer performs primary medical services within the area of the relevant HWB; or

(c) all the arrangements that the dispensing doctor has with the NHSCB to perform or provide pharmaceutical services at or from (what were) the relevant listed dispensing premises 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 member of 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 the NHSCB lists that provider instead of them as the dispensing doctor (or doctors) on a dispensing doctors list.

(5) In the circumstances described in paragraph (4)—

(a) the NHSCB must agree to that request;

(b) the arrangements that the NHSCB 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 that individual general practitioner or 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 NHSCB—

(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 and when, in the case of a general practitioner who has been so notified, 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 NHSCB must include the names of any general practitioner notified under sub-paragraph (a)(i), unless the NHSCB 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 or 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 [M1] (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 or obligations are applicable in the case of the dispensing doctor; and

(d) are—

(i) included in regulations under section 225 of the 2007 Act [M2] (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and

(ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider.

(2) The NHSCB must ensure that those terms of service—

(a) if the dispensing doctor has arrangements with the NHSCB 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, are terms of service of, and so are enforceable under, the arrangements that the NHSCB 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.

Marginal Citations

M1 Prior to its revocation, regulation 20 was amended by S.I. 2006/552.

M2 Section 225 has been amended by the Health and Social Care Act 2012 (c. 7), section 186(6) to (10), **Schedule 14**, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.

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 (E) by whom D is employed or engaged.

(2) Condition 1 is that P satisfies the NHSCB 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 for the area in which P resides, 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 2012 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 whilst residing in the area of the relevant HWB,

(bb) has been so included but now resides at a different address in the area of the relevant HWB, 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 in the area of the relevant HWB under arrangements with the NHSCB, 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 the NHSCB, enclosing P's request, the NHSCB 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, the NHSCB 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) The NHSCB must not, under paragraph (5)(b), require D to undertake to provide services to P, if D satisfies the NHSCB 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 the NHSCB 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 the NHSCB 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, the general practitioner or any other general practitioner who performs primary medical services on behalf of that provider.

(9) To be valid, a notification under paragraph (5)(b) by the NHSCB 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 the NHSCB has arrangements (whether they were made under these Regulations or were made under or continued by virtue of the 2012 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 NHSCB 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 NHSCB determines that Condition 3 in regulation 48(4) does not apply in respect of P, or

(ii) the NHSCB determines that Condition 3 in regulation 48(4) does apply in respect of P, but P informs the NHSCB that P wishes 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);

(e) P is resident in a reserved location, and—

(i) had previously informed the NHSCB (or a Primary Care Trust) that P wished to be provided with pharmaceutical services by D, but

(ii) P has since informed the NHSCB 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 NHSCB in accordance with paragraphs (2) to (6).

(2) The NHSCB 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) the NHSCB grants a routine or excepted application, the result of which is the inclusion in a 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 NHSCB, 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 the NHSCB is required to terminate the provision of pharmaceutical services pursuant to paragraph (1)(f) but the NHSCB is satisfied that the determination that led to the decision to terminate has adversely affected D.

(5) Where paragraph (3) or (4) applies, the NHSCB may postpone the discontinuation for such period as it thinks fit.

(6) The NHSCB must postpone the discontinuation—

(a) while it is forming the opinion mentioned in paragraph (3)(c); or

(b) for such period as the NHSCB considers necessary in order to give the doctor reasonable notice (in any case to which paragraph (1) applies) of the discontinuation.

(7) The NHSCB 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 NHSCB;

(c) any Local Pharmaceutical Committee whose area includes the listed dispensing premises at or from which D has been providing pharmaceutical services to P; and

(d) any Local Medical Committee whose area includes the listed dispensing premises at or from which D has been providing pharmaceutical services to P.

(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, who wishes to be granted the right to provide pharmaceutical services to patients on their own list or the provider's list (if the patients apply under regulation 48(1) on the basis of Condition 2 or 3) may apply in writing to the NHSCB 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, 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, the NHSCB is to determine applications for outline consent and premises approval in such manner (including with regard to procedures) as it sees fit.

(5) The NHSCB 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) The NHSCB 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 the NHSCB 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), the NHSCB 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 the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB.

(9) If the NHSCB 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 the area of—

(a) the relevant HWB; or

(b) a neighbouring HWB of the relevant HWB,

it may grant the application in respect of that smaller area.

(10) The NHSCB 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,

(ii) under regulation 51 of the 2012 Regulations (outline consent and premises approval: applications by doctors), or

(iii) by virtue of regulation 18(2) of the 2005 Regulations [M3] (refusal: outline consent and premises approval where patients are in a controlled locality),

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 NHSCB 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.

Marginal Citations

M3 Prior to its revocation, regulation 18(2) was amended by S.I. 2005/1501 and 2010/914.

Notification of applications for outline consent and premises approval

52.—(1) Where the NHSCB receives an application for outline consent or premises approval (including an application for premises approval to which regulation 54 or 55 applies, but not an application for temporary premises approval to which regulation 58 or 61 applies), as soon as is practicable, it must give notice of that application to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes the medical practice premises or all or part of the area to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the medical practice premises to which the application relates;

(b) any Local Medical Committee—

(i) whose area includes the medical practice premises or all or part of the area to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the medical practice premises to which the application relates;

(c) any person—

(i) included in a pharmaceutical list for the area of the relevant HWB, or

(ii) who is entitled to be included in that 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 the NHSCB, be significantly affected if the application were granted;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(e) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application;

(f) any provider of primary medical services, or any other person on the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services), who in the opinion of the NHSCB has a significant interest in the outcome of the application;

(g) any Local Health Board any part of whose area is within 2 kilometres of the medical practice premises to which the application relates; and

(h) the relevant HWB and any other HWB (HWB2) any part of whose area—

(i) is within 2 kilometres of the medical practice premises to which the application relates, or

(ii) in the case of an application for outline consent, is part of the area specified in the application;

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

(3) If a HWB is notified under paragraph (1)(h), the NHSCB must also give notice of the application to—

(a) any person—

(i) included in a pharmaceutical list for the area of HWB2, or

(ii) who is entitled to be included in that 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 the NHSCB, be significantly affected if the application were granted;

(b) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB2, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted,

(c) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application; and

(d) any provider of primary medical services, or any other person on the dispensing doctors list for the area of HWB2 if there is one (being a performer but not a provider of primary medical services), who in the opinion of the NHSCB has a significant interest in the outcome of the application.

(4) A person (P) notified under paragraphs (1) to (3) may make representations in writing about the application that is the subject of the notification to the NHSCB, provided P does so within 45 days of the date on which notice of the application was given to them.

(5) If the NHSCB 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) 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) 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 the relevant 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 NHSCB 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 NHSCB 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 the NHSCB 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) to (3) in relation to the application.

(2) Each notification under paragraph (1) 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.

(3) When outline consent is granted, subject to paragraphs (11) and (13)(b), the NHSCB must determine when the outline consent is to take effect.

(4) 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).

(5) 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.

(6) 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.

(7) 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 the relevant HWB), or

(ii) from a person included in a pharmaceutical list—

(aa) to relocate to different premises in the area of the relevant HWB, or

(bb) to open, within the area of that HWB, 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.

(8) In a case where outline consent is not to take effect on the date on which it is granted, the NHSCB 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.

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

(a) the determination by the NHSCB 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.

(10) The NHSCB 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 (8).

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

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

(13) Where the NHSCB receives a request under paragraph (12), 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 (11),

and it must inform D accordingly.

(14) The NHSCB must notify the applicant for outline consent of its determination under paragraph (10) or (13) 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 NHSCB to change the premises from which D wishes to dispense to other premises in the area of the relevant HWB.

(2) The NHSCB 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 the NHSCB 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 NHSCB.

(4) The NHSCB 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 NHSCB for premises approval for the new medical practice premises from which D wishes to dispense.

(2) Subject to paragraph (3), the NHSCB must grant that application if it is of the type described in this paragraph, that is to say if the NHSCB 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 the area of the relevant HWB, or

(ii) in a controlled locality in the area of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate; and

(c) the NHSCB is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB.

(3) The NHSCB must, unless it has good cause not to do so, refuse an application under paragraph (1) if an application under—

(a) that paragraph;

(b) regulation 55(1) of the 2012 Regulations (premises approval: relocations of practice premises which are not significant after outline consent has taken effect); or

(c) regulation 65(4)(a) of the 2005 Regulations [M4] (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 NHSCB 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.

Marginal Citations

M4 Prior to its revocation, regulation 65 was amended by S.I. 2006/3373.

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

56.—(1) Where—

(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 NHSCB 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 the NHSCB 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), the NHSCB 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 NHSCB 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 NHSCB 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 whose area includes the medical practice premises to which the decision relates; and

(d) any Local Medical Committee whose area includes the medical practice premises to which the decision relates.

(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 NHSCB 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 the NHSCB 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 whose area includes the medical practice premises for which temporary premises approval has been granted; and

(d) any Local Medical Committee whose area includes the medical practice premises for which temporary premises approval has been granted;

(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.

(4) If the NHSCB refuses an application to grant temporary premises approval under paragraph (1), the NHSCB 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 providers of primary medical services.

(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 providers of primary medical services 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(11) and (13)(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 NHSCB 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 NHSCB 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 one of the provisions mentioned in paragraph (6).

(6) Those provisions are—

(a) regulation 57;

(b) regulation 57 of the 2012 Regulations (gradual introduction of premises approval); and

(c) regulation 20(2) of the 2005 Regulations [M5] (imposition of conditions) or by virtue of regulation 57.

Marginal Citations

M5 Prior to its revocation, regulation 20 was amended by S.I. 2006/552.

Temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor

61.—(1) During an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may require a dispensing doctor 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 the area of the relevant HWB, the NHSCB considers that, in order to secure continuing adequate provision of pharmaceutical services in that 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 NHSCB may extend or curtail in appropriate circumstances.

(2) The NHSCB 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) The NHSCB 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,

because there is 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 NHSCB 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 NHSCB, on giving the NHSCB at least 24 hours notice.

(5) The NHSCB may grant temporary premises approval if there is a temporary suspension in the provision of dispensing services at listed dispensing premises (P1) for a reason (for example, fire or flooding) that is beyond the control of the dispensing doctor (D) listed in relation to P1.

(6) In the circumstances described in paragraph (5), the NHSCB may make a temporary amendment to the entry of D in the relevant dispensing list in order to allow D to provide the services that D ordinarily provided at P1 at other premises nearby (P2), at the days on which and times at which those services were ordinarily provided at P1, for a period specified by the NHSCB.

(7) A period specified under paragraph (6) must not be longer (initially) than 6 months, and the NHSCB may under that paragraph—

(a) if it has good cause to do so, extend the period specified under that paragraph (but not beyond 12 months from the date on which D starts to provide the services in question from P2); or

(b) curtail the period specified,

in appropriate circumstances.

(8) For the period specified under paragraph (6), but subject to paragraph (9) and regulation 118, P2 instead of P1 are to be treated as listed in relation to D for the purposes of these Regulations (albeit that the premises actually listed in relation to D are P1).

(9) D may revert to the overridden premises approval before the end of the period specified under paragraph (6), on giving the NHSCB at least 24 hours notice.

(10) Planned refurbishment is not a "reason beyond the control" of D for the purposes of paragraph (5).

(11) There is no right of appeal under these Regulations in respect of a decision of the NHSCB under this regulation.

(12) If the NHSCB grants an application for temporary premises approval under this regulation, it must notify that decision to the persons who would have been notified about the application had the application been an application to which regulation 55 applies.

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

(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 the NHSCB—

(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 by the NHSCB;

(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(10), or

(ii) whether outline consent is to come into effect under regulation 53(13),

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 the NHSCB was required to notify about the relevant application for outline consent or premises approval by virtue of P1 being—

(i) included in a pharmaceutical list,

(ii) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but not (yet) included,

(iii) an LPS chemist with whom the NHSCB 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 the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services),

and a person whose interests might, in the opinion of the NHSCB, 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), the NHSCB 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 the relevant pharmaceutical needs assessment, or to the fairness of the process by which that assessment was undertaken, and

(bb) are not vexatious or frivolous.

(4) If the NHSCB considers that a person notified under regulation 52(1) to (3) 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 NHSCB that they are person with third party appeal rights may appeal to the Secretary of State against the

determination (D2) by the NHSCB that it is not satisfied as mentioned in sub-paragraph (3)(c), provided that P2—

(a) notifies the Secretary of State within 30 days of the date on which that person was notified of the NHSCB'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).

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– blanket amendment words substituted by S.I. 2023/1071 Sch. para. 1