STATUTORY INSTRUMENTS

1992 No. 662

The National Health Service (Pharmaceutical Services) Regulations 1992

PART II

PROVISION OF PHARMACEUTICAL SERVICES BY CHEMISTS

Pharmaceutical lists

4.—(1) An FHSA shall prepare lists, to be called pharmaceutical lists, of the persons, other than doctors and dentists—

(a) whose applications to be included in a pharmaceutical list have been granted by the FHSA, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the FHSA's locality by way of the provision of drugs; and

(b) whose applications to be included in a pharmaceutical list have been granted by the FHSA, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the FHSA's locality by way of the provision of appliances,

and each such list shall contain the addresses of premises in the FHSA's locality from which those services are provided and particulars of the days and hours at which those premises are open for such provision and, in the case of a list referred to in sub-paragraph (a) of this paragraph, shall indicate whether or not the chemist has undertaken to provide supplemental services under regulation 16.

(2) A person, other than a doctor or dentist—

(a) who wishes to be included in a pharmaceutical list for the provision of pharmaceutical services from premises in an FHSA's locality; or

(b) who is already included in a pharmaceutical list but wishes—

(i) to open, within an FHSA's locality, additional premises from which to provide the same or different pharmaceutical services,

(ii) to change the premises from which he provides pharmaceutical services to other premises within that locality from which he wishes to provide the same or different pharmaceutical services, or

(iii) to provide from his existing premises in that locality pharmaceutical services other than those already listed in relation to him,

shall apply to the FHSA in the form set out in Part I of Schedule 3, and in this regulation "applicant" and "application" shall be construed accordingly.

(3) In the case of any application under paragraph (2), where the applicant intends—

(a) to change within the neighbourhood the premises from which he provides pharmaceutical services, being the same services as he intends to provide from the new premises, and the FHSA is satisfied that the change is a minor relocation; or

(b) to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by a person who is included in a pharmaceutical list prepared by the FHSA in accordance with paragraph (1)(a) or (b), and the FHSA is satisfied that the same services will be provided from those premises,

and, in either case, the provision of pharmaceutical services will not be interrupted (except for such period as the FHSA may for good cause allow), the application shall be granted by the FHSA, subject, in a case falling within sub-paragraph (b) above, to paragraph (5).

(4) An application in any case other than those specified in paragraph (3) shall be granted by the FHSA only if it is satisfied that it is necessary or desirable to grant the application in order to secure, in the neighbourhood in which the premises from which the applicant intends to provide the services are located, the adequate provision, by persons included in the list, of the services, or some of the services, specified in the application.

(5) An application, other than one to which paragraph (3)(a) applies, which is made by a person who qualified to have his name registered under the Pharmacy Act 1954(**1**) by virtue of section 4A of that Act (qualification by European diploma) shall not be granted unless the applicant satisfies the FHSA that he has the knowledge of English which, in the interests of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the FHSA's locality.

(6) An application to an FHSA may be granted either in respect of all, or in respect of some only, of the services specified in it.

(7) Subject to paragraph (8), any question whether an application should or should not be granted (whether in respect of some or all of the services specified in it) in accordance with the provisions of paragraphs (3) to (6), shall be determined by the FHSA in accordance with the procedure set out in regulations 5, 6, 7 and 8.

(8) Where, by virtue of regulation 11, an application is one which falls to be determined in accordance with regulation 12, the FHSA shall not include the applicant in the relevant pharmaceutical list unless the application is finally granted under the provisions of regulation 12(16).

(9) Where an application is granted by the FHSA, the applicant shall be included in the relevant pharmaceutical list or lists only if, not less than 14 days before the expiry of six months after the date on which the grant was notified to him by the FHSA in accordance with regulation 7, or of such further period or periods, not in all exceeding 24 months from the date of the grant, as it, or, on appeal the Secretary of State, may for good cause allow, he notifies the FHSA, in the form set out in Part II of Schedule 3, that he will, within the next 14 days, commence the provision of the services in respect of which the application was made at the premises to which the application related.

(10) Where, at any time after making the application, but before the expiry of the six months referred to in paragraph (9), or of any further period allowed by the FHSA or, on appeal, by the Secretary of State in accordance with that paragraph, the applicant notifies the FHSA that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the FHSA is satisfied that the change is a minor relocation, it may amend the premises named in the original application.

(11) For the purposes of regulation 4(9), the date of the notification of a grant of any application shall be—

(a) where no appeal is made under regulation 8(3) against the decision of the FHSA, the day after the expiry of the period of 30 days beginning on the date on which notice of that decision is given under regulation 7(1);

(b) where such an appeal is made, the date on which the Secretary of State gives notice of his decision under regulation 8(15).

(**1**) 1954 c. 61. Section 4A was inserted by S.I. 1987/2202, Article 2(4).

Notification of applications

5.—(1) Where, on receiving an application under regulation 4(2), an FHSA is satisfied that the application is one to which regulation 4(4) applies, it shall, as soon as is practicable, give notice in writing, of the application, to—

(a) the Local Pharmaceutical Committee;

(b) the Local Medical Committee;

(c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the FHSA, be significantly affected if the application were granted;

(d) any FHSA any part of whose locality is within two kilometres of the premises; and

(e) any Community Health Council serving the locality of the FHSA or of any other FHSA notified under sub-paragraph (d),

and any person so notified may, within 30 days from the date on which the notification was sent, make representations in writing to the FHSA.

(2) An FHSA which is notified under paragraph (1)(d) shall, as soon as is practicable, give notice in writing, of the application, to—

(a) the Local Pharmaceutical Committee for its locality;

(b) the Local Medical Committee for its locality; and

(c) any person whose name is included in a pharmaceutical list and whose interests might, in the opinion of the FHSA, be significantly affected if the application were granted,

and any person so notified may, within 30 days from the date on which the notification was sent, make representations in writing to the FHSA to which the application was made.

(3) Any notice given under paragraph (1) or (2) shall include a notification of the right to make representations in accordance with that paragraph.

Determination of applications

6.—(1) In considering any application to which regulation 4(4) applies, an FHSA shall have regard in particular to—

(a) whether or not any of the pharmaceutical services specified in the application are already provided by persons included in a pharmaceutical list in the neighbourhood in which the premises named in the application are located;

(b) any information available to the FHSA which, in its opinion, is relevant to the consideration of the application; and

(c) any representations received by the FHSA under regulation 5(1) or (2).

(2) The FHSA may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.

(3) In any case where the FHSA decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under regulation 5(1) or (2) not less than 14 days notice of the time and place at which the oral representations are to be heard.

(4) The applicant and any person mentioned in paragraph (3) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(5) The procedure by which representations are heard shall be such as the FHSA may determine.

(6) No person who provides or assists in providing general medical services or pharmaceutical services under Part II of the Act shall take part in any decision under this regulation.

(7) The FHSA may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it shall give notice in writing to the applicants and any persons to whom copies of the application were sent under regulation 5(1).

Notification of decisions

7.—(1) An FHSA shall, as soon as practicable, give notice in writing of its decision on an application under regulation 4(2), or of its decision whether or not to amend the premises named in the original application as mentioned in regulation 4(10), to—

(a) in the case of an application to which regulation 4(3) or (10) applies—

(i) the applicant,

(ii) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the FHSA, be significantly affected by the decision,

(iii) the Local Pharmaceutical Committee,

(iv) the Local Medical Committee,

(v) any FHSA any part of whose locality is within two kilometres of the premises, and

(vi) any Community Health Council serving the locality of the FHSA or of any other FHSA notified under regulation 5(1)(d); and

(b) in the case of an application to which regulation 4(4) applies—

(i) the applicant, and

(ii) any person who has made representations to the FHSA in accordance with regulation 5(1) or (2),

and shall include with the notice a statement of the reasons for the decision and of any rights of appeal.

(2) Any FHSA which is notified under sub-paragraph (1)(a)(v) shall, as soon as practicable, give notice in writing of the decision and reasons to—

(a) the Local Pharmaceutical Committee for its locality;

(b) the Local Medical Committee for its locality; and

(c) any person whose name is included in the pharmaceutical list and whose interests might in the opinion of that Authority be significantly affected by the decision;

and shall notify them of any rights of appeal arising under regulation 8.

Appeals

8.—(1) Where an FHSA has determined an application to which regulation 4(3) applied or made a decision whether or not to amend the premises named in the original application as mentioned in regulation 4(10), the applicant and any person who has been notified of the decision under regulation 7(1)(a)(ii) or regulation 7(2)(c) may appeal to the Secretary of State.

(2) Where an FHSA has determined an application to which regulation 4(4) applied, the persons who may appeal to the Secretary of State are—

(a) the applicant; and

(b) any person who—

(i) has been notified of the decision under regulation 7(1)(a)(ii) or regulation 7(2)(c), and

(ii) made representations to the FHSA in accordance with regulation 5(1) or (2).

(3) Where an FHSA refuses to allow an extension to the period within which an applicant is to notify the FHSA that he will commence the provision of services, as mentioned in regulation 4(9), the applicant may appeal to the Secretary of State.

(4) Any appeal under this regulation shall be made by sending to the Secretary of State a notice of appeal in writing within 30 days from the date on which the FHSA sent its decision to the appellant or, in the case of an appeal against a determination to which regulation 4(3) applied or a decision pursuant to regulation 4(10), such longer period as the Secretary of State may for reasonable cause allow.

(5) Where in determining an application, an FHSA has, pursuant to regulation 6(7), considered that application together with one or more other applications, any of the applicants and any of the persons mentioned in paragraph (1) or (2) may appeal against the determination of any of the applications, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(6) Any notice of appeal made under this regulation shall contain a concise statement of the grounds of appeal.

(7) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(8) Unless paragraph (7) applies, the Secretary of State shall send a copy of the notice of appeal to the FHSA whose determination is appealed against and—

(a) in the case of an appeal to which paragraph (1) or (3) relates, to the persons mentioned in regulation 7(1)(a); or

(b) in the case of an appeal to which paragraph (2) relates, to the persons mentioned in regulation 7(1)(b).

(9) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (8) may, within 30 days from the date on which the notice was sent to him, make representations in writing to the Secretary of State on the appeal.

(10) The Secretary of State may require an oral hearing before he determines the appeal.

(11) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(12) The procedure of any oral hearing shall be determined by the person or persons hearing the appeal.

(13) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (8).

(14) The appellant and any person to whom a notice of the hearing is sent under paragraph (13) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and the FHSA may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(15) On determining an appeal under this regulation, the Secretary of State shall either—

(a) allow the appeal; or

(b) confirm the decision of the FHSA.

(16) The Secretary of State shall, as soon as practicable, send to the appellant and to any person to whom a copy of the notice of appeal was sent pursuant to paragraph (8) and who made representations under paragraph (9) notice in writing of his decision on the appeal and shall include in the notice a statement of his reasons for the decision and of his findings of fact.

Determination of controlled locality

9.—(1) Where, before the coming into force of these Regulations, it was determined under any provision of regulations revoked by and not re-enacted in these Regulations, that an area was a controlled locality, subject to the provisions of this regulation, that area shall continue to be a controlled locality.

(2) Subject to paragraph (11), an FHSA may at any time consider and determine whether or not an area is rural in character.

(3) A Local Medical Committee or a Local Pharmaceutical Committee may at any time apply in writing to an FHSA to consider and determine whether or not an area specified in the application is rural in character.

(4) On receiving an application under paragraph (3) the FHSA shall, subject to paragraph (11), consider and determine whether or not the area specified in the application or any part of such area is rural in character.

(5) The FHSA shall, before making a determination under this regulation, give notice in writing to the Local Medical Committee, the Local Pharmaceutical Committee and any doctor or chemist who, in the opinion of the FHSA, may be affected by the determination, and shall inform them that they may make representations in writing within 30 days from the date on which the notice was sent.

(6) Where the FHSA determines that any area of part of an area is or is not rural in character, it shall consider whether the provision of general medical services by any doctor, or pharmaceutical services by any chemist, is likely to be adversely affected in consequence of that determination.

(7) Where the FHSA considers that the provision of general medical services by any doctor or pharmaceutical services by any chemist is likely to be adversely affected in consequence of a determination under paragraph (4), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients.

(8) The FHSA shall determine the boundaries of any area or part of an area referred to in the application which it determines to be rural in character, and—

(a) any area determined to be rural in character by the FHSA or, on appeal under regulation 10, by the Secretary of State shall be a controlled locality; and

(b) the FHSA shall delineate precisely the boundaries of any controlled locality on a map.

(9) Any area forming part of an area referred to in an application under paragraph (3) which is determined not to be rural in character shall not be or, as the case may require, shall cease to be a controlled locality.

(10) The FHSA shall not in consequence of a determination under paragraph (4)—

(a) include any particulars in a pharmaceutical list;

(b) give notice to a doctor pursuant to regulation 20(6); or

(c) determine an application under regulation 12,

during the period for bringing an appeal or pending the determination of any such appeal.

(11) Subject to paragraph (12), where the question whether or not an area is rural in character has been determined—

(a) by an FHSA under this regulation; or

(b) on appeal, under regulation 10,

that question shall not again be considered in relation to that area or any part of it during the period of five years immediately following the date of the determination.

(12) A question to which paragraph (11) applies may be considered by an FHSA during the period referred to in that paragraph only where it is satisfied, whether on an application under paragraph (3)

or otherwise, that there has been a substantial change of circumstances in relation to the area in question, or the relevant part of it, since the question was last determined.

(13) The FHSA shall, upon any determination by it under this regulation, give to the persons mentioned in paragraph (5) notice in writing of its determination and of the reasons for it, and shall inform the Local Medical Committee and Local Pharmaceutical Committee that they may appeal to the Secretary of State in accordance with regulation 10.

Appeals relating to rurality of an area

10.—(1) Where an FHSA—

(a) has determined, pursuant to regulation 9, that an area is, or is not, rural in character;

(b) has refused to consider that question on the ground that it is not satisfied as mentioned in paragraph (12) of that regulation; or

(c) has determined that it should, or should not, postpone the making or determination of arrangements, as mentioned in paragraph (7) of that regulation,

the Local Medical Committee or the Local Pharmaceutical Committee may appeal to the Secretary of State against any such determination or, as the case may be, refusal, by giving notice of appeal in accordance with paragraph (2).

(2) Any notice of appeal under paragraph (1) shall be sent to the Secretary of State, within 30 days of the date on which the decision of the FHSA was sent to the Local Medical Committee or the Local Pharmaceutical Committee making the appeal, and shall contain a concise statement of the grounds of appeal.

(3) The Secretary of State shall, on receipt of any notice of appeal under this regulation, send copies thereof to the FHSA and to all the persons to whom it has given notice of its determination under regulation 9(13).

(4) The FHSA and the persons to whom the notice of appeal was sent under paragraph (3) may, within 30 days from the date on which the Secretary of State sent copies to them of the notice of appeal under this regulation, make representations in writing to him on the appeal.

(5) The Secretary of State may require an oral hearing before he determines an appeal under this regulation.

(6) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(7) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(8) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (3).

(9) The appellant and any person to whom a notice of the hearing is sent under paragraph (8) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and the FHSA may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(10) On determining an appeal under this regulation, the Secretary of State—

(a) shall, where he allows an appeal against a refusal mentioned in paragraph (1)(b), also determine the question whether or not the relevant area is rural in character;

(b) may, in a case where the FHSA, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients, himself postpone, for such a period as he thinks fit, the making or termination of such arrangements;

(c) shall, in a case where that question was not considered by the FHSA when it determined the application, remit the question to the FHSA for determination.

(11) The Secretary of State shall, upon the determination by him of an appeal under this regulation, give notice of the decision in writing, together with his reasons for it, to all the persons to whom the notice of appeal was sent under paragraph (3).

Applications for inclusion in pharmaceutical lists in respect of controlled localities

11.—(1) Subject to paragraph (4), where the premises specified in an application under regulation 4(2)(a) are in a controlled locality, that application shall be determined in accordance with regulation 12 unless—

(a) the applicant is seeking only to change within that controlled locality the premises at which he provides pharmaceutical services; and

(b) the granting of the application would not, in the view of the FHSA, result in a significant change in the arrangements for the provision of pharmaceutical services in any part of a controlled locality.

(2) Subject to paragraph (4), where—

(a) the premises specified in an application under regulation 4(2)(a) (not being in a controlled locality) are within one mile of any part of any controlled locality in which reside patients for whom a doctor provides pharmaceutical services; and

(b) the granting of the application would, in the view of the FHSA, result in a significant change in the arrangements for the provision of pharmaceutical services in any part of a controlled locality,

the FHSA shall, where it grants the application, consider the conditions (if any) which are to be imposed in relation to that grant under regulation 12(15) and, pending the final determination of such conditions, shall not in consequence of the grant give notice to any doctor to discontinue the provision of pharmaceutical services to any patient.

(3) Where the premises specified in an application under regulation 4(2)(a) are within one mile of the locality of another FHSA, the FHSA shall make enquiries as to controlled localities in that locality in order to determine—

(a) whether the application is of the description specified in paragraph (2); and

(b) which controlled localities are to be considered for the purposes of paragraph (1)(b) or (2)(b),

and where it is satisfied that there is a relevant controlled locality in that locality, it shall consult that other FHSA before forming a view for the purposes of paragraph (1)(b) or (2)(b).

(4) An application shall not be determined under regulation 12—

(a) where regulation 15 applies; or

(b) where the applicant intends to provide pharmaceutical services in the place of, and at the same location as, another person who provides pharmaceutical services.

Determination of applications in respect of controlled localities

12.—(1) Where an FHSA receives an application which it is required, by virtue of regulation 11, 14(3) or 21, to determine in accordance with the provisions of this regulation, it shall send a notice of the application and a copy of the application to—

(a) the Local Medical Committee;

(b) the Local Pharmaceutical Committee;

(c) any person whose name is included in the medical list or the pharmaceutical list of the FHSA who, in its opinion, might be affected by the grant of the application;

(d) any other FHSA in whose medical list or pharmaceutical list is included the name of a person who, in the opinion of the FHSA, might be so affected; and

(e) any Community Health Council serving the locality of the FHSA or of any other FHSA notified under sub-paragraph (d).

(2) Where an FHSA is sent a copy of an application under paragraph (1)(d), it shall, as soon as practicable, send a copy to—

(a) the Local Medical Committee for its locality;

(b) the Local Pharmaceutical Committee for its locality; and

(c) any person whose name is included in its medical list or pharmaceutical list who might, in its opinion, be affected by the grant of the application.

(3) Any person to whom an FHSA has sent a copy of the application may, within 30 days of the date on which that copy was sent to him make representations in writing to the FHSA to which the application was made.

(4) Any other person who considers that he might be affected by the decision on the application may, within such reasonable period as the FHSA to whom the application was made may allow, make representations in writing to it.

(5) The FHSA may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.

(6) In any case where the FHSA decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under paragraph (3) or (4) not less than 14 days notice of the time and place at which the representations are to be heard.

(7) The FHSA may invite any other person to give oral evidence as it thinks fit.

(8) The applicant and any person mentioned in paragraph (6) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(9) The procedure by which representations are heard shall be such as the FHSA may determine.

(10) No person who provides or assists in providing general medical services or pharmaceutical services under Part II of the Act shall take part in any decision under this regulation.

(11) The FHSA shall, as soon as practicable after determining the application, give notice in writing—

(a) of its decision and the reasons for that decision to—

(i) the applicant,

(ii) the Local Medical Committee,

(iii) the Local Pharmaceutical Committee,

(iv) any other FHSA to which notice was sent pursuant to paragraph (1)(d),

(v) any Local Medical Committee or Local Pharmaceutical Committee notified pursuant to paragraph (2)(a), and

(vi) any other person who has given evidence under the provisions of paragraph (3) or (4); and

(b) of the rights of appeal arising under regulation 13 to—

(i) the applicant, and

(ii) any person who gave evidence under the provisions of paragraph (3).

(12) The FHSA may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it shall so inform the applicants and the persons to whom copies of the applications were sent under this regulation.

(13) The FHSA—

(a) shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of general medical services or pharmaceu tical services in any locality;

(b) shall refuse an application under regulation 21 in relation to any part of the area specified in the application—

(i) which is not in a controlled locality, or

(ii) which is within one mile of any pharmacy; and

(c) may refuse an application in a case to which paragraph (12) applies (notwithstanding that it would, if determining that application in isolation, grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all (or more than one of them) would prejudice the proper provision of general medical services or pharmaceutical services in any locality;

and any refusal of such an application may relate to all or any part of the area within the controlled locality.

(14) Subject to paragraph (13) and to regulation 4(4), the FHSA shall grant every application and shall consider whether the provision of general medical services by any doctor or pharmaceutical services by any chemist is likely to be adversely affected in consequence of that grant.

(15) Where the FHSA considers that the provision of general medical services by any doctor or pharmaceutical services by any chemist is likely to be adversely affected in consequence of a grant under paragraph (14), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients.

(16) An application granted in accordance with the provisions of this regulation shall not be treated as finally granted for the purposes of these Regulations until the end of the period for bringing an appeal under regulation 13 or until the determination of any such appeal, whichever is the later, and "final grant" shall be construed accordingly.

(17) Subject to paragraph (18), an FHSA shall not consider under this regulation—

(a) any application for outline consent under regulation 21 where, during the relevant period, an application made under that regulation in respect of the same area has been finally refused;

(b) any application to which regulation 11 or 14 applies, where the location of the premises at which the pharmacist intends to provide pharmaceutical services is in a controlled locality and—

(i) is in an area in respect of which an application under regulation 21 was finally granted during the relevant period, or

(ii) is within one mile of the location of premises in respect of which an application to which regulation 4 or 11 applies was finally refused during the relevant period.

(18) An FHSA may at any time consider an application to which paragraph (17) applies where it is satisfied that, since the date of the refusal or, as the case may be, grant referred to in paragraph (17) (a) or (b), or, where there has been more than one such refusal or grant during the relevant period, the last such refusal or grant, there has been a substantial change of circumstances affecting the controlled locality.

(19) In this regulation "relevant period" means the period of 5 years immediately preceding the making of the application.

Appeals in connection with determinations under regulation 12

13.—(1) Where an FHSA—

(a) has determined an application under regulation 12;

(b) has refused to consider an application under that regulation on the ground that it is not satisfied as mentioned in paragraph (18) of that regulation;

(c) has determined that it should, or should not, postpone the making or termination of arrangements under regulation 20, as mentioned in regulation 12(15); or

(d) has refused to consider an application for preliminary consent under regulation 14(1) on the ground that it is not satisfied as mentioned in regulation 14(4),

an appeal to the Secretary of State may be made, in accordance with paragraph (4), against that determination or, as the case may be, against that refusal, by any person specified in paragraph (2).

(2) The persons who may make an appeal under this regulation are—

(a) in the case of an appeal against a determination under regulation 12, the applicant or any person whose name is included in the medical list or a pharmaceutical list of—

(i) the FHSA, or

(ii) any other FHSA to which a copy of the application was sent under regulation 12(1)(d),

and who submitted evidence pursuant to paragraph (3) of that regulation in connection with the application; and

(b) in the case of an appeal against a refusal mentioned in paragraph (1)(b), the applicant.

(3) Where, in determining any application, an FHSA has, pursuant to regulation 12(12), considered that application together with one or more other applications, any of the applicants and any of the persons mentioned in paragraph (2)(a) may appeal against the determination of any of the applications, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(4) An appeal shall be made in writing within 30 days from the date on which notice of the decision was sent to the appellant and shall contain a concise statement of the grounds of appeal upon which the appellant intends to rely.

(5) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(6) Unless paragraph (5) applies, the Secretary of State shall send a copy of the notice of appeal to the FHSA whose determination is appealed against and to those persons mentioned in paragraph (2)(a).

(7) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (6) may, within 30 days from the date the copy was sent to him, make representations in writing on the appeal to the Secretary of State.

(8) The Secretary of State may require an oral hearing of an appeal before he determines it.

(9) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal who shall report to him thereon with recommendations as to the relevant findings of fact and their conclusions.

(10) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(11) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to—

(a) the appellant;

(b) the FHSA;

(c) the Local Medical Committee;

(d) the Local Pharmaceutical Committee; and

(e) any other person who gave evidence to the FHSA in connection with the application.

(12) The appellant and any of the persons to whom notice of the hearing is required to be sent under paragraph (11) may attend and be heard in person or by counsel, solicitor or other representative, and the FHSA may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(13) On an appeal under this regulation, the Secretary of State—

(a) may allow the appeal;

(b) may, in a case where the FHSA, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;

(c) shall, in a case where that question was not considered by the FHSA when it determined the application, remit the question to the FHSA for determination;

(d) shall, where he allows an appeal against a refusal of the FHSA as mentioned in paragraph (1)(b), remit the application to the FHSA and direct that regulation 12(17) shall not apply; or

(e) may dismiss the appeal.

(14) The decision of the Secretary of State shall be given in writing and shall—

(a) include a statement of his reasons for the decision and of his findings of fact; and

(b) as soon as practicable, be sent to the persons mentioned in paragraph (11).

Preliminary consent to be included in a pharmaceutical list

14.—(1) A person who wishes to be granted the right under regulation 4 to be included in a pharmaceutical list upon a subsequent application may apply to an FHSA for consent (in these Regulations referred to as "preliminary consent").

(2) An application for preliminary consent shall be in writing and shall specify—

(a) the location of the premises at which it is proposed to provide pharmaceutical services; and

(b) the pharmaceutical services which it is proposed to provide.

(3) Where any application for preliminary consent under this regulation would, if it were an application under regulation 4(2), fall, by virtue of regulation 11, to be determined in accordance with regulation 12, the provisions of regulations 12 and 13 shall apply to the determination of that application as if it were an application under regulation 4(2).

(4) An application for preliminary consent, other than an application to which paragraph (3) applies, shall be determined as if it were an application under regulation 4(2) and the provisions of regulations 4, 5, 6, 7 and 8 shall apply to that determination.

(5) A preliminary consent shall have effect for a period of 12 months from its final grant, but if, before the expiration of that period, the FHSA allows an extension for such further period as

it considers reasonable in the circumstances, the preliminary consent shall have effect for such extended period.

Effect of preliminary consent

15.—(1) Subject to paragraph (2), where the applicant has been finally granted preliminary consent, the FHSA shall grant an application under regulation 4(2) provided that—

(a) the date specified for inclusion in the pharmaceutical list falls within the period referred to in regulation 14(5);

(b) the pharmaceutical services which it is proposed to provide are the same as those specified in the application for preliminary consent; and

(c) the premises specified in the application have the same location as that in respect of which the preliminary consent was granted.

(2) Where sub-paragraphs (a) and (b) of paragraph (1) are satisfied but the premises specified in the application have a different location from that in respect of which preliminary consent was granted, the FHSA shall treat the application as though it were an application under regulation 4(2)(b) to change the location of the premises.

(3) The grant of an application under this regulation shall be subject to any conditions imposed under regulation 12(15) or 13(13)(b) in relation to the final grant of the corresponding preliminary consent.

Supplemental services

16.—(1) A chemist may, in addition, undertake to provide either or both of the supplemental services specified in paragraph (2)(a) and (b).

(2) In these Regulations "supplemental services" means—

(a) where a chemist regularly provides drugs to persons resident in a home registered under the Registered Homes Act 1984(**2**) or in respect of which registration is, by virtue of section 1(5)(j) of that Act, not required—

(i) giving advice for the safe keeping and correct administration of those drugs; and

(ii) keeping records of visits made to those homes;

(b) keeping records in connection with drugs supplied to any person—

(i) who claims exemption under regulation 6(1)(c) of the National Health Service (Charges for Drugs and Appliances) Regulations 1989(**3**)(remission from charges for drugs and appliances), or

(ii) who, in the opinion of the pharmacist providing the drug, is likely to have difficulty understanding the nature and dosage of the drug provided and the times at which it is to be taken,

in circumstances where the nature of the drug is such that, in the opinion of the pharmacist providing it, the same or a similar drug is likely to be prescribed for that person regularly on future occasions.

(3) In this regulation "records" shall include—

(a) in the case of those kept for the purposes of paragraph (2)(a), a record of—

(i) the name and address of the home,

(ii) the date of each visit by the pharmacist, and

(**2**) 1984 c. 23, as amended by the Registered Homes (Amendment) Act 1991 (c. 20).
(**3**) S.I. 1989/419, as amended by S.I. 1990/537.

(iii) the nature of any advice given by him in the course of the visit; and

(b) in the case of those kept for the purposes of paragraph (2)(b), a record of—

(i) the name and address of the person to whom the drug is supplied,

(ii) the name, quantity and dosage of the drug provided, and

(iii) the date on which it is provided.

Removal from pharmaceutical lists

17.—(1) Where an FHSA determines that a chemist—

(a) has died; or

(b) is no longer a chemist,

the FHSA shall, subject to paragraph (2), remove his name from that list.

(2) The name of any chemist whose business is carried on by representatives in accordance with the provisions of the Pharmacy Act 1954(**4**) shall not be removed from the pharmaceutical list under paragraph (1) so long as the business is carried on by them in accordance with the provisions of that Act, and the representatives agree to be bound by the terms of service.

(3) Where an FHSA determines that a chemist, whose name has been included for the preceding six months in a pharmaceutical list, has not during that period provided pharmaceutical services, it may remove the chemist's name from that list.

(4) Before making any determination under paragraph (3), the FHSA shall—

(a) give the chemist 28 days' notice of its intention;

(b) afford the chemist an opportunity of making representations to the FHSA in writing or, if he so desires, in person; and

(c) consult the Local Pharmaceutical Committee.

(5) Where under paragraph (3) the FHSA decides to remove a chemist's name from its pharmaceutical list, it shall give notice in writing of its decision to the chemist.

(6) A chemist to whom a notice has been given under paragraph (5) may, within 30 days of receiving the notice, appeal to the Secretary of State against the decision of the FHSA and the FHSA shall not remove the chemist's name from the pharmaceutical list until—

(a) if no appeal is made, the expiration of the period of 30 days; or

(b) if an appeal is made, the appeal is determined.

(7) An appeal under paragraph (6) shall be in writing and shall set out the grounds of appeal.

(8) Where the Secretary of State allows the appeal, he shall direct the FHSA not to remove the chemist's name from the pharmaceutical list.

(9) Nothing in this regulation shall—

(a) prejudice the right of a chemist to be included again in a pharmaceutical list; or

(b) affect a chemist who is performing a period of relevant service, and no removal under paragraph (3) shall be effected in respect of any such chemist until six months after he has completed that service.

(**4**) 1954 c. 61.

Standards of, and payments for, drugs and appliances

18.—(1) For the purpose of enabling arrangements to be made for the provision of pharmaceutical services, the Secretary of State shall compile and publish a statement (in these Regulations referred to as "the Drug Tariff") which he may amend from time to time and which shall include—

(a) the list of appliances for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

(b) the list of chemical reagents for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

(c) the list of drugs for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

(d) the prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated;

(e) the method of calculating the payment for drugs not mentioned in the Drug Tariff;

(f) the method of calculating the payment for containers and medicine measures;

(g) the dispensing or other fees payable in respect of the supply of drugs and appliances and of supplemental services;

(h) arrangements for claiming fees, allowances and other remuneration for the provision of pharmaceutical services;

(i) the method by which a claim may be made for compensation for financial loss in respect of oxygen equipment.

(2) The prices referred to in paragraph (1)(d) may be fixed prices or may be subject to monthly or other periodical variations to be determined by reference to fluctuations in the cost of drugs and appliances.

(3) A chemist shall supply, in response to a request from the Secretary of State within 30 days of the notification of the request, any information which the Secretary of State may require for the purpose of conducting any inquiry into the prices, payments, fees, allowances and remuneration specified in paragraph (1)(d) to (i).