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STATUTORY INSTRUMENTS

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**2002 No. 2548**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Out of Hours Medical  
Services) and National Health Service (General  
Medical Services) Amendment Regulations 2002**

<i>Made</i>	- - - -	<i>9th October 2002</i>
<i>Laid before Parliament</i>		<i>9th October 2002</i>
<i>Coming into force</i>	- -	<i>1st November 2002</i>

The Secretary of State, in exercise of the powers conferred upon him by sections 15(1) and (1ZA), 17A(3), 29 and 126(4) of the National Health Service Act 1977(1) and sections 18 and 64(6) of the Health and Social Care Act 2001(2), and all other powers enabling him in that behalf, hereby makes the following Regulations:

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002 and shall come into force on 1st November 2002.

(2) These Regulations apply to England only.

**Interpretation**

2. In these Regulations—

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- (1) 1977 c. 49. Section 15(1) was amended by the Health and Social Security Act 1984 (c. 48), section 5(2); the National Health Service and Community Care Act 1990 (c. 19) (“the 1990 Act”), section 12(1); the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 6, and the National Health Service Reform and Health Care Professions Act 2002 (c. 17) (“the 2002 Act”), Schedule 2, paragraph 2. Section 15(1ZA) was inserted by the National Health Service (Primary Care) Act 1997 (c. 46) (“the 1997 Act”) Schedule 2, paragraph 4(2), and amended by Schedule 3, paragraph 11 of the 2002 Act. Section 17A(3) was inserted by the Health Act 1999 (c. 8), section 12(1), and is substituted by section 3(3) of the 2002 Act. Section 29 has been extended by the Health and Medicines Act 1988 (c. 49), section 17; and is amended by the following: Health Services Act 1980 (c. 53), sections 1 and 7 and Schedule 1, paragraph 42(b); Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 6, paragraph 2; the Medical Act 1983 (c. 54), section 56(1) and Schedule 5, paragraph 16(a); by S.I.1985/39, article 7(3); the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 18; the 1997 Act, Schedule 2, paragraph 8; the Health and Social Care Act 2001 (“the 2001 Act”), section 17, and the 2002 Act, Schedule 2, paragraph 3. See section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i) for the definitions of “prescribed” and “regulations”. These functions of the Secretary of State under the 1977 Act are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the Health Act 1999. See also section 40(1) of the 2002 Act.
- (2) 2001 c. 15. Section 18 is amended by paragraph 72 of Schedule 2 to the 2002 Act. By section 66 of the 2001 Act, “regulations” means regulations made by the relevant authority which, in relation to England, is the Secretary of State.

“the 1977 Act” means the National Health Service Act 1977;

“the 1997 Act” means the National Health Service (Primary Care) Act 1997(3);

“accrediting authority” means, in relation to a service provider(4), the Primary Care Trust which is responsible, in accordance with regulation 4(3) and (4), for determining its application for approval;

“accredited service provider” means a relevant service provider which is approved in accordance with these Regulations to provide out of hours services(5) in a specified area;

“assessing authority” has the meaning given to it by regulation 4(5);

“existing service provider” means—

- (a) a relevant service provider with which a doctor has an out of hours arrangement, which has been approved in accordance with paragraph 18A(9) of Schedule 2 to the General Medical Services Regulations; or
- (b) a relevant service provider which has an arrangement in connection with a pilot scheme under which personal medical services are performed outside the normal hours, otherwise than by the doctors named in the pilot scheme agreement as primarily responsible for the performance of those services;

“General Medical Services Regulations” means the National Health Service (General Medical Services) Regulations 1992(6);

“National Health Service Counter Fraud Service” means the service established by the Secretary of State to deal with inquiries and investigations relating to any allegation of fraud or corruption in the health service;

“necessary quality standards” means the standards set out in the document entitled “Quality Standards in the Delivery of GP Out of Hours Services” published on 20th June 2002(7);

“normal hours” means those days and hours specified in a pilot scheme agreement as being those days on which, and times at which, a doctor will normally be available to perform personal medical services;

“out of hours arrangement” means an arrangement under paragraph 18A(2) of Schedule 2 to the General Medical Services Regulations;

“pilot scheme agreement” means an agreement which constitutes, or is one of the agreements which together constitute, a pilot scheme under section 1(1) of the 1997 Act;

“relevant service provider” means any service provider except—

- (a) an individual medical practitioner; or
- (b) a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota arrangements;

“specified area” means—

- (a) in relation to a relevant service provider, the geographical area in England for which it seeks approval, or

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(3) 1997 c. 46.

(4) By section 18(3) of the 2001 Act, “service provider” means, in relation to arrangements to which the section applies, the person or persons undertaking to provide out of hours services under the arrangements.

(5) By section 18(3) of the 2001 Act, “out of hours services” means general medical services or personal medical services (as the case may be) provided during part or all of an out of hours period.

(6) S.I. 1992/635. Relevant amendments are made by S.I. 1996/702, S.I. 1998/682, S.I. 2001/3742 and S.I. 2002/2469.

(7) The document “Quality Standards in the delivery of GP Out of Hours Services” published on 20th June 2002 is published by the Department of Health on its website at <http://www.doh.gov.uk/pricare/qualitystandards.htm> or a copy may be obtained by writing to Primary Care, Room 7E28, Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE, or by e-mailing [OOHAccreditation@doh.gov.uk](mailto:OOHAccreditation@doh.gov.uk).

- (b) in relation to an accredited service provider, the geographical area in England for which it is approved,  
to provide out of hours services.

### **Meaning of out of hours period**

3.—(1) The “out of hours period” has the meaning given to it in paragraphs (2) and (3).

(2) In relation to the provision of general medical services under arrangements under section 29 of the 1977 Act, the “out of hours period” means—

- (a) the period beginning at 7pm on any day from Monday to Friday and ending at 8am on the following day;
- (b) the period between 1pm on Saturday and 8am on the following Monday; and
- (c) Good Friday, Christmas Day and bank holidays.

(3) In relation to the provision of personal medical services under a pilot scheme agreement, the “out of hours period” means any period which does not fall within the normal hours.

### **Application for approval**

4.—(1) A relevant service provider shall make a written application for approval to any Primary Care Trust in whose area it proposes to provide out of hours services.

(2) The application shall include the information and undertakings set out in the Schedule.

(3) Where the specified area is entirely within the area of the Primary Care Trust to which the application is made, that Primary Care Trust shall be the accrediting authority.

(4) Where the specified area includes the area of any other Primary Care Trust, the Primary Care Trust to which the application is made shall—

- (a) notify any other Primary Care Trust whose area is included in the specified area of the application; and
- (b) after consultation with any such Primary Care Trust, determine which Primary Care Trust shall be the accrediting authority.

(5) The accrediting authority shall arrange with a Primary Care Trust whose area is not included in any part of the specified area (“the assessing authority”), for that Primary Care Trust to assess the application.

(6) The relevant service provider shall provide the accrediting authority and the assessing authority with any further information they may reasonably require in relation to the application.

(7) The assessing authority shall—

- (a) visit the relevant service provider and make such other enquiries as it considers necessary in order to assess the application;
- (b) prepare a written report on the application and forward it to the relevant service provider;
- (c) invite the relevant service provider to make written representations on the report within 28 days of receipt of the report; and
- (d) having considered any such representations, recommend to the accrediting authority whether or not approval should be granted, and if it recommends approval, whether approval should be granted—

- (i) under regulation 5(1)(a)(i) or (ii) or, as the case may be, (1)(b);
- (ii) in relation to the whole of the specified area or any part of it.

(8) The accrediting authority shall, taking into account the recommendation of the assessing authority, approve the application in accordance with regulation 5 or refuse it in accordance with regulation 6.

### **Approval**

5.—(1) The accrediting authority shall approve the relevant service provider to provide out of hours services if it is satisfied—

- (a) in the case of an existing service provider—
  - (i) that it meets the necessary quality standards; or
  - (ii) in relation to any respect in which it is not meeting the necessary quality standards, that its proposals to do so are realistic and achievable;
- (b) in any other case, that the relevant service provider has the capacity to provide the service, and that its proposals to meet the necessary quality standards are realistic and achievable.

(2) In approving the application, the accrediting authority shall also specify the geographical area in respect of which approval is granted.

(3) If approval is granted under paragraph (1)(a)(i), it shall be for a period of up to three years, beginning with the date on which the decision to approve is notified to the relevant service provider.

(4) If approval is granted under paragraph (1)(a)(ii) or (1)(b), it shall be for a period of up to twelve months beginning with the date on which the decision to approve is notified to the relevant service provider.

(5) At the end of any period of approval granted under paragraph (4), the accrediting authority shall if it is satisfied that the relevant service provider is meeting the necessary quality standards, approve the relevant service provider for a period of three years, beginning with the date on which the decision under this paragraph is notified to the relevant service provider.

### **Grounds for refusal**

6.—(1) An accrediting authority may refuse an application if it is satisfied that a relevant service provider—

- (a) does not have the capacity to provide the service; or
- (b) does not meet the necessary quality standards and has not made satisfactory proposals to address the shortcomings.

(2) When refusing an application, the accrediting authority shall notify the relevant service provider—

- (a) of its decision and the reasons for it (including any facts relied upon);
- (b) of its right of appeal under regulation 10; and
- (c) that it has 28 days from the date of the decision in which to appeal, and how to do so.

### **Requirements with which an accredited service provider must comply**

7.—(1) An accredited service provider shall comply with any reasonable request from the accrediting authority or the assessing authority for information about its provision of out of hours services.

(2) An accredited service provider shall, on receipt of a written request from the assessing authority admit at all reasonable times for the purposes of assessing its provision of out of hours services a person authorised by the assessing authority for the purpose.

(3) An accredited service provider shall comply with the undertakings set out in the Schedule.

(4) An accredited service provider shall provide a report on its compliance with the necessary quality standards to—

- (a) the accrediting authority;
- (b) any other Primary Care Trust whose area is included in the specified area.

(5) The report referred to in paragraph (4) shall be provided at such intervals as the accrediting authority may require, but in any case at least—

- (a) quarterly, where the accredited service provider is approved for a period of three years; and
- (b) monthly, where the accredited service provider is approved for a period of up to twelve months.

### **Withdrawal of accreditation**

8.—(1) Subject to paragraphs (2) and (3), an accrediting authority may withdraw the approval of an accredited service provider if—

- (a) the accredited service provider has persistently failed to meet any of the necessary quality standards;
- (b) the accredited service provider has failed to comply with any requirement of regulation 7; or
- (c) the accrediting authority considers that it is necessary to do so for the protection of members of the public or is otherwise necessary in the public interest.

(2) Where an accrediting authority is considering withdrawing approval from an accredited service provider under paragraph (1), it shall—

- (a) give the accredited service provider notice in writing of its intention to withdraw approval and specifying, in a case to which paragraph (1)(a) applies, the respects in which the necessary quality standards are not being met;
- (b) inform the accredited service provider that it may within 28 days of the date of the notice, make written representations to the accrediting authority, to include, in a case to which paragraph (1)(a) applies, its proposals to address its shortcomings; and
- (c) inform the accredited service provider that it may request an oral hearing before the accrediting authority within the 28 day period mentioned in sub-paragraph (b).

(3) In a case where paragraph (1)(a) applies, if, in the opinion of the accrediting authority any proposals provided in accordance with paragraph (2)(b), would, if implemented, rectify the shortcomings, the accrediting authority shall not withdraw approval for a period of six months, beginning with the date on which it notifies the accredited service provider that its proposals are accepted.

(4) If no representations are received within the period specified in paragraph (2)(b), the accrediting authority shall notify the accredited service provider of its decision and the reasons for it (including any facts relied upon).

(5) Subject to paragraph (6), if any representations are received in accordance with paragraph (2)(b), the accrediting authority must take them into account in reaching its decision, and shall then notify the service provider of its decision and the reasons for it (including any facts relied upon).

(6) If the accredited service provider requests an oral hearing—

- (a) the hearing must take place before the accrediting authority reaches its decision; and
- (b) the accrediting authority must then notify the accredited service provider of its decision, and the reasons for it (including any facts relied upon).

(7) When an accrediting authority notifies an accredited service provider of any decision under paragraph (4), (5) or (6), it shall also notify it—

- (a) of its right of appeal under regulation 10; and
- (b) that it has 28 days from the date of the decision in which to appeal, and how to do so.

### **Suspension of approval**

9.—(1) Subject to paragraph (7), if an accrediting authority is satisfied that it is necessary for the protection of members of the public or is otherwise in the public interest, it may suspend the approval of an accredited service provider—

- (a) while it decides whether or not to exercise its powers under regulation 8(1)(c) to withdraw approval;
- (b) where it has decided to withdraw approval under regulation 8(1)(c), but before that decision takes effect; or
- (c) pending an appeal of a decision under regulation 8(1)(c).

(2) In a case falling within paragraph (1)(a), the accrediting authority must specify a period, which shall not exceed six months, as the period of suspension.

(3) In a case falling within paragraph (1)(b) or (c), the suspension has effect until the expiry of any appeal period or, if the accredited service provider appeals under regulation 10, until the appeal has been disposed of.

(4) Subject to paragraph (7), the accrediting authority may extend a period of suspension in a case falling within paragraph (1)(a), so long as the total period of suspension does not exceed six months.

(5) The effect of suspension is that the accredited service provider is treated as not being an accredited service provider.

(6) The accrediting authority may at any time revoke the suspension, and if it does so shall without delay inform the accredited service provider of its decision.

(7) Where an accrediting authority is considering suspending the approval of an accredited service provider under paragraph (1), or extending a period of suspension under paragraph (4), it shall—

- (a) give the accredited service provider written notice of its intention to suspend its approval, and of the grounds of the proposed suspension; and
- (b) give the accredited service provider at least 24 hours written notice of the date and time of an oral hearing at which it may, if it wishes, make representations to the accrediting authority.

(8) If the accredited service provider does not wish to have an oral hearing or does not attend the oral hearing, the accrediting authority shall notify the accredited service provider of its decision and the reasons for it (including any facts relied upon), and may suspend the approval with immediate effect.

(9) If an oral hearing does take place, the accrediting authority shall take into account any representations made by the accredited service provider before it reaches its decision, and shall then notify the accredited service provider of its decision and the reasons for it (including any facts relied upon).

(10) The accrediting authority may suspend the approval of the accredited service provider with immediate effect following an oral hearing.

## Appeal

**10.**—(1) A service provider or an accredited service provider (as the case may be) may appeal to the FHSAA<sup>(8)</sup> against a decision mentioned in paragraph (2) by giving notice in writing to the FHSAA.

- (2) The decisions in question are—
- (a) a decision to refuse an application under regulation 6; and
  - (b) a decision to withdraw the approval of an accredited service provider under regulation 8.
- (3) The appeal shall be by way of a redetermination of the accrediting authority's decision.
- (4) On appeal the FHSAA may make any decision which the Primary Care Trust could have made.

## Notification

**11.**—(1) Where an accrediting authority—

- (a) refuses to approve a relevant service provider under regulation 6;
- (b) withdraws approval under regulation 8; or
- (c) suspends approval under regulation 9,

it shall notify the persons and bodies specified in paragraph (2) of the matters set out in paragraph (3).

- (2) The persons and bodies specified for the purposes of paragraph (1) are—
- (a) the Secretary of State;
  - (b) any Primary Care Trust whose area is included in the specified area;
  - (c) any medical practitioner or party to a pilot scheme agreement who, to the knowledge of the Primary Care Trust, has made arrangements for the provision of out of hours services with the accredited service provider;
  - (d) the local medical committee, being a committee recognised under section 44 of the 1977 Act as being representative of doctors in the area;
  - (e) in a fraud case, the National Health Service Counter Fraud Service.
- (3) The matters referred to in paragraph (1) are—
- (a) the name and address of the relevant service provider or accredited service provider;
  - (b) the date of, and a copy of the decision of the accrediting authority;
  - (c) the name of an individual who may be contacted for further information.

(4) The accrediting authority may also notify any person or body which it is satisfied is considering making arrangements with the relevant service provider for the provision of out of hours services or otherwise has a proper interest in receiving the information, of the matters set out in paragraph (3).

(5) Where a decision is changed following an appeal under regulation 10, the accrediting authority shall notify the persons or bodies that were notified of the original decision of the later decision.

## Amendment of paragraph 18A of Schedule 2 to the General Medical Services Regulations

**12.**—(1) In Schedule 2 (terms of service) to the General Medical Services Regulations, paragraph 18A shall be amended in accordance with the following provisions.

- (2) In sub-paragraph (1)—
- (a) before sub-paragraph (1)(a), insert—

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<sup>(8)</sup> By section 128(1) of the National Health Service Act 1977, the FHSAA means the Family Health Services Appeal Authority.

- “(za) “accredited service provider” and “necessary quality standards” have the meaning given to them by regulation 2 of the Out of Hours Regulations;
- (zb) “Out of Hours Regulations” means the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002(9);”;
- (b) in sub-paragraph (1)(c), at the end, add “referred to in sub-paragraph (2)(b).”.
- (3) For sub-paragraph (2) substitute—
- “(2) Subject to the provisions of this paragraph, a doctor may, with the approval of the Primary Care Trust, make an arrangement to transfer his obligations under the terms of service during part or all of the out of hours period to—
- (a) an accredited service provider; or
- (b) a doctor who is included in the medical list.
- (2A) An arrangement referred to in sub-paragraph (2)(a) shall—
- (a) terminate if the approval of the accredited service provider is withdrawn under regulation 8 of the Out of Hours Regulations; or
- (b) be suspended if the approval of the accredited service provider is suspended under regulation 9 of the Out of Hours Regulations.
- (2B) Where an arrangement terminates or is suspended in accordance with sub-paragraph (2A), the provisions of paragraphs 18B and 18C shall not apply.
- (2C) An arrangement referred to in sub-paragraph (2A)(b) shall terminate if the doctor with whom it is made ceases to be included in a medical list.”.
- (4) In sub-paragraph (3), after “transferee doctors” insert “or accredited service providers”.
- (5) In sub-paragraph (6), after “on an obstetric list” add “, or the accredited service provider undertakes to provide a doctor who is on an obstetric list”.
- (6) In sub-paragraph (7)—
- (a) after sub-paragraph (7)(a) insert—
- “(aa) the name and address of the accredited service provider;”;
- (b) in sub-paragraphs (c), (d) and (g), after each time that the words “transferee doctor” appear insert “or accredited service provider”.
- (7) In sub-paragraph (9)—
- (a) before sub-paragraph (9)(a) insert—
- “(za) having regard to the overall provision of out of hours services in its area, that the arrangement is reasonable and will contribute to the efficient provision of such services in the area;”;
- (b) after sub-paragraph (9)(b) insert—
- “(bb) that any arrangement referred to in sub-paragraph (2)(b) will be of an equivalent standard to an arrangement referred to in sub-paragraph (2)(a);
- (bc) that in the case of an arrangement referred to in sub-paragraph (2)(a), the practice premises are within the geographical area in respect of which approval is given under regulation 5 of the Out of Hours Regulations;”.
- (8) In each of sub-paragraphs (14) and (15), after the words “has approved an out of hours arrangement” insert “with a transferee doctor”.

### **Further amendment of Schedule 2 to the General Medical Services Regulations**

13.—(1) Schedule 2 (terms of service) to the General Medical Services Regulations shall be further amended in accordance with the following provisions.

(2) In paragraph 18B, in sub-paragraph (1) for “sub-paragraphs (a) to (d)” substitute “sub-paragraphs (za) to (d)”.

(3) In paragraph 20(1)—

(a) omit sub-paragraph (b); and

(b) in sub-paragraph (c), omit the words “or such an organisation”.

(4) Paragraph 22 (organisations providing deputy doctors) shall be omitted.

### **Transitory provision**

14. These Regulations and the General Medical Services Regulations shall apply to any relevant service provider which on or before 1 December 2002 makes an application for approval in accordance with regulation 4, as if that service provider were an accredited service provider in respect of the area specified in its application, until—

(a) the date on which the application is approved under regulation 5; or

(b) if the application is refused under regulation 6, the time allowed for any appeal has expired and no appeal has been submitted, or, where an appeal has been submitted, it has been determined by the FHSAA.

### **Prescribed functions of Primary Care Trusts and Strategic Health Authorities**

15.—(1) Each Primary Care Trust shall have the function of co-ordinating and facilitating the effective provision of out of hours general medical services in its area.

(2) Each Strategic Health Authority shall have the function of co-ordinating and facilitating the effective provision of personal medical services provided out of hours in connection with pilot scheme agreements in its area.

### **Amendment of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002**

16.—(1) The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002(10) shall be amended as follows.

(2) In regulation 4 (functions relating to pilot schemes), in sub-paragraph (5)(b)—

(a) at the end of sub-paragraph (i), the word “and” is omitted; and

(b) at the end of sub-paragraph (ii), add—

“; and

(i) the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002(11), regulation 15 (prescribed functions of Primary Care Trusts and Strategic Health Authorities).”.

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(10) S.I. 2002/2375.

(11) S.I. 2002/2548.

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Signed by authority of the Secretary of State for Health.

9th October 2002.

*John Hutton*  
Minister of State,  
Department of Health

## SCHEDULE

Regulation 4(2)

### INFORMATION AND UNDERTAKINGS

#### **Information**

1. Name.
2. Address.
3. Details of services it intends to provide.
4. A description of the specified area in respect of which the application is made.
5. A plan in the form of a written statement setting out the action which the relevant service provider is taking, or proposes to take (as the case may be) in order to comply with the necessary quality standards.

#### **Undertakings to be complied with if approved**

6. Undertaking only to provide service in the specified area.
7. Undertaking that it will not use the services of a doctor for the provision of out of hours services, whether as an employee or otherwise, unless the doctor's name is included in a medical list or a supplementary list or he is named in an agreement under section 2 of the 1997 Act as a performer of personal medical services.

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### **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations implement section 18 of the Health and Social Care Act 2001 (out of hours medical services), and make related provision, in respect of England only.

In particular, the Regulations provide for the approval by a Primary Care Trust of providers of out of hours medical services, other than individual doctors, or groups of doctors operating an informal rota system.

Regulation 3 defines the "out of hours" period. Regulation 4 sets out the procedure for approval. Regulations 5 and 6 set out the basis on which approval is given, or may be refused. By regulation 7 an accredited service provider must comply with certain requirements, in particular to report at periodic intervals on its performance of quality standards published by the Secretary of State.

Regulations 8 and 9 make provision for the withdrawal and suspension of approval. Regulation 10 confers a right of appeal to the Family Health Service Appeals Authority in respect of the refusal or withdrawal of approval, and regulation 11 provides for the notifications to be given by a Primary Care Trust in connection with an out of hours service provider.

Regulations 12 and 13 made amendments to the National Health Service (General Medical Services) Regulations 1992 so that a doctor providing general medical services may only make arrangements for out of hours services with a doctor who is included in the medical list, or an accredited service provider.

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By regulation 14, a service provider which makes an application for approval in accordance with these Regulations on or before 1 December 2002 is to be treated as an accredited service provider until the application is determined and any appeal right exhausted.

Regulation 15 confers a new function of co-ordinating and facilitating the effective provision of out of hours services on each Primary Care Trust. In the case of personal medical services provided under a pilot scheme arrangement, the function is, in accordance with section 15(1ZA) conferred on each Strategic Health Authority. However the effect of regulation 16 is to require the function to be performed by Primary Care Trusts acting on behalf of Strategic Health Authorities.