

2003 No. 26

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Out of Hours Provision of
Personal Medical Services and Miscellaneous Amendments)
(England) Regulations 2003**

<i>Made</i>	- - - -	<i>9th January 2003</i>
<i>Laid before Parliament</i>		<i>10th January 2003</i>
<i>Coming into force</i>		<i>1st February 2003</i>

The Secretary of State, in exercise of the powers conferred upon him by sections 15(1) and (1ZA), 29 and 126(4) of the National Health Service Act 1977(a), sections 18 and 64(6) and (8) of the Health and Social Care Act 2001(b) and all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Out of Hours Provision of Personal Medical Services and Miscellaneous Amendments) (England) Regulations 2003 and shall come into force on 1st February 2003.

(2) These Regulations apply to England only.

PART I

OUT OF HOURS PROVISION OF PERSONAL MEDICAL SERVICES

Interpretation

2.—(1) In this Part—

“accredited service provider” has the same meaning as in the Out of Hours Regulations;

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- (a) 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 29 was extended by the Health and Medicines Act 1988 (c.49), section 17 and amended by: the 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); 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. Section 126(4) was amended by the 1990 Act, section 65(2). 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”. As regards Wales, these functions of the Secretary of State under the 1977 Act were 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 and as read with section 40(1) of the 2002 Act.
- (b) 2001 c.15; section 18 was amended by paragraph 72 of Schedule 2 to the National Health Service Reform and Health Care Professions Act 2002. See section 66 of the 2001 Act, by virtue of which “regulations” means regulations made by the relevant authority which, in relation to England, is the Secretary of State.

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

“out of hours arrangement” shall be construed in accordance with regulation 3(1);

“out of hours period” means any period which does not fall within the normal hours;

“Out of Hours Regulations” means the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002(a);

“pilot area” means the area specified in a pilot scheme agreement as the area in which piloted services are to be provided;

“pilot scheme” means any agreement under section 1(1) of the National Health Service (Primary Care) Act 1997(b) (pilot schemes) other than a scheme under which personal dental services are provided;

“pilot scheme agreement” means an agreement which constitutes, or is one of the agreements which together constitute, a pilot scheme;

“piloted services” means services provided in accordance with a pilot scheme;

“relevant body” means—

- (a) in the case where a pilot scheme provider is a party to a pilot scheme agreement with a Strategic Health Authority, that Strategic Health Authority; or
- (b) in the case where a pilot scheme provider is a party to a pilot scheme agreement with a Primary Care Trust, that Primary Care Trust.

(2) In this Part, subject to paragraph (3), “pilot scheme provider” means a person, other than a Primary Care Trust or a Strategic Health Authority, who is a party to a pilot scheme agreement.

(3) Where a Primary Care Trust is providing services under a pilot scheme agreement, “pilot scheme provider” means that Primary Care Trust.

Out of hours arrangements

3.—(1) A pilot scheme provider may, with the approval of the relevant body, make an arrangement under which any of its liabilities and obligations under a pilot scheme are transferred to an accredited service provider during part or all of the out of hours period (“an out of hours arrangement”).

(2) An out of hours arrangement shall—

- (a) terminate if the approval of the accredited service provider is withdrawn under regulation 8 of the Out of Hours Regulations (withdrawal of accreditation); or
- (b) be suspended if the approval of the accredited service provider is suspended under regulation 9 of the Out of Hours Regulations (suspension of approval),

and in these circumstances, the provisions of regulations 5 and 6 below shall not apply.

(3) A pilot scheme provider may—

- (a) make more than one out of hours arrangement, for example with different accredited service providers and in respect of different patients, different times and different parts of the pilot area;
- (b) retain responsibility for, or make separate out of hours arrangements in respect of, the provision of maternity medical services, and any separate out of hours arrangements it makes may encompass all or any part of the maternity medical services it provides.

(4) Nothing in this regulation prevents a pilot scheme provider from retaining or resuming its obligations in relation to named patients.

Form of applications for approval of out of hours arrangements and determinations of applications

4.—(1) An application for approval of an out of hours arrangement shall be made by the pilot scheme provider in writing to the relevant body and shall state—

(a) S.I. 2002/2548.

(b) 1997 c.46.

- (a) the name and address of the accredited service provider;
 - (b) the periods during which the pilot scheme provider's liabilities and obligations under the pilot scheme are to be transferred to the accredited service provider;
 - (c) how it is proposed that the accredited service provider will meet the pilot scheme provider's liabilities and obligations during the periods specified under sub-paragraph (b);
 - (d) the arrangements for the transfer of the pilot scheme provider's liabilities and obligations to and from the accredited service provider at the beginning and end of the periods specified under sub-paragraph (b);
 - (e) whether the proposed out of hours arrangement includes the pilot scheme provider's liabilities and obligations in respect of maternity medical services, and if so, details of any doctor who will perform maternity medical services during the periods specified under sub-paragraph (b);
 - (f) how long the proposed out of hours arrangement is intended to last and the circumstances in which the pilot scheme provider's liabilities and obligations during the periods specified under sub-paragraph (b) would revert to it; and
 - (g) what arrangements are proposed to enable patients in respect of whom piloted services are provided to contact the accredited service provider.
- (2) The relevant body shall determine the application before the end of the period of 28 days beginning with the day on which the relevant body received it.
- (3) The relevant body shall approve a proposed out of hours arrangement if it is satisfied—
- (a) 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) having regard to the interests of the patients in respect of whom piloted services are provided, that the arrangement is reasonable;
 - (c) having regard to all reasonably foreseeable circumstances, that the arrangement is practicable and will work satisfactorily;
 - (d) that the area covered by the proposed out of hours arrangement is within the specified geographical area in respect of which the accredited service provider is approved under regulation 5 of the Out of Hours Regulations (approval);
 - (e) that it will be clear to the patients in respect of whom piloted services are provided how to seek personal medical services outside normal hours;
 - (f) where maternity medical services are to be provided under the out of hours arrangement, that they will be performed by a doctor who has such medical experience and training as are necessary to enable the doctor properly to perform such services; and
 - (g) that if the out of hours arrangement comes to an end, the pilot scheme provider has in place proper arrangements for the immediate resumption of its responsibilities.
- (4) The relevant body shall inform the pilot scheme provider of its determination as to whether or not to approve the application by a notice in writing, and where it refuses an application, it shall—
- (a) include in the notice a statement of the reasons for its determination; and
 - (b) inform the pilot scheme provider of its right of appeal under paragraph (5).
- (5) A pilot scheme provider may, before the end of the period of 30 days beginning with the day on which the notice referred to in paragraph (4) was sent, appeal in writing to the Secretary of State against any refusal of an application under this regulation.
- (6) The Secretary of State may, when determining an appeal, either confirm the determination of the relevant body or substitute his own determination for that of the relevant body.

(7) The Secretary of State shall inform the pilot scheme provider of his determination of the appeal by a notice in writing, and shall include in the notice a written statement of the reasons for the determination.

Review of, and withdrawal of approval of, out of hours arrangements by the relevant body

5.—(1) Subject to regulation 6, where, in respect of any out of hours arrangement with a pilot scheme provider, it appears to a relevant body that it may no longer be satisfied as to one or more of the matters referred to in regulation 4(3), it may inform the pilot scheme provider by a notice in writing that it proposes to review its approval of the arrangement, and in that notice it shall—

- (a) explain why it appears to the relevant body that it may no longer be satisfied as to one or more of the matters referred to in regulation 4(3); and
- (b) inform the pilot scheme provider that it may, within 30 days of the date of the notice, make representations in writing to the relevant body addressing the concerns raised in the notice.

(2) After considering any representations made in accordance with paragraph (1)(b), the relevant body may determine either to allow the arrangement to continue or to withdraw its approval.

(3) The relevant body shall give notice to the pilot scheme provider of its determination and, where it withdraws approval, it shall—

- (a) include with the notice a statement in writing of the reasons for its determination; and
- (b) inform the pilot scheme provider of its right of appeal under paragraph (4).

(4) A pilot scheme provider may, before the end of the period of 30 days beginning with the day on which the notice referred to in paragraph (3) was sent, appeal in writing to the Secretary of State against the withdrawal of approval under this regulation, and if it does so, the Secretary of State—

- (a) may, when determining the appeal, either confirm the determination of the relevant body or substitute his own determination for that of the relevant body; and
- (b) shall inform the pilot scheme provider of his determination of the appeal by a notice in writing, and shall include in the notice a written statement of the reasons for the determination.

(5) Where the relevant body withdraws approval, the withdrawal shall take effect—

- (a) at the end of the period of two months beginning with the date on which the notice referred to in paragraph (3) was sent; or
- (b) where there is an appeal and the appeal is dismissed, the date on which the pilot scheme provider receives notice from the Secretary of State under paragraph (4)(b) that the appeal has been dismissed,

whichever is the later.

Withdrawal of approval of out of hours arrangements with immediate effect

6.—(1) Where, in respect of any out of hours arrangement with a pilot scheme provider, it appears to a relevant body that it is necessary in the interests of the patients in respect of whom piloted services are provided under the arrangement to withdraw its approval of that arrangement with immediate effect, it may withdraw its approval of that arrangement with immediate effect, and in these circumstances it shall inform the pilot scheme provider by a notice in writing—

- (a) that it is withdrawing its approval with immediate effect, giving the reasons for that determination; and
- (b) of the pilot scheme provider's right of appeal under paragraph (2).

(2) A pilot scheme provider may, before the end of the period of 30 days beginning with the day on which the notice referred to in paragraph (1) was sent, appeal in writing to the Secretary of State against the withdrawal of approval with immediate effect under this regulation, and if it does so, the Secretary of State—

- (a) may, when determining the appeal either confirm the determination of the relevant body or substitute his own determination for that of the relevant body; and

- (b) shall inform the pilot scheme provider of his determination of the appeal by a notice in writing, and shall include in the notice a written statement of the reasons for the determination.

PART II

AMENDMENT OF OTHER REGULATIONS

Amendment of the National Health Service (General Medical Services) Regulations 1992

7.—(1) The National Health Service (General Medical Services) Regulations 1992(a) are amended as follows.

- (2) In paragraph 18A of Schedule 2 (terms of service)—
- (a) in sub-paragraph (1)(za), for “and “necessary quality standards” have the meaning given to them” substitute “has the meaning given to it”;
 - (b) in sub-paragraph (2), after “to transfer” insert “any of his liabilities and”;
 - (c) in sub-paragraph (2C) for “(2A)(b)” substitute “(2)(b)”;
 - (d) in sub-paragraph (4), after “regulation 31” insert “, and any separate out of hours arrangements he makes may encompass all or any part of the maternity medical services he provides”;
 - (e) sub-paragraph (6) is omitted;
 - (f) in sub-paragraph (9), after paragraph (c) insert the following paragraph—
 - “(cc) where maternity medical services are to be provided under the out of hours arrangement, that they will be performed by a doctor who has such medical experience and training as are necessary to enable the doctor properly to perform such services;”.
- (3) After paragraph 21 of Schedule 2 insert the following paragraph—
- “**21A.**—(1) In this paragraph, “organisation providing deputy doctors” means a person who provides deputies to doctors, and includes a body which—
- (a) consists only of—
 - (i) doctors whose names are included in the list of a Primary Care Trust and who arrange to act as deputies to each other, or
 - (ii) pilot doctors and doctors whose names are included in the list of a Primary Care Trust who co-operate in such a way that one doctor will cover for another to secure the performance of personal medical services or, as the case may be, the provision of general medical services for their patients; and
 - (b) keeps separate accounts in relation to such arrangements.
- (2) Before entering into arrangements with an organisation providing deputy doctors for the provision of any deputy, a doctor shall—
- (a) obtain the written agreement of the organisation that any doctor it provides to him—
 - (i) will not be subject to a declaration under section 46(2)(c) of the Act, or under any corresponding provision in force in Scotland or Northern Ireland, that he is not fit to be engaged in any capacity in the provision of general medical services,
 - (ii) will not be suspended by any direction of the Tribunal, other than in a case falling within section 49B(3) of the Act,
 - (iii) will (unless he is a trainee general practitioner acting in the place of and under the supervision of a doctor responsible for his training) be suitably experienced within the meaning of section 31 of the Act (other than by

(a) S.I. 1992/635; the relevant amending instruments are S.I. 1992/2412, 1993/2421, 1994/2620, 1995/3093, 1996/702, 1997/981, 1998/682, 1999/1627, 2000/1645, 2001/3386 and 3742, and 2002/1768, 2469 and 2548.

virtue of being a restricted services principal) or will have the acquired rights specified in regulation 5(1)(d) of the Vocational Training for General Medical Practice (European Requirements) Regulations 1994,

- (iv) will not be subject to a declaration under paragraph 4(3) of Schedule 1 to the 1997 Act that he is not fit to be engaged in any capacity in the provision of general medical services, and
 - (v) is on a supplementary medical list, medical list or is named as a performer of personal medical services in a pilot scheme; and
- (b) take all reasonable steps to satisfy himself that the service provided by the organisation (including its monitoring arrangements) will be adequate and appropriate having regard in particular to the interests of the doctor's patients.
- (3) A doctor shall notify the Primary Care Trust of any arrangements he makes with an organisation providing deputy doctors.
- (4) A doctor shall, from time to time and at any time when there are grounds for doing so, take reasonable steps to satisfy himself that an organisation providing deputy doctors with which he has entered into arrangements for the provision of any deputy—
- (a) continues to comply with the agreement referred to in sub-paragraph (2)(a); and
 - (b) continues to provide a service which is adequate and appropriate as mentioned in sub-paragraph (2)(b).
- (5) Subject to sub-paragraph (6), if the Primary Care Trust so requests, a doctor shall furnish it with evidence that such an organisation is continuing—
- (a) to comply with the agreement mentioned in sub-paragraph (2)(a); or
 - (b) to provide a service which is adequate and appropriate as mentioned in sub-paragraph (2)(b) above,
- as the case may be.
- (6) A Primary Care Trust shall not make a request for evidence under sub-paragraph (5)(b) unless—
- (a) it has reasonable grounds for believing that the organisation providing deputy doctors is not providing a service which is adequate and appropriate as mentioned in sub-paragraph (2)(b); and
 - (b) it has consulted the Local Medical Committee.
- (7) Subject to sub-paragraph (8), where as a result of evidence provided under sub-paragraph (5)(b), the Primary Care Trust continues to have reasonable grounds for believing that the organisation providing deputy doctors is not providing a service which is adequate and appropriate as mentioned in sub-paragraph (2)(b), it shall give notice (in this paragraph referred to as a "remedial notice") to the doctor specifying—
- (a) the grounds for its concern;
 - (b) the remedial action it considers necessary; and
 - (c) the date before which such action must be taken.
- (8) A Primary Care Trust shall not issue a remedial notice under sub-paragraph (7) without first consulting the Local Medical Committee.
- (9) Where a Primary Care Trust issues a remedial notice under sub-paragraph (7), it shall also send a copy of that notice to any other doctor who has made arrangements with the same organisation.
- (10) Where it appears to a Primary Care Trust that—
- (a) an organisation providing deputy doctors with which a doctor has made arrangements for the provision of a deputy—
 - (i) is not complying with the agreement referred to in sub-paragraph (2)(a), or
 - (ii) has not taken the action specified in a remedial notice issued under sub-paragraph (7) within the time specified in that notice; or

(b) a doctor's arrangement with such an organisation is such that the doctor's patients are at risk,

it may give notice to the doctor requiring him to bring his arrangement with that organisation to an end either immediately or before such date as is stated in the notice.”.

(4) In Schedule 10 (drugs and other substances not to be prescribed for supply under pharmaceutical services), omit the following entries—

Fabrol Granules

Fluimucil Granules

Methylcysteine Tablets 100 mg

Mucodyne Capsules

Mucodyne Syrup

Mucodyne Forte Syrup

Mucodyne Forte Tablets

Mucodyne Paediatric Syrup

Visclair Tablets.

(5) In Schedule 11 (drugs to be prescribed under pharmaceutical services only in certain circumstances)—

(a) omit “Acetylcysteine Granules” in column 1 and the entries in columns 2 and 3 which relate to that entry;

(b) omit “Carbocysteine” in column 1 and the entries in columns 2 and 3 which relate to that entry; and

(c) after “Apomorphine Hydrochloride (Uprima)” in columns 1 and 2, insert in each of those columns “, Tadalafil (Cialis)”.

Amendment of the Out of Hours Regulations

8. The National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002 are amended as follows—

(a) in regulation 5(5) (approval), for “At the end” substitute “During or at the end”;

(b) in regulation 10(4) (appeal), for “Primary Care Trust” substitute “accrediting authority”; and

(c) in regulation 11(2)(c) (notification), for “Primary Care Trust” substitute “accrediting authority”.

Signed by authority of the Secretary of State for Health

9th January 2003

John Hutton
Minister of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations enable providers of personal medical services under a pilot scheme under Part I of the National Health (Primary Care) Act 1997 to transfer their liabilities and obligations under the pilot scheme outside normal hours to an accredited service provider under an out of hours arrangement. Provision for accredited service providers is made by the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002 (“the Out of Hours Regulations”).

Regulation 2 is an interpretation provision. Regulation 3 allows pilot scheme providers to enter into an out of hours arrangement with an accredited service provider, with the approval of the relevant body, which will be the Primary Care Trust unless the Primary Care Trust is itself the pilot scheme provider, in which case it will be the Strategic Health Authority. Regulation 4 sets out the matters which must be included in the application and the grounds on which the application is to be approved. There is provision for an appeal against refusal to be made to the Secretary of State.

Regulations 5 and 6 make provision for the review and withdrawal of approval, and immediate withdrawal where necessary in the interests of the patients. There are rights of appeal to the Secretary of State.

Regulation 7 makes amendments to the National Health Service (General Medical Services) Regulations 1992 (“the 1992 Regulations”). In Schedule 2 of the 1992 Regulations, which relates to terms of service for doctors—

- a paragraph is inserted relating to the procedure for the making of arrangements between doctors and organisations providing deputy doctors, and the monitoring of those arrangements by Primary Care Trusts;
- three minor drafting errors which were introduced into Schedule 2 by the Out of Hours Regulations are corrected; and
- the requirements included in that Schedule in respect of out of hours cover for maternity medical services are amended so that they match with the corresponding provisions in these Regulations.

Schedules 10 and 11 of the 1992 Regulations are also amended to remove certain oral mucolytic drugs from Schedules 10 and 11 to the 1992 Regulations. This has the effect that those drugs may now be prescribed under the National Health Service in England. Regulation 7(5)(c) includes Cialis in Schedule 11 to the 1992 Regulations, which has the effect that this drug may only be prescribed under the National Health Service in England in the circumstances specified in that Schedule.

Regulation 8 amends the Out of Hours Regulations to correct two further drafting errors, and to allow accrediting authorities, in prescribed circumstances, to grant three-year approvals for relevant service providers before the end of the twelve month trial period.

£2.00

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E1884 1/03 ON (MFK)