

NATIONAL HEALTH SERVICE ACT 1977

THE PRIMARY CARE TRUSTS OUT OF HOURS SERVICES (SUPPLY OF MEDICINES ETC.) DIRECTIONS 2005

The Secretary of State for Health, in exercise of the powers conferred on him by section 17 of the National Health Service Act 1977(a) and of all other powers enabling him in that behalf, hereby gives the following Directions:

Citation , application, commencement and interpretation

1.—(1) These Directions, which may be cited as the Primary Care Trusts Out of Hours Services (Supply of Medicines etc.) Directions 2005, are given to Primary Care Trusts in England and shall come into force on 1st April 2005.

(2) In these Directions—

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

“APMS contract” means arrangements made under section 16CC(2)(b) of the Act (primary medical services)(b) for the provision of primary medical services and “APMS contractor” shall be construed accordingly;

“bank holiday” means any day that is specified or proclaimed as a bank holiday in England and Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(c);

“the Charges Regulations” means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(d);

“complete course” means the course of treatment appropriate to the patient’s condition, being the same as the amount that would have been prescribed if the patient had been seen during core hours;

“core hours” means the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday except Good Friday, Christmas Day or bank holidays;

“Drug Tariff” has the same meaning as in Regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005(e);

“essential services” means the services described in regulation 15(3), (5), (6) and (8) of the GMS Contracts Regulations (essential services) or services that are equivalent to those services and which are provided during core hours;

“GMS contractor” means a contractor within the meaning of the GMS Contracts Regulations;

“GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004(f);

“health care professional” has the same meaning as in section 28M of the Act(g);

“independent nurse prescriber” means a person—

(a) 1977 c.49; section 17 was substituted by the Health Act 1999 (c.8), s. 12(1), and amended by the Health and Social Care Act 2001 (c.15), Schedule 5, paragraph 5(3) and the National Health Service Reform and Health Care Professions Act 2002 (c.17), Schedule 1, paragraph 7.

(b) Section 16CC was inserted into the Act by section 174 of the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”).

(c) 1971 c.80.

(d) S.I. 2000/620.

(e) S.I. 2005/641.

(f) S.I. 2004/291 as amended by S.I. 2004/906 and 2694 and 2005/28 and 2005/893.

(g) Section 28M was inserted into the Act by section 172(1) of the 2003 Act.

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) in respect of whom there is an annotation recorded in that register signifying that he is qualified to order drugs, medicines and appliances from—
 - (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff, or
 - (ii) the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff;

“local pharmaceutical services” has the same meaning as in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(a);

“necessary drugs, medicines and appliances” has the meaning given in direction 2(2);

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(b);

“out of hours period” means—

- (a) the period beginning at 6.30pm on any day from Monday to Thursday and ending at 8am on the following day,
- (b) the period between 6.30pm on Friday and 8am on the following Monday, and
- (c) Good Friday, Christmas Day and bank holidays,

and “part” of an out of hours period means any part of one or more of the periods described in paragraphs (a) to (c);

“out of hours services” means services required to be provided in all or part of the out of hours period which would be essential services if provided in core hours;

“out of hours performer” means a prescriber, a person acting in accordance with a Patient Group Direction or any other health care professional employed or engaged by the provider of out of hours services who can lawfully supply a drug, medicine or appliance, who is performing the out of hours services on behalf of the provider of out of hours services;

“Patient Group Direction” has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997(c);

“PMS contractor” means a contractor within the meaning of the National Health Service (Personal Medical Services Agreements) Regulations 2004(d);

“practice” means a practice established by a Primary Care Trust for the purposes of its provision of primary medical services under section 16CC(2)(a) of the Act;

“practice statement” means the statement prepared by a Primary Care Trust in respect of a practice pursuant to direction 2 of the Primary Care Trust Medical Services (No. 2) Directions 2004(e) dated 3rd November 2004;

“prescriber” means—

- (a) a medical practitioner,
- (b) an independent nurse prescriber, or
- (c) a supplementary prescriber,

who is either a provider of out of hours services or who is engaged or employed by a provider of out of hours services;

“provider of out of hours services” means:—

- (a) an APMS contractor,
- (b) a practice, or

(a) S.I. 2002/888, to which there are amendments not relevant to these Directions.

(b) S.I. 2002/253.

(c) S.I. 1997/1830; relevant amending instruments are S.I. 2000/1917 and S.I. 2003/2915.

(d) S.I. 2004/627 as amended by S.I. 2004/906 and 2694 and 2005/28 and 2005/893.

(e) These Directions are available on the Department of Health's website (www.dh.gov.uk) or a copy may be obtained by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

(c) an out of hours services sub-contractor of a GMS contractor or PMS contractor;
“restricted availability appliance” means an appliance which is approved for particular categories of persons or particular purposes only;

“supplementary prescriber” means a person—

(a) whose name is registered in—

- (i) the Nursing and Midwifery Register,
- (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(a),
- (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(b), or
- (iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(c) relating to—
 - (aa) chiropodists and podiatrists;
 - (bb) physiotherapists; or
 - (cc) radiographers: diagnostic or therapeutic, and

(b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber; and

“supply form” means a form provided by a Primary Care Trust and completed by or on behalf of a provider of out of hours services for the purpose of recording the provision of drugs, medicines or appliances to a patient during the out of hours period.

Provision of out of hours services

2.—(1) Primary Care Trusts shall exercise their powers under section 16CC(2) of the Act so as to make such arrangements as they consider appropriate to ensure that recipients of out of hours services receive without delay from providers of out of hours services any necessary drugs, medicines and appliances.

(2) Necessary drugs, medicines and appliances are those drugs, medicines and appliances which the patient requires and for which, in the reasonable opinion of the provider of out of hours services, and in the light of the patient’s medical condition, it would not be reasonable in all the circumstances for the patient to wait until such time as he could obtain them during core hours.

(3) It is not reasonable for the patient to wait until core hours where , for example,

- (a) his condition would become more serious, or there would be an increased risk of his developing complications of his condition;
- (b) he is suffering significant pain or distress which the supply without delay of a medicine, drug or appliance would help alleviate; or
- (c) the medicine, drug or appliance would be less effective or not at all effective if the prescriber were not to supply it without delay.

(4) Primary Care Trusts shall keep any arrangements made pursuant to paragraph (1) under review.

Effect on pharmaceutical services and local pharmaceutical services

3. Before making arrangements pursuant to direction 2, a Primary Care Trust shall consider what pharmaceutical services and local pharmaceutical services are available to recipients of out of

(a) 1954 c.61.
(b) S.I. 1976/1213 (NI 22)
(c) S.I. 2002/254.

hours services in its area, and the effect that the proposed arrangements would have on those services.

Considerations by the Primary Care Trust

4. In making arrangements pursuant to direction 2, the Primary Care Trust shall take account of—

- (a) Delivering the Out-of Hours Review, Securing Proper Access to Medicines in the Out-of-Hours Period, Guidance for PCTs and Organised Providers published in December 2004; and
- (b) Delivering the Out-of Hours Review, Securing Proper Access to Medicines in the Out-of-Hours Period, a practical guide for PCTs and Organised Providers published in December 2004(a).

Content of arrangements

5.—(1) Primary Care Trusts shall ensure that the practice statement, in the case of arrangements for the out of hours supply of necessary drugs, medicines and appliances made under section 16CC(2)(a) of the Act or the APMS contract, in the case of such arrangements made under section 16CC(2)(b)—

- (a) provides that only necessary drugs, medicines and appliances are supplied by out of hours performers;
- (b) provides for the complete course of the necessary medicine or drug required to treat the patient to be supplied;
- (c) prevents the supply by an out of hours performer of—
 - (i) drugs, medicines and appliances which that out of hours performer could not lawfully supply, and
 - (ii) appliances which are not listed in Part IX of the Drug Tariff;
- (d) prevents the supply by an out of hours performer, other than in the course of treating a patient under a private arrangement, of—
 - (i) restricted availability appliances, except where the patient is a person, or it is for a purpose, specified in the Drug Tariff, or
 - (ii) a drug, medicine or other substance listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004(b), or a drug, medicine or other substance listed in Schedule 2 to those Regulations other than in the circumstances specified in that Schedule;
- (e) requires the out of hours performer to record on a separate supply form for each patient any drugs, medicines or appliances supplied to the patient, provided that a single supply form may be completed where an out of hours performer supplies necessary drugs, medicines or appliances to two or more persons in a school or other institution in which at least 20 persons normally reside, when the out of hours performer may write on the supply form the name of the school or institution rather than the name of the individual patient;
- (f) requires the out of hours performer to—
 - (i) ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations(c) by virtue of either—

(a) Both of the publications referred to in direction 4 are published electronically at www.out-of-hours.info or a copy may be obtained by writing to Primary Care, Room 4N34E, Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE.

(b) S.I. 2004/629.

(c) Regulation 4(1) was amended by S.I. 2002/548 and 2004/663 and 2005/578.

(aa) entitlement to exemption under regulation 7(1) of the Charges Regulations^(a),
or

(bb) entitlement to remission of charges under regulation 5 of the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003^(b),

to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations, and at the time of the declaration the out of hours performer already has such evidence available to him; and

(ii) if no satisfactory evidence is produced to him (and, where it is relevant none is already available to him as mentioned in paragraph (i)) endorse the supply form to that effect; and

(g) provides that—

(i) direction 8(a) of the Alternative Provider Medical Services (No. 2) Directions 2004^(c), in the case of an APMS contract; or

(ii) direction 25(1) of the Primary Care Trust Medical Services (No. 2) Directions 2004, in the case of a practice statement,

shall apply in respect of the supply of necessary drugs, medicines and appliances as it applies in respect of prescriptions for drugs, medicines and appliances.

(2) Paragraph (1)(a) shall not prevent the administration or supply of drugs, medicines or appliances that could otherwise be administered or supplied by the provider of out of hours services.

Signed by the authority of the Secretary of State for Health



July 2005

Department of Health
A member of the Senior Civil Service

^(a) Regulation 7(1) was amended by S.I. 2000/3189 and 2002/2352.

^(b) S.I. 2003/2382. Regulation 5 was amended by S.I. 2004/663 and 936 and 2005/578.

^(c) These directions were made on 3rd November 2004 and are available on the Department of Health's website at www.dh.gov.uk or a copy can be obtained by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

