

## **DIRECTIONS**

### **THE NATIONAL HEALTH SERVICE ACT 1977/2006**

#### **The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005**

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 17, 41A, 41B and 126(4) of the National Health Service Act 1977<sup>1</sup>, and sections 8,127 and 272(7) and (8) of the National Health Service Act 2006<sup>2</sup> and of all other powers enabling him in that behalf, hereby gives the following Directions:

#### ***Citation, commencement and application***

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005 and shall come into force on 1st April 2005.

(2) These Directions are given to Primary Care Trusts in England and apply in relation to England only.

#### ***Interpretation***

2. In these Directions—

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

“clinical management plan” has the same meaning as in the POM Order;

“drug misuser” means a person who is misusing drugs by self-injection;

“drugs” includes medicines;

“Drug Tariff” means the Drug Tariff published under regulation 56 (standards of, and payments for, drugs and appliances) of the Pharmaceutical Services Regulations;

“financial year” means the period of twelve months ending on 31st March in any year;

“gluten free foods” means only those gluten free foods that are listed in Part XV (borderline substances) of the Drug Tariff;

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<sup>1</sup> 1977 c.49. Section 17 of the 1977 Act is as substituted by the Health Act 1999 (c.8) (“the 1999 Act”), section 12(1), and thereafter amended by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), Schedule 5, paragraph 5(3), and the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”), Schedule 1, paragraph 7. Section 41A of the 1977 Act was inserted into the 1977 Act by the National Health Service (Primary Care) Act 1997 (c. 46) (“the 1997 Act”), section 27(1); and has been amended by the 2001 Act, section 43(1) and the 2002 Act, Schedule 2, Part 1, paragraphs 1 and 14. Section 41B was inserted into the 1977 Act by the 1997 Act, section 28(1) and has been amended by the 2002 Act, Schedule 2, Part 1, paragraphs 1 and 15. Section 126(4) of the 1977 Act was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2). As regards Wales, the 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 1999 Act and as read with section 40(1) of the 2002 Act.

<sup>2</sup> 2006 c.41.

“GMS contract essential services” has the meaning given to it in regulations 2(1) of the National Health Service (General Medical Services Contracts) Regulations 2004<sup>3</sup>

“health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) (the Council for the Regulation of Health Care Professionals) of the National Health Service Reform and Health Care Professions Act 2002<sup>4</sup>;

“independent prescriber” means a doctor or dentist who is a party to a clinical management plan with a supplementary prescriber;

“MUR certificate” means a statement of satisfactory performance certificate awarded or endorsed by a higher education institute being evidence that he has satisfactorily completed an assessment relating to the competency framework for pharmacists providing MUR services approved by the Secretary of State<sup>5</sup>;

“out of hours period” means in relation to a pharmacy, the days and times at which the pharmacy is not obliged to remain open by virtue of paragraph 22(1) (pharmacy opening hours: general) of Schedule 1 (terms of service of pharmacists) to the Pharmaceutical Services Regulations;

“patient’s care record” means the patient records kept by the person or body who is providing the patient with GMS contract essential services or their equivalent;

“pharmaceutical essential services” has the same meaning as that given to essential services in the Pharmaceutical Services Regulations;

“pharmaceutical list” means a list referred to in regulation 4(1)(a) (preparation of lists) of the Pharmaceutical Services Regulations;

“Pharmaceutical Services Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005<sup>6</sup>;

“pharmacist” means, except where the context otherwise requires—

- (a) a registered pharmacist; or
- (b) a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions) of the Medicines Act 1968,

whose name is included in the pharmaceutical list of a Primary Care Trust (including a pharmacist who is suspended from such a list), but does not include a supplier of appliances only;

“pharmacist independent prescriber” has the meaning given in regulation 2(1) of the Pharmaceutical Services Regulations;

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<sup>3</sup> S.I. 2004/291. There are no relevant amendments

<sup>4</sup> 2002 c.17.

<sup>5</sup> This document “Competency Framework for the Assessment of Pharmacists Providing the Medicines Use Review (MUR) and Prescription Intervention Service” dated 23rd December 2004 is published by the Department of Health on its website [www.dh.gov.uk/mpi](http://www.dh.gov.uk/mpi).

<sup>6</sup> S.I. 2005/641

“pharmacy” has the meaning given to it in the Pharmaceutical Services Regulations;

“the POM Order” means the Prescription Only Medicines (Human Use) Order 1997<sup>7</sup>; and

“supplementary prescriber” has the meaning given to it in the Pharmaceutical Services Regulations.

***Advanced Services: Medicines Use Review and Prescription Intervention Service***

3.—(1) Each Primary Care Trust shall make arrangements for the provision of medicines use review and prescription intervention services (“MUR services”) for persons within or outside its area with any pharmacist on its pharmaceutical list who—

(a) meets the conditions set out in paragraphs (3), (4) and (5); and

(b) wishes to enter into such arrangements or is required to do so by virtue of regulation 13(3) or 14 of the Pharmaceutical Services Regulations.

(2) The underlying purpose of MUR services is, with the patient’s agreement, to improve his knowledge and use of drugs by in particular—

(a) establishing the patient’s actual use, understanding and experience of taking drugs;

(b) identifying, discussing and assisting in the resolution of poor or ineffective use of drugs by the patient;

(c) identifying side effects and drug interactions that may affect the patient’s compliance with instructions given to him by a health care professional for the taking of drugs; and

(d) improving the clinical and cost effectiveness of drugs prescribed to patients thereby reducing the wastage of such drugs.

(3) The first condition is

(a) if the pharmacist is a registered pharmacist, that he has an MUR certificate;

(b) if the pharmacist is a registered pharmacist, but he intends to employ or engage a registered pharmacist to provide MUR services, that that registered pharmacist has an MUR certificate; or

(c) if the pharmacist is not a natural person, that any registered pharmacist that it intends to employ or engage to provide MUR services has an MUR certificate,

and the pharmacist has supplied a copy of such certificates to the Primary Care Trust prior to entering into an arrangement to provide MUR services.

(4) Subject to paragraph (4A), the second condition is that the MUR services are provided at an acceptable location, and for these purposes, an “acceptable location” means—

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<sup>7</sup> S.I. 1997/1830; relevant amending instruments are S.I. 2000/1917 and 2003/2915.

(a) an area for confidential consultations within the pharmacist's pharmacy, which is—

- (i) clearly designated as an area for confidential consultations,
- (ii) distinct from the general public areas of the pharmacy, and
- (iii) an area where both the person receiving MUR services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff),

except that paragraphs (i) and (ii) shall not apply in circumstances where the pharmacy is closed to other members of the public;

(b) an area for confidential consultations which is not at the pharmacist's pharmacy but which—

- (i) is clearly designated as an area for confidential consultations—
- (ii) is distinct from the general public areas of the premises in which it is situated, and
- (iii) is an area where both the person receiving MUR services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person,

and the Primary Care Trust has approved the premises where the area is situated as being premises at which MUR services may be provided (and that approval has not been withdrawn); or

(c) premises to which neither sub-paragraph (a) or (b) applies, but which are —

- (i) premises as regards which the pharmacist has obtained the approval of the Primary Care Trust to provide MUR services to a particular patient on a particular occasion, or
- (ii) premises or a category of premises as regards which the pharmacist has obtained the approval of the Primary Care Trust (which has not been withdrawn) to provide MUR services to a particular category of patients, in such circumstances and subject to such conditions as the Primary Care Trust may have specified (which the Primary Care Trust may vary without withdrawing its approval).

(4A) A pharmacist may provide MUR services other than at an acceptable location, if he does so—

- (a) by telephone to a particular patient on a particular occasion;
- (b) in circumstances where the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer); and
- (c) having obtained the approval of the Primary Care Trust to do so on that occasion.

(5) Subject to direction 6(2), the third condition is that the pharmacist is satisfactorily complying with his obligation under Schedule 1 to the Pharmaceutical Services Regulations to provide pharmaceutical essential services and has an acceptable system of clinical governance.

(6) The Primary Care Trust shall ensure that the arrangements made pursuant to paragraph (1) provide that—

(a) only a registered pharmacist who has an MUR certificate may perform MUR services;

(b) MUR services are only provided—

(i) at an acceptable location, except in the circumstances set out in paragraph (4A), and

(ii) at a location for which the PCT's approval is required by virtue of paragraph (4)(b) or (c) for the location to be considered acceptable, if the necessary approval has been given by the PCT and has not been withdrawn;

(c) where MUR services are provided other than at an acceptable location, they are only provided by telephone, and with its approval, to a particular patient on a particular occasion;

(d) no more than 400 MUR services consultations may be carried out under the arrangements with a pharmacist to provide those services, whether at an acceptable location or in the circumstances set out in paragraph (4A), in any financial year;

(e) an MUR service consultation which is not triggered by concerns over patient concordance shall not be offered to a patient unless the patient has been receiving pharmaceutical services from the pharmacy for a period of at least three consecutive months;

(f) a patient may not have more than one MUR service consultation in any one period of twelve months unless in the reasonable opinion of the registered pharmacist the patient's circumstances have changed sufficiently to justify one or more further consultations during this period;

(g) where the Primary Care Trust has notified pharmacists in its area of the categories of patients who would benefit from the provision of MUR services, the pharmacist shall have regard to the notification in determining who to offer an MUR service consultation to;

(h) the pharmacist shall ensure that a written record of each MUR service consultation held with a patient is prepared by the registered pharmacist carrying out the consultation on a form approved for this purpose by the Secretary of State<sup>8</sup>;

(i) the pharmacist shall be required to provide a copy of the record prepared pursuant to sub-paragraph (h) to the patient;

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<sup>8</sup> A copy of the form is published by the Department of Health on its website at [www.dh.gov.uk/mpi](http://www.dh.gov.uk/mpi).

(ia) the pharmacist shall be required to provide<sup>9</sup> to a person with whom the patient is registered for the provision of GMS contract essential services or their equivalent-

- (i) a copy of the record prepared pursuant to sub-paragraph (h),
- (ii) a copy of part of that record, or
- (iii) a notification that the patient has received MUR services,

such copy or notification to be provided in the circumstances and in accordance with the time limits set out in guidance, entitled Guidance on the Provision of MUR Service Consultation Record issued on 14<sup>th</sup> December 2007 by the Secretary of State<sup>10</sup>.

(j) the pharmacist shall keep a copy of the record prepared pursuant to sub-paragraph (h) for such period as the Primary Care Trust may reasonably require; and

(k) the arrangements shall be terminated where after 1st October 2005 the pharmacist is not satisfactorily complying with his obligation under Schedule 1 to the Pharmaceutical Services Regulations to provide pharmaceutical essential services and have an acceptable system of clinical governance.

(6A) Paragraph (6)(d) shall apply as if for "400" there were substituted "200" as regards the first financial year of any arrangements made pursuant to paragraph (1), if the arrangements made pursuant to paragraph (1) only took effect on or after 1st October of that financial year, but for these purposes, arrangements with a pharmacist to provide MUR services at an acceptable location to which paragraph (4)(a) applies are to be treated as taking effect once the pharmacist has—

(a) declared in writing to the Primary Care Trust, in terms, that he has an acceptable location that meets the requirements of paragraph (4)(a); and

(b) supplied the Primary Care Trust with a copy of the MUR certificate that he has to supply in order to meet the first condition.

(7) The record referred to in paragraph (6)(h) may be in the form of an electronic record and may be sent or stored electronically.

### **Enhanced services**

4.—(1) Each Primary Care Trust is authorised to arrange for the provision of the following additional pharmaceutical services to persons within or outside its area with pharmacists included in its pharmaceutical list or in the pharmaceutical list of a neighbouring Primary Care Trust—

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<sup>9</sup> Transitional Provision - In a case where the record prepared pursuant to direction 3(6)(h) is on the form which was approved by the Secretary of State on 1st April 2005 and that form is provided to the patient before 1st October 2008, the pharmacist shall be required to provide a copy of that record to the patient and to the person with whom the patient is registered for the provision of GMS essential services or their equivalent.

<sup>10</sup> A copy of the guidance is published by the Department of Health on its website at [www.dh.gov.uk/mpj](http://www.dh.gov.uk/mpj).

- (a) an Anticoagulant Monitoring Service, the underlying purpose of which is for the pharmacist to test the patient's blood clotting time, review the results and adjust (or recommend the adjustment to) the anticoagulant dose accordingly;
- (b) a Care Home Service, the underlying purpose of which is for the pharmacist to provide advice and support to residents and staff in a care homes relating to—
  - (i) the proper and effective ordering of drugs and appliances for the benefit of residents in the care home,
  - (ii) the clinical and cost effective use of drugs,
  - (iii) the proper and effective administration of drugs and appliances in the care home,
  - (iv) the safe and appropriate storage and handling of drugs and appliances, and
  - (v) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;
- (c) a Disease Specific Medicines Management Service, the underlying purpose of which is for the pharmacist to advise on, support and monitor the treatment of patients with specified conditions, and where appropriate to refer the patient to another health care professional;
- (d) a Gluten Free Food Supply Service, the underlying purpose of which is for the pharmacist to supply gluten free foods to patients;
- (e) a Home Delivery Service, the underlying purpose of which is for the pharmacist to deliver drugs and appliances to patients at their home;
- (f) a Language Access Service, the underlying purpose of which is for the pharmacist to provide, either orally or in writing, advice and support to patients in a language understood by them relating to—
  - (i) drugs which they are using,
  - (ii) their health, and
  - (iii) general health matters relevant to them,and where appropriate referral to another health care professional;
- (g) a Medication Review Service, the underlying purpose of which is for the pharmacist to—
  - (i) conduct a review of the drugs used by a patient, including on the basis of information and test results included in the patient's care record with the objective of considering the continued appropriateness and effectiveness of the drugs for the patient,
  - (ii) advise and support a patient regarding his use of drugs including encouraging the active participation of the patient in decision making relating

to his use of drugs, and

(iii) where appropriate, refer the patient to another health care professional;

(h) a Medicines Assessment and Compliance Support Service, the underlying purpose of which is for the pharmacist to-

(i) assess the knowledge of, compliance with and use of, drugs by vulnerable patients and patients with special needs, and

(ii) offer advice, support and assistance to vulnerable patients and patients with special needs regarding the use of drugs with a view to improving the patient's knowledge of, compliance with and use of, such drugs;

(i) a Minor Ailment Scheme, the underlying purpose of which is for the pharmacist to provide advice and support to eligible patients complaining of a minor ailment, and where appropriate to supply drugs to them for the treatment of the minor ailment;

(j) a Needle and Syringe Exchange Service, the underlying purpose of which is for the pharmacist to-

(i) provide sterile needles, syringes and associated materials to drug misusers,

(ii) receive from drug misusers used needles, syringes and associated materials, and

(iii) offer advice to drug misusers and where appropriate referral to another health care professional or a specialist drug treatment centre;

(k) an On Demand Availability of Specialist Drugs Service, the underlying purpose of which is for the pharmacist to ensure that patients or health care professionals have prompt access to specialist drugs;

(l) Out of Hours Services, the underlying purpose of which is for the pharmacist to dispense drugs and appliances in the out of hours period (whether or not for the whole of the out of hours period);

(m) a Patient Group Direction Service, the underlying purpose of which is for the pharmacist to supply a prescription only medicine to a patient under a Patient Group Direction;

(n) a Prescriber Support Service, the underlying purpose of which is for the pharmacist to support health care professionals who prescribe drugs, and in particular to offer advice on-

(i) the clinical and cost effective use of drugs,

(ii) prescribing policies and guidelines, and

(iii) repeat prescribing;

(o) a Schools Service, the underlying purpose of which is for the pharmacist to provide advice and support to children and staff in schools relating to—

- (i) the clinical and cost effective use of drugs in the school,
- (ii) the proper and effective administration and use of drugs and appliances in the school,
- (iii) the safe and appropriate storage and handling of drugs and appliances, and

(iv) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;

(p) a Screening Service, the underlying purpose of which is for the pharmacist to-

- (i) identify patients at risk of developing a specified disease or condition,
- (ii) offer advice regarding testing for a specified disease or condition,
- (iii) carry out such a test with the patient's consent, and
- (iv) offer advice following a test and referral to another health care professional where appropriate;

(q) a Stop Smoking Service, the underlying purpose of which is for the pharmacist to-

- (i) advise and support patients wishing to give up smoking, and
- (ii) where appropriate, to supply appropriate drugs and aids;

(r) a Supervised Administration Service, the underlying purpose of which is for the pharmacist to supervise the administration of prescribed medicines in the pharmacy; and

(s) a Supplementary Prescribing Service, the underlying purpose of which is for the pharmacist who is a supplementary prescriber to implement with an independent prescriber a clinical management plan for a patient with that patient's agreement.

(1A) Each Primary Care Trust is authorised to arrange for the provision of an Independent Prescribing Service, the underlying purpose of which is to provide a framework within which pharmacist independent prescribers may act as such under arrangements to provide an additional pharmaceutical service between the Primary Care Trust and a person included in the Primary Care Trust's pharmaceutical list or in a pharmaceutical list of a neighbouring Primary Care Trust.

(2) The Primary Care Trust shall ensure that the arrangements for the services referred to in paragraphs (1) and (1A) make provision for those services to be provided-

- (a) only by appropriately trained and qualified persons;
- (b) in accordance with relevant national guidelines or standards;

- (c) from premises that are suitable for the purpose; and
- (d) using the appropriate or necessary equipment.

**Revocation**

5. The Directions to Health Authorities concerning arrangements for providing additional pharmaceutical services which came into force on 1st April 1999 are hereby revoked.

**Transitional provisions**

6.—(1) Any arrangements pursuant to the Directions referred to in direction 5 shall continue in effect for a period of twelve months beginning with the date of the coming into force of these Directions unless-

- (a) the pharmacist notifies the Primary Care Trust in writing that the arrangements should terminate before the end of this period, in which case the arrangements shall terminate on-
  - (i) the date specified by the pharmacist in his notice,
  - (ii) the date agreed with the Primary Care Trust, or
  - (iii) if no date is specified or agreed, on the last day of the calendar month following the giving of the notice;
- (b) the Primary Care Trust requests the pharmacist to enter into arrangements for a Care Home Service or Out of Hours Services pursuant to direction 4 and the pharmacist refuses such a request, in which case the arrangements shall terminate on the last day of the third calendar month following the date of the Primary Care Trust's request; or
- (c) the arrangements would otherwise come to an end before this date, for example, because the pharmacist ceases to be included in the Primary Care Trust's pharmaceutical list.

(2) Direction 3(5) shall not apply to any arrangement entered into before 1st October 2005.