

NATIONAL ASSEMBLY FOR WALES

DIRECTIONS

NATIONAL HEALTH SERVICE, WALES

The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005

The National Assembly for Wales in exercise of the powers conferred by sections 16BB(4), 41A, 41B and 126(4) of the National Health Service Act 1977(1) hereby gives the following Directions:

Title, commencement and application

1.—(1) The title of these Directions is the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005 and will come into force on 5 May 2005.

(2) These Directions are given to Local Health Boards and apply in relation to Wales.

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 18 of the Pharmaceutical Services Regulations;

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

(1) 1977 c.49 (“the 1977 Act”); section 16BB(4) was inserted by the National Health Service Reform and Health Care Professions Act 2002 (c.17)(“the 2002 Act”), section 6(1). Date in force 10.10.02; see SI 2002/2532 and was amended by section 184 of and paragraphs 7 and 10 of Schedule 11 to the Health and Social Care (Community Health and Standards Act 2003 (c.43) (“the 2003 Act”).

Section 41A was inserted into the 1977 by the National Health Service (Primary Care) Act 1997 (c.46) (“the 1997 Act”), section 27(1); and has been amended by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), section 43(1)(b) and the 2002 Act, section 2(5) and Schedule 2, Part I, 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, section 2(5) and Schedule 2, Part 1, paragraphs 1 and 15.

Section 126(4) was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2); and by the 2001 Act, section 67(1) and Schedule 5, Part 1, paragraphs 5(1) and 13(b), by the 2002 Act, section 6(3)(c) and by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”), section 184 and Schedule 11, paragraphs 7 and 38.

The functions of the Secretary of State under sections 41A, 41B and 126(4) of the 1977 Act were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, SI 1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5), the 2001 Act, section 68(1), the 2002 Act, section 40(1) and by the 2003 Act, section 197(1).

“GMS contract essential services” has the meaning given to it in regulation 2(1) of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004⁽²⁾;

“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⁽³⁾;

“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 awarded or endorsed by a higher education institute being evidence that a person has satisfactorily completed an assessment relating to the competency framework for chemists providing MUR services approved by the National Assembly for Wales;⁽⁴⁾

“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 21(1) (pharmacy opening hours: general) of Schedule 2 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 Services Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992⁽⁵⁾;

“chemist” means, except where the context otherwise required—

- (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⁽⁶⁾,

whose name is included in the pharmaceutical list of a Local Health Board (including a chemist who is suspended from such a list), but does not include a supplier of appliances only;

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

“the POM Order” means the Prescription Only Medicines (Human Use) Order 1997⁽⁷⁾; 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 Local Health Board must 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.

(2) The underlying purpose of MUR services is, with the patient’s agreement, to improve his or her 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;

(2) SI 2004/478 (W.48) to which there are no relevant amendments.

(3) 2002 c.17

(4) A copy of the document “Competency Framework for the Assessment of Pharmacists Providing the Medicines Use Review (MUR) and prescription intervention service” dated [insert date] is available on the website of the National Assembly for Wales – www.wales.gov.uk

(5) SI 1992/662; for relevant amendments see SI 2005/1013 (W.67)

(6) 1968 c.67

(7) SI 1997/1839; relevant amending instruments are SI 2000/1917 and 2003/2915.

- (c) identifying side effects and drug interactions that may affect the patient's compliance with instructions given to him or her 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 chemist is a registered pharmacist, that he or she has an MUR certificate;
 - (b) if the chemist is a registered pharmacist, but he or she intends to employ or engage a registered pharmacist to provide MUR services, that that registered pharmacist has an MUR certificate;
 - (c) if the chemist 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 chemist has supplied a copy of the relevant certificates to the Local Health Board prior to entering into an arrangement to provide MUR services.

(4) The second condition is that the pharmacy meets the following requirements, namely that it has a consultation area which—

- (a) must be a clearly designated area for confidential consultations which is distinct from the general public areas of the pharmacy; and
- (b) must be an area where both the person receiving MUR services and the registered pharmacist providing MUR services can sit down together and talk at normal speaking volumes without being overheard by other visitors to the pharmacy or by any other person, including pharmacy staff.

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

(6) The Local Health Board must ensure that the arrangements made pursuant to paragraph (1) provide—

- (a) only a registered pharmacist who has an MUR certificate may perform MUR services;
- (b) MUR services that are provided in a pharmacy may only be provided from a consultation area that meets the requirements set out in paragraph (4) unless the pharmacy is closed to other members of the public in which case the consultation may take place in another part of the pharmacy provided that the condition in paragraph (4)(b) is met;
- (c) MUR services may be provided outside the pharmacy or exceptionally by telephone only where the Local Health Board consents;
- (d) no more than 200 MUR services consultations may be carried out in each pharmacy (or outside it in accordance with sub-paragraph (c)) in any one period of twelve months under the arrangements;
- (e) an MUR service consultation must 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 Local Health Board has notified chemists in its area of the categories of patients who would benefit from the provision of MUR services, the chemist must have regard to the notification in determining to whom to offer a MUR service consultation;

- (h) the chemist must 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 by the National Assembly for Wales⁽⁸⁾;
- (i) the chemist must provide a copy of the record prepared pursuant to sub-paragraph (h) to the patient and to a person with whom the patient is registered for the provision of GMS contract essential services or their equivalent;
- (j) the chemist must keep a copy of the record prepared pursuant to sub-paragraph (h) for such period as the Local Health Board may reasonable require; and
- (k) the arrangements will be terminated where after 1 October 2005 the chemist is not satisfactorily complying with his or her obligation under Schedule 2 to the Pharmaceutical Services Regulations to provide pharmaceutical essential services and to have an acceptable system of clinical governance.

Enhanced services

4.—(1) Each Local Health Board is authorised to arrange for the provision of the following additional pharmaceutical services to persons within or outside its area with chemists included in its pharmaceutical list or in the pharmaceutical list of a neighbouring Local Health Board—

- (a) an Anticoagulant Monitoring Service, the underlying purpose of which is for the chemist to test the patient's blood clotting time, review the results and adjust (or recommend an adjustment to) the anticoagulant dose accordingly;
- (b) a Care Home Service, the underlying purpose of which is for the chemist to provide advice and support to residents and staff in a care home 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 Management Service, the underlying purpose of which is for the chemist 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 chemist to supply gluten free foods to patients;
- (e) a Home Delivery Service, the underlying purpose of which is for the chemist to deliver drugs and appliances to patients at their home;
- (f) a Language Access Service, the underlying purpose of which is for the chemist to provide, either orally or in writing, advice and support to patients in a language understood by them relation 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 chemist to—
 - (i) conduct a review of the drugs used by a patient 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,

(8) A copy of the form is available on [insert reference to relevant website and address]

- (ii) advise and support a patient regarding the use of his or her drugs including encouraging the active participation of the patient in decision making relating to his or her 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 chemist 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 chemist 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 Scheme, the underlying purpose of which is for the chemist to—
 - (i) to 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 chemist 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 chemist 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 chemist 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 chemist 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 chemist 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 chemist 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 chemist 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 chemist to supervise the administration of prescribed medicines in the pharmacy; and
 - (s) a Supplementary Prescribing Service, the underlying purpose of which is for the chemist who is a supplementary prescriber to implement with an independent prescriber a clinical management plan for a patient with that patient's agreement.
- (2) The Local Health Board must ensure that the arrangements for the services referred to in paragraph (1) 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.

Signed by authority of the National Assembly for Wales

[Insert date] 2005

A Member of the Senior Civil Service