THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

2010 NO. 13

The Pharmaceutical Services (Advanced Services) (Appliances) (Wales) Directions 2010

The Welsh Ministers, in exercise of the powers conferred by sections 80, 83, 121 and 203(9) and (10) of the National Health Service (Wales) Act 2006(**1**), hereby give the following Directions—

Title, commencement and application

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced Services) (Appliances) (Wales) Directions 2010 and come into force on 1st April 2010.

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

Interpretation

2. In these Directions—

"the 2005 Directions" ("cyfarwyddiadau 2005") means the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005(**2**);

"Drug Tariff" ("Tariff Cyffuriau") has the meaning given in regulation 2(1) of the Pharmaceutical Services Regulations;

"financial year" ("blwyddyn ariannol") means a period of 12 months ending with 31 March in any year;

"health care professional" ("gweithiwr gofal iechyd proffesiynol") means a person who is a

(**1**) 2006 c.42.

(**2**) Signed on 4 May 2005. These Directions were amended by the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2006, signed on 15 December 2006 and the Pharmaceutical Services (Advanced and Enhanced Services)(Wales) (Amendment) Directions 2008, made on 3 March 2008.

member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**1**) (the Council for Healthcare Regulatory Excellence);

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

"Pharmaceutical Services Regulations" ("Rheoliadau Gwasanaethau Fferyllol") means the National Health Service (Pharmaceutical Services) Regulations 1992(**2**);

"pharmacist"("fferyllydd")—

(a) means—

(i) a registered pharmacist, or

(ii) a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions) of the Medicines Act 1968(**3**),

whose name is included in the pharmaceutical list of a Local Health Board (including a pharmacist who is suspended from such a list); but

(b) does not include a supplier of appliances only;

"pharmacy" ("fferyllfa") has the meaning given in regulation 2(1) of the Pharmaceutical Services Regulations;

"registered patient"("claf cofrestredig") means a patient who is included in a list that is a registered patient list for the purposes of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) (Wales) Regulations 2004(**4**);

"specialist nurse" ("nyrs arbennigol") means a person who is—

(a) registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**5**)

(**1**) 2002 c.17. The Council's name was changed to the Council for Healthcare Regulatory Excellence by section 113 of the Health and Social Care Act 2008 (c.14).

(**2**) S.I. 1992/662 Relevant amending instruments are S.I. 2007/205 (W.19) and S.I. 2009/1491 (W.144).

(**3**) 1998 c.67. Section 69 was amended by Part 12 of Schedule 1 to the Statute Law Repeals Act 1993 (c.50); by regulation 13 of the European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/182); and by S.I. 1976/1213 and 2007/289 and 3101.

(**4**) S.I. 2004/1017 (W.114); *see* regulation 2(2) of those Regulations.

(5) S.I. 2002/253.

(establishment and maintenance of register); and

(b) employed or engaged by any pharmacist or supplier of appliances for the purposes of conducting a review of a person's use of specified appliances;

"specified appliance" ("cyfarpar penodedig") means—

(a) any of the following appliances listed in Part IXA of the Drug Tariff—

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a wound drainage pouch;

(b) an incontinence appliance listed in Part IXB of the Drug Tariff; or

(c) a stoma appliance listed in Part IXC of the Drug Tariff;

"stoma appliance customisation" ("addasu cyfarpar stoma") means the customisation of a quantity of more than one stoma appliance, where—

(a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;

(b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and

(c) that modification is based on the patient's measurements or record of those measurements and, if applicable, a template; and

"supplier of appliances" ("cyflenwr cyfarpar") means a person with whom a Local Health Board has entered into arrangements for the provision of pharmaceutical services, being arrangements which are incorporated into terms of service as a consequence of regulation 3(c) of the Pharmaceutical Services Regulations.

Stoma appliance customisation services

Establishing and maintaining stoma appliance customisation services

3.—(1) The underlying purpose of a stoma appliance customisation service is to—

(a) ensure the proper use and comfortable fitting of the stoma appliance by a patient; and

(b) improve the duration of usage of the appliance, thereby reducing wastage of such appliances.

(2) Each Local Health Board must make arrangements for the provision of stoma appliance customisation services for persons within or outside its area by any pharmacist ("P") or supplier of appliances ("S")—

(a) who is on the Local Health Board's pharmaceutical list;

(b) who supplies stoma appliances listed in Part IXC of the Drug Tariff in the normal course of business;

(c) who wishes to enter into the arrangements; and

(d) in relation to whom—

(i) Conditions 1, 2 and 3 are met, and

(ii) if services are to be provided elsewhere than at P's pharmacy or S's premises, Condition 4 is also met.

(3) Condition 1 is that, before any arrangements are entered into, the Local Health Board has been supplied with notice that P or S wishes to provide stoma appliance customisation services.

(4) Condition 2 is that P or S—

(a) is satisfactorily complying with P's obligations under Schedule 1 to the Pharmaceutical Services Regulations or S's obligations under Schedule 3 to those Regulations (as the case may be);

(b) has an acceptable system of clinical governance; and

(c) has procedures in place to ensure referral of a patient to the prescriber of the appliance in any case where—

(i) a customised stoma appliance is not suitable for further customisation, or

(ii) a stoma appliance has been customised and is not a proper fit for the patient.

(5) Condition 3 is that stoma appliance customisation services must be provided at an acceptable location and, for these purposes, an "acceptable location" ("lleoliad derbynid") means—

(a) an area within P's pharmacy or S's premises which—

(i) is distinct from the general public areas,

(ii) at all times when stoma appliance customisation services are being provided, is clearly designated as a private area,

(iii) is suitable and designated for the retention of the appropriate equipment for stoma appliance customisation,

(iv) is suitable and designated for the carrying out of modification of stoma appliances, and

(v) is suitable and designated for the volume of stoma appliances that may be customised at any given time; or

(b) an area elsewhere than at P's pharmacy or S's premises which—

(i) is distinct from the general public areas of the premises in which it is situated, and

(ii) meets the requirements of paragraph (a)(ii) to (v).

(6) Condition 4 is that, in any case where any stoma appliance customisation services are to be provided elsewhere than at P's pharmacy or S's premises, procedures must be in place to ensure co-operation with any reasonable inspection or review of the premises by the Local Health Board of the area where the services are provided.

Requirements applying to stoma customisation services

4.—(1) This direction has effect in relation to any arrangements with a pharmacist ("P") or supplier of appliances ("S") which are made pursuant to direction 3.

(2) The Local Health Board must ensure that the arrangements provide that—

(a) only appropriately trained and qualified persons are permitted to customise a stoma appliance;

(b) a record of each stoma customisation must be completed;

(c) each record must include the information listed in paragraph (3);

(d) each record must be retained for a minimum period of 12 months or such longer period as the Local Health Board may reasonably require;

(e) a copy of the record must be supplied to the patient or, if requested by the patient, to the prescriber or another health care professional; and

(f) unless prevented from doing so by illness or other reasonable cause, P or S must give at least 3 months' notice in writing to both the Local Health Board in advance of ceasing to

provide any stoma appliance customisation services.

(3) Each stoma customisation record must include—

(a) details of advice given;

(b) the type of stoma appliance customised;

(c) dimensions used in respect of the modification of parts of the appliance;

(d) measurements of the patient (if taken);

(e) dimensions of any template made or modification of any existing template;

(f) any referrals made to the prescriber; and

(g) such other details as may be specified in the arrangements made with P or S.

(4) Stoma customisation records may be in the form of an electronic record and may be stored electronically.

Appliance use review services for specified appliances

Establishing and maintaining appliance use review services for specified appliances

5.—(1) The underlying purpose of an appliance use review service ("AUR service") is, with a patient's agreement, to improve the patient's knowledge and use of any specified appliance by, in particular—

(a) establishing the way the patient uses the specified appliance and the patient's experience of such use;

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

(c) advising the patient on the safe and appropriate storage of the specified appliance; and

(d) advising the patient on the safe and proper disposal of specified appliances that are used or unwanted,

and an AUR service may be provided either when a pharmacist or specialist nurse visits a patient at home or when a patient visits a pharmacy or visits the premises of a supplier of appliances.

(2) Each Local Health Board must make arrangements for the provision of AUR services for persons within or outside its area by any pharmacist ("P") or supplier of appliances ("S")—

(a) who is on the Local Health Board's pharmaceutical list;

(b) who supplies specified appliances in the normal course of business;

(c) who wishes to enter into the arrangements; and

(d) in relation to whom—

(i) Conditions 1, 2 and 3 are met, and

(ii) if services are to be provided at a pharmacy or at the premises of a supplier of appliances, Condition 4 is also met.

(3) Condition 1 is that, before any arrangements are entered into, the Local Health Board have each been supplied with—

(a) notice that P or S wishes to provide AUR services;

(b) a statement of whether or not P or S proposes to provide any services to patients at home; and

(c) unless services are to be provided solely during visits to a patient at home, a statement of each location at which services are to be provided.

(4) Condition 2 is that, before any arrangements are entered into, the Local Health Board has also been supplied with the following information in relation to each pharmacist or specialist nurse who, as part of the AUR services to be provided by P or S, is to review the use of specified appliances—

(a) full name;

(b) documentary evidence of qualifications; and

(c) details as to competency in respect of the use of specified appliances.

(5) Condition 3 is that P or S—

(a) is satisfactorily complying with P's obligations under Schedule 1 to the Pharmaceutical Services Regulations or S's obligations under Schedule 3 to those Regulations (as the case may be);

(b) has an acceptable system of clinical governance; and

(c) has procedures in place to ensure referral of a patient to the prescriber of the appliance in any case where a matter relating to a patient's use of a specified appliance arises in the course of an AUR service but falls outside the scope of the service.

(6) Condition 4 is that, where any AUR services are to be provided at a pharmacy or at the premises of a supplier of appliances, there is a consultation area at the pharmacy or premises which—

(a) is distinct from the general public areas;

(b) at all times when a pharmacist or specialist nurse is reviewing the use of specified appliances, is clearly designated as an area for confidential consultation;

(c) allows all persons taking part in the review to sit down together and talk at normal speaking volumes without being overhead by other visitors to, or staff at, the pharmacy or the premises; and

(d) having regard to the nature of specified appliances and the underlying purpose of AUR services, is suitable for a consultation to determine how a patient uses an appliance and the extent of the patient's knowledge about it.

Requirements applying to appliance use review services

6.—(1) This direction has effect in relation to any arrangements with a pharmacist ("P") or supplier of appliances ("S") which are made pursuant to direction 5.

(2) The Local Health Board must ensure that the arrangements include such provision about—

(a) the qualifications of persons who review a patient's use of specified appliances;

(b) the delivery of each AUR service; and

(c) the administration of AUR services,

as is set out in the following provisions of this direction.

(3) The provision referred to in paragraph (2)(a) is that—

(a) only a pharmacist or specialist nurse is permitted to review the use of specified appliances; and

(b) the Local Health Board must be sent the following information in relation to each pharmacist or specialist nurse who, as part of the AUR services provided by P or S, reviews the use of specified appliances—

(i) full name,

(ii) documentary evidence of education, training or experience in respect of the use of specified appliances, and

(iii) details as appropriate of relevant clinical training and practice in respect of the use of specified appliances.

(4) The provision referred to in paragraph (2)(b) is that—

(a) where reasonably possible, an AUR service must be provided within 2 working days of the day on which a patient requests a review or agrees to one at the suggestion of P or S;

(b) the pharmacist or specialist nurse who reviews the patient's use of a specified

appliance must obtain the patient's prior written consent to receiving the service;

(c) a record of each service must be completed;

(d) each record must include—

(i) the date of the review of the patient's use of the specified appliance,

(ii) the name of the pharmacist or specialist nurse who carried out the review,

(iii) the name of the patient and the address at which the review took place,

(iv) the name of any other person present (and their relationship with the patient),

(v) the reason why a review is required,

(vi) the advice given to the patient, and

(vii) any intervention made; and

(e) the patient must be informed in writing that the record will be kept and that information from it will be forwarded in accordance with paragraphs (5)(a) to (d).

(5) The provision referred to in paragraph (2)(c) is that—

(a) a copy of each record of an AUR service must be forwarded to P or S;

(b) if the patient is a registered patient, the information referred to in paragraph (4)(d)(i), (ii) and (iii) must be forwarded to any provider of primary medical services with which the patient is a registered patient;

(c) if the patient is a registered patient and the pharmacist or specialist nurse considers it necessary for the provider of primary medical services with which the patient is registered to be aware of other information from the record, all such information must be forwarded to that provider;

(d) any information forwarded to any provider of primary medical services under this paragraph must be copied to any nurse employed by a Local Health Board who is practising with the provider and providing relevant primary medical services to the patient, if it is known that there is such a nurse;

(e) each record must be retained for a minimum period of 12 months or for such longer period as the Local Health Board may reasonably require; and

(f) information about the number of AUR services provided in any financial year must be submitted in accordance with any arrangements for payment of which P or S is notified.

(6) The record of an AUR service may be in the form of an electronic record and may be stored electronically.

Maximum number of appliance use review services eligible for payment

7. The maximum number of AUR services for which a pharmacist ("P") or a supplier of appliances (S") is eligible for payment in any financial year is not more than 1/35th of the aggregate number of specified appliances dispensed during that financial year by P or S (as the case may be).

Amendment of the 2005 Directions

8. In the 2005 Directions, for paragraph (1)(e) of direction 4 (enhanced services), substitute—

"(e) a Home Delivery Service, the underlying purpose of which is for the pharmacist to deliver to the patient's home—

(i) drugs, and

(ii) appliances other than specified appliances within the meaning of regulation 2(1) of the Pharmaceutical Services Regulations;".

Transitional provision

9.—(1) Paragraph (2) applies to any arrangements which were made between a Local Health Board and a pharmacist under direction 4(1)(e) of the 2005 Directions and which were in force immediately before 1 April 2010.

(2) In so far as the arrangements relate to home delivery by the pharmacist of any specified appliance, the arrangements may continue in force until—

(a) the pharmacist enters into arrangements to provide appliance use review services in accordance with directions 5 and 6; or

(b) if later, 31 December 2010.

Signed by the authority of the Welsh Ministers

2010