

2010 No. 1648 (W. 156)

**NATIONAL HEALTH
SERVICE, WALES**

The National Health Service
(Pharmaceutical Services)
(Amendment) (Wales) (No 2)
Regulations 2010

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I. 1992/662) (“the principal Regulations”) in respect of the terms of service for pharmacists and suppliers of appliances; and make minor amendments to the transitional provisions in the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010 (S.I. 2010/868 (W.90)).

Regulation 2 of the Regulations amends regulation 2 (interpretation) of the principal Regulations to provide that the meaning of “terms of service” encompasses the terms of service for suppliers of appliances; and to provide that references to a “Health Authority” are treated as references to a “Local Health Board” except in relation to the definition of an “equivalent body”.

Regulation 3 of the Regulations amends Schedule 2 to the principal Regulations which sets out the terms of service for pharmacists.

Regulation 4 of the Regulations amends Schedule 2A to the principal Regulations which sets out the terms of service for suppliers of appliances.

Regulation 5 of the Regulations amends regulation 16 (transitional arrangement) of the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010 to make the correct reference to the Pharmaceutical Services (Advanced Services) (Appliances) (Wales) Directions 2010 and to remove the impression that the definition of “transitional period” falls within the definition of “the terms of service”.

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**NATIONAL HEALTH
SERVICE, WALES**

The National Health Service
(Pharmaceutical Services)
(Amendment) (Wales) (No 2)
Regulations 2010

Made 21 June 2010

Laid before the National Assembly for Wales
23 June 2010

Coming into force 14 July 2010

The Welsh Ministers, in exercise of the powers conferred by sections 80, 83, 86, 121 and 203(9) and (10) of the National Health Service (Wales) Act 2006(1) hereby make the following Regulations:

Title, commencement, application and interpretation

1.—(1) The title of these Regulations is The National Health Service (Pharmaceutical Services) (Amendment) (Wales) (No 2) Regulations 2010 and they come into force on 14 July 2010.

(2) These Regulations apply in relation to Wales.

(3) In these Regulations “the principal Regulations” (“y *prif Reoliadau*”) means the National Health Service (Pharmaceutical Services) Regulations 1992(2).

Amendment of regulation 2 of the principal Regulation

2. In regulation 2 (interpretation) of the principal Regulations—

(1) 2006 c.42.

(2) S.I. 1992/662. Relevant amending instruments are S.I. 2007/205 (W.19), S.I. 2009/1491 (W.144) and S.I. 2010/868 (W.90).

- (a) in the definition of “terms of service”—
 - (i) in sub-paragraph (b) after the words “Schedule 2” omit “.” and insert “, and”, and
 - (ii) insert as sub-paragraph (c) the words “in relation to suppliers of appliances, in Schedule 2A.”; and
- (b) in paragraph (1C) after the words “where these words occur” insert “except in the definition of “equivalent body””.

Amendments to Schedule 2 to the principal Regulations

3.—(1) Schedule 2 to the principal Regulations is amended in accordance with the following provisions of this regulation.

(2) In paragraph 10A (additional requirements in relation to specified appliances), in sub-paragraph (6)(a) for “25(A)(1)” substitute “24A(1)”.

(3) In paragraph 24A, before the words “24A” insert as the title to the paragraph “Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services”.

Amendments to Schedule 2A to the principal Regulations

4.—(1) Schedule 2A to the principal Regulations is amended in accordance with the following provisions of this regulation.

(2) In paragraph 6 (preliminary matters before providing appliances)—

- (a) for sub-paragraph (3)(a) substitute—
 - “(a) the supplier of appliances must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3 of the Charges Regulations by virtue of either—
 - (i) entitlement to exemption under regulation 8 of the Charges Regulations, or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission

of Charges Regulations and at the time of the declaration the supplier of appliances already has such evidence available to him;” and

(b) for sub-paragraph (3)(c) substitute—

“(c) in the case of an electronic prescription form or an electronic repeatable prescription, the supplier of appliances must comply with any requirements of the ETP service to provide—

(i) a record of the exemption from or remission of charges claimed and whether satisfactory evidence was produced, as referred to in sub-paragraph (a), and

(ii) in any case where a charge is due, confirmation that the relevant charge was paid.”.

(3) In paragraph 12 (opening hours: general)—

(a) in sub-paragraphs (1)(b) and (c) for “paragraph 4 of Schedule 2” substitute “Part 3 of Schedule 2”; and

(b) in sub-paragraph (5) after the words “obligations under sub-paragraph (1) the supplier of appliances” insert “must”.

(4) In paragraph 14 (determination of opening hours instigated by the Local Health Board)—

(a) in sub-paragraphs (3)(b) and (c) for “paragraph 4 of Schedule 2” substitute “Part 3 of Schedule 2”; and

(b) in sub-paragraph (3)(c) for “paragraph 13(1)(a)” substitute “paragraph 12(1)(a)”.

(5) In paragraph 15 (determination of opening hours instigated by the supplier of appliances)—

(a) in sub-paragraphs (4)(b) and (c) for “paragraph 4 of Schedule 2” substitute “Part 3 of Schedule 2”; and

(b) in sub-paragraph (4)(c) for “paragraph 13(1)(a)” substitute “paragraph 12(1)(a)”.

(6) In paragraph 18 (inducements)—

(a) in sub-paragraph (3)(a) for “11(1)(4) or 12(1)(a)” substitute “10(4) or 11(1)(b)”; and

(b) in sub-paragraph (3)(b) for “12(1)(a)” substitute “11(1)(a)”.

(7) The first paragraph 20 (duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1 April 2010) is amended as follows—

(a) renumbered as paragraph 19;

(b) in sub-paragraph (1) for “paragraph 22” substitute “paragraph 21”; and

(c) in sub-paragraph (2) for “paragraph 26” substitute “paragraph 21”.

(8) Paragraph 19 (duty to provide information about fitness to practise matters as they arise) is amended as follows—

(a) renumbered as paragraph 20;

(b) in sub-paragraph (1) for “paragraph 26” substitute “paragraph 21”; and

(c) in sub-paragraph (2) for “paragraph 22” substitute “paragraph 21”.

(9) The second paragraph 20 (home Local Health Board of bodies corporate) is amended as follows—

(a) renumbered as paragraph 21; and

(b) for “paragraphs 20 and 21 and 25(4)(a) and (b)” substitute “paragraphs 19, 20 and 24(3) and (4)”.

(10) Paragraph 21 (complaints) is amended as follows—

(a) renumbered as paragraph 22; and

(b) substitute for the paragraph the paragraph set out in the Schedule to these Regulations.

(11) Paragraph 22 (directed services) is renumbered as paragraph 23.

(12) Paragraph 23 (information to be supplied) is amended as follows—

(a) renumbered as paragraph 24; and

(b) in sub-paragraphs (3) and (5) for “sub-paragraph (9)” substitute “sub-paragraph (7)”.

(13) Paragraph 24 (withdrawal from pharmaceutical lists) is renumbered as paragraph 25.

(14) Paragraph 25 (charges for appliances) is renumbered as paragraph 26.

(15) Paragraph 26 (inspections and access to information) is renumbered as paragraph 27.

Amendments to the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010

5.—(1) Regulation 16 (transitional arrangement) of the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010⁽¹⁾ is amended in accordance with the following provisions of this regulation.

(2) In paragraph (3), for “Pharmaceutical Services (Wales) Directions 2010” substitute “Pharmaceutical

(1) S.I. 2010/868 (W.90).

Services (Advanced Services) (Appliances) (Wales) Directions 2010”(1).

(3) For the English language text of paragraph (5) substitute—

“(5) In this regulation—

- (a) “the terms of service” (*“telerau gwasanaethu”*)—
 - (i) in relation to a pharmacist, means the terms of service set out in Schedule 2 to the principal Regulations;
 - (ii) in relation to a supplier of appliances, means the terms of service set out in Schedule 2A to the principal Regulations; and
- (b) “transitional period” (*“cyfnod trosiannol”*) means the nine month period that ends at the end of 31 December 2010.”.

(4) In the Welsh language text of paragraph (5)(b) after the words ““cyfnod trosiannol”” insert “(“transitional period”)”.

Edwina Hart

Minister for Health and Social Services, one of the Welsh Ministers

21 June 2010

(1) Available on the Welsh Assembly Government’s website: www.wales.gov.uk/legislation.

SCHEDULE

Regulation 4(10)

Paragraph to be substituted for paragraph 22 (complaints) of Schedule 2A to the principal Regulations

“Complaints

22.—(1) A supplier of appliances must establish and operate in accordance with this paragraph a procedure (in this paragraph referred to as a “complaints procedure”) to deal with any complaints made by or on behalf of any person to whom the supplier of appliances has provided pharmaceutical services.

(2) The complaints procedure to be established by a supplier of appliances may be such that it also deals with complaints made in relation to one or more other suppliers of appliances.

(3) The complaints procedure to be established by a supplier of appliances who provides pharmaceutical services from more than one set of premises may be such that it relates to all of those premises together.

(4) A complaints procedure shall apply to complaints made in relation to any matter reasonably connected with the provision of pharmaceutical services by the supplier of appliances and within the responsibility or control of—

- (a) the supplier of appliances;
- (b) where the supplier of appliances is a body corporate, any of its directors or former directors;
- (c) a former partner of the supplier of appliances; and
- (d) any employee of the supplier of appliances,

and in this paragraph references to “complaint” means a complaint falling within this sub-paragraph.

(5) A complaint may be made on behalf of any person with his or her consent, or—

- (a) where the person is under 16 years of age—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child, or
 - (ii) where the person is in the care of an authority to whose care he or she has been committed under the provisions of the Children Act 1989 or in the care of a voluntary organisation, by that authority or voluntary organisation; or

- (b) where the person is incapable of making a complaint, by a relative or other adult person who has an interest in the person's welfare.

(6) A complaint may be made as respects a person who has died by a relative or other adult person who had an interest in his or her welfare or, as respects a person to whom paragraph (a)(ii) of sub-paragraph (5) applies, by the authority or voluntary organisation.

(7) A complaints procedure shall comply with the following requirements—

- (a) the supplier of appliances must specify a person (who need not be connected with the supplier of appliances and who, in the case of an individual, may be specified by his or her job title) to be responsible for receiving and investigating all complaints;
- (b) all complaints must be—
 - (i) recorded in writing,
 - (ii) acknowledged, either orally or in writing, within the period of two days (excluding Saturdays, Sundays, Christmas Day, Good Friday and bank holidays) beginning with the day on which the complaint was received by the person specified under paragraph (a), or where that is not possible as soon as reasonably practicable, and
 - (iii) properly investigated;
- (c) within the period of 20 days (excluding Saturdays, Sundays, Christmas Day, Good Friday and bank holidays) beginning with the day on which the complaint was received by the person specified under paragraph (a), or where that is not possible as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions;
- (d) where the investigation of the complaint requires consideration of any records relating to the person as respects whom the complaint is made, the person specified under paragraph (a) must inform him or her or the person acting on his or her behalf if the investigation will involve disclosure of information contained in those records to a person other than the supplier of appliances or a director, partner or employee of the supplier of appliances;
- (e) the supplier of appliances must keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from any

records relating to the person by whom the complaint was made; and

- (f) a complainant must be advised of his or her right to request a review, in accordance with the Directions, where he or she is dissatisfied with the results of the investigation conducted under the complaints procedure.

(8) At each of the premises at which the supplier of appliances provides pharmaceutical services he or she must provide information about the complaints procedure and give the name (or title) and address of the person specified under paragraph (a) of sub-paragraph (7).

(9) A supplier of appliances must cooperate with any investigation of a complaint by the Local Health Board in accordance with the procedures operated by the Local Health Board under the Directions, whether or not that investigation follows one under the complaints procedure operated by the supplier of appliances.

(10) The cooperation required by sub-paragraph (9) includes—

- (a) answering questions reasonably put to the supplier of appliances by the Local Health Board;
- (b) providing any information relating to the complaint reasonably required by the Local Health Board; and
- (c) attending any meeting to consider the complaint, if held at a reasonably accessible place and at a reasonable hour and due notice has been given, if the presence of the supplier of appliances at the meeting is reasonably required by the Local Health Board.

(11) In this paragraph “the Directions” means the Directions to Local Health Boards on dealing with complaints about family health services practitioners, providers of personal medical services and providers of personal dental services other than personal dental services provided by NHS Trusts, coming into force on 1 April 2003.”.