WELSH STATUTORY INSTRUMENTS

2010 No. 868 (W. 90)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the National Health Service (Pharmaceutical Services) Regulations 1992 ("the principal Regulations") in respect of the terms of service for pharmacists and suppliers of appliances.

Regulation 2 of the Regulations amends certain definitions and inserts new definitions into regulation 2(1) of the principal Regulations.

Regulation 3 of the Regulations contains amendments to the terms of service for pharmacists, which are set out in Schedule 2 to the principal Regulations.

Regulation 4 of the Regulations removes certain definitions in paragraph 1(2) of Schedule 2 which have been amended and are now in regulation 2(1) of the principal Regulations.

Regulation 5 of the Regulations amends paragraph 6 of Schedule 2 so as to add appliances to the items that can, if certain conditions are met, be dispensed without a prescription by a pharmacist in an urgent case – and to remove the requirement that the prescriber be personally known to the pharmacist.

Regulation 6 of the Regulations amends paragraph 9 of Schedule 2 so that pharmacists providing an appliance on a repeat prescription must satisfy themselves that there has been no change in a patient's use of the appliance which calls for a review of treatment.

Regulation 7 of the Regulations adds to paragraph 10 of Schedule 2 a number of additional activities that must be carried out by a pharmacist when dispensing appliances.

Regulation 8 of the Regulations inserts a new paragraph 10A into Schedule 2 setting out what pharmacists must do when dispensing "specified appliances". They must provide a home delivery service for these appliances and must ensure that appropriate advice is given as to their use.

Regulation 9 of the Regulations amends paragraph 18 of Schedule 2 to require pharmacists to refer prescription forms or repeatable prescriptions, or to give contact details of other pharmacists or suppliers of appliances, in any case where providing a particular appliance or providing stoma appliance customisation is not within their normal course of business.

Regulation 10 of the Regulations inserts sub-paragraph (1A) into paragraph 21 of Schedule 2 in relation to supplementary opening hours.
Regulation 11 of the Regulations amends paragraph 25 of Schedule 2 in relation to clinical effectiveness programmes.

Regulation 12 of the Regulations inserts a new paragraph 24A into Schedule 2 in respect of emergency opening hours.

Regulation 13 of the Regulations amends paragraph 27 of Schedule 2 to prohibit gifts or rewards where a pharmacist provides no additional services other than referring a prescription onward or providing contact details of persons who are able to provide a particular service.

Regulation 14 of the Regulations amends paragraph 42 of Schedule 2 to ensure that Local Health Boards can check on arrangements concerning the provision of appliances which are made between a pharmacist and a third party.

Regulation 15 of the Regulations and the Schedule inserts a new Schedule 2A in to the principal Regulations in relation to terms of service for suppliers of appliances.

Regulation 16 of the Regulations contains transitional provision allowing existing contractors to choose, until the end of 31 December 2010, to comply with the previous version of their terms of service, as set out in the relevant Schedule to the principal Regulations.

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2010 No. 868 (W. 90)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010

Made	*18 March 2010*
Laid before the National Assembly for Wales	*19 March 2010*
Coming into force	*1 April 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) Regulations 2010 and they come into force on 1 April 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 the principal Regulations

2.—(1) The principal Regulations are amended in accordance with the following provisions of this regulation.

(**1**) 2006 c.42.
(**2**) S.I.1992/662 Relevant amending instruments are S.I. 2007/205 (W.19) and S.I. 2009/1491 (W.144).

(2) In regulation 2(1) (interpretation) of the principal Regulations, in the appropriate alphabetical position, insert —

““advanced electronic signature” means an electronic signature which is—

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) created using means that the signatory can maintain under his sole control; and

(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;”;

““appliance” means an appliance which is included in a list for the time being approved by the Welsh Ministers for the purposes of section 80 (arrangements for pharmaceutical services) of the 2006 Act;”;

““appliance use review service” means arrangements made in accordance with section 81 of the 2006 Act (arrangements for additional Pharmaceutical Services) for a pharmacist or specialist nurse to review a person's use of any specified appliance;”;

““associated batch issue” means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;”;

““batch issue” means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services which is in the required format, and which—

(a) is generated by a computer and not signed by a repeatable prescriber;

(b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;

(c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and

(d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);”;

““contingent removal” means removal from a pharmaceutical list contingently, within the meaning of section 108 (contingent removal) of the 2006 Act, and “contingently remove” shall be construed accordingly;”;

““electronic prescription” means an electronic prescription form or an electronic repeatable prescription;”;

““electronic prescription form” means a prescription which falls within paragraph (b) of the definition of “prescription form;”;

““electronic repeatable prescription” means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription;”;

““employment” means any employment whether paid or unpaid and whether under a contract for services or a contract of service, and “employed” and “employer” shall be construed accordingly;”;

““equivalent body” means a Primary Care Trust in England, a Health Board or an NHS trust in Scotland, a Health and Social Services Board in Northern Ireland, (in relation to any time prior to 1 October 2002) a Strategic Health Authority in England or (in relation to any time prior to 1st April 2003) a Health Authority in Wales or an NHS trust in England or in Wales;”;

““equivalent lists” means lists kept by an equivalent body;”;

““ESP scheme” means an Essential Small Pharmacies Local Pharmaceutical Services scheme;”;

““ETP service” means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;”.

““fraud case” means a case where a person meets the second condition for removal from the pharmaceutical list, set out in section 107(3) (disqualification of practitioners) of the 2006 Act, or by virtue of section 109 (fraud and unsuitability cases: supplementary) of the 2006 Act is treated as doing so;”;

““health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25 of the National Health Service Reform and Healthcare Professions Act 2002(**1**);”;

““licensing or regulatory body” means a body that licenses or regulates any profession of which the person is or has been a member, and includes any body which licenses or regulates any such profession in a country other than the United Kingdom;”;

(**1**) 2002 c.17.

""list", unless the context otherwise requires, means —

(a) a list referred to in section 115(1) (national disqualification) of the 2006 Act;

(b) a list of persons undertaking to provide general medical services prepared in accordance with regulations made under section 29 (arrangements and regulations for general medical services) of the Act, as the list existed on or before 31 March 2004;

(c) a list of persons approved by a Local Health Board for the purpose of assisting in the provision of general medical services prepared in accordance with regulations made under section 43D(1) (supplementary lists) of the Act as the list existed on or before 31 March 2004; or

(d) a services list referred to in section 8ZA(1)(a) (lists of persons who may perform personal medical services or personal dental services) of the 1997 Act as the list existed on or before 31 March 2004;";

""LPS chemist" means—

(a) a registered pharmacist,

(b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(**1**), or

(c) a supplier of appliances,

who provides local pharmaceutical services under a pharmacy scheme or an LPS scheme;";

""LPS scheme" has the same meaning as in paragraph 1(2) of Schedule 7 to the 2006 Act;";

""NHS Business Services Authority" means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**2**);";

""NHS Individual Health Record" means the records relating to an individual patient held by the NHS individual Health Record Service;";

""NHS Individual Health Record Service" means the information technology systems which hold medical records relating to patients in Wales;";

""NHS services" means services provided as part of the health service in Wales";"

""National Health Service Counter Fraud and Security Management Service" means the NHS Business Services Authority;";

(**1**) 1968 c.67.
(**2**) S.I. 2005/2414.

““non-electronic prescription form” means a prescription form which falls within paragraph (a) of the definition of “prescription form;”;

““non-electronic repeatable prescription” means a prescription which falls within paragraph (a)(i) of the definition of “repeatable prescription”;”;

““originating events” means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;”;

““professional conduct” includes matters relating both to professional conduct and professional performance;”;

““specified appliance” 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” 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 a record of those measurements and, if applicable, a template;”; and

““supplier of appliances” means a person with whom a Local Health Board has entered into arrangements for the provision of pharmaceutical services, being terms of service under regulation 3;”.

(3) In regulation 2(1) of the principal Regulations for the definition of “local pharmaceutical services” there is substituted —

““local pharmaceutical services” means local pharmaceutical services under —

(a) an LPS scheme established under paragraph 1(1) of Schedule 7 to the 2006 Act; or

(b) an ESP scheme;";

(4) In regulation 2(1) of the principal Regulations, for the definition of "prescription form" there is substituted —

""prescription form" means —

(a) a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust or NHS Foundation Trust, and issued by a prescriber; or

(b) a form containing data that are created in an electronic format, uniquely identified using a prescriber's code and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services, and does not include a repeatable prescription";.

(5) In regulation 2(1) of the principal Regulations, in the definition of "repeatable prescriber" there is substituted —

""repeatable prescriber" means a person who is —

(a) a pharmacist independent prescriber who —

(i) is included in a pharmaceutical list, and —

(aa) with whom a Local Health Board has made an arrangement for the provision of a directed service which is an independent prescribing service; and

(bb) who is issuing or creating a repeatable prescription as part of that arrangement;

(ii) is employed or engaged by a person who is included in a pharmaceutical list, and —

(aa) a Local Health Board has made an arrangement with that person for the provision of a directed service which is an independent prescribing service; and

(bb) the pharmacist independent prescriber is issuing or creating a repeatable prescription as part of that arrangement;

(iii) is a party to an LPS scheme or LPS arrangements, and —

(aa) with whom a Local Health Board has made an arrangement for the provision of an Independent Prescribing Service; and

(bb) who is issuing or creating a repeatable prescription as part of that arrangement; or

(iv) is employed or engaged by a party to an LPS scheme or LPS arrangements (other than a Local Health Board), and —

(aa) a Local Health Board has made an arrangement with that party for the provision of an independent prescribing service; and

(bb) the pharmacist independent prescriber is issuing or creating a repeatable prescription as part of that arrangement;".

(6) In regulation 2(1) of the principal Regulations, for the definition of "repeatable prescription" there is substituted —

""repeatable prescription" means a prescription contained in a form provided by a Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services which is in the format specified in Part I of Schedule 1 to the NHS (General Medical Services Contracts) (Wales) Regulations 2004(**1**) and which is either —

(a) —

(i) generated by a computer but signed by a prescriber; or

(ii) a form containing data that are created in an electronic format, identified using a repeatable prescriber's code and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service;

(b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services; and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;".

(**1**) S.I. 2004/478 (W.48).

(7) In regulation 2(1)(c) of the principal Regulations, after the words "where these words occur" there is added —

"except in the definition of "equivalent body"".

Amendments to Schedule 2 to the principal Regulations

3. Schedule 2 to the principal Regulations is amended in accordance with regulations 4 to 13.

Amendment of paragraph 1

4. Remove sub-paragraph 1(2) of Schedule 2 to the principal Regulations and renumber sub-paragraph 1(3) as 1(2).

Amendment of paragraph 6

5. For paragraph 6 substitute —

"**6. Urgent supply without a prescription**

(1) This paragraph applies where, in a case of urgency, a prescriber requests a pharmacist to provide a drug or appliance.

(2) The pharmacist may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that —

(a) in the case of a request for a drug, the drug is neither —

(i) a Scheduled drug, nor

(ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971(**1**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**2**); and

(b) in the case of a request for a drug or an appliance, the prescriber undertakes to —

(i) give the pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or

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(**1**) 1971 c.38.

(**2**) S.I. 2001/3998.

(ii) give the pharmacist an electronic prescription form or electronic repeatable prescription form complying with the ETP service within 72 hours of the request being made.".

Amendment of paragraph 9

6. In paragraph 9 (Refusal to provide drugs or appliances ordered), in sub-paragraph (4)(b), after "the medication regimen of" insert ", or manner of utilisation of the appliance by," and after "prescription was written has" insert "not".

Amendment of paragraph 10

7.—(1) Amend paragraph 10 (Further activities to be carried out in connection with the provision of dispensing services) as follows.

(2) Renumber the existing provision as sub-paragraph (1).

(3) In that sub-paragraph —

(a) for paragraph (c) substitute —

"(c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;

(ca) when providing appliances to patients in accordance with a prescription form or repeatable prescription —

(i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

(ii) for those purposes, have regard to the details contained in the records maintained under sub-paragraph (e) in respect of the provision of appliances and prescribing pattern relating to the patient in question;";

(b) omit "and" at the end of sub-paragraph (k); and

(c) after sub-paragraph (l) insert —

"(m)when providing appliances, provide a patient with a written note of the pharmacist's name, address and telephone number; and

(n) when providing specified appliances, comply with the additional

requirements set out in paragraph 10A.
".

(4) After sub-paragraph (1) insert —

"(2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, a pharmacist is unable to provide an appliance, or stoma appliance customisation is required and the pharmacist is unable to provide that, the pharmacist must —

(a) if the patient consents, refer the prescription form or repeatable prescription to another pharmacist or to a supplier of appliances; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.".

Insertion of new paragraph 10A

8. After paragraph 10 insert —

"**10A. Additional requirements in relation to specified appliances**

(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(n) relating to the provision of specified appliances.

(2) A pharmacist who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service —

(a) the pharmacist must offer to deliver the specified appliance to the patient's home;

(b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;

(c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and

(d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the pharmacist must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and —

(a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or

(b) if the pharmacist believes it is appropriate to do so, must —

(i) refer the patient to a prescriber, or

(ii) offer the patient an appliance use review service.

(4) If the pharmacist is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the pharmacist must give the patient the contact details of at least two people who are pharmacists or suppliers of appliances who are able to arrange for the service to be provided, if these details are known to the pharmacist.

(5) Where a pharmacist provides a telephone care line in respect of the dispensing of any specified appliance, the pharmacist must ensure that during out of hours periods —

(a) advice is made available to patients through that telephone care line; or

(b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph —

"expert clinical advice", in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods", in relation to a pharmacy, means the periods outside the periods during which the pharmacist —

(a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 21(1) or 25(A)(1); or

(b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 21(1A).

Amendment of paragraph 18

9.—(1) Amend paragraph 18 (service outline in respect of signposting) as follows.

(2) After sub-paragraph (1) insert —

"(1A) Where, on presentation of a prescription form or repeatable prescription, a pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacist's normal course of business, the pharmacist must —

(a) if the patient consents, refer the prescription form or repeatable prescription to another pharmacist or to a supplier of appliances; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.".

(3) In sub-paragraph (3), after "under sub-paragraph (1)" insert "or (1A)".

Amendment of paragraph 21

10. After paragraph 21(1) (pharmacy opening hours: general) insert—

"(1A) A pharmacist shall also notify the Local Health Board of other hours during which the premises from which the pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to as "supplementary opening hours")."

Amendment of paragraph 25

11. In paragraph 25 (clinical governance), in sub-paragraph (2), for paragraph (d) substitute —

"(d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a pharmacist —

(i) in respect of the provision of drugs in accordance with a repeatable prescription,

(ii) in respect of the provision of appliances in accordance with a

prescription form or repeatable prescription, or

(iii) to people caring for themselves or their families,

and arrangements for ensuring that the pharmacist, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 10(1)(e) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;".

Insertion of paragraph 24A

12. After paragraph 24 insert —

"**24A.**

(1) Notwithstanding the provisions of this Schedule, during an emergency requiring the flexible provision of pharmaceutical services, Local Health Board may, on application from a pharmacist ("P"), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at the premises from which P has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if —

(a) P gives at least 24 hours notice of the change or closure; and

(b) the reasons given by P for the request are, in the opinion of the Local Health Board, adequate reasons.

(2) The Local Health Board need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that P's reasons are not, in its opinion, adequate reasons, then the days on which or times at which P is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to P."

Amendment of paragraph 27

13. After paragraph 27(2) (inducements) insert —

"(3) In the case of the provision of appliances, neither a pharmacist nor any person employed or engaged by a pharmacist must accept or receive any gift or reward in respect of only —

(a) providing contact details of alternative pharmacists or suppliers of appliances pursuant to paragraph 10(2)(b), 10A(4) or 18(1A)(b); or

(b) referring a prescription form or repeatable prescription to another pharmacist or supplier of appliances pursuant to paragraph 10(2)(a) or 18(1A)(a) and providing no additional service in connection with the item on that prescription.".

Amendment of paragraph 42(1)

14. In paragraph 42(1) (inspections and access to information), in paragraph (b)(i), after "patient care and treatment," insert "including any arrangement made with a person in respect of provision of appliances,".

Insertion of the Schedule into the principal Regulations

15. Immediately after Schedule 2 of the principal Regulations, insert the Schedule.

Transitional arrangement

16.—(1) This regulation has effect only in relation to the provision of pharmaceutical services at any time before the end of the transitional period by any pharmacist or supplier of appliances whose name was, immediately before 1 April 2010, already on a pharmaceutical list maintained by a Local Health Board under the principal Regulations.

(2) Subject to paragraph (3), during the transitional period the pharmacist or supplier of appliances is not bound by such amendments to terms of service as are made by these Regulations, if they choose instead to comply with the terms of service as they had effect prior to those amendments (in these circumstances, the terms of service that are binding upon them are the terms of service as they had effect on 31 March 2010).

(3) Paragraph (2) does not apply in any case where the pharmacist or supplier of appliances first notifies the Local Health Board of its intention to enter into new arrangements, which are to be made in accordance with the Pharmaceutical Services (Wales) Directions 2010, to provide services for stoma appliance customisation or appliance use reviews (or has entered into such arrangements).

(4) Nothing in this regulation affects the duty of a pharmacist or supplier of appliances —

(a) before the end of the transitional period, to comply with the terms of service as they otherwise have effect; and

(b) at or after the end of the transitional period, to comply with the terms of service as amended by these Regulations.

(5) In this regulation —

"the terms of service"—

(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

(iii) "transitional period" means the nine month period that ends at the end of 31 December 2010.

Edwina Hart

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

18 March 2010

SCHEDULE

SCHEDULE INSERTED IMMEDIATELY AFTER SCHEDULE 2 TO THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) REGULATIONS 1992

"SCHEDULE 2A

Regulation 3

TERMS OF SERVICE OF SUPPLIERS OF APPLIANCES

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of suppliers of appliances must be deemed to form part of the terms of service for suppliers of appliances —

(a) these Regulations;

(b) the Drug Tariff in so far as it lists appliances for the purposes of section 38 of the 2006 Act;

(c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992(**1**) as relates to —

(i) the investigation of questions arising between suppliers of appliances and persons receiving pharmaceutical services and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Local Health Board as a result of such investigations, and

(ii) appeals to the Welsh Ministers from decisions of the Local Health Board; and

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(**1**) S.I. 1992/674.

(d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010(**1**) as relate to the entry and inspection of premises either owned or controlled by the supplier of appliances or where pharmaceutical services are provided by him or her.

Division of responsibilities between individuals and corporate bodies

2.—(1) To the extent that this Schedule imposes a requirement on a supplier of appliances in respect of an activity which could only, or would normally, be undertaken by a natural person —

(a) if the supplier of appliances is a registered pharmacist —

(i) that registered pharmacist must comply with that requirement, or

(ii) if he or she employs or engages a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by a person whom he or she employs or engages; and

(b) if the supplier of appliances is not a natural person, that supplier of appliances must secure compliance with that requirement by a person whom it employs or engages,

and references in this Schedule to a supplier of appliances must be construed accordingly.

(2) Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, breach of that requirement must be deemed to be a breach by the body corporate of its terms of service.

Dispensing services

3. A supplier of appliances must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances by health care professionals in pursuance of their functions.

(**1**) S.I. 2010/[1288 (W.37).

Dispensing of appliances

4.—(1) In this paragraph, "signed" includes signature with a prescriber's advanced electronic signature.

(2) Subject to the provisions of this Schedule, where —

(a) any person presents a non-electronic prescription form which contains —

(i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or

(ii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS", “Selected List Scheme” or “Drug Tariff”; or

(b) a supplier of appliances receives an electronic repeatable prescription complying with the ETP service which contains an order of a kind specified in paragraph (a)(i) and (ii) and —

(i) any person requests the provision of an appliance in accordance with that prescription, or

(ii) the supplier of appliances has previously arranged with the patient that it will dispense that prescription on receipt,

a supplier of appliances must, with reasonable promptness, provide such of the appliances so ordered as the supplier supplies in the normal course of business.

(3) Subject to the following provisions of this Schedule, where —

(a) any person presents a non-electronic repeatable prescription which contains —

(i) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or

(ii) an order for a restricted availability appliance, signed by a repeatable prescriber and including the reference “SLS”, “Selected List Scheme” or “Drug Tariff”, and also presents an associated batch issue; or

(b) a supplier of appliances receives an electronic repeatable prescription complying with the ETP service which contains an order of a kind specified in paragraph (a)(i) and (ii) and —

(i) any person requests the provision of appliances in accordance with that prescription, or

(ii) the supplier of appliances has previously arranged with the patient that the supplier will dispense that prescription on receipt,

the supplier of appliances shall, with reasonable promptness, provide such of the appliances so ordered as the supplier supplies in the normal course of business.

(4) For the purposes of this paragraph, a non-electronic repeatable prescription for appliances shall be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where —

(a) the supplier of appliances has that prescription in the supplier's possession; and

(b) that person presents, or the supplier of appliances has in the supplier's possession, an associated batch issue.".

Urgent supply without a prescription

5.—(1) This paragraph applies where, in a case of urgency, a prescriber requests a supplier of appliances to provide an appliance.

(2) The supplier of appliances may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to —

(a) give the supplier of appliances a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or

(b) give the supplier of appliances an electronic prescription form complying with the ETP service within 72 hours of the request being made.

Preliminary matters before providing appliances

6.—(1) If the person specified in sub-paragraph (2) asks the supplier of appliances to do so —

(a) the supplier of appliances must give an estimate of the time when the appliance will be ready; and

(b) if it is not ready by then, the supplier of appliances must give a revised estimate of the time when it will be ready.

(2) A person specified in this sub-paragraph is a person —

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription —

(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 under regulation 8 of the National Health Service (Free Prescriptions and Charges) for Drugs and Appliances (Wales) Regulations 2007(**1**);

(b) if, in the case of a non-electronic prescription form or a non-electronic repeatable prescription no satisfactory evidence, as required by sub-paragraph (a), is produced to the supplier of appliances, the supplier of appliances must endorse the form on which the declaration is made to that effect; and

(c) in the case of an electronic prescription form or an electronic repeatable prescription, the supplier of appliances must dispense in accordance with the ETP service —

(i) in a case where a person does not have to pay for their prescription under regulation 8 of the National Health Service Free Prescriptions and Charges for Drugs and Appliances (Wales) Regulations 2007 a record of —

(aa) the exemption category; and

(bb) whether or not satisfactory evidence was produced to the supplier as required by sub-paragraph (a), and

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

Providing appliances

7.—(1) Where a supplier of appliances is presented with a prescription form or a repeatable prescription, the supplier of appliances shall only provide the appliances so ordered —

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and

(b) in accordance with the order on the prescription form or repeatable prescription,

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(**1**) S.I. 2007/121 (W.11).

subject to any regulations in force under the Weights and Measures Act 1985(**1**) and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting by the supplier of appliances the supplier of appliances must make all necessary arrangements for —

(a) measuring the person named on the prescription form or repeatable prescription for the appliance; and

(b) fitting the appliance.

(3) If the order is for an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

Refusal to provide appliances ordered

8.—(1) A supplier of appliances may refuse to provide an appliance ordered on a prescription form or repeatable prescription where —

(a) the supplier of appliances reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription;

(b) it appears to the supplier of appliances that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to the clinical judgement of the supplier of appliances;

(c) the supplier of appliances or other persons are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with a prescription form or repeatable prescription or by any person accompanying that person; or

(d) the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or electronic repeatable prescription or any other person accompanying that person, commits or threatens to commit a criminal offence.

(**1**) 1985 c.72.

(2) A supplier of appliances shall refuse to provide appliances ordered on a repeatable prescription where —

(a) the supplier has no record of that prescription;

(b) the supplier does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to the supplier;

(c) it is not signed by a repeatable prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than six months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) the supplier has been informed by the repeatable prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), a supplier of appliances shall only provide the appliance ordered if satisfied that —

(a) the patient to whom the prescription relates —

(i) is using and is likely to continue to use the appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment;

(b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

9.—(1) In connection with the services provided under paragraph 3, a supplier of appliances must —

(a) ensure that appropriate advice is given to patients about any appliances provided to them —

(i) to enable them to utilise the appliances appropriately, and

(ii) to meet the patients' reasonable needs for general information about the appliances;

(b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;

(c) when providing appliances to a patient in accordance with a prescription form or repeatable prescription —

(i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

(ii) for those purposes, have regard to the details contained in the records maintained under sub-paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

(d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;

(e) provide a patient with a written note of the supplier's name, address and telephone number;

(f) keep and maintain records —

(i) of appliances provided, in order to facilitate the continued care of the patient,

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under paragraph (d);

(g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;

(h) if the supplier takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(i) if the supplier provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription

and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;

(j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);

(k) destroy any surplus batch issues relating to appliances —

(i) which are not required, or

(ii) where a patient is refused an appliance pursuant to paragraph 8;

(l) ensure that where a person is refused appliances pursuant to paragraph 8(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;

(m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;

(n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 8(3); and

(o) when providing specified appliances, comply with the additional requirements set out in paragraph 10.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, a supplier of appliances is unable to provide an appliance, or stoma appliance customisation is required and the supplier of appliances is unable to provide that, the supplier of appliances shall —

(a) if the patient consents, refer the prescription form or repeatable prescription to another supplier of appliances or to a pharmacist; or

(b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the supplier.

Additional requirements in relation to specified appliances

10.—(1) This paragraph sets out the additional requirements referred to in paragraph 9(1)(o) relating to the provision of specified appliances.

(2) A supplier of appliances who dispenses specified appliances in the normal course of business shall

provide a home delivery service in respect of those appliances and, as part of that service —

(a) the supplier of appliances must offer to deliver the specified appliance to the patient's home;

(b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;

(c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and

(d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the supplier of appliances shall provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and —

(a) shall ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or

(b) if the supplier of appliances believes it is appropriate to do so, shall —

(i) refer the patient to a prescriber, or

(ii) offer the patient an appliance use review service.

(4) If the supplier of appliances is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the supplier must give the patient the contact details of at least two people who are pharmacists or suppliers of appliances who are able to arrange for the service to be provided, if these details are known to the supplier of appliances.

(5) Where a supplier of appliances provides a telephone care line in respect of the dispensing of any specified appliance, the supplier shall ensure that during out of hours periods —

(a) advice is made available to patients through that telephone care line; or

(b) the telephone number of NHS Direct Wales or website address of NHS Direct Wales, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph —

"expert clinical advice", in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods", in relation to each of the premises from which a supplier of appliances has undertaken to provide pharmaceutical services, means the periods outside the periods during which the supplier of appliances is obliged to provide pharmaceutical services by virtue of paragraph 12 or 16.

Signposting

11.—(1) Where, on presentation of a prescription form or repeatable prescription, a supplier of appliances is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the supplier's normal course of business, the supplier of appliances shall —

(a) if the patient consents, refer the prescription form or repeatable prescription to another supplier of appliances or to a pharmacist; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the supplier.

(2) The supplier of appliances shall, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record shall be in a form that facilitates —

(a) auditing of the provision of pharmaceutical services by the supplier of appliances; and

(b) follow-up care for the person who has been given the information or in respect of whom the referral has been made

Opening hours: general

12.—(1) A supplier of appliances must ensure that pharmaceutical services are provided at each of the premises from which he or she has undertaken to provide pharmaceutical services —

(a) for not less than 30 hours each week;

(b) if the supplier of appliance's Local Health Board, or on appeal the Welsh Ministers, have directed (either under this Schedule or paragraph 4 of Schedule 2) that the supplier of appliances may provide pharmaceutical services at the premises for fewer than 30 hours per week, provided that those services are provided at set times and on set days, at the times and on the days so set;

(c) if the supplier of appliance's Local Health Board, or on appeal the Welsh Ministers, have

directed under paragraph 4 of Schedule 2, that the supplier of appliances must provide pharmaceutical services at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set; or

(d) if the supplier of appliance's Local Health Board, or on appeal the Welsh Ministers, have directed under this Schedule that the supplier of appliances must provide pharmaceutical services at the premises for more than 30 hours each week —

(i) for the total number of hours each week required by virtue of that direction, and

(ii) as regards the additional hours for which the supplier of appliances is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which the supplier of appliances is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received three months notice of the proposed suspension.

(2) At each of the premises from which a supplier of appliances has undertaken to provide pharmaceutical services, a supplier of appliances must exhibit a notice specifying the days on which and times at which the premises are open for the provision of appliances.

(3) A supplier of appliances must, on request, submit a return to the Local Health Board setting out —

(a) the days on which and times at which pharmaceutical services are provided at each of the premises from which the supplier of appliances has undertaken to provide pharmaceutical services (including times at which he or she is providing pharmaceutical services when the supplier is not obliged to do so by virtue of sub-paragraph (1)); and

(b) the pharmaceutical services which the supplier of appliances ordinarily provides at each of those premises.

(4) Where a supplier of appliances changes —

(a) the days on which or times at which pharmaceutical services are to be provided at premises from which the supplier has undertaken to provide pharmaceutical services; or

(b) the pharmaceutical services which the supplier is ordinarily to provide at those premises,

the supplier must supply the Local Health Board with a return informing it of the change.

(5) Subject to sub-paragraph (6), where a supplier of appliances is prevented by illness or other reasonable cause from complying with its obligations under sub-paragraph (1) the supplier of appliances, where practicable, make arrangements with one or more suppliers of appliances, pharmacists or LPS chemists whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) A supplier of appliances may make an arrangement with an LPS chemist under sub-paragraph (5) only where that LPS chemist provides local pharmaceutical services which are of a similar description, and a similar extent to, the pharmaceutical services which the supplier of appliances ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by a supplier of appliances for a reason beyond the control of the supplier of appliances, the supplier of appliances must not be in breach of sub-paragraphs (1) and (2), provided that the supplier of appliances —

(a) notifies the Local Health Board of that suspension as soon as practicable; and

(b) uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(8) Planned refurbishment of premises is neither a “reasonable cause” for the purposes of sub-paragraph (5) nor a “reason beyond the control of the supplier of appliances” for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday or a bank holiday, it is deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(10) In this Schedule, the "additional hours" for which a supplier of appliances is to be required to provide pharmaceutical services are those hours during which the supplier of appliances would not be providing pharmaceutical services, were the supplier of appliances subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d).

(11) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, a Local Health Board may, on application from a supplier of appliances (“S”), permit S a temporary change to the days on which or times at which S is obliged to provide pharmaceutical services at the premises from

which S has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if —

(a) S gives at least 24 hours notice of the change or closure; and

(b) the reasons given by S for the request are, in the opinion of the Local Health Board, adequate reasons.

(12) The Local Health Board need not approve the request referred to in sub-paragraph 11, in advance of the change or closure, and if it does not do so but decides subsequently that S's reasons are not, in its opinion, adequate reasons, then the days on which or times at which S is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to S.

Matters to be considered when issuing directions in respect of opening hours

13.—(1) Where a Local Health Board issues a direction setting any days or times under this Schedule, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Local Health Board —

(a) must treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided; and

(b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the person providing the services is not obliged to provide those services.

(3) The Local Health Board may only direct that a supplier of appliances may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood are likely to be adequate to meet the need for such services at times when the supplier of appliances is not providing pharmaceutical services.

(4) A Local Health Board may only direct that a supplier of appliances must provide pharmaceutical services at premises for more than 30 hours in any week if a Local Health Board is satisfied that the supplier of appliances will receive reasonable

remuneration in respect of the additional hours for which he or she is required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is "reasonable remuneration" for these purposes).

Determination of opening hours instigated by the Local Health Board

14.—(1) Where it appears to the Local Health Board, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of —

(a) people in the neighbourhood; or

(b) other likely users of the supplier of appliance's premises,

for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the supplier of appliances to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board must —

(a) give notice to the supplier of appliances of any proposed changes to the days on which or times at which the premises are to be open; and

(b) allow him or her 60 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must —

(a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5); or

(b) confirm any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph; or

(c) either —

(i) revoke (without replacing it) any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises,

whether issued under this Schedule or paragraph 4 of Schedule 2, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 13(1)(a), the premises will need to be open for not less than 30 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of premises that are to be required to be open —

(a) for more than 30 hours each week, it must set out in that direction —

(i) the total number of hours each week for which the supplier of appliances must provide pharmaceutical services at the premises, and

(ii) as regards the additional hours for which the supplier of appliances is to provide pharmaceutical services, the days on which and the times at which he or she is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the supplier of appliances is to provide pharmaceutical services during hours which are not additional hours; or

(b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Local Health Board must notify the supplier of appliances in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the supplier of appliances is to provide pharmaceutical services at the premises, it must include with the notification a statement of —

(a) the reasons for the change; and

(b) the supplier of appliances' right of appeal under sub-paragraph (7).

(7) A supplier of appliances may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which

the supplier of appliances is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the supplier of appliances of a determination in sub-paragraph (8) and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which a supplier of appliances is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the supplier of appliances must introduce the changes —

(a) if the supplier has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives his or her notification under sub-paragraph (6); or

(b) if the supplier has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he or she receives his or her notification under sub-paragraph (9).

Determination of opening hours instigated by the supplier of appliances

15.—(1) A supplier of appliances may apply to a Local Health Board in writing with 90 days' notice for it to change the days on which or times at which the supplier is obliged to provide pharmaceutical services at the supplier's premises, in a way that —

(a) reduces the total number of hours for which the supplier of appliances is obliged to provide pharmaceutical services each week; or

(b) keeps that total number of hours the same.

(2) Where a supplier of appliances makes an application under sub-paragraph (1), as part of that application the supplier must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must —

(a) issue a direction (which will replace any existing direction) which meets the

requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;

(b) confirm any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2, would meet the requirements of sub-paragraphs (5) and (6); or

(c) either —

(i) revoke (without replacing it) any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, whether issued under this Schedule or paragraph 4 of Schedule 2, where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 13(1)(a), the premises will need to be open for not less than 30 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of premises that are to be required to be open —

(a) for more than 30 hours each week, it must set out in that direction —

(i) the total number of hours each week for which the supplier of appliances must provide pharmaceutical services at the premises, and

(ii) as regards the additional hours for which the supplier of appliances is to provide pharmaceutical services, the days on which and the times at which the supplier is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the supplier of appliances is to provide pharmaceutical services during hours which are not additional hours; or

(b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the

direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the supplier of appliances of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the supplier of appliances a statement setting out —

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) the supplier of appliances' right of appeal under sub-paragraph (9).

(9) A supplier of appliances may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the supplier of appliances in writing of its determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which the supplier of appliances is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the supplier of appliances must introduce the changes —

(a) if the supplier has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which the supplier receives a notification under sub-paragraph (4); or

(b) if the supplier has appealed under sub-paragraph (9), not earlier than 30 days after the date on which the supplier receives his or her notification under sub-paragraph (11).

Clinical governance

16.—(1) A supplier of appliances shall, in connection with all the pharmaceutical services the supplier of appliances provides, participate, in the manner reasonably required by the Local Health Board, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is acceptable if it is considered acceptable by the Welsh Ministers and comprises the following components —

(a) a patient and public involvement programme, which includes —

(i) a requirement that the supplier of appliances produces in an approved manner a practice leaflet containing approved particulars in respect of each of the premises from which the supplier provides pharmaceutical services,

(ii) a requirement that the supplier of appliances publicises the NHS services that are available at or from such premises,

(iii) a requirement that the supplier of appliances undertakes an approved patient satisfaction survey annually, in an approved manner,

(iv) the monitoring arrangements of the supplier of appliances in respect of appliances owed to patients but which are out of stock,

(v) an approved complaints system (which meets the requirements of this Schedule),

(vi) a requirement that the supplier of appliances co-operates appropriately with visits by an authorised representative of any relevant local involvement network and takes appropriate action following the outcome of such visits,

(vii) a requirement that the supplier of appliances co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and

(viii) the monitoring arrangements of the supplier of appliances in respect of the supplier's compliance with the Disability Discrimination Act 1995(**1**);

(b) a clinical audit programme (normally of five days) twice in each financial year;

(c) a risk management programme, which includes —

(i) arrangements for ensuring that all stock is procured and handled in an appropriate way,

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(**1**) 1995 c.50.

(ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,

(iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,

(iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,

(v) appropriate waste disposal arrangements for clinical and confidential waste,

(vi) identifying a clinical governance lead person in respect of each of the premises from which the supplier provides pharmaceutical services,

(vii) appropriate child protection procedures, and

(viii) the monitoring arrangements of the supplier of appliances in respect of the supplier's compliance with the Health and Safety at Work etc Act 1974(**1**);

(d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a supplier of appliances —

(i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or

(ii) to people caring for themselves or their families,

and arrangements for ensuring that the supplier, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 9(1)(f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

(e) a staffing and staff management programme, which includes —

(i) arrangements for appropriate induction for staff and locums,

(ii) appropriate training for all staff in respect of any role they are asked to perform,

(iii) arrangements for the checking of qualifications and references of all staff

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(**1**) 1974 c.37.

engaged in the provision of NHS services,

(iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service, including continuing professional development for registered pharmacists, registered nurses and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services, and

(v) arrangements for addressing poor performance (in conjunction with a Local Health Board as appropriate); and

(f) a use of information programme, which includes —

(i) appropriate arrangements (having regard to issues both of rights of access to information and of confidentiality) to support both health care delivery and clinical governance,

(ii) appropriate arrangements in respect of compliance with "Confidentiality: the Code of Practice for Health and Social Care in Wales",

(iii) the monitoring arrangements of the supplier of appliances in respect of the supplier's compliance with the Data Protection Act 1998 and with regard to patient confidentiality, and

(iv) appropriate training for staff with regard to compliance with the Data Protection Act 1998(**1**) and patient confidentiality.

(3) For the purposes of sub-paragraph (2), "approved" means approved by the Welsh Ministers.

Professional Standards

17. A supplier of appliances must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements

18.—(1) Neither a supplier of appliances nor any person employed or engaged by a supplier of appliances must give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of

(**1**) 1995 c.46.

discount or rebate or otherwise) as an inducement to or in consideration of his or her —

(a) presenting an order for appliances on a prescription form or repeatable prescription; or

(b) nominating the supplier of appliances as his or her dispensing contractor (or one of them).

(2) Promising, offering or providing a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) Neither a supplier of appliances nor any person employed or engaged by a supplier of appliances shall accept or receive any gift or reward in respect of only —

(a) providing contact details of alternative pharmacists or suppliers of appliances pursuant to paragraph 9(2)(b), 11(1)(4) or 12(1)(a); or

(b) referring a prescription form or repeatable prescription to another supplier of appliances or pharmacist pursuant to paragraph 9(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription

Duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1 April 2010

20.—(1) In the case of a supplier of appliances who is on a pharmaceutical list on 1st April 2010, subject to paragraph 22, the supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, must, by 3 October 2010, supply in writing information to the supplier's Local Health Board as to whether he or she —

(a) has any criminal convictions in the United Kingdom;

(b) has accepted a police caution in the United Kingdom;

(c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him or her absolutely (without proceeding to conviction);

(d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(**1**) (fixed penalty: conditional offer by procurator fiscal)

(**1**) 1995 c.46.

or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(**1**) (penalty as alternative to prosecution);

(e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;

(f) has been charged with an offence and is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board;

(g) has been subject to any investigation into his or her professional conduct by any licensing, regulatory or other body, where the outcome was adverse;

(h) is currently subject to any investigation into his or her professional conduct by any licensing, regulatory or other body;

(i) is to his or her knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;

(j) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to the supplier of appliance's removal from any list or equivalent list;

(k) is, or has been where the outcome was adverse, subject to an investigation into his or her professional conduct in respect of any current or previous employment; or

(l) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Local Health Board's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds

and if so, the supplier of appliances must give details of any investigation or proceedings which were or are to be brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(**1**) 1997 c.47.

(2) Subject to paragraph 26, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, he or she must in addition and at the same time supply in writing information to the Local Health Board as to whether the body corporate —

(a) has any criminal convictions in the United Kingdom;

(b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;

(c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board;

(d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;

(e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;

(f) is to his or her knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;

(g) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from any list or equivalent list; or

(h) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Local Health Board's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds,

and if so, he or she must give the name and registered office of the body corporate, and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

(4) A person need not supply information under sub-paragraph (1)(a) to (e) or (2)(a) or (b) if that information would not be included in an enhanced criminal record certificate issued to that person by the Secretary of State under section 113(B) of the Police Act 1997(**1**) (enhanced criminal record certificates) on the day on which that person supplies the information to the Local Health Board.

Duty to provide information about fitness to practise matters as they arise

19.—(1) Subject to paragraph 26, a supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, must, within 7 days of its occurrence, inform the Local Health Board in writing if it—

(a) is convicted of any criminal offence in the United Kingdom;

(b) is bound over following a criminal conviction in the United Kingdom;

(c) accepts a police caution in the United Kingdom;

(d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him or her absolutely (without proceeding to conviction);

(e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995 or a penalty under section 115A of the Social Security Administration Act 1992;

(f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;

(g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;

(h) is notified by any licensing, regulatory or other body of the outcome of any

(**1**) 1977 c.50.

investigation into his or her professional conduct, and there is a finding against him or her;

(i) becomes the subject of any investigation into his or her professional conduct by any licensing, regulatory or other body;

(j) becomes subject to an investigation into his or her professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him or her;

(k) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;

(l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from any list or equivalent list; or

(m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, any list, or equivalent list, on fitness to practise grounds,

and if so, the supplier of appliances must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 22, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, must in addition inform the Local Health Board within 7 days if any such body corporate —

(a) is convicted of any criminal offence in the United Kingdom;

(b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;

(c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;

(d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;

(e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;

(f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;

(g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from any list or equivalent list; or

(h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he or she must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Local Health Board of bodies corporate

20. Where a supplier of appliances is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 20 and 21 and 25(4)(a) and (b) must be provided to the Local Health Board in whose pharmaceutical list the supplier of appliances is included and to whom the supplier of appliances makes an application to be included in its pharmaceutical list.

Complaints

21. A supplier of appliances must have in place arrangements for the handling and consideration of complaints about any matter connected with the supplier of appliance's provision of pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004(**1**). In this paragraph "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the supplier of appliances.

(**1**) S.I. 2004/1768.

Directed Services

22. A supplier of appliances with whom a Local Health Board makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

Information to be supplied

23.—(1) A supplier of appliances must give notice to the relevant Local Health Board(s) within 28 days (or if this is impracticable, as soon as practicable thereafter) of —

(a) any occurrence requiring a change in the information recorded about the supplier of appliances in the pharmaceutical list which the supplier has not otherwise notified to the Local Health Board in accordance with these Regulations;

(b) in the case of a supplier of appliances who is an individual, any change to the name, registration number, telephone number, relating to their office of the body corporate or the name and address of any director of a body corporate; and

(c) in the case of a supplier of appliances that is a body corporate, any change to the address of his or her registered office;.

(2) A supplier of appliances must give the Local Health Board, if it so requests, the name of any registered pharmacist employed by the supplier who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (9), a supplier of appliances that is a body corporate must (if the supplier of appliances is on a pharmaceutical list on 1 April 2010, by 3 October 2010) supply to the supplier's Local Health Board in writing the name and address of each of its directors, and any changes to the names and addresses of each of its directors.

(4) Subject to sub-paragraph (7), if a supplier of appliances or the director of a supplier of appliances that is a body corporate is on, or is a director of a body corporate which is on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person must supply in writing to the Local Health Board —

(a) if he or she is a director of a body corporate, the name and registered office of the body corporate on the other NHS performers or providers list; and

(b) particulars of the other NHS performers or providers list.

(5) Subject to sub-paragraph (9), if a supplier of appliances or the director of a supplier of appliances that is a body corporate has in the five years prior to 1 April 2010 been on, or has in the five years prior to 1 April 2010 been the director of a body corporate which was when it was a director on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person must supply in writing to the Local Health Board —

(a) the name and registered office of the body corporate on the other NHS performers or providers list; and

(b) particulars of the NHS performers or providers list,

unless that information has already been supplied pursuant to sub-paragraph (4).

(6) Subject to sub-paragraph (7), if a supplier of appliances, or the director of a supplier of appliances that is a body corporate, must inform the Local Health Board —

(a) if he or she, or a body corporate of which he or she is a director, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application; and

(b) if he or she becomes a director of a body corporate which is on any of another Local Health Board's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(7) Where a supplier of appliances is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (6) may be provided only to the Local Health Board in which that registered office is located, if the supplier of appliances also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board —

(a) in whose pharmaceutical list the supplier of appliances is included; or

(b) to whom the supplier of appliances makes an application to be included in its pharmaceutical list, that requests it.

(8) In this paragraph, “NHS performers or providers list” means —

(a) a pharmaceutical list; or

(b) any other list.

Withdrawal from pharmaceutical lists

24. Where a supplier of appliances intends to withdraw from the pharmaceutical list in respect of particular premises, the supplier must notify the Local Health Board of this at least three months in advance of that date unless it is impracticable for the supplier to do so in which case it must notify the Local Health Board or as soon as it is practicable for the supplier to do so.

Charges for appliances

25. Subject to regulations made under section 121 of the 2006 Act, all appliances provided under these terms of service must be provided free of charge.

Inspections and access to information

26.—(1) A supplier of appliances must allow persons authorised in writing by the Local Health Board to enter and inspect any premises he or she uses for the provision of pharmaceutical services at any reasonable time, for the purposes of —

(a) ascertaining whether or not the supplier of appliances is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing —

(i) the provision made by the supplier of appliances, in the course of providing pharmaceutical services, for patient care and treatment including any arrangement made with a person in respect of provision of appliances, and

(ii) the management by the supplier of appliances of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that —

(a) reasonable notice of the intended entry has been given;

(b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the supplier of appliances;

(c) the person authorised in writing carries written evidence of his or her authorisation, which he or she produces on request; and

(d) he or she does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A supplier of appliances must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him or her access to any information which it or he or she reasonably requires —

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services."