

SCHEDULE 5

Regulation 5

Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of NHS appliance contractors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
 - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and 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
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010⁽¹⁾ (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by the NHS appliance contractor 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 an NHS appliance contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the NHS appliance contractor 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 NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by a person whom it employs or engages,

and references in this Schedule to an NHS appliance contractor 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. An NHS appliance contractor 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.2010/288 (W.37).

Dispensing of appliances

4.—(1) In this paragraph, “signed” (“*wedi ei llofnodi*”) 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) an NHS appliance contractor 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 NHS appliance contractor has previously arranged with the patient that he or she will dispense that prescription on receipt,

an NHS appliance contractor must, with reasonable promptness, provide such of the appliances so ordered as he or she supplies in the normal course of business.

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

- (a) the NHS appliance contractor has that prescription in his or her possession; and
- (b) that person presents, or the NHS appliance contractor has in his or her possession, an associated batch issue.

Urgent supply without a prescription

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

(2) The NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor to do so—

- (a) the NHS appliance contractor must give an estimate of the time when the appliance will be ready; and
- (b) if it is not ready by then, the NHS appliance contractor 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 NHS appliance contractor must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3 of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
 - (i) entitlement to exemption under regulation 8 of the Charges Regulations (exemptions), or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations and at the time of the declaration the NHS appliance contractor already has such evidence available to him or her;
 - (b) if, in the case of a non-electronic prescription form or a non-electronic repeatable prescription no satisfactory evidence, as required by paragraph (a), is produced to the NHS appliance contractor, the NHS appliance contractor 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 NHS appliance contractor must comply with any requirements of the ETP service to provide—
 - (i) a record of the exemption from or remission of charges claimed and whether satisfactory evidence was produced, as referred to in paragraph (a), and
 - (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

Providing appliances

7.—(1) Where an NHS appliance contractor is presented with a prescription form or a repeatable prescription, the NHS appliance contractor must 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,

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

(2) If the order is for an appliance of a type requiring measuring and fitting by the NHS appliance contractor, the NHS appliance contractor 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) An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) the NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor;
- (c) the NHS appliance contractor 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.

(2) An NHS appliance contractor must refuse to provide appliances ordered on a repeatable prescription where—

- (a) he or she has no record of that prescription;
- (b) he or she does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to him or her;
- (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) he or she 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), an NHS appliance contractor must 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, an NHS appliance contractor 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 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 NHS appliance contractor'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 NHS appliance contractor 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 NHS appliance contractor 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 may 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

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- (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, an NHS appliance contractor is unable to provide an appliance, or stoma appliance customisation is required and the NHS appliance contractor is unable to provide that, the NHS appliance contractor must—
 - (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS 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 NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

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) An NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), he or she must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to him or her.

(5) Where an NHS appliance contractor provides a telephone care line in respect of the dispensing of any specified appliance, he or she 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 the telephone care line.

(6) For the purposes of this paragraph—

“expert clinical advice” (“*cyngor clinigol arbenigol*”), 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” (“*cyfnodau y tu allan i oriau*”), in relation to each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, means the periods outside the periods during which the NHS appliance contractor is obliged to provide pharmaceutical services by virtue of paragraph 12.

Signposting

11.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within his or her normal course of business, the NHS appliance contractor must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS 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 NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to him or her.

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

- (a) auditing of the provision of pharmaceutical services by the NHS appliance contractor; 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) An NHS appliance contractor 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 Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 2A to the 1992 Regulations), that the NHS appliance contractor 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 Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Part 3 of Schedule 1), that the NHS appliance contractor 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 Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed under this Schedule that the NHS appliance contractor 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 NHS appliance contractor is required to provide pharmaceutical services by virtue of that direction, at the days on which and

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times at which the NHS appliance contractor 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 3 months notice of the proposed suspension.

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

(3) An NHS appliance contractor 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 NHS appliance contractor has undertaken to provide pharmaceutical services (including times at which he or she is providing pharmaceutical services when he or she is not obliged to do so by virtue of sub-paragraph (1)); and
- (b) the pharmaceutical services which the NHS appliance contractor ordinarily provides at each of those premises.

(4) Where an NHS appliance contractor changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which he or she has undertaken to provide pharmaceutical services; or
- (b) the pharmaceutical services which he or she is ordinarily to provide at those premises,

the NHS appliance contractor must supply the Local Health Board with a return informing it of the change.

(5) Subject to sub-paragraph (6), where an NHS appliance contractor is prevented by illness or other reasonable cause from complying with its obligations under sub-paragraph (1) the NHS appliance contractor must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists or providers of local pharmaceutical services under a pilot scheme whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) An NHS appliance contractor may make an arrangement with a provider of local pharmaceutical services under a pilot scheme under sub-paragraph (5) only where that provider provides local pharmaceutical services which are of a similar description, and a similar extent to, the pharmaceutical services which the NHS appliance contractor ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by an NHS appliance contractor for a reason beyond his or her control, the NHS appliance contractor will not be in breach of sub-paragraphs (1) and (2), provided that the NHS appliance contractor—

- (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 his or her control” 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, Easter Sunday 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” (“*oriau ychwanegol*”) for which an NHS appliance contractor is to be required to provide pharmaceutical services are those hours during which the NHS appliance contractor would not be providing pharmaceutical services, were the NHS appliance

contractor 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 an NHS appliance contractor, permit him or her a temporary change to the days on which or times at which he or she is obliged to provide pharmaceutical services at the premises from which he or she has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS appliance contractor gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by the NHS appliance contractor 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 the NHS appliance contractor's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS appliance contractor 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 the NHS appliance contractor.

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 an NHS appliance contractor 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 NHS appliance contractor is not providing pharmaceutical services.

(4) A Local Health Board may only direct that an NHS appliance contractor must provide pharmaceutical services at premises for more than 30 hours in any week if a Local Health Board is satisfied that the NHS appliance contractor 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

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(b) other likely users of the NHS appliance contractor's premises,
for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

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

- (a) give notice to the NHS appliance contractor 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 days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 2A to the 1992 Regulations, 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 days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 2A to the 1992 Regulations, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 12(1)(a), the premises must 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 NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 right of appeal of the NHS appliance contractor under sub-paragraph (7).

(7) An NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor of a determination under 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 an NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if he or she 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 he or she 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 NHS appliance contractor

15.—(1) An NHS appliance contractor 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 he or she is obliged to provide pharmaceutical services at his or her premises, in a way that—

- (a) reduces the total number of hours for which the NHS appliance contractor is obliged to provide pharmaceutical services each week; or
- (b) keeps that total number of hours the same.

(2) Where an NHS appliance contractor makes an application under sub-paragraph (1), as part of that application he or she 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 days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or the 1992 Regulations, would meet the requirements of sub-paragraphs (5) and (6); or
- (c) either—

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- (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or the 1992 Regulations, 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 12(1)(a), the premises must 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 NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor 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 right of appeal of the NHS appliance contractor under sub-paragraph (9).
- (9) An NHS appliance contractor 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 NHS appliance contractor 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 NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if he or she has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives a notification under sub-paragraph (4); or
- (b) if he or she has appealed under sub-paragraph (9), not earlier than 30 days after the date on which he or she receives his or her notification under sub-paragraph (11).

Clinical governance

16.—(1) An NHS appliance contractor must, in connection with all the services that he or she provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list he or she is included, in an acceptable system of clinical governance.

- (2) A system of clinical governance is “acceptable” if it provides for—
 - (a) compliance with the clinical governance components set out in sub-paragraph (3), and
 - (b) submission of an annual self assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.
- (3) The clinical governance components comprise of the following—
 - (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the NHS appliance contractor should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of each of the premises from which he or she provides pharmaceutical services,
 - (ii) a requirement that the NHS appliance contractor publicises the NHS services that are available at or from the premises from which the NHS appliance contractor provides services,
 - (iii) a requirement that where the NHS appliance contractor publicises the NHS services that are available at or from premises from which the NHS appliance contractor provides services (whether he or she is producing his or her own publicity material or advertising services in material published by another person), the NHS appliance contractor does so in a manner which makes clear that the services are funded as part of the health service,
 - (iv) a requirement that the NHS appliance contractor should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS appliance contractor intends to take,
 - (v) monitoring arrangements for appliances owed to patients but which are out of stock,
 - (vi) an approved complaints system (which meets the requirements of this Part),
 - (vii) a requirement that the NHS appliance contractor co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
 - (viii) a requirement that the NHS appliance contractor co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
 - (ix) monitoring arrangements for compliance with the Equality Act 2010(2);
 - (b) a clinical audit programme (normally of five days), which includes at least one premises-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year;

(2) 2010 c. 15.

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- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is handled in an appropriate way,
 - (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, which comprises of—
 - (aa) a patient safety incident log, and
 - (bb) a near-miss log,
 - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,
 - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (vi) appropriate waste disposal arrangements for clinical and confidential waste,
 - (vii) a clinical governance lead person for each of the premises from which the NHS appliance contractor provides services, who is knowledgeable about both the procedures of the NHS appliance contractor and the other NHS services that are available in the locality,
 - (viii) appropriate child protection procedures, and
 - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(3);
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS appliance contractor—
- (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 NHS appliance contractor, 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 the prescribing pattern relating to the patient in question;
- (e) a staffing and staff management programme, which includes—
- (i) arrangements for appropriate induction training for staff, including any locum,
 - (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 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 and any necessary accreditation in respect of the provision of directed services,
 - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and

(3) 1974 c. 37.

- (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum who, arising out of their employment with the NHS appliance contractor—
 - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996⁽⁴⁾ (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and
 - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;
- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment; and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the premises from which the NHS appliance contractor provides services which is designed to ensure, in a proportionate manner, that the risk to people at the premises of healthcare acquired infection is minimised, and
 - (ii) arrangements for there to be a clear separation between the areas of the premises which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

Professional Standards

17. An NHS appliance contractor 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 an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor 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 discount or rebate or otherwise) as an inducement to or in consideration of his or her presenting an order for appliances on a prescription form or repeatable prescription.

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

(3) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor may accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 9(2)(b), 10(4) or 11(1)(b); or

(4) 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

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- (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 9(2)(a) or 11(1)(a) and providing no additional service in connection with the item on that prescription.

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

19.—(1) Subject to paragraph 20, an NHS appliance contractor, and where the NHS appliance contractor is a body corporate every director of the body corporate, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS appliance contractor or a director—

- (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⁽⁵⁾ (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992⁽⁶⁾ (penalty as alternative to prosecution);
- (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 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 NHS Business Services Authority 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 a relevant list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness to practise grounds,

and if so, the NHS appliance contractor 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 20, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person 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;

⁽⁵⁾ 1995 c. 46.

⁽⁶⁾ 1992 c. 5.

- (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 a relevant list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness to practise grounds,

and if so, that person 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 an NHS appliance contractor is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 19 and 23(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 46). When the NHS appliance contractor provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS appliance contractor is included.

Complaints

21. An NHS appliance contractor must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

Directed Services

22. An NHS appliance contractor 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) An NHS appliance contractor must give written notice to the Local Health Board on whose pharmaceutical list he or she is included 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 NHS appliance contractor in the pharmaceutical list which the NHS appliance contractor has not otherwise notified to the Local Health Board in accordance with these Regulations;

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- (b) in the case of an NHS appliance contractor who is an individual, any change of his or her private address; and
 - (c) in the case of an NHS appliance contractor that is a body corporate, any change to the address of its registered office.
- (2) An NHS appliance contractor must give the Local Health Board, if it so requests, the name of any registered pharmacist employed by the NHS appliance contractor who is responsible for dispensing a particular prescription.
- (3) Subject to sub-paragraph (6), an NHS appliance contractor that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impractical, as soon as practicable thereafter) of any changes to the names and addresses of its directors.
- (4) Subject to sub-paragraph (6), if an NHS appliance contractor that is a body corporate appoints a director or superintendent that was not listed on the NHS appliance contractor's application for inclusion in a pharmaceutical list, the NHS appliance contractor must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.
- (5) Subject to sub-paragraph (6), an NHS appliance contractor or the director or superintendent of an NHS appliance contractor 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 or superintendent, 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 or superintendent of a body corporate which is on any of another Local Health Board's NHS performers or providers list, or which applies to be included in such a list, and the outcome of any such application.
- (6) Where an NHS appliance contractor is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS appliance contractor 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 NHS appliance contractor is included; or
 - (b) to whom the NHS appliance contractor makes an application to be included in its pharmaceutical list, that requests it.
- (7) In this paragraph, "NHS performers or providers list" (*"rhestr cyflawnwyr neu ddarparwyr GIG"*) means—
- (a) a pharmaceutical list; or
 - (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

Withdrawal from pharmaceutical lists

24. Where an NHS appliance contractor intends to withdraw from the pharmaceutical list in respect of particular premises, the NHS appliance contractor must notify the Local Health Board of this at least three months in advance of that date unless it is impracticable for the NHS appliance contractor to do so in which case the NHS appliance contractor must notify the Local Health Board as soon as it is practicable 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) An NHS appliance contractor 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 NHS appliance contractor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the NHS appliance contractor, 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 NHS appliance contractor 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 NHS appliance contractor;
- (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) An NHS appliance contractor 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.