

## SCHEDULE 5

Regulation 11(2)(a)(i)

### Terms of service of NHS appliance contractors

#### **Division of responsibilities between individuals and corporate bodies**

1.—(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 natural person—
  - (i) that person must comply with that requirement, or
  - (ii) if the NHS appliance contractor employs or engages other natural persons in connection with the provision of pharmaceutical services, the NHS appliance contractor must either comply with that requirement or secure compliance with that requirement by the other natural persons whom the NHS appliance contractor 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 the natural persons whom the NHS appliance contractor employs or engages in connection with the provision of pharmaceutical services.

(2) Where in this Schedule reference is made to an NHS appliance contractor—

- (a) being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or
- (b) forming a view,

that reference is to be construed, as referring, as appropriate to the NHS appliance contractor (if a natural person) or to the NHS appliance contractor's staff.

(3) References in this Schedule to an NHS appliance contractor are to be construed in accordance with sub-paragraphs (1) and (2).

#### **Breaches by directors**

2. Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, a breach of that requirement is to 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 ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

#### **Dispensing of appliances**

4.—(1) In this Part, “signed” includes signature with a prescriber’s advanced electronic signature.

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

- (a) any person presents to an NHS appliance contractor (C) a non-electronic prescription form which contains—
  - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or

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- (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”; or
- (b) C receives from the Electronic Prescription Service an electronic prescription form 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) C has previously arranged with the patient that C will dispense that prescription on receipt,

C must, with reasonable promptness, provide the appliance so ordered if C supplies it in the normal course of business.

- (3) Subject to the following provisions of this Schedule, where—
  - (a) any person presents to C 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”,and also presents an associated batch issue; or
  - (b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) or (ii) and—
    - (i) any person requests the provision of appliances in accordance with that prescription, or
    - (ii) C has previously arranged with the patient that the supplier will dispense that prescription on receipt,

C must, with reasonable promptness, provide such of the appliances so ordered as C 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) C has that prescription in the supplier’s possession; and
  - (b) that person presents, or C has in C’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 an NHS appliance contractor (C) to provide an appliance.

- (2) C 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 C 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) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

**Preliminary matters before providing appliances**

- 6.—(1) If a person specified in sub-paragraph (2) asks an NHS appliance contractor (C) to do so—
  - (a) C must give an estimate of the time when the appliance will be ready; and

- (b) if it is not ready by then, P must give a revised estimate of the time when it will be ready (until it is 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) C 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(1) or (1A) of the Charges Regulations<sup>(1)</sup> (supply of drugs and appliances by chemists) by virtue of either—
    - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations<sup>(2)</sup> (exemptions), or
    - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations<sup>(3)</sup> (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 sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) 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 C already has such evidence available to C;
  - (b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by paragraph (a), is produced to C, C 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, C must transmit to the Electronic Prescription Service—
    - (i) in a case where exemption from or remission of charges is claimed, a record of—
      - (aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case; and
      - (bb) whether or not satisfactory evidence was produced to C 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 an NHS appliance contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C 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,

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(1) Regulation 3 has been amended by [S.I. 2002/2352](#), [2003/1084](#), [2004/865](#), [2005/578](#), [2008/571](#), [2009/411](#), [2010/1727](#) and [2011/518](#).

(2) Regulation 7 has been amended by [S.I. 2000/3189](#), [2002/2352](#), [2004/696](#), [2005/578](#) and [2009/29](#).

(3) Regulation 5 has been amended by [S.I. 2004/663](#) and [936](#), [2006/562](#), [2008/1697](#) and [2009/411](#).

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subject to any regulations in force under the Weights and Measures Act 1985<sup>(4)</sup> and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting (for example a truss), C must make all necessary arrangements for—

- (a) measuring the person named on the prescription form 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 (C) may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) C reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription (for example because C reasonably believes it has been stolen or forged);
- (b) it appears to C 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 C’s clinical judgement;
- (c) C or other persons on the premises 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 an electronic prescription form or repeatable prescription, or by any person accompanying that person; or
- (d) the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) C must refuse to provide appliances ordered on a repeatable prescription where—

- (a) C has no record of that prescription (other than on the first occasion on which the prescription is presented);
- (b) C 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 6 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) C has been informed by the repeatable prescriber that the prescription is no longer required.

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(4) 1985 c. 72.

(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), C must only provide the appliance ordered if C is 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 (C) 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 patient's 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 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 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 C'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 prescription), 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 C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
- (i) if C 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;

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- (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 11.
- (2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, C is unable to provide an appliance, or stoma appliance customisation is required and C is unable to provide that, C 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 2 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 C.

#### **Additional requirements in relation to electronic prescribing**

- 10.—**(1) An NHS appliance contractor (C) must, if requested to do so by any person—
- (a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through C's appliance contractor premises; and
  - (b) where the Electronic Prescription Service is not available through C's appliance contractor premises, provide that person with the names of at least 2 NHS appliance contractors through whom the Electronic Prescription Service is available, if these details are known to C.
- (2) Where the Electronic Prescription Service is available through C's appliance contractor premises, C must, if requested to do so by any person, enter in that person's entry in the NHS Care Record—
- (a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; and
  - (b) where the person does have a nominated dispensing contractor—
    - (i) a replacement dispensing contractor, or
    - (ii) a further dispensing contractor,chosen by that person.
- (3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors would thereby exceed the maximum number permitted by the Electronic Prescription Service.
- (4) Regulation 102(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

### **Additional requirements in relation to specified appliances**

**11.**—(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 (C) 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) C 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), C 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 C 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 C is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), C must give the patient the contact details of at least 2 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 C.

(5) Where C provides a telephone care line in respect of the dispensing of any specified appliance, C 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 National Health Service Trust<sup>(5)</sup>, or website address of NHS Direct National Health Service Trust on line, 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 the appliance contractor premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

### **Signposting**

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

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; and

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(5) Established by [S.I. 2007/478](#).

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- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 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 C.
- (2) C 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 C; 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**

**13.—**(1) An NHS appliance contractor (C) must ensure that pharmaceutical services are provided at C’s appliance contractor premises—

- (a) for not less than 30 hours each week;
- (b) for not less than 100 hours per week, in the case of which a 100 hours condition (originally imposed under the 2005 Regulations) applies;
- (c) if a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 30 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;
- (d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided 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
- (e) if a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 30 hours each week, but only on set times and on set days as regards the additional opening hours—
  - (i) for the total number of hours each week required by virtue of that direction, and
  - (ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

but a Primary Care Trust 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) The hours during which appliance contractor premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as “core opening hours”.

(3) C must exhibit a notice specifying the days on which and times at which the appliance contractor premises are open for the provision of appliances.

(4) C must, on request, submit a return to the Primary Care Trust setting out—

- (a) the days on which and times at which pharmaceutical services are provided at C’s appliance contractor premises (including times at which C is providing pharmaceutical services when C is not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as “supplementary opening hours”); and
- (b) the pharmaceutical services which C ordinarily provides at those premises.

(5) Where C changes—

- (a) the supplementary opening hours of C's appliance contractor premises; or
- (b) the pharmaceutical services which C is ordinarily to provide at those premises,

C must supply the Primary Care Trust with a return informing it of the change.

(6) Where C has notified to a Primary Care Trust the days on which and the times at which pharmaceutical services are to be provided at C's appliance contractor premises (for example, in a return under sub-paragraph (4) or (5) or in an application for inclusion in a pharmaceutical list)—

- (a) C must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the time set out in that notification (unless the notification has been superseded by a return, or further return, under sub-paragraph (5)); and
- (b) C must not change—

- (i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours that are neither additional opening hours nor in total less than 30 (but if those core opening hours are additional opening hours, or are in total less than 30, regulation 65(5) to (7) and paragraphs 15 and 16 apply,
- (ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 15 and 16 apply to changes to the total number of core opening hours),
- (iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or
- (iv) the pharmaceutical services which P is ordinarily to provide at those premises,

for a period of at least 3 months after that notification was received by the Primary Care Trust, unless the Primary Care Trust agrees otherwise.

(7) Subject to sub-paragraph (8), where C is prevented by illness or other reasonable cause from complying with C's obligations under sub-paragraph (1), C must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists or LPS chemists whose premises are situated in the same area for the provision of pharmaceutical services or local pharmaceutical services during that time.

(8) C may only make an arrangement with an LPS chemist under sub-paragraph (7) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which C ordinarily provides.

(9) Where there is a temporary suspension in the provision of pharmaceutical services by C for a reason beyond the control of C, C is not in breach of sub-paragraphs (1) and (6), provided that—

- (a) C notifies the Primary Care Trust of that suspension as soon as practical; and
- (b) C uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(10) Planned refurbishment of appliance contractor premises is neither a "reasonable cause" for the purposes of sub-paragraph (7) nor a "reason beyond the control of C" for the purposes of sub-paragraph (9).

(11) 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 shall be 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.

(12) In this Schedule, the "additional opening hours", when they are required, are those hours during which C would not be providing pharmaceutical services, were C subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

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

14.—(1) Where a Primary Care Trust issues a direction setting any days or times under this Schedule, it shall 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 its area, or other likely users of the premises, for pharmaceutical services.

- (2) In considering the matters mentioned in sub-paragraph (1), the Primary Care Trust—
- (a) must treat any local pharmaceutical services being provided in its area 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 its area in circumstances where the person providing the services is not obliged to provide those services.

(3) The Primary Care Trust may only direct that an NHS appliance contractor (C) may provide pharmaceutical services at appliance contractor premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in its area are likely to be adequate to meet the need for such services at times when C is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65, the Primary Care Trust may only direct that C must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that C is to receive reasonable remuneration in respect of the additional opening hours for which C is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(2) in respect of those hours is “reasonable remuneration” for these purposes).

### **Determination of core opening hours instigated by the Primary Care Trust**

15.—(1) Where it appears to the Primary Care Trust, 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 appliance contractor premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—

- (a) people in its area; or
- (b) other likely users of the appliance contractor premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor (C) 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 Primary Care Trust must—
- (a) give notice to C of any proposed changes to the days on which or times at which the appliance contractor premises are to be open; and
  - (b) allow C 30 days within which to make written representations to the Primary Care Trust about the proposed changes.
- (3) After considering any representations made in accordance with sub-paragraph (2)(b), the Primary Care Trust must—
- (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
  - (b) confirm any existing direction in respect of the times at which C must provide pharmaceutical services at the appliance contractor premises, provided that the existing

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direction (whether issued under regulation 65, this Schedule, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5);

(c) either—

(i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises, whether issued under regulation 65, this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, or

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

in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(4) Where a Primary Care Trust issues a direction under sub-paragraph (3) in respect of appliance contractor premises that are to be required to be open—

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

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

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

but it shall not set out in that direction the days on which or times at which C is to provide pharmaceutical services during hours which are not additional opening hours; or

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

(5) The Primary Care Trust shall 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 Primary Care Trust shall notify C 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 shall include with the notification a statement of—

(a) the reasons for the change; and

(b) C's right of appeal under paragraph (7).

(7) C may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which C is to provide pharmaceutical services.

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under paragraph (3).

(9) The Secretary of State must notify C of the determination and shall in every case include with the notification a statement of the reasons for the determination.

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

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

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- (b) if C has appealed under sub-paragraph (7), not later than 8 weeks after the date on which C receives notification under sub-paragraph (9).
- (11) This paragraph does not apply where regulation 65(5) to (7) applies.

#### **Determination of core opening hours instigated by the NHS appliance contractor**

**16.**—(1) An NHS appliance contractor (C) may apply to a Primary Care Trust for it to change the days on which or times at which C is obliged to provide pharmaceutical services at C's premises, in a way that—

- (a) reduces the total number of hours for which C is obliged to provide pharmaceutical services each week (but not any of those required under a 100 hours condition); or
- (b) keeps that total number of hours the same.

(2) Where C makes an application under sub-paragraph (1), as part of that application C must provide the Primary Care Trust with such information as the Primary Care Trust may reasonably request in respect of any changes to the needs of the people in its area, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Primary Care Trust must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of C in accordance with sub-paragraph (2)).

(4) In determining the application, the Primary Care Trust must—

- (a) issue a direction (which replaces 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 C must provide pharmaceutical services at the premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2005 Regulations or the 1992 Regulations) 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 C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, the 2005 Regulations 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 whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(5) Where a Primary Care Trust issues a direction under sub-paragraph (4) in respect of appliance contractor 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 C must provide pharmaceutical services at the premises, and
  - (ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours,

but it shall not set out in that direction the days on which or times at which C is to provide pharmaceutical services during hours which are not additional opening 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 Primary Care Trust must not issue a direction under sub-paragraph (4) that has the effect simply of requiring appliance contractor 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 appliance contractor premises to be open for either more or less than 30 hours each week).
- (7) Where the Primary Care Trust 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 Primary Care Trust must notify C 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 C 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) C's right of appeal under sub-paragraph (9).
- (9) C may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State 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 Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under sub-paragraph (4).
- (11) The Secretary of State must notify C of the determination and must in every case include with the notification a statement of the reasons for the determination.
- (12) If the days on which or times at which C is to provide pharmaceutical services at appliance contractor premises have been changed in accordance with this paragraph, C must introduce the changes—
  - (a) if C has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (4); or
  - (b) if C has appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (11).
- (13) This paragraph does not apply where regulation 65(5) to (7) applies.

### **Temporary open hours and closures during an emergency requiring the flexible provision of pharmaceutical services**

- 17.—**(1) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, a Primary Care Trust may, on application from an NHS appliance contractor (C), permit C a temporary change to the days on which or times at which C is obliged to provide pharmaceutical services at appliance contractor premises, or permit temporary closure of those premises, if—
- (a) C gives at least 24 hours notice of the change or closure; and
  - (b) the reasons given by C for the request are, in the opinion of the Primary Care Trust, adequate reasons.
- (2) The Primary Care Trust need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that C's reasons are not, in its opinion, adequate reasons, then the days on which or times at which C 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 C.

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## Clinical governance

**18.**—(1) An NHS appliance contractor (C) must, in connection with the pharmaceutical services provided by C, participate, in the manner reasonably required by the Primary Care Trust, 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 Secretary of State and comprises the following components—

- (a) a patient and public involvement programme, which includes—
  - (i) a requirement that C 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 C publicises the NHS services that are available at or from C’s appliance contractor premises,
  - (iii) a requirement that C undertakes an approved patient satisfaction survey annually, in an approved manner,
  - (iv) C’s monitoring arrangements 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 C 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 C co-operates appropriately with any reasonable inspection or review that the Primary Care Trust or any relevant statutory authority wishes to undertake, and
  - (viii) C’s monitoring arrangements in respect of C’s compliance with the Equality Act 2010<sup>(6)</sup>;
- (b) a clinical audit programme (normally of 5 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,
  - (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 C’s appliance contractor premises,
  - (vii) the monitoring arrangements of the NHS appliance contractor in respect of the supplier’s compliance with the Health and Safety at Work etc. Act 1974<sup>(7)</sup>;
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by C—

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<sup>(6)</sup> 2010 c. 15.

<sup>(7)</sup> 1974 c. 37.

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- (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 C, 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 (including 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 engaged in the provision of NHS services,
    - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services, 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 Primary Care Trust as appropriate); and
  - (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 Primary Care Trust to access that assessment.
- (3) For the purposes of sub-paragraph (2), “approved” means approved by the Secretary of State.

### **Professional Standards**

**19.** 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 etc.**

**20.—(1)** An NHS appliance contractor (C) (including C’s staff) must not give, promise or offer to any person (X) 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—

- (a) presenting an order for appliances on a prescription form or repeatable prescription; or
  - (b) nominating C as X’s dispensing contractor (or one of them) in X’s entry in the NHS Care Record.
- (2) Promising, offering or providing a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).
- (3) C (including C’s staff) must not 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), 11(4) or 12(1)(b); or

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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 12(1)(a) and providing no additional service in connection with the item on that prescription.

### **Duty to provide information about fitness matters as they arise**

**21.**—(1) Subject to paragraph 23, an NHS appliance contractor (C) and, where C is a body corporate every director of C must, within 7 days of its occurrence, inform the Primary Care Trust in writing if they—

- (a) are convicted of any criminal offence in the United Kingdom;
- (b) are bound over following a criminal conviction in the United Kingdom;
- (c) accept a police caution in the United Kingdom;
- (d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);
- (e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(8)</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992<sup>(9)</sup> (penalty as alternative to prosecution);
- (f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;
- (i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;
- (j) become subject to an investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;
- (k) become the subject of any investigation by NHS BSA in relation to fraud;
- (l) become the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to their removal from a relevant list; or
- (m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and 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 23, if a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director of a body corporate, X must in addition inform the Primary Care Trust within 7 days if any such body corporate—

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(8) 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; and the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1).

(9) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and has been amended by the Social Security Fraud Act 2001 (c. 11), section 14.

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (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 by the NHS BSA 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 Primary Care Trust or other primary care organisation which might lead to its removal from any relevant list; or
- (h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and X 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) C or X must consent to a request being made by the Primary Care Trust 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.

#### **Other information to be supplied**

**22.**—(1) An NHS appliance contractor (C) must give notice to the Primary Care Trust within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about C in the pharmaceutical list which C has not otherwise notified to the Primary Care Trust in accordance with these Regulations;
- (b) if C is an individual, any change of C's private address;
- (c) if C is a body corporate, any change to the name, registered number, registered office, telephone number relating to that office of the body corporate or the name and address of any director of the body corporate; and
- (d) any occurrence requiring C's addition to or removal from the EPS list or a change in the information recorded about C in that list.

(2) C must give the Primary Care Trust, if it so requests, the name of any pharmacist employed or engaged by C who is responsible for dispensing a particular prescription.

(3) Subject to paragraph 23, if C is a body corporate, it must give notice to the Primary Care Trust within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors.

(4) Subject to paragraph 23, if C is a body corporate and appoints a director who was not listed on C's application for inclusion on a pharmaceutical list, C must, within 30 days of the person's appointment, supply to the Primary Care Trust the information mentioned in paragraphs 3 and 4 of Schedule 2 about that person.

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(5) Subject to paragraph 23, if C or a director of C (if C is a body corporate) is on, or is a director of a body corporate which is on, a relevant list other than the Primary Care Trust's pharmaceutical list, they must supply in writing to the Primary Care Trust—

- (a) in the case of a director of a body corporate, the name and registered office of the body corporate on the other relevant list; and
- (b) particulars of the other relevant list.

(6) Subject to paragraph 23, C or a director C (if C is a body corporate) must inform the Primary Care Trust—

- (a) if they, or a body corporate of which they are a director, apply to be included in a relevant list other than the Primary Care Trust's pharmaceutical list, and of the outcome of any such application; and
- (b) if they become a director of another body corporate which is on the relevant list of another Primary Care Trust, or which applies to be included in such a list, and the outcome of any such application.

### **Home Primary Care Trust of bodies corporate**

**23.** Where an NHS appliance contractor (C) is a body corporate with a registered office in England, the information to be provided under paragraphs 21 and 22(3) to (6) may be provided instead to C's home Primary Care Trust, if C, when C provides the information to the home Primary Care Trust, also provides the home Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists C is included.

### **Complaints**

**24.—(1)** An NHS appliance contractor must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009<sup>(10)</sup>, for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

### **Inspections and access to information**

**25.—(1)** An NHS appliance contractor (C) must allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises C uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not C is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by C, 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 C of the pharmaceutical services C 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 C;

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<sup>(10)</sup> S.I. 2009/309; amended by S.I. 2009/1768.

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- (c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and
  - (d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.
- (3) C must, at the request of the Primary Care Trust or of X, allow it or X access to any information which it or X reasonably requires—
- (a) for the purposes mentioned in sub-paragraph (1); or
  - (b) in the case of the Primary Care Trust, in connection with its functions that relate to pharmaceutical services.