

## SCHEDULE 3

Regulation 3(c)

### TERMS OF SERVICE OF SUPPLIERS OF APPLIANCES

#### **Incorporation of provisions**

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

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists appliances for the purposes of section 41 of the Act;
- (c) so much of Part II of the National Health Service (Service Committees and Tribunal) Regulations 1992(1) as relates to—
  - (i) the investigation of questions arising between suppliers of appliances and persons receiving pharmaceutical services and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Primary Care Trust as a result of such investigations, and
  - (ii) appeals to the Secretary of State from decisions of the Primary Care Trust; and
- (d) so much of regulation 3 of the Patients' Forums (Functions) Regulations 2003(2) as relate to the entry and inspection of premises either owned or controlled by the supplier of appliances or where pharmaceutical services are provided by him.

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

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

- (a) if the supplier of appliances is a registered pharmacist—
  - (i) that registered pharmacist must comply with that requirement, or
  - (ii) if he 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 employs or engages; and
- (b) if the supplier of appliances is not a natural person, that supplier of appliances must secure compliance with that requirement by a person whom he employs or engages,

and references in this Schedule to a supplier of appliances shall 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 shall be deemed to be a breach by the body corporate of its terms of service.

#### **Dispensing services**

**3.** A supplier of appliances shall, to the extent that paragraphs 4 to 7 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 in the health service, the Scottish health service or the Northern Ireland health service.

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(1) S.I. 1992/664.

(2) S.I. 2003/2124. Regulation 3 has been amended by S.I. 2004/540, 696 and 865.

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### **Dispensing of appliances**

- 4.—(1) In this paragraph, “signed” includes signature with a prescriber’s electronic signature.
- (2) Subject to paragraphs 5 to 7, 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”; or
  - (b) a supplier of appliances receives from the ETP 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) the supplier of appliances has previously arranged with the patient that he will dispense that prescription on receipt,
- a supplier of appliances shall, with reasonable promptness, provide the appliance so ordered if he supplies it in the normal course of his business.

### **Preliminary matters before providing appliances**

- 5.—(1) If the person presenting the non-electronic prescription form or requesting the provision of an appliance in accordance with an electronic prescription form asks the supplier of appliances to do so—
- (a) the supplier of appliances shall give an estimate of the time when the appliance will be ready; and
  - (b) if it is not ready by then, the supplier of appliances shall give a revised estimate of the time when it will be ready (and so on).
- (2) Before providing an appliance in accordance with a prescription form—
- (a) the supplier of appliances shall ask any person who makes a declaration that the person named on the prescription form does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations by virtue of either—
    - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations, or
    - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of 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 the supplier of appliances already has such evidence available to him;
  - (b) if, in the case of a non-electronic prescription form, no satisfactory evidence, as required by sub-paragraph (a), is produced to the supplier of appliances, the supplier of appliances shall endorse the form on which the declaration is made to that effect; and
  - (c) in the case of an electronic prescription form, the supplier of appliances shall transmit to the ETP 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 him 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**

6.—(1) Where a supplier of appliances is presented with a non-electronic prescription form or receives a prescription form from the ETP service, the supplier of appliances shall only provide the drugs or 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,

subject to any regulations in force under the Weights and Measures Act 1985<sup>(3)</sup> and the following provisions of this Part.

(2) If the order is for an appliance of a type requiring measuring and fitting by the supplier of appliances (for example a truss) the supplier of appliances shall 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 shall comply with the standard or formula specified therein.

### **Refusal to provide appliances ordered**

7. A supplier of appliances may refuse to provide an appliance ordered on a prescription form where—

- (a) the supplier of appliances reasonably believes that it is not a genuine order for the person named on the prescription form (for example because he reasonably believes it has been stolen or forged);
- (b) it appears to the supplier of appliances that there is an error on the prescription form (including a clinical error made by the prescriber);
- (c) the supplier of appliances or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form 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 any other person accompanying that person, commits or threatens to commit a criminal offence.

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

8. In connection with the services provided under paragraph 3, a supplier of appliances shall—

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(3) 1985 c. 72.

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- (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) 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;
- (d) keep and maintain records—
  - (i) of appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient,
  - (ii) in appropriate cases, of advice given and any interventions or referrals made, and
  - (iii) of notes provided under sub-paragraph (c); and
- (e) if he provides an appliance under an electronic prescription form, provide the patient, if he so requests, with a written record of the appliances ordered on that prescription.

**Additional requirements in relation to electronic prescribing**

- 9.—(1) A supplier of appliances shall, if requested to do so by any person—
- (a) explain to him the ETP service, whether or not it is a service which is available through him; and
  - (b) where the ETP service is not available through him, provide him with the names of at least two suppliers of appliances through whom the ETP service is available, if these details are known to the supplier of appliances.
- (2) Where the ETP service is available through him, the supplier of appliances shall, if requested to do so by any person, enter in that person’s 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) shall not apply if the number of nominated dispensing contractors would thereby exceed the maximum number permitted by the ETP service.
- (4) Regulation 72(a) to (c) shall apply to a request under this paragraph as it applies to an application to a chemist for pharmaceutical services.

**Opening hours: general**

- 10.—(1) A supplier of appliances shall ensure that pharmaceutical services are provided at each of the premises from which he has undertaken to provide pharmaceutical services—
- (a) for not less than 30 hours each week;
  - (b) for not less than 100 hours each week, in the case of premises in respect of which the condition imposed by regulation 13(2)(a) applies as regards the supplier of appliances' inclusion in a pharmaceutical list;
  - (c) if his Primary Care Trust, or on appeal the Secretary of State, has directed (either under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations) that he may provide

pharmaceutical services at the premises for fewer than 30 hours per week, provided that he provides those services at set times and on set days, at the times and on the days so set;

- (d) if his Primary Care Trust, or on appeal the Secretary of State, has directed under paragraph 4 of Schedule 2 to the 1992 Regulations, that he 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
- (e) if his Primary Care Trust, or on appeal the Secretary of State, has directed under this Schedule that he 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 he is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which he is required to provide pharmaceutical services during those additional 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 three months notice of the proposed suspension.

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

(3) A supplier of appliances shall, 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 each of the premises from which he has undertaken to provide pharmaceutical services (including times at which he is providing pharmaceutical services when he is not obliged to do so by virtue of sub-paragraph (1)); and
- (b) the pharmaceutical services which he ordinarily provides at each of those premises.

(4) Where a supplier of appliances changes—

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

he shall supply the Primary Care Trust with a return informing it of the change.

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

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

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

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

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

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday or a bank holiday, it 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.

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

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

**11.**—(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 the neighbourhood, 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) shall 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 Primary Care Trust may only direct that a supplier of appliances may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood is likely to be adequate to meet the need for such services at times when the supplier of appliances is not providing pharmaceutical services.

(4) A Primary Care Trust may only direct that a supplier of appliances must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that it will receive reasonable remuneration in respect of the additional hours for which he 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 Primary Care Trust**

**12.**—(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 premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of—

- (a) people in the neighbourhood; or
- (b) other likely users of his premises,

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

(2) Before concluding the assessment under sub-paragraph (1) the Primary Care Trust shall—

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

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- (b) allow him 60 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 shall—
  - (a) issue a direction (which will replace 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 the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2 to the 1992 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph;
  - (c) either—
    - (i) revoke (without replacing it) any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, whether issued under this Schedule or paragraph 4 of Schedule 2 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 10(1)(a), the premises will need to be open for not less than 30 hours each week.
- (4) Where a Primary Care Trust 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 shall set out in that direction—
    - (i) the total number of hours each week for which the supplier of appliances shall provide pharmaceutical services at the premises, and
    - (ii) as regards the additional hours for which he is to provide pharmaceutical services, the days on which and the times at which he is required to provide those services during those additional hours,but it shall not set out in that direction the days on which or times at which he is to provide pharmaceutical services during hours which are not additional 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 the supplier of appliances in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the supplier of appliances is to provide pharmaceutical services at the premises, it shall include with the notification a statement in writing of—
  - (a) the reasons for the change; and
  - (b) the supplier of appliances' right of appeal under paragraph (7).
- (7) A supplier of appliances 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 the supplier of appliances is to provide pharmaceutical services.

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(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 shall notify the supplier of appliances in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

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

- (a) if he has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (6); or
- (b) if he has appealed under sub-paragraph (7), not later than 8 weeks after the date on which he receives his notification under sub-paragraph (9).

#### **Determination of opening hours instigated by the supplier of appliances**

**13.**—(1) A supplier of appliances may apply to a Primary Care Trust for it to change the days on which or times at which he is obliged to provide pharmaceutical services at his premises, in a way that—

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

(2) Where a supplier of appliances makes an application under sub-paragraph (1), as part of that application he shall 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 the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Primary Care Trust shall 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 Primary Care Trust shall—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;
- (b) confirm any existing direction in respect of the times at which the supplier of appliances must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or paragraph 4 of Schedule 2 to 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 the supplier of appliances must provide pharmaceutical services at the premises, whether issued under this Schedule or paragraph 4 of Schedule 2 to 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 10(1)(a), the premises will need to be open for not less than 30 hours each week.

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

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

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

(6) The Primary Care Trust shall 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 Primary Care Trust is considering taking action under sub-paragraph (4)(a) or (c) (i), it shall consult the Local Pharmaceutical Committee before determining the application.

(8) A Primary Care Trust shall notify the supplier of appliances in writing 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 shall send the supplier of appliances a statement in writing setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
- (b) the supplier of appliances' right of appeal under sub-paragraph (9).

(9) A supplier of appliances may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal 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 shall notify the supplier of appliances in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

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

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

## **Professional Standards**

**14.** A supplier of appliances shall 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.

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### **Inducements etc.**

**15.**—(1) A supplier of appliances or his staff shall not 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—

- (a) presenting an order for appliances on a prescription form; or
- (b) nominating the supplier of appliances as his dispensing contractor (or one of them) in his 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).

### **Duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1st April 2005**

**16.**—(1) In the case of a supplier of appliances who is on a pharmaceutical list on 1st April 2005, subject to paragraph 18, the supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, shall, by 3rd October 2005, supply in writing information to the Primary Care Trust as to whether he—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(4)</sup> (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992<sup>(5)</sup> (penalty as alternative to prosecution);
- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) has been charged with an offence and is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing, regulatory or other body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing, regulatory or other body;
- (i) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list;
- (k) is, or has been where the outcome was adverse, subject to an investigation into his professional conduct in respect of any current or previous employment; or
- (l) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds

<sup>(4)</sup> 1995 c. 46.

<sup>(5)</sup> 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).

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

(2) Subject to paragraph 18, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, he shall in addition and at the same time supply in writing information to the Primary Care Trust as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (g) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds,

and if so, he shall 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 shall 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.

(4) A person need not supply information under sub-paragraph (1)(a) to (e) or (2)(a) or (b) if that information would not be included in an enhanced criminal record certificate issued to that person by the Secretary of State under section 115(1) of the of the Police Act 1997<sup>(6)</sup> (enhanced criminal record certificates) on the day on which that person supplies the information to the Primary Care Trust.

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

17.—(1) Subject to paragraph 18, a supplier of appliances, and where the supplier of appliances is a body corporate every director of the supplier of appliances, shall, within 7 days of its occurrence, inform the Primary Care Trust in writing if he—

- (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 absolutely (without proceeding to conviction);

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(6) 1997 c. 50.

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- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995 or a penalty under section 115A of the Social Security Administration Act 1992;
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into his professional conduct, and there is a finding against him;
- (i) becomes the subject of any investigation into his professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his 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;
- (k) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (l) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, any list, or equivalent list, on fitness to practise grounds,

and if so, he shall 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 18, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, he shall in addition inform the Primary Care Trust within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence;
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service 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 equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall 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 shall 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.

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

**18.** Where a supplier of appliances is a body corporate with a registered office in England, the information to be provided under paragraphs 16 and 17 may be provided only to the Primary Care Trust in which that registered office is located, if the supplier of appliances also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

- (a) in whose pharmaceutical list the supplier of appliances is included; or
- (b) to whom the supplier of appliances makes an application to be included in its pharmaceutical list,

that requests it.

### **Complaints**

**19.** A supplier of appliances shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004(7).

### **Directed Services**

**20.—(1)** A supplier of appliances with whom a Primary Care Trust makes an arrangement for the provision of any directed services shall comply with the terms and conditions of the arrangement.

(2) Where, by virtue of regulation 13(3)(b), it is a condition of a supplier of appliances' inclusion in a pharmaceutical list that he provides specified directed services where requested to do so by the Primary Care Trust, that supplier of appliances shall comply with any such request within such period as the Primary Care Trust may specify.

### **Information to be supplied**

**21.—(1)** A supplier of appliances shall give notice to the Primary Care Trust 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 him in the pharmaceutical list which he has not otherwise notified to him in accordance with these Regulations;
- (b) in the case of a supplier of appliances who is an individual, any change of his private address;
- (c) in the case of a supplier of appliances that is a body corporate, any change to the address of his registered office; and
- (d) any occurrence requiring his addition to or removal from the ETP list or a change in the information recorded about him in that list.

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(7) [S.I. 2004/1768](#); *see also* regulation 4 of those Regulations which imposes a requirement on Primary Care Trusts to ensure that suppliers of appliances have such arrangements in place.

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(2) A supplier of appliances shall give the Primary Care Trust, if it so requests, the name of any registered pharmacist employed by him who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (7), a supplier of appliances that is a body corporate shall (if he is on a pharmaceutical list on 1st April 2005, by 3rd October 2005) supply to his Primary Care Trust in writing the name and address of each of his directors, and any changes to the names and addresses of each of its directors.

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

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

(5) Subject to sub-paragraph (7), if a supplier of appliances or the director of a supplier of appliances that is a body corporate has himself in the five years prior to 1st April 2005 been on, or has in the five years prior to 1st April 2005 been the director of a body corporate which was when he was a director on, another NHS performers or providers list (that is, on a list other than the pharmaceutical list referred to in sub-paragraph (1)), that person shall supply in writing to the Primary Care Trust—

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

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

(6) Subject to sub-paragraph (7), if a supplier of appliances, or the director of a supplier of appliances that is a body corporate, shall inform the Primary Care Trust—

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

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

- (a) in whose pharmaceutical list the supplier of appliances is included; or
- (b) to whom the supplier of appliances makes an application to be included in its pharmaceutical list,

that requests it.

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

- (a) a pharmaceutical list; or
- (b) any other list.

### **Withdrawal from pharmaceutical lists**

**22.** Where a supplier of appliances intends to withdraw from the pharmaceutical list in respect of particular premises, he shall notify the Primary Care Trust of this—

- (a) at least three months in advance of that date; or
- (b) in the case of a supplier of appliances in respect of whom a condition is imposed by virtue of regulation 13(2)(a) as regards those premises, at least six months in advance of that date,

unless it is impracticable for him to do so in which case he shall notify the Primary Care Trust as soon as it is practicable for him to do so.

### **Charges for appliances**

**23.** Subject to regulations made under section 77 of the Act, all appliances provided under these terms of service shall be provided free of charge.

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

**24.—(1)** A supplier of appliances shall allow persons authorised in writing by the Primary Care Trust to enter and inspect any premises he uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the supplier of appliances is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by the supplier of appliances, in the course of providing pharmaceutical services, for patient care and treatment, and
  - (ii) the management by the supplier of appliances of the pharmaceutical services he provides,

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

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the supplier of appliances;
- (c) the person authorised in writing carries written evidence of his authorisation, which he produces on request; and
- (d) he does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A supplier of appliances shall, at the request of the Primary Care Trust or of a person authorised in writing mentioned in sub-paragraph (1), allow it or him access to any information which it or he 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.