
STATUTORY INSTRUMENTS

2009 No. 3340

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical Services)
(Appliances) (Amendment) Regulations 2009**

<i>Made</i>	- - - -	<i>16th December 2009</i>
		<i>22nd December</i>
<i>Laid before Parliament</i>		<i>2009</i>
<i>Coming into force</i>	- -	<i>1st April 2010</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126, 129 and 272(7) and (8) of the National Health Service Act 2006(1).

PART 1

Introduction

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Appliances) (Amendment) Regulations 2009 and come into force on 1st April 2010.

(2) These Regulations apply in relation to England.

(3) In these Regulations, the “principal Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(2).

PART 2

New definitions in the principal Regulations

Amendment of regulation 2

2. In regulation 2(1)(3) (interpretation) of the principal Regulations, in the appropriate alphabetical position, insert—

(1) 2006 c.41. See section 275(1) of the Act for the definitions of “prescribed” and “regulations” which are relevant to the powers being exercised in the making of these Regulations.
(2) S.I.2005/641.
(3) Amended by S.I. 2005/1501 and 3491, 2006/552, 562, 913, 1501 and 3373, 2007/289 and 674, 2008/528 and 2009/2205.

““appliance use review service” means arrangements made in accordance with section 127 of the 2006 Act for a pharmacist or specialist nurse to review a person’s use of any specified appliance;”;

““specified appliance” means—

- (a) any of the following appliances listed in Part IXA of the Drug Tariff—
 - (i) a catheter appliance (including a catheter accessory and maintenance solution),
 - (ii) a laryngectomy or tracheostomy appliance,
 - (iii) an anal irrigation system,
 - (iv) a vacuum pump or constrictor ring for erectile dysfunction, or
 - (v) a wound drainage pouch;
- (b) an incontinence appliance listed in Part IXB of the Drug Tariff; or
- (c) a stoma appliance listed in Part IXC of the Drug Tariff;”;

““stoma appliance customisation” means the customisation of a quantity of more than one stoma appliance, where—

- (a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;
- (b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and
- (c) that modification is based on the patient’s measurements or a record of those measurements and, if applicable, a template;”;

““supplier of appliances” means a person with whom a Primary Care Trust has entered into arrangements for the provision of pharmaceutical services, being arrangements which are incorporated into terms of service as a consequence of regulation 3(c);”.

PART 3

Amendments to the terms of service of pharmacists

Amendments to Schedule 1 to the principal Regulations

- 3. Schedule 1 to the principal Regulations is amended in accordance with regulations 4 to 11.

Amendment of paragraph 6

- 4. For paragraph 6 substitute—

“Urgent supply without a prescription

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

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

- (a) in the case of a request for a drug, the drug is neither—
 - (i) a Scheduled drug, nor

- (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971(4), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(5); and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
 - (i) give the pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
 - (ii) transmit an electronic prescription to the ETP service within 72 hours of the request being made.”.

Amendment of paragraph 9

5. In paragraph 9 (refusal to provide drugs or appliances ordered), in sub-paragraph (4)(b), after “the medication regimen of” insert “, or manner of utilisation of the appliance by,”.

Amendment of paragraph 10

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

- (2) Renumber the existing provision as sub-paragraph (1).
- (3) In that sub-paragraph—
 - (a) for paragraph (c) substitute—
 - “(c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;
 - (ca) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
 - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (e) in respect of the provision of appliances and prescribing pattern relating to the patient in question;”;
 - (b) omit “and” at the end of paragraph (l); and
 - (c) after paragraph (m) insert—
 - “(n) when providing appliances, provide a patient with a written note of the pharmacist’s name, address and telephone number; and
 - (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11A.”.
- (4) After sub-paragraph (1) insert—
 - “(2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, a pharmacist is unable to provide an appliance, or stoma appliance customisation is required and the pharmacist is unable to provide that, the pharmacist shall—

(4) 1971 c. 38.

(5) S.I. 2001/3998; Schedule 4 was amended by S.I. 2003/1432, 2005/3372 and 2007/2154, and Schedule 5 was amended by S.I. 2005/2864.

- (a) if the patient consents, refer the prescription form or repeatable prescription to another pharmacist or to a supplier of appliances; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.”.

Insertion of new paragraph 11A

7. After paragraph 11 insert—

“Additional requirements in relation to specified appliances

11A.—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(o) relating to the provision of specified appliances.

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

- (a) the pharmacist must offer to deliver the specified appliance to the patient’s home;
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

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

- (a) shall ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or
- (b) if the pharmacist believes it is appropriate to do so, shall—
 - (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.

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

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

- (a) advice is made available to patients through that telephone care line; or
- (b) the telephone number of NHS Direct National Health Service Trust⁽⁶⁾, or the website address of NHS Direct National Health Service Trust on line, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

(6) Established by the NHS Direct National Health Service Trust (Establishment) Order 2007 (S.I. 2007/478).

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

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

- (a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 22(1) or 25A(1); or
- (b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 22(1A).”.

Amendment of paragraph 19

8.—(1) Amend paragraph 19 (service outline in respect of signposting) as follows.

(2) After sub-paragraph (1) insert—

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

- (a) if the patient consents, refer the prescription form or repeatable prescription to another pharmacist or to a supplier of appliances; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.”.

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

Amendment of paragraph 26

9. In paragraph 26(7) (clinical governance), in sub-paragraph (2), for paragraph (d) substitute—

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

- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
- (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
- (iii) to people caring for themselves or their families,

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

Amendment of paragraph 28

10. After paragraph 28(5)(8) (inducements etc.) insert—

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

(7) Amended by S.I. 2008/528 and 683.

(8) Sub-paragraphs (3) to (5) of paragraph 28 were inserted by S.I. 2009/2205.

- (a) providing contact details of alternative pharmacists or suppliers of appliances pursuant to paragraph 10(2)(b), 11A(4) or 19(1A)(b); or
- (b) referring a prescription form or repeatable prescription to another pharmacist or supplier of appliances pursuant to paragraph 10(2)(a) or 19(1A)(a) and providing no additional service in connection with the item on that prescription.”.

Amendment of paragraph 37

11. In paragraph 37(1) (inspections and access to information), in paragraph (b)(i), after “patient care and treatment,” insert “including any arrangement made with a person in respect of provision of appliances,”.

PART 4

Amendments to the terms of service of suppliers of appliances

Amendments to Schedule 3 to the principal Regulations

12. Schedule 3 to the principal Regulations is amended in accordance with regulations 13 to 22.

Amendment of paragraph 4

13.—(1) Amend paragraph 4 (dispensing of appliances) as follows.

(2) In sub-paragraph (2), for “paragraphs 5 to 7” substitute “the following provisions of this Schedule”.

(3) After sub-paragraph (2) insert—

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

- (a) any person presents a non-electronic repeatable prescription which contains—
 - (i) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a repeatable prescriber and including the reference “SLS”,and also presents an associated batch issue; or
- (b) a supplier of appliances receives from the ETP 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) the supplier of appliances has previously arranged with the patient that the supplier will dispense that prescription on receipt,

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

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

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

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

Insertion of new paragraph 4A

14. After paragraph 4 insert—

“Urgent supply without a prescription

4A.—(1) This paragraph applies where, in a case of urgency, a prescriber requests a supplier of appliances to provide an appliance.

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

- (a) give the supplier of appliances a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or
- (b) transmit an electronic prescription to the ETP service within 72 hours of the request being made.”.

Amendment of paragraph 5

15.—(1) Amend paragraph 5 (preliminary matters before providing appliances) as follows.

(2) In sub-paragraph (1), for the words from “If the person” to “an electronic prescription form” substitute “If a person specified in sub-paragraph (1A)”.

(3) After sub-paragraph (1) insert—

“(1A) 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.”.

(4) In sub-paragraph (2)—

- (a) after “in accordance with a prescription form” insert “or repeatable prescription”;
- (b) in paragraph (a), after “named on the prescription form” insert “or repeatable prescription”;
- (c) in paragraph (b), after “in the case of a non-electronic prescription form” insert “or non-electronic repeatable prescription”; and
- (d) in paragraph (c), after “in the case of an electronic prescription form” insert “or an electronic repeatable prescription”.

Amendment of paragraph 6

16.—(1) Amend paragraph 6 (providing appliances) as follows.

(2) For sub-paragraph (1) substitute—

“(1) Where a supplier of appliances is presented with, or receives from the ETP service, a prescription form or a repeatable prescription, the supplier of appliances shall only provide the appliances so ordered—

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

(b) in accordance with the order on the prescription form or repeatable prescription, subject to any regulations in force under the Weights and Measures Act 1985⁽⁹⁾ and the following provisions of this Schedule.”.

(3) In sub-paragraph (2)(a), after “named on the prescription form” insert “or repeatable prescription”.

Amendment of paragraph 7

17.—(1) Amend paragraph 7 (refusal to provide appliances ordered) as follows.

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

(3) In that sub-paragraph—

(a) after “ordered on a prescription form” insert “or repeatable prescription”;

(b) in paragraph (a), after “the prescription form” insert “or repeatable prescription”;

(c) for paragraph (b), substitute—

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

(d) in paragraphs (c) and (d)—

(i) after each reference to “the prescription form” insert “or repeatable prescription”, and

(ii) after each reference to “an electronic prescription form” insert “or repeatable prescription”.

(4) After sub-paragraph (1) insert—

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

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

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

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

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

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

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

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

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

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

(9) 1985 c. 72.

- (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.”

Amendment of paragraph 8

18.—(1) Amend paragraph 8 (further activities to be carried out in connection with the provision of dispensing services) as follows.

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

(3) In that sub-paragraph, for paragraphs (c) to (e) substitute—

“(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 the supplier’s name, address and telephone number;

(f) keep and maintain records—

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

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

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

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

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

(i) if the supplier provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;

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

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

- (i) which are not required, or
 - (ii) where a patient is refused an appliance pursuant to paragraph 7;
 - (l) ensure that where a person is refused appliances pursuant to paragraph 7(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 7(3); and
 - (o) when providing specified appliances, comply with the additional requirements set out in paragraph 9A.”.
- (4) After sub-paragraph (1) insert—
- “(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, a supplier of appliances is unable to provide an appliance, or stoma appliance customisation is required and the supplier of appliances is unable to provide that, the supplier of appliances shall—
- (a) if the patient consents, refer the prescription form or repeatable prescription to another supplier of appliances or to a pharmacist; or
 - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the supplier.”.

Insertion of new paragraphs 9A and 9B

19. After paragraph 9 insert—

“Additional requirements in relation to specified appliances

9A.—(1) This paragraph sets out the additional requirements referred to in paragraph 8(1)(o) relating to the provision of specified appliances.

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

- (a) the supplier of appliances must offer to deliver the specified appliance to the patient’s home;
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

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

- (a) shall ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or
- (b) if the supplier of appliances believes it is appropriate to do so, shall—

- (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.
- (4) If the supplier of appliances is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the supplier must give the patient the contact details of at least two people who are pharmacists or suppliers of appliances who are able to arrange for the service to be provided, if these details are known to the supplier of appliances.
- (5) Where a supplier of appliances provides a telephone care line in respect of the dispensing of any specified appliance, the supplier shall ensure that during out of hours periods—
- (a) advice is made available to patients through that telephone care line; or
 - (b) the telephone number of NHS Direct National Health Service Trust, 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 each of the premises from which a supplier of appliances has undertaken to provide pharmaceutical services, means the periods outside the periods during which the supplier of appliances is obliged to provide pharmaceutical services by virtue of paragraph 10 or 13A.

Signposting

- 9B.**—(1) Where, on presentation of a prescription form or repeatable prescription, a supplier of appliances is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the supplier’s normal course of business, the supplier of appliances shall—
- (a) if the patient consents, refer the prescription form or repeatable prescription to another supplier of appliances or to a pharmacist; and
 - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are pharmacists or suppliers of appliances who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the supplier.
- (2) The supplier of appliances shall, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record shall be in a form that facilitates—
- (a) auditing of the provision of pharmaceutical services by the supplier of appliances; and
 - (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.”.

Insertion of new paragraph 13A

- 20.** After paragraph 13 insert—

“Clinical governance

13A.—(1) A supplier of appliances shall, in connection with all the pharmaceutical services the supplier of appliances provides, participate, in the manner reasonably required by the 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 the supplier of appliances produces in an approved manner a practice leaflet containing approved particulars in respect of each of the premises from which the supplier provides pharmaceutical services,
 - (ii) a requirement that the supplier of appliances publicises the NHS services that are available at or from such premises,
 - (iii) a requirement that the supplier of appliances undertakes an approved patient satisfaction survey annually, in an approved manner,
 - (iv) the monitoring arrangements of the supplier of appliances in respect of appliances owed to patients but which are out of stock,
 - (v) an approved complaints system (which meets the requirements of this Schedule),
 - (vi) a requirement that the supplier of appliances co-operates appropriately with visits by an authorised representative of any relevant local involvement network and takes appropriate action following the outcome of such visits,
 - (vii) a requirement that the supplier of appliances co-operates appropriately with any reasonable inspection or review that the Primary Care Trust or any relevant statutory authority wishes to undertake, and
 - (viii) the monitoring arrangements of the supplier of appliances in respect of the supplier’s compliance with the Disability Discrimination Act 1995⁽¹⁰⁾;
- (b) a clinical audit programme (normally of five days) twice in each financial year;
- (c) a risk management programme, which includes—
 - (i) arrangements for ensuring that all stock is procured and handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,
 - (iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (v) appropriate waste disposal arrangements for clinical and confidential waste,
 - (vi) identifying a clinical governance lead person in respect of each of the premises from which the supplier provides pharmaceutical services,
 - (vii) appropriate child protection procedures, and

⁽¹⁰⁾ 1995 c. 50.

- (viii) the monitoring arrangements of the supplier of appliances in respect of the supplier's compliance with the Health and Safety at Work etc. Act 1974⁽¹¹⁾;
 - (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a supplier of appliances—
 - (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (ii) to people caring for themselves or their families,and arrangements for ensuring that the supplier, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 8(1)(f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;
 - (e) a staffing and staff management programme, which includes—
 - (i) arrangements for appropriate induction for staff and locums,
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service, including continuing professional development for registered pharmacists, registered nurses and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services, and
 - (v) arrangements for addressing poor performance (in conjunction with a Primary Care Trust as appropriate); and
 - (f) a use of information programme, which includes—
 - (i) appropriate arrangements (having regard to issues both of rights of access to information and of confidentiality) to support both health care delivery and clinical governance,
 - (ii) appropriate arrangements in respect of compliance with “Confidentiality: the National Health Service Code of Practice”⁽¹²⁾,
 - (iii) the monitoring arrangements of the supplier of appliances in respect of the supplier's compliance with the Data Protection Act 1998⁽¹³⁾ and with regard to patient confidentiality, and
 - (iv) appropriate training for staff with regard to compliance with the Data Protection Act 1998 and patient confidentiality.
- (3) For the purposes of sub-paragraph (2), “approved” means approved by the Secretary of State.”.

Amendments of paragraph 15

- 21.**—(1) Amend paragraph 15 (inducements etc.) as follows.
- (2) In sub-paragraph (1)—

⁽¹¹⁾ 1974 c. 37.

⁽¹²⁾ This Code of Practice is available on the Department of Health's website, www.dh.gov.uk.

⁽¹³⁾ 1998 c. 29.

- (a) for “A supplier of appliances or his staff shall not give” substitute “Neither a supplier of appliances nor any person employed or engaged by a supplier of appliances shall give”; and
 - (b) in paragraph (a), after “a prescription form” insert “or repeatable prescription”.
- (3) After sub-paragraph (2) insert—
- “ (3) Neither a supplier of appliances nor any person employed or engaged by a supplier of appliances shall accept or receive any gift or reward in respect of only—
- (a) providing contact details of alternative pharmacists or suppliers of appliances pursuant to paragraph 8(2)(b), 9A(4) or 9B(1)(b); or
 - (b) referring a prescription form or repeatable prescription to another supplier of appliances or pharmacist pursuant to paragraph 8(2)(a) or 9B(1)(a) and providing no additional service in connection with the item on that prescription.”.

Amendment of paragraph 24

22. In paragraph 24(1) (inspections and access to information), in paragraph (b)(i), after “patient care and treatment,” insert “including any arrangement made with a person in respect of provision of appliances,”.

PART 5

Transitional arrangement

Transitional arrangement

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

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

(3) Paragraph (2) does not apply in any case where the pharmacist or supplier of appliances proposes to enter into new arrangements, which are to be made in accordance with the Pharmaceutical Services (Advanced Services) (Appliances) (England) Directions 2009(14), to provide services for stoma appliance customisation or appliance use reviews (or has entered into such arrangements).

- (4) Nothing in this regulation affects the duty of a pharmacist or supplier of appliances—
 - (a) before the end of the transitional period, to comply with the terms of service as they otherwise have effect; and
 - (b) at or after the end of the transitional period, to comply with the terms of service as amended by these Regulations.
- (5) In this regulation—
 - “the terms of service”—

- (a) in relation to a pharmacist, means the terms of service set out in Schedule 1 to the principal Regulations;
 - (b) in relation to a supplier of appliances, means the terms of service set out in Schedule 3 to the principal Regulations; and
- “transitional period” means the nine month period that ends at the end of 31st December 2010.

Signed by authority of the Secretary of State for Health.

16th December 2009

Mike O'Brien
Minister of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the National Health Service (Pharmaceutical Services) Regulations 2005 (“the principal Regulations”) in respect of the terms of service for pharmacists and suppliers of appliances.

Regulation 2 inserts new definitions into regulation 2 of the principal Regulations. These include a definition of “specified appliances” which are a particular group of appliances which are listed in Parts IXA, IXB and IXC of the Drug Tariff (the Secretary of State for Health’s determination of remuneration for pharmaceutical services, issued under section 164 of the National Health Service Act 2006).

Part 3 of the Regulations contains amendments to the terms of service for pharmacists, which are set out in Schedule 1 to the principal Regulations. Regulation 4 amends paragraph 6 of Schedule 1 so as to add appliances to the items that can, if certain conditions are met, be dispensed without a prescription by a pharmacist in an urgent case – and to remove the requirement that the prescriber be personally known to the pharmacist. Regulation 5 amends paragraph 9 of Schedule 1 so that pharmacists providing an appliance on a repeat prescription must satisfy themselves that there has been no change in a patient’s use of the appliance which calls for a review of treatment. Regulation 6 adds to paragraph 10 of Schedule 1 a number of additional activities that must be carried out by a pharmacist when dispensing appliances. Regulation 7 inserts a new paragraph 11A into Schedule 1 setting out what pharmacists must do when dispensing “specified appliances”. They must provide a home delivery service for these appliances and must ensure that appropriate advice is given as to their use.

Regulation 8 amends paragraph 19 of Schedule 1 to require pharmacists to refer prescriptions, or to give contact details of other pharmacists or suppliers of appliances, in any case where providing a particular appliance or providing stoma appliance customisation is not within their normal course of business. Regulation 9 extends the requirements for clinical effectiveness programmes in paragraph 26 of Schedule 1 so as to cover advice about single prescriptions for appliances and includes procedures to encourage patients who are prescribed appliances not to stockpile. Regulation 10 amends paragraph 28 of Schedule 1 to prohibit gifts or rewards where a pharmacist provides no additional services other than referring a prescription onward or providing contact details of persons who are able to provide a particular service. Regulation 11 amends paragraph 37 of Schedule 1 to ensure that Primary Care Trusts can check on arrangements concerning the provision of appliances which are made between a pharmacist and a third party.

Part 4 of the Regulations contains amendments to the terms of service for suppliers of appliances, which are set out in Schedule 3 to the principal Regulations. Regulation 13 amends paragraph 4 of Schedule 3 so as to enable a supplier of appliances to dispense repeatable prescriptions in specified circumstances and regulations 15, 16, 17 and 21(2) make a number of consequential amendments. Regulation 14 inserts a new paragraph 4A into Schedule 3 so as to enable suppliers of appliances, if certain conditions are met, to dispense appliances without prescription in urgent cases. Regulation 18 adds to paragraph 8 of Schedule 3 a number of additional activities that must be carried out by a supplier of appliances when dispensing appliances. Regulation 19 inserts a new paragraph 9A and 9B into Schedule 3. Under paragraph 9A, suppliers of appliances must provide a home delivery service for “specified appliances” and must ensure that appropriate advice is given as to their use. Paragraph 9B requires suppliers of appliances to refer prescriptions, or to give contact details of

other suppliers of appliances or pharmacists, in any case where providing a particular appliance or providing stoma appliance customisation is not within their normal course of business.

Regulation 20 inserts a new paragraph 13A into Schedule 3 to impose clinical governance arrangements on suppliers of appliances, which have to include a number of specified components, such as a patient and public involvement programme. Regulation 21(3) amends paragraph 15 of Schedule 3 to prohibit gifts or rewards where a supplier of appliances provides no additional services other than referring a prescription onward or providing contact details of persons who can provide a particular service. Regulation 22 amends paragraph 24 of Schedule 3 to ensure that Primary Care Trusts can check on arrangements concerning the provision of appliances which are made between a supplier of appliances and a third party.

Part 5 contains transitional provision allowing existing contractors to choose, until the end of 31st December 2010, to comply with the previous version of their terms of service, as set out in the relevant Schedule to the principal Regulations.

An Impact Assessment has been prepared and can be obtained from www.dh.gov.uk. Copies are also available from the Department of Health, Skipton House, 80 London Road, London SE1 8LH.