## SCOTTISH STATUTORY INSTRUMENTS

# 2011 No. 55

## The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Scotland) Regulations 2011

## **Citation and Commencement**

**1.** These Regulations may be cited as the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Scotland) Regulations 2011 and come into force on 1st April 2011.

#### Interpretation

**2.**—(1) In these Regulations—

"the Act" means the National Health Service (Scotland) Act 1978;

"the 2000 Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(1);

"the 2003 Regulations" means the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) (No. 2) Regulations 2003(2);

"the 2009 Regulations" means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(**3**);

"accepted disablement" means physical or mental injury or disease which is accepted by the Secretary of State as attributable to, or aggravated by, service in the armed forces of the Crown or such other service as the Secretary of State may determine;

"appliance" means an appliance other than a contraceptive appliance which is a listed appliance within section 27(1) of the Act;

"drugs" includes medicines but does not include contraceptive substances;

"elastic hosiery" means anklet, legging, knee-cap, below knee or thigh stocking;

"English prescription form" means-

- (a) a form provided and issued under arrangements having effect in England, equivalent to those in place for a Scottish prescription form, to enable a person to obtain services in England which are equivalent to pharmaceutical services;
- (b) a form on which domiciliary oxygen has been ordered by a prescriber in England for a patient normally resident there;

"entitlement card" means a document issued by a Health Board(4) to a qualifying patient for the purposes of these Regulations;

"equivalent prescription form" means-

S.I. 2000/620 as amended by 2000/2393 and 3189, 2001/746 and 2887, 2002/548, 1386 and 2352, 2003/585, 699 and 1084, 2004/663 and 696, 2005/578, 2006/675, 2007/543, 674, 1510 and 1975, 2008/571, 1697, 1700 and 2593, 2009/29, 166, 411 and 2230 and 2010/231 and 1727.

<sup>(2)</sup> S.S.I. 2003/460 as amended by S.S.I. 2004/102 and 160, 2005/3 and 179, 2006/142, 183 and 440, 2007/225, 259 and 391, 2008/27, 105, 147, 288 and 390, 2009/124 and 2010/94 and 319.

<sup>(3)</sup> S.S.I. 2009/183 as amended by S.S.I. 2009/209, S.I. 2010/231 and S.S.I. 2010/128 and 2011/32.

<sup>(4)</sup> Health Board is defined in section 108(1) of the National Health Service (Scotland) Act 1978 (c.29) (the "1978 Act"), as relevantly amended by the 1990 Act, section 66, Schedule 9, paragraph 19.

- (a) a form provided and issued under arrangements having effect in Wales or Northern Ireland, equivalent to those in place for a Scottish prescription form, to enable a person to obtain services in Wales or Northern Ireland (as the case may be) which are equivalent to pharmaceutical services;
- (b) a form on which domiciliary oxygen has been ordered by a prescriber in Wales for a patient normally resident there;

"exemption" means any exemption provided for in regulation 4;

"exemption certificate" means any certificate provided under or referred to in regulation 4;

"patient" means any person who applies to a pharmacist for the provision of pharmaceutical services and includes for the purpose of these Regulations a person acting on behalf of such a person;

"pharmaceutical list" has the same meaning as in the 2009 Regulations;

"pharmaceutical services" means services provided under section 27 of the Act;

"pharmacist" means any person who provides pharmaceutical services;

"prescriber" has the same meaning as in the 2009 Regulations;

"qualifying patient" means a person who—

- (a) is ordinarily resident in Scotland; and
- (b) receives primary medical services in England under the National Health Service Act 2006(5);

"Scottish prescription form" means a form provided by the Agency(6) on which the provision of pharmaceutical services can be ordered, or equivalent data created on an electronic form.

- (2) For the purposes of these Regulations—
  - (a) the supply of quantities of the same drug in more than one container against an order on a single English prescription form is deemed to be the supply of only one quantity of a drug;
  - (b) the supply against an order on-
    - (i) a single English prescription form of more than one appliance of the same type; or
    - (ii) a single English prescription form of two or more component parts of the same appliance,

is deemed to be the supply of only one appliance, however any piece of elastic hosiery is deemed to be a separate appliance; and

(c) the supply of quantities of the same drug in more than one strength against an order on a single English prescription form (or more than one form where the forms presented have been ordered by the same person, for the patient, on the same date) is deemed to be the supply of only one quantity of a drug.

## Supply of drugs and appliances

**3.**—(1) A pharmacist who provides pharmaceutical services to a patient must not make or recover any charge from the patient, where the patient presents a Scottish prescription form or equivalent prescription form.

(2) Except as provided for in paragraph (3), a pharmacist who provides pharmaceutical services to a patient must, where the patient presents an English prescription form, make and recover from the patient—

<sup>(5) 2006</sup> c.41.

<sup>(6)</sup> The Agency is defined in section 108(1) of the 1978 Act.

- (a) in respect of the supply of an item of elastic hosiery, the charge that is specified in regulation 3(1)(a) of the 2000 Regulations as in force at 1st April 2011(7);
- (b) in respect of the supply of each other appliance and each quantity of drug, the charge that is specified in regulation 3(1)(b) of the 2000 Regulations as in force at 1st April 2011(8).
- (3) A pharmacist must not make or recover any charge specified in paragraph (2) where-
  - (a) a declaration of entitlement to exemption on an English prescription form is duly completed and signed by or on behalf of the patient;
  - (b) the patient presents an English prescription form that relates to a supply, replacement or repair referred to in paragraph 1(1) of Schedule 11 to the Act (occasion where no charge is to be made) but only in respect of the supply, replacement or repair to which that paragraph relates; or
  - (c) the patient presents an English prescription form together with a valid entitlement card.

(4) Where a quantity of a drug ordered on an English prescription from is to be supplied in instalments during a period of not more than 14 days, only one charge is payable and it must be paid upon the supply of the first instalment.

(5) A pharmacist is under no obligation to provide pharmaceutical services in respect of an English prescription form unless the patient has paid the pharmacist any charge due to be paid under paragraph (2), or paragraph (3) applies.

(6) A pharmacist who makes and recovers a charge under paragraph (2) must, if required by the patient, give the patient a receipt for the amount paid, on a form provided for that purpose by the Health Board, which contains a declaration in support of an application for a refund.

(7) Any sum which a Health Board is under a duty to pay or cause to be paid to a pharmacist in respect of the provision of pharmaceutical services is reduced by the relevant sum specified in paragraph (2).

#### Exemptions

4.—(1) No charge is payable under these Regulations by—

- (a) a person who is under the age of 16 years;
- (b) a person who is under the age of 19 years and is receiving qualifying full time education within the meaning of paragraph 7 (full time education) of Schedule 11 to the Act(9);
- (c) a person who is aged 60 years of age or over;
- (d) a woman to whom a Health Board has issued an exemption certificate on the ground that she is an expectant mother or has within the last 12 months given birth to a live child or a child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965(10);
- (e) a woman with a valid exemption certificate, issued under arrangements for exemptions from charges for drugs and appliances in England or Wales, on the ground that she is an expectant mother or has within the last 12 months given birth to a live child or a child registrable as still-born under the Births and Deaths Registration Act 1953(11);
- (f) a person with a valid exemption certificate on the ground that the person is suffering from one or more of the following conditions:—

<sup>(7)</sup> The charge specified in regulation 3(1)(a) of the 2000 Regulations, as at 1st April 2011 is £7.40 that is to say £14.80 per pair.

<sup>(8)</sup> The charge specified in regulation 3(1)(b) of the 2000 Regulations, as at 1st April 2011 is £7.40.

<sup>(9)</sup> Paragraph 7 of Schedule 11 was inserted by the 1980 Act, section 26 and Schedule 5, paragraph 8.

<sup>(</sup>**10**) 1965 c.49.

<sup>(11) 1953</sup> c.20.

- (i) permanent fistula (including caecostomy, colostomy, laryngostomy or ileostomy) requiring continuous surgical dressing or an appliance;
- (ii) forms of hypoadrenalism (including Addison's disease) for which specific substitution therapy is required;
- (iii) diabetes insipidus and other forms of hypopituitarism;
- (iv) diabetes mellitus, except where treatment is by diet alone;
- (v) hypoparathyroidism;
- (vi) myasthenia gravis;
- (vii) myxoedema;
- (viii) epilepsy requiring continuous anti-convulsive therapy; or
- (ix) a continuing physical disability which prevents a patient from leaving a residence without the help of another person;
- (g) a person with a valid exemption certificate issued under arrangements for exemptions from charges for drugs and appliances in England or Wales;
- (h) a person to whom the Secretary of State has issued a valid exemption certificate in respect of the supply of drugs and appliances for the treatment of accepted disablement but only in respect of those supplies to which the certificate relates;
- (i) a person with a valid pre-payment certificate issued under arrangements having effect in England in respect of charges for drugs and appliances;
- (j) a person who presents an English prescription form that relates to a supply, replacement or repair referred to in paragraph 1(1) of Schedule 11 to the Act, but only in respect of the supply, replacement or repair to which that paragraph relates;
- (k) a person with a valid entitlement card.
- (2) Except in the case of paragraph (1)(j) no exemption will be granted unless either—
  - (a) a declaration of entitlement to exemption on an English prescription form presented to a pharmacist is duly completed and signed by or on behalf of the person claiming the exemption; or
  - (b) in the case of paragraph (1)(k) the patient presents an English prescription form together with a valid entitlement card.

(3) A person who wishes to claim exemption under paragraph (1)(d) or (f) must apply to the Health Board for an exemption certificate on a form provided by the Board for that purpose.

(4) If the Health Board is satisfied that an applicant is entitled to exemption from charges under paragraph (1)(d), it must issue an exemption certificate which will have effect in the case of an expectant mother until the end of her pregnancy, and—

- (a) where she gives birth to a child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965, until the end of the period of 12 months beginning with the expected date of confinement; or
- (b) in the case of a mother who has given birth to a live child, until the end of the period of 12 months beginning with the date of birth of that child.

(5) If a Health Board is satisfied that an applicant is entitled to exemption under paragraph (1) (f), it must issue an exemption certificate to the applicant which will have effect for such period as it may determine.

(6) A person who wishes to claim exemption under paragraph (1)(k) must apply to the Agency for an entitlement card on a form provided by the Agency for that purpose.

(7) The Agency, on being satisfied that the person is a qualifying patient, must issue to that person an entitlement card which will be valid for a period of 5 years from the date of issue.

(8) The charges which may be made and recovered by virtue of these Regulations are subject to the provisions of the 2003 Regulations.

### **Refunds of charges paid**

**5.**—(1) Where a charge has been paid under these Regulations by or on behalf of a person who was at the time of payment eligible for exemption from that charge, a claim for a refund may be made by or on behalf of that person.

(2) A claim under this regulation for a refund of charges must be-

- (a) made on a form provided for that purpose by the Scottish Ministers, accompanied by the appropriate receipt and declaration in support of the claim;
- (b) made not less than 1 month and not more than 3 months after the date on which the charge was paid; and
- (c) made to the Health Board which received payment of the charge.

(3) Any refund will be made in such manner and subject to such conditions as the Scottish Ministers may determine.

#### **Consequential amendments**

6. The amendments listed in the Schedule have effect.

#### Revocations

- 7. The following regulations are revoked:—
  - (a) the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008(12);
  - (b) the National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2008(13);
  - (c) the National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2009(14);
  - (d) the National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2010(15);
  - (e) the National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment (No. 2) Regulations 2010(16).

St Andrew's House, Edinburgh 31st January 2011

SHONA ROBISON Authorised to sign by the Scottish Ministers

<sup>(12)</sup> S.S.I. 2008/27.

<sup>(</sup>**13**) S.S.I. 2008/105.

<sup>(14)</sup> S.S.I. 2009/37.(15) S.S.I. 2010/1.

<sup>(16)</sup> S.S.I. 2010/1.