
SCOTTISH STATUTORY INSTRUMENTS

2008 No. 27

The National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008

Citation and commencement

1. These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008 and come into force on 1st April 2008.

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 2001 Regulations” means the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001(2);

“the 2007 Regulations” means the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2007(3);

“the 2007 (No. 2) Regulations” means the National Health Service (Charges for Drugs and Appliances) (Scotland) (No. 2) Regulations 2007(4);

“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;

“advanced electronic signature” means an electronic signature which is—

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under his or her sole control; and
- (d) linked to the data to which it relates in such manner that any subsequent change of data is detectable;

“the Agency” means the Common Services Agency for the Scottish Health Service constituted under section 10 of the Act(5);

(1) S.I.2000/620; amended by S.I. 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 and 2008/571.

(2) S.S.I. 2001/430; amended by S.S.I. 2002/100, 2003/130 and 295, 2004/66 and 212, 2005/124, 326 and 617, and 2006/149 and 246; and S.I. 2004/1771; revoked by S.S.I. 2007/139 but continued to apply for certain purposes by virtue of S.S.I. 2007/139 and 389.

(3) S.S.I. 2007/139, amended by S.S.I. 2007/317; revoked by S.S.I. 2007/389 but continued to apply for certain purposes by regulation 10 of S.S.I. 2007/389.

(4) S.S.I. 2007/389.

(5) Section 10 was amended by the National Health Service and Community Care Act 1990 (c. 19), section 66(2) and Schedule 10; the Health Act 1999 (c. 8), section 65(1) and Schedule 4, paragraph 44(a); S.S.I. 1999/90, article 2 and Schedule 1; and the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), schedule 2, paragraph 2(4).

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

“chemist” includes any person, other than a doctor, providing pharmaceutical services;

“dentist” means a registered dental practitioner;

“doctor” means a registered medical practitioner;

“drugs” includes medicines but does not include contraceptive substances;

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

“electronic communication” has the same meaning as in section 15 of the Electronic Communications Act 2000(6);

“electronic prescription form” means a Scottish prescription form as defined in paragraph (b) of the definition of “Scottish prescription form”;

“electronic signature” has the meaning attributed to it in section 7(2) of the Electronic Communications Act 2000;

“entitlement card” means a card provided by the Agency in accordance with regulation 9;

“e-Pharmacy Service” means the electronic system provided by the Agency by which electronic prescription forms are transmitted;

“equivalent prescription form” means—

- (a) a non-electronic form provided and issued under arrangements having effect in England, Wales or Northern Ireland, equivalent to those in place for a Scottish prescription form, to enable a person to obtain services in England, Wales or Northern Ireland which are equivalent to pharmaceutical services;
- (b) a form on which domiciliary oxygen has been ordered—
 - (i) by a prescriber in England or Wales for a patient normally resident in England or Wales; and
 - (ii) in relation to which the patient named on the form (or a person on the patient’s behalf) completes and signs a declaration of entitlement to exemption or a statement that a charge has been paid;

“exemption” means any exemption provided for in regulation 7;

“exemption certificate” means any certificate provided under or referred to in regulation 7;

“GMS contract” means a general medical services contract under section 17J of the Act(7);

“GMS contractor” means a party to a GMS contract other than a Health Board;

“Health Board” means a Health Board constituted under section 2(1)(a) of the Act(8);

“independent nurse prescriber” means a person—

- (a) who is registered in the Nursing and Midwifery Register; and
- (b) against whose name is recorded in that register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(9);

(6) 2000 c. 7; amended by paragraph 158 of Schedule 17 to the Communications Act 2003 (c. 21).

(7) Section 17J was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4.

(8) Section 2 was amended by the National Health Service Reform (Scotland) Act 2004 (asp 7), schedule 1, paragraph 1(2)(a) and (b).

(9) S.I. 2002/253, to which there are no relevant amending instruments.

“out-patient” means a person receiving treatment under the Act otherwise than under Part II of the Act and who is not for the purpose of receiving that treatment resident in a hospital;

“patient” means–

- (a) any person who is provided with primary medical services under Part I of the Act; or
- (b) any person who applies to a chemist for the provision of pharmaceutical services, and includes for the purposes of these Regulations a person acting on behalf of such a person;

“Patient Group Direction” has the meaning ascribed in article 1(2) (interpretation) of the Prescription Only Medicines (Human Use) Order 1997(10);

“pharmaceutical services” means services provided under section 27 of the Act;

“pharmacist” means a pharmacist within the meaning of section 132(1) of the Medicines Act 1968(11);

“pharmacist independent prescriber” means a person–

- (a) who is registered in Part 1 of the register maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007(12) or the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(13); and
- (b) against whose name in that register is recorded an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

“pilot scheme” shall be construed in accordance with section 1(1) of the National Health Service (Primary Care) Act 1997(14);

“prescriber” means a doctor, a pharmacist independent prescriber, an independent nurse prescriber or a supplementary prescriber;

“Scottish prescription form” means–

- (a) a form provided by the Agency–
 - (i) on which the provision of pharmaceutical services may be ordered by–
 - (aa) a Health Board;
 - (bb) a dentist pursuant to the provisions of his or her terms of service;
 - (cc) a dentist performing personal dental services in accordance with a pilot under Part I of the National Health Service (Primary Care) Act 1997;
 - (dd) a prescriber; and
 - (ii) which contains on its reverse side a form of declaration of entitlement to exemption or a statement that a charge has been paid; or
- (b) data that is created in an electronic form for the provision of pharmaceutical services ordered by–
 - (i) a dentist pursuant to the provisions of his or her terms of service;
 - (ii) a dentist performing personal dental services in accordance with a pilot under Part I of the National Health Service (Primary Care) Act 1997; or

(10) S.I. 1997/1830. The definition of “Patient Group Direction” was inserted by S.I. 2007/289.

(11) 1968 c. 67. Section 132(1) has been amended by: the National Health Reorganisation Act 1973 (c.32), Schedule 4, paragraph 128(3); the National Health Service Act 1977 (c.49), Schedule 15, paragraph 50; the Medical Act 1983 (c.54), Schedule 5, paragraph 5; the Dentists Act 1984 (c.24), Schedule 5, paragraph 2; the Animal Health and Welfare Act 1984, section 13(3); the Food Safety Act 1990 (c.16), Schedule 3, paragraph 11, and Schedule 5; and by S.I. 1976/1213, 1992/3271, 1996/1496, 2002/236, 2003/232, 2004/1031 and 2007/289.

(12) S.I. 2007/289.

(13) S.I. 1976/1213 (N.I. 22).

(14) 1997 c. 46.

(iii) a prescriber,

and signed with such person's advanced electronic signature and transmitted as an electronic communication through the e Pharmacy service;

“section 17C provider” means a party to a section 17C agreement⁽¹⁵⁾ other than a Health Board;

“supplementary prescriber” means a person whose name is registered in–

- (a) the Nursing and Midwifery Register;
- (b) Part 1 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007⁽¹⁶⁾;
- (c) the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽¹⁷⁾;
- (d) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001⁽¹⁸⁾ relating to–
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) diagnostic or therapeutic radiographers; or
- (e) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989⁽¹⁹⁾,

and against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber or, in the case of the Nursing and Midwifery Register, a nurse independent/supplementary prescriber;

“supply form” means a form issued by a Health Board to a pharmacist to record a supply of pharmaceutical services made to a patient under the terms of a Patient Group Direction issued by a Health Board in accordance with article 12C of the Prescription Only Medicines (Human Use) Order 1997 (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)⁽²⁰⁾;

“terms of service” has the meaning respectively in respect of a pharmacist or a dentist assigned to it in the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995⁽²¹⁾ or the National Health Service (General Dental Services) (Scotland) Regulations 1996⁽²²⁾;

“the Travelling Expenses and Remission of Charges Regulations” means the National Health Service (Travelling Expenses and Remission of Charges) (No. 2) Regulations 2003⁽²³⁾;

“treatment” includes examination and diagnosis;

(2) For the purpose of these Regulations–

- (a) the supply of quantities of the same drug in more than one container against an order on a single Scottish prescription form or a single equivalent prescription form shall be deemed to be the supply of only one quantity of a drug; and
- (b) the supply against an order on–

⁽¹⁵⁾ This is an agreement under section 17C of the National Health Service (Scotland) Act 1978 (c. 29).

⁽¹⁶⁾ S.I. 2007/289.

⁽¹⁷⁾ S.I. 1976/1213 (N.I. 22).

⁽¹⁸⁾ S.I. 2002/254 to which there are no relevant amending instruments.

⁽¹⁹⁾ 1989 c. 44; section 7 was amended by S.I. 2005/848, article 7.

⁽²⁰⁾ S.I. 1997/1830. Article 12C was inserted by S.I. 2000/1917 and amended by S.I. 2000/2899, 2003/696 and 2007/2178.

⁽²¹⁾ S.I. 1995/414; relevant amending instruments are S.S.I. 2005/618, 2007/208 and 390.

⁽²²⁾ S.I. 1996/177 to which there are amendments not relevant to these Regulations.

⁽²³⁾ S.S.I. 2003/460, amended by S.S.I. 2004/102 and 166, 2005/3 and 179, 2006/142, 183 and 440, 2007/225, 259 and 391.

- (i) a single Scottish prescription form or a single equivalent prescription form of more than one appliance of the same type; or
- (ii) a single Scottish prescription form or a single equivalent prescription form of two or more component parts of the same appliance,

shall be deemed to be the supply of only one appliance, however any piece of elastic hosiery shall be deemed to be a separate appliance.

(3) For as long as there are in existence contracts entered into under article 13 of the General Medical Services (Transitional and Other Ancillary Provisions) (Scotland) Order 2004(24) (“default contracts”) any reference in these Regulations to a GMS contract shall be read as including a reference to a contract entered into under that article and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term of the default contract.

(4) For as long as there are in existence transitional agreements as defined in article 1(2) of the General Medical Services and Section 17C Agreements (Transitional and Other Ancillary Provisions) (Scotland) Order 2004(25), any reference in these Regulations to a section 17C agreement shall be read as including a reference to a transitional agreement and any reference to a term of a section 17C agreement shall be read as including a reference to any equivalent term in the transitional agreement.

(5) In these Regulations—

- (a) any reference to a numbered regulation or a numbered Schedule is, unless otherwise expressly provided, a reference to the regulation or the Schedule bearing that number in these Regulations; and
- (b) any reference in a regulation to a numbered paragraph is, unless otherwise expressly provided, a reference to the paragraph bearing that number in that regulation.

Supply of drugs and appliances by chemists

3.—(1) Except as provided for in paragraph (2), a chemist who provides pharmaceutical services to a patient shall make and recover from the patient—

- (a) in respect of the supply of an item of elastic hosiery—
 - (i) where the patient presents a Scottish prescription form, or where the patient presents both an equivalent prescription form and a valid entitlement card, a charge of £5.00, that is to say a charge of £10.00 per pair; and
 - (ii) where the patient presents an equivalent prescription form without a valid entitlement card, the charge that is specified in regulation 3(1)(a) of the 2000 Regulations, as in force at 1st April 2008(26);
- (b) in respect of the supply of each other appliance and each quantity of a drug—
 - (i) where the patient presents a Scottish prescription form, or where the patient presents both an equivalent prescription form and a valid entitlement card, a charge of £5.00; and
 - (ii) where the patient presents an equivalent prescription form without a valid entitlement card, the charge that is specified in regulation 3(1)(b) of the 2000 Regulations, as in force at 1st April 2008(27);

(24) [S.S.I. 2004/142](#).

(25) [S.S.I. 2004/163](#).

(26) The charge specified in regulation 3(1)(a) of the 2000 Regulations, as at 1st April 2008, is £7.10, that is to say a charge of £14.20 per pair.

(27) The charge specified in regulation 3(1)(b) of the 2000 Regulations, as at 1st April 2008, is £7.10.

(2) A chemist who provides pharmaceutical services to a patient shall not make or recover any charge as specified in paragraph (1) where—

- (a) a declaration of entitlement to exemption on a Scottish prescription form as defined in paragraph (a) of the definition of “Scottish prescription form”, on an equivalent prescription form, or on a supply form, or a declaration of entitlement in respect of pharmaceutical services ordered on an electronic prescription form, is duly completed and signed by or on behalf of the patient; or
- (b) a declaration of entitlement to exemption is duly completed and signed in respect of an order for domiciliary oxygen issued by a prescriber in England or Wales for a patient normally resident in England or Wales.

(3) For the purposes of this regulation, where a quantity of a drug ordered on a single Scottish prescription form or a single equivalent prescription form is to be supplied by instalments during a period of not more than 14 days, only one charge shall be payable and it must be paid upon the supply of the first instalment.

(4) A chemist shall be under no obligation to provide pharmaceutical services in respect of an order on a Scottish prescription form or an equivalent prescription form, or in terms of the Patient Group Direction, unless the patient has paid the chemist any charge payable under paragraph (1), or one of the exceptions set out in paragraph (2) applies.

(5) A chemist who makes and recovers a charge under paragraph (1) shall, if required by the patient, give the patient a receipt for the amount paid, on a form provided for the purpose by the Health Board, which contains forms of declaration in support of an application for a refund.

(6) Any sum which a Health Board is under a duty to pay or cause to be paid to a chemist in respect of the provision by the chemist of pharmaceutical services, other than such provision in respect of which a declaration of entitlement to exemption has been made under paragraph (2)(a) or (b), shall be reduced by—

- (a) where the patient presents a Scottish prescription form, the sum specified in paragraph (1)(b)(i) in respect of each quantity of a drug supplied and by the sum specified in paragraph (1)(a)(i) or, as the case may require, paragraph (1)(b)(i), in respect of each appliance as supplied as part of such services; and
- (b) where the patient presents an equivalent prescription form, the sum referred to in paragraph (1)(b)(ii), in respect of each quantity of a drug supplied and by the sum referred to in paragraph (1)(a)(ii) or, as the case may require, paragraph (1)(b)(ii) in respect of each appliance as supplied as part of such services.

Supply of drugs and appliances by doctors

4.—(1) Except as provided for in paragraph (2), a doctor who provides services corresponding to pharmaceutical services under the terms of a GMS contract which gives effect to paragraph 44 of Schedule 5 to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004⁽²⁸⁾ or under the terms of a section 17C agreement which gives effect to paragraph 15 of Schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004⁽²⁹⁾ shall make and recover from the patient—

- (a) in respect of the supply of an item of elastic hosiery, a charge of £5.00, that is to say a charge of £10.00 per pair; and
- (b) in respect of the supply of each other appliance and each quantity of a drug, a charge of £5.00.

⁽²⁸⁾ S.S.I. 2004/115. Paragraph 44 of Schedule 5 was amended by S.S.I. 2007/206, 392 and 501.

⁽²⁹⁾ S.S.I. 2004/116. Paragraph 15 of Schedule 1 was amended by S.S.I. 2007/205, 393 and 502.

(2) A doctor who provides services corresponding to pharmaceutical services as described in paragraph (1) shall not make or recover any charge as specified in paragraph (1) where the patient or a person on the patient's behalf declares that the patient is entitled to exemption under regulation 7.

(3) For the purposes of this regulation, where a doctor supplies a quantity of a drug by instalments during a period of not more than 14 days, only one charge shall be payable and it shall be payable upon the supply of the first instalment.

(4) A doctor shall be under no obligation to supply drugs or appliances unless the patient has paid the doctor any charge payable under paragraph (1), or the exception set out in paragraph (2) applies.

(5) After the end of each month, a GMS contractor or section 17C provider shall send the total charges recovered by a doctor during the month to the Health Board with which the GMS contractor or section 17C provider has a GMS contract or section 17C agreement.

(6) A doctor who makes and recovers a charge under paragraph (1) shall, if required by the patient, give the patient a receipt for the amount paid, on a form provided for the purpose by the Health Board, which contains forms of declaration in support of an application for a refund.

Supply of drugs and appliances to out-patients

5.—(1) Except as provided for in paragraph (2), a Health Board which supplies an out-patient attending hospital with appliances or drugs (to be administered outwith the hospital), shall make and recover from the out-patient—

- (a) in respect of the supply of an item of elastic hosiery, a charge of £5.00, that is to say a charge of £10.00 per pair;
- (b) in respect of the supply of a pair of tights, a charge of £10.00; and
- (c) in respect of the supply of each other appliance and each quantity of a drug, a charge of £5.00.

(2) A Health Board which supplies an out-patient attending hospital with appliances or drugs as described in paragraph (1) shall not make or recover any charge as specified in paragraph (1) where the out-patient or a person on the out-patient's behalf declares that the out-patient is entitled to exemption.

(3) For the purposes of this regulation, where a quantity of a drug supplied by a hospital against an order on one Scottish prescription form is to be supplied by instalments during a period of not more than 14 days, only one charge shall be payable and it shall be payable on supply of the first instalment.

(4) A Health Board which makes and recovers a charge under paragraph (1) shall, if required by the patient, give the patient a receipt for the amount paid, on a form provided for the purpose by the Health Board, which contains forms of declaration in support of an application for a refund.

Fabric support and wigs

6.—(1) Except as provided for in paragraph (2), a Health Board which, otherwise than under Part II of the Act, supplies a patient with an appliance specified in column 1 of Schedule 1, shall make and recover from the patient the charge specified in column 2 of Schedule 1 in respect of that appliance.

(2) A Health Board which supplies a patient with any appliance under paragraph (1) shall not make or recover any charge as specified in Schedule 1 where the patient or a person on the patient's behalf declares that the patient is entitled to exemption.

(3) A Health Board which makes and recovers a charge under paragraph (1) shall, if required by the patient, give the patient a receipt for the amount paid, on a form provided for the purpose by the Health Board, which contains forms of declaration in support of an application for a refund.

Exemptions

7.—(1) Subject to the provisions of paragraphs 1(1) and 4 of Schedule 11 to the Act and to the following provisions of this regulation, no charge shall be 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 of Schedule 11 to the Act⁽³⁰⁾;
- (c) a person who is 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⁽³¹⁾;
- (e) a woman with a valid exemption certificate issued under arrangements for exemptions from charges for drugs and appliances in England, Wales or Northern Ireland 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⁽³²⁾;
- (f) a person with a valid exemption certificate on the ground that the person is suffering from one or more of the following conditions—
 - (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, Wales or Northern Ireland on the ground that he or she is suffering from one or more of the conditions specified in sub paragraph (f);
- (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 in respect of the supply to that person of the drugs or preparations specified in Schedule 2;
- (j) a person to whom a valid pre-payment certificate has been granted pursuant to regulation 8;
- (k) a person with a valid pre-payment certificate issued under arrangements having effect in England or Northern Ireland in respect of charges for drugs and appliances.

(2) No exemption from a charge payable under these Regulations shall be granted unless—

⁽³⁰⁾ Paragraph 7 of Schedule 11 was inserted by the Health Services Act 1980 (c. 53), section 26(2) and Schedule 5, Part II, paragraph 8.

⁽³¹⁾ 1965 c. 49.

⁽³²⁾ 1953 c. 20.

- (a) in the case of a charge payable to a chemist—
 - (i) a declaration of entitlement to exemption on a Scottish prescription form as defined in paragraph (a) of the definition of “Scottish prescription form”, on an equivalent prescription form, or on a supply form presented to a chemist, is duly completed and signed by or on behalf of the person claiming exemption;
 - (ii) on a supply form presented to the chemist, or a declaration of entitlement in respect of pharmaceutical services ordered on an electronic prescription form is duly completed and signed by or on behalf of the person claiming exemption; or
 - (iii) a declaration of entitlement to exemption is duly completed and signed by the patient or the patient’s representative in respect of an order for domiciliary oxygen issued by a prescriber in England or Wales for a patient normally resident in England or Wales;
 - (b) in the case of a charge payable to a doctor, a declaration of entitlement to exemption, which shall be in writing if the doctor so requires, is made to that doctor by the patient or the patient’s representative; or
 - (c) in the case of a charge payable by a Health Board under regulation 5, the person claiming exemption provides such evidence as the Health Board may reasonably require that the person is entitled to such exemption.
- (3) A person who wishes to claim exemption under paragraph (1)(d) or (f) shall apply to the Health Board for an exemption certificate on a form provided by the Health 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 shall issue an exemption certificate which shall 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 shall issue an exemption certificate to the applicant which shall have effect for such period as it may determine.
- (6) Where a claim for exemption has been made but is not substantiated and in consequence of that claim a chemist, a doctor or a Health Board has not recovered a charge in respect of the supply of any drugs or appliances, the Health Board shall recover such charge from the person concerned.
- (7) Any claim for exemption by reference to a patient’s age or the validity of an exemption certificate shall be determined by reference to the age or validity on the date on which any order for drugs or appliances is presented for dispensing or drugs appliances are supplied by a doctor or a Health Board.
- (8) The charges which may be made and recovered by virtue of these Regulations are subject to the provisions of the Travelling Expenses and Remission of Charges Regulations.

Pre-payment certificates

8.—(1) A person who holds a Community Health Index number or a person who holds a valid entitlement certificate may apply for a pre-payment certificate by completing and sending a form provided for that purpose by the Health Board to the address specified in the form.

(2) A pre-payment certificate granted upon receipt of an application by a person referred to in paragraph (1) shall be valid for a period of either 4 months or 12 months and an application under paragraph (1) shall state the period for which it is required to be valid.

- (3) A pre-payment certificate shall be valid—
- (a) from the date the application under paragraph (1) is made, where that date—
 - (i) was specified by the applicant when making the application; and
 - (ii) is no more than 7 days prior to the date upon which the application was received at the address referred to in paragraph (1); or
 - (b) from a date after the application under paragraph (1) is made, where that date—
 - (i) was specified by the applicant when making the application; and
 - (ii) is no more than one month after the date upon which the application was made under paragraph (1); or
 - (c) if the applicant does not specify the date under sub-paragraphs (a)(i) or (b)(i), from the date upon which the application is received at the address referred to in paragraph (1).

- (4) A pre-payment certificate shall be granted either—
- (a) by a Health Board as soon as reasonably practicable following; or
 - (b) by a pharmacist or doctor duly approved by a Health Board to grant such certificates immediately upon,

payment of the sum of £17.00 for a certificate valid for 4 months or £48.00 for a certificate valid for 12 months.

(5) The payment of a sum prescribed under this regulation shall not be deemed to be the payment of a charge under these Regulations.

(6) Where not more than one month after the date on which a person's pre-payment certificate became valid the person—

- (a) becomes a person to whom any of the provisions of regulation 7(1)(b) to (h) applies;
- (b) becomes a person entitled to remission under regulation 3 (entitlement to full remission and payment) of the Travelling Expenses and Remission of Charges Regulations;
- (c) dies; or
- (d) becomes resident in a hospital and thereafter either—
 - (i) dies while resident in hospital before the expiry of the pre-payment certificate; or
 - (ii) remains in hospital until the expiry of the pre-payment certificate,
 an application for a refund of the amount paid in respect of the pre-payment certificate may be made by or on behalf of that person or that person's estate in accordance with paragraphs (11) to (13).

(7) Where a person dies or becomes resident in hospital and thereafter dies during the period of validity of a pre-payment certificate, excluding the month in respect of which an application under paragraph (6) may be made, an application for a refund may be made by or on behalf of that person's estate in accordance with paragraphs (11) to (13).

- (8) The refund referred to in paragraph (7) shall be—
- (a) in the case of a pre-payment certificate valid for 4 months, $\frac{1}{4}$ of the amount paid in respect of the pre-payment certificate for each complete month after the date of death during which the pre-payment certificate would have remained valid;
 - (b) in the case of a pre-payment certificate valid for 12 months, $\frac{1}{12}$ of the amount paid in respect of the pre-payment certificate for each complete month after the date of death during which the pre-payment certificate would have remained valid,

and for the purposes of these calculations a complete month is a month beginning on the date of death and ending on the date immediately preceding that date in the following month.

(9) Where, during the period of 3 months following the month in respect of which a claim for a refund may be made under paragraph (6), a person with a pre-payment certificate valid for 12 months—

- (a) becomes a person to whom any of the provisions of regulation 7(1)(b) to (h) applies; or
- (b) becomes a person entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations,

an application for a refund may be made by or on behalf of that person in accordance with paragraphs (11) to (13).

(10) The refund which is referred to in paragraph (9) shall be the amount which is the difference between the amount paid in respect of the pre-payment certificate valid for 12 months and the amount payable for a certificate valid for 4 months on the date that the sum prescribed was paid.

(11) Applications under this regulation for refunds shall be made to the Health Board which either received the amount paid in respect of the pre-payment certificate or approved by the pharmacist or doctor to grant pre-payment certificates and shall be accompanied by the certificate (where granted) and a declaration in support of the application and any refund shall be made in such manner and subject to such conditions as the Scottish Ministers may determine.

(12) Subject to paragraph (13) an application for a refund shall be made where the person—

- (a) dies, or becomes resident in hospital and thereafter dies, within 24 months of the date of death;
- (b) has a pre-payment certificate for 4 months and becomes a person—
 - (i) to whom any of the provisions of regulation 7(1)(b) to (h) applies; or
 - (ii) entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations,within 4 months of the date of expiry of the pre-payment certificate;
- (c) has a pre-payment certificate for 12 months and becomes a person—
 - (i) to whom any of the provisions of regulation 7(1)(b) to (h) applies; or
 - (ii) entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations,within 7 months of the date of expiry of the pre-payment certificate;
- (d) becomes resident in hospital and remains there until the expiry of a pre-payment certificate, within 3 months of the date of expiry.

(13) Where an application under this regulation is made outside the time limits specified in paragraph (12) the Health Board shall accept the application if the Scottish Ministers are satisfied that the delay was for good cause.

(14) In this regulation a “Community Health Index number” means a patient identifying number issued to patients by the Agency.

Entitlement cards

9.—(1) Any qualifying patient may apply for a card (in these Regulations referred to as an “entitlement card”) by completing and sending a form provided for that purpose by the Agency to the address specified in the form.

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

(3) An entitlement card which is issued confers on the qualifying patient—

- (a) upon presenting an equivalent prescription form which has been issued in England to a chemist supplying pharmaceutical services under regulation 3, the right to obtain drugs and appliances at the charge specified under paragraph (1)(a)(i) or (1)(b)(i) of regulation 3, as the case may require; and
 - (b) the right to apply for a pre-payment certificate under regulation 8, where an application for such a certificate is accompanied by notification of the serial number of the entitlement card.
- (4) For the purposes of this regulation a “qualifying patient” means a person who–
- (a) is resident in Scotland; and
 - (b) receives primary medical services under Part 4 of the National Health Service Act 2006⁽³³⁾ from a provider who is contracted to provide such services with a Primary Care Trust;
- (5) Where a qualifying patient receives pharmaceutical services under regulation 3 by presenting a valid entitlement card and an equivalent prescription form to a chemist, in regulation 3(6)–
- (a) “the sum referred to in paragraph (1)(b)(ii)” shall read as “the sum specified in paragraph (1)(b)(i)”; and
 - (b) “the sum referred to in paragraph (1)(a)(ii)” shall read as “the sum specified in paragraph (1)(a)(i)”.

Refunds of charges paid

10.—(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 refund may be made by or on behalf of that person.

(2) A claim under this regulation for a refund of charges shall be made on a form provided by the Scottish Ministers and shall be accompanied by the appropriate receipt and the appropriate declaration in support of the claim.

(3) A claim under this regulation shall be made not less than one month but not more than 3 months after the date on which the charge was paid.

(4) A claim under this regulation for a refund shall be made to the Health Board which received payment of the charge, and any refund shall be made in such manner and subject to such conditions as the Scottish Ministers may determine.

Partial refunds of pre-payment certificates due to price reduction

11.—(1) Where a person has obtained a pre-payment certificate prior to 1st April 2008 by virtue of making any payment in accordance with–

- (a) regulation 8 of the 2007 Regulations⁽³⁴⁾;
- (b) regulation 8 of the 2007 (No. 2) Regulations⁽³⁵⁾,

and the pre-payment certificate remains valid for one or more complete months following 1st April 2008, an application for a partial refund of the sum paid for the pre-payment certificate may be made, by or on behalf of that person or his or her estate, in accordance with paragraphs (3) and (4) in respect of each complete month beginning with 1st April 2008.

(2) The partial refund referred to in paragraph (1) is calculable as follows–

⁽³³⁾ 2006 c. 41.

⁽³⁴⁾ S.S.I. 2007/139, amended by S.S.I. 2007/317; S.S.I. 2007/139 and 317 were revoked by S.S.I. 2007/389, but the provisions of S.S.I. 2007/139 continue to apply after 1st October 2007 in respect of pre-payment certificates issued under regulation 8 of those Regulations (by virtue of regulation 10(2)(c)(ii) of S.S.I. 2007/389).

⁽³⁵⁾ S.S.I. 2007/389.

- (a) in the case of a pre-payment certificate valid for a period of 4 months, the sum of £4.72 for each complete month during which the pre-payment certificate remains valid beginning with 1st April 2008;
 - (b) in the case of a pre-payment certificate valid for a period of 12 months, the sum of £4.23 for each complete month during which the pre-payment certificate remains valid beginning with 1st April 2008.
- (3) An application under this regulation for a partial refund shall be made to the Agency and must be received by the Agency not more than 3 months after the date on which the pre-payment certificate expires.
- (4) An application under this regulation for a partial refund shall be made on a form provided for the purpose by the Agency and shall be accompanied by a declaration in support of the application.
- (5) Any partial refund under this regulation shall be made in such a manner and subject to such conditions as the Scottish Ministers may determine.
- (6) For the purposes of this regulation, “complete month” means the month beginning on the monthly anniversary of the date upon which the pre-payment certificate became valid and ending on the date immediately preceding that date in the following month.

Revocations and transitional provisions

12.—(1) The 2007 (No. 2) Regulations are revoked.

(2) Notwithstanding the provisions of paragraph (1) and without prejudice to the provisions of section 16 of the Interpretation Act 1978⁽³⁶⁾—

- (a) the provisions of the 2001 Regulations shall continue to apply on or after 1st April 2008—
 - (i) in respect of any drugs or appliances supplied prior to 1st April 2007;
 - (ii) in respect of any claims for refunds in respect of charges paid for drugs and appliances supplied prior to 1st April 2007;
 - (iii) in respect of any appliance listed in Schedule 1 where the examination or first examination leading to the supply of that appliance took place prior to 1st April 2007;
- (b) the provisions of the revoked 2007 Regulations shall continue to apply on or after 1st April 2008—
 - (i) in respect of any drugs or appliances supplied between 1st April 2007 and 30th September 2007;
 - (ii) in respect of any claims for refunds in respect of charges paid for drugs and appliances supplied between 1st April 2007 and 30th September 2007;
 - (iii) in respect of any appliance listed in Schedule 1 where the examination or first examination leading to the supply of that appliance took place between 1st April 2007 and 30th September 2007;
- (c) the provisions of the revoked 2007 (No. 2) Regulations shall continue to apply on or after 1st April 2008—
 - (i) in respect of any drugs or appliances supplied between 1st October 2007 and 31st March 2008;
 - (ii) in respect of any claims for refunds in respect of charges paid for drugs and appliances supplied between 1st October 2007 and 31st March 2008;

(36) 1978 c. 30.

- (iii) in respect of any appliance listed in Schedule 1 where the examination or first examination leading to the supply of that appliance took place between 1st October 2007 and 31st March 2008;
- (d) Any—
 - (i) exemption certificate issued by or on behalf of a Health Board under regulation 7 of the 2001 Regulations, regulation 7 of the revoked 2007 Regulations or regulation 7 of the revoked 2007 (No. 2) Regulations; and
 - (ii) pre-payment certificate issued by or on behalf of a Health Board under regulation 8 of the revoked 2007 Regulations or the revoked 2007 (No. 2) Regulations,shall be valid for the purposes of these Regulations, as if such certificates had been issued under regulation 7 or regulation 8 respectively of these Regulations.

Consequential amendments

- 13.** The provisions listed in Schedule 3 are amended as specified in that Schedule.

St Andrew's House,
Edinburgh
31st January 2008

SHONA ROBISON
Authorised to sign by the Scottish Ministers