

2007 No. 389

NATIONAL HEALTH SERVICE

**The National Health Service (Charges for Drugs and
Appliances) (Scotland) (No. 2) Regulations 2007**

Made - - - - - *29th August 2007*

Laid before the Scottish Parliament *3rd September 2007*

Coming into force - - - *1st October 2007*

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The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 25(2), 27(2), 69(1) and (2), 75(a), 105(7) and 108(1) of the National Health Service (Scotland) Act 1978(a) and all other powers enabling them to do so.

Citation and commencement

1. These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) (Scotland) (No. 2) Regulations 2007 and shall come into force on 1st October 2007.

Interpretation

2.—(1) In these Regulations—

“the Act” means the National Health Service (Scotland) Act 1978;

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

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

“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 a 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(d);

“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;

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- (a) 1978 c.29; section 25(2) was amended by the European Communities (Medical, Dental and Nursing Professions) (Linguistic Knowledge) Order 1981 (S.I. 1981/432), article 4(3), the Health and Medicines Act 1988 (c.49), Schedule 2, paragraph 11, the National Health Service and Community Care Act 1990 (c.19) (“The 1990 Act”), section 40(2) and Schedule 9, paragraph 19(6), the National Health Service (Primary Care) Act 1997 (c.46), Schedule 2, paragraph 43 and Schedule 3, Part I and the Health Act 1999 (c.8) (“the 1999 Act”), section 56(3); section 27(2) was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(3) and the 1990 Act, Schedule 9, Part I, paragraph 19(7); section 105(7), which was amended by the Health Services Act 1980 (c.41), Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 9, paragraph 24, and by the 1999 Act, Schedule 4, paragraph 60, contains provisions relevant to the making of these regulations; section 108(1) contains definitions of “prescribed” and “regulations” relevant to the exercise of the statutory powers under which these Regulations are made. See section 66(1) of the 1999 Act in relation to any provision of that Act being taken to be a pre-commencement enactment within the meaning of the Scotland Act 1998 (c.46) (“the 1998 Act”). The functions of the Secretary of State were transferred to the Scottish Ministers, by virtue of section 53 of the 1998 Act.
- (b) S.S.I. 2001/430, amended by S.S.I. 2002/100, 2003/130 and 295, 2004/66 and 212, S.S.I. 2005/124, 326 and 617, and 2006/149 and 246; and S.I. 2004/1771.
- (c) S.S.I. 2007/139, amended by S.S.I. 2007/317.
- (d) 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).

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

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

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

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

“exemption” means any remission granted under or by virtue of these Regulations;

“exemption certificate” means a certificate issued under these Regulations authorising a person to claim exemption from charges payable under these Regulations;

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

“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(c);

“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;

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

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

“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(e);

“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(f);

“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(g) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(h); 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;

(a) 2000 c.7.

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

(c) Section 2 was amended by the National Health Service Reform (Scotland) Act 2004 (asp.7), Schedule 1, para 1(2)(b).

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

(e) S.I. 1997/1830. The definition of “Patient Group Direction” was inserted by S.I. 2000/1917.

(f) 1968 c.67. Section 132 was amended by S.I. 2007/289.

(g) S.I. 2007/289.

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

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

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

“prescription form” means–

- (a) a form–
 - (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; or
 - (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,
and includes a prescription form provided and issued under equivalent arrangements having effect in England, Wales and Northern Ireland; or
- (b) data that are 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
 - (iii) a prescriber,
and signed with such person’s advanced electronic signature and transmitted as an electronic communication through the ePharmacy service; or
- (c) 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;

“section 17C provider” means a party to a section 17C agreement(b) 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(c);
- (c) the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(d);
- (d) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(e) relating to–
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists; or
 - (iii) diagnostic or therapeutic radiographers; or

(a) 1997 c.46.

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

(c) S.I. 2007/289.

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

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

(e) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(a),

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)(b);

“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(c) or the National Health Service (General Dental Services) (Scotland) Regulations 1996(d);

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

“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 one prescription form shall be deemed to be the supply of only one quantity of a drug; and
- (b) the supply against an order on one prescription form of more than one appliance of the same type or the supply against an order on one 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(f) (“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(g), 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.

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

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

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

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

(e) S.S.I. 2003/460, amended by S.S.I. 2004/102 and 116, 2005/3 and 179, 2006/142, 183 and 440, 2007/225, 259 and 391.

(f) S.S.I. 2004/142.

(g) S.S.I. 2004/163.

Supply of drugs and appliances by chemists

3.—(1) A chemist who provides pharmaceutical services to a patient shall make and recover from the patient—

- (a) in respect of the supply of an appliance specified in column 1 of Schedule 1 the charge specified in column 2 of Schedule 1 in respect of that appliance; and
- (b) in any other case, in respect of the supply of each quantity of a drug and each appliance not so specified, a charge of £6.85,

except where—

- (i) a declaration of entitlement to exemption on a non-electronic 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
- (ii) 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.

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

(3) A chemist shall be under no obligation to provide pharmaceutical services in respect of an order on a prescription form, or in terms of a 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 (1) applies.

(4) A chemist who makes and recovers a charge under paragraph (1) or (2) 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.

(5) 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 to which the exceptions set out in paragraph (1) apply, shall be reduced by the sum specified in paragraph (1)(b) in respect of each quantity of a drug supplied and by the sum specified in paragraph (1)(b), or as the case may require, the sum specified in column 2 of Schedule 1 in respect of each appliance supplied as part of such services.

Supply of drugs and appliances by doctors

4.—(1) 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(a) 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(b) shall make and recover from the patient—

- (a) in respect of the supply of an appliance specified in column 1 of Schedule 1 the charge specified in column 2 of Schedule 1 in respect of that appliance; and
- (b) in any other case, in respect of the supply of each quantity of a drug and each appliance not so specified, a charge of £6.85,

except where the patient or a person on the patient's behalf declares that the patient is entitled to exemption.

(2) 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.

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

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

(3) 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 (1) applies.

(4) 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.

(5) A doctor who makes and recovers a charge under paragraph (1) or (2) 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) 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 appliance specified in column 1 of Schedule 1 or Schedule 2, the charge specified in column 2 of Schedule 1 or Schedule 2 in respect of that appliance; and
- (b) in respect of the supply of each quantity of a drug and each appliance not so specified, a charge of £6.85,

except where the out-patient or person on the out-patient's behalf, declares that the out-patient is entitled to exemption.

(2) For the purposes of this regulation, where a quantity of a drug supplied by a hospital against an order on one 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 upon the supply of the first instalment.

(3) A Health Board which makes and recovers a charge under paragraph (1) or (2) 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 supports and wigs

6.—(1) A Health Board which, otherwise than under Part II of the Act, supplies a patient with an appliance specified in column 1 of Schedule 3, shall make and recover from the patient the charge specified in column 2 of Schedule 3 in respect of that appliance.

(2) 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(a);
- (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

(a) 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.

child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965^(a);

- (e) a person to whom a Health Board has issued an 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 the patient from leaving a residence without the help of another person;
- (f) 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;
- (g) a person in respect of the supply to that person of the drugs or preparations specified in Schedule 4; or
- (h) a person to whom a pre-payment certificate has been granted pursuant to regulation 8.

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

- (a) in the case of a charge payable to a chemist—
 - (i) a declaration of entitlement to exemption on a non-electronic prescription form, or 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
 - (ii) 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 to 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 (1)(e) 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

(a) 1965 c.49.

(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)(e), 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 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 or 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) Any person 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 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 £35.85 for a certificate valid for 4 months or £98.70 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 (f) 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 (f) 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 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 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 valid for 4 months and becomes a person—
 - (i) to whom any of the provisions of regulation 7(1)(b) to (f) apply; 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 valid for 12 months and becomes a person—
 - (i) to whom any of the provisions of regulation 7(1)(b) to (f) apply; 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; or
- (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.

Refunds

9.—(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 shall be made on a form provided for the purpose 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 for a refund 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.

Revocations and transitional provisions

10.—(1) The Regulations specified in column 1 of Schedule 5 are hereby revoked.

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

- (a) the provisions of the 2001 Regulations shall continue to apply on and after 1st October 2007—
 - (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 or appliances supplied prior to 1st April 2007;
 - (iii) in respect of any appliance listed in Schedule 3 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 and after 1st October 2007—
 - (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 or appliances supplied between 1st April 2007 and 30th September 2007;
 - (iii) in respect of any appliance listed in Schedule 3 where the examination or first examination leading to the supply of that appliance took place between 1st April 2007 and 30th September 2007; and
- (c) (i) any exemption certificate issued by or on behalf of a Health Board under regulation 7 of the 2001 Regulations or regulation 7 of the revoked 2007 Regulations; and
 - (ii) any pre-payment certificate issued by or on behalf of a Health Board under regulation 8 of the 2001 Regulations or regulation 8 of the revoked 2007 Regulations,

(a) 1978 c.30.

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.

St Andrew's House,
Edinburgh
29th August 2007

S ROBISON
Authorised to sign by the Scottish Ministers

SCHEDULE 1

Regulations 3, 4 and 5

CHARGES FOR ELASTIC HOSIERY

<i>Column 1 Appliance</i>	<i>Column 2 Charge</i>
Anklet, legging, knee-cap, below-knee or thigh stocking.	£6.85 each (£13.70 per pair)

SCHEDULE 2

Regulation 5

CHARGES FOR TIGHTS

<i>Column 1 Appliance</i>	<i>Column 2 Charge</i>
Tights (per pair)	£13.70

SCHEDULE 3

Regulation 6

CHARGES FOR FABRIC SUPPORTS AND WIGS

<i>Column 1 Appliance</i>	<i>Column 2 Charge</i>
Surgical Brassiere	£23.10
Abdominal or Spinal Support	£34.95
Stock Modacrylic Wig	£6.85
Partial Human Hair Wig	£150.75
Full Bespoke Human Hair Wig	£220.50

SCHEDULE 4

Regulation 7(1)

SCHEDULE OF DRUGS TO TREAT TUBERCULOSIS

1. Any of the following drugs or preparations containing these drugs, used for the purpose of treating Tuberculosis.

Capreomycin

Cylocersine

Ethambutol

Isoniazid

Pyrazinamide

Rifabutin

Rifampicin

Streptomycin

2. Any of the following drugs or preparations containing these drugs, used for the purpose of treating drug resistant Tuberculosis or associated infections:

Amikacin

Macrolides

Quinolones

Protionamide

3. The following drug or preparation used prophylactically, when treating Tuberculosis:

Pyridoxine

SCHEDULE 5

Regulation 10

REVOCATIONS

<i>Column 1</i> <i>Regulations revoked</i>	<i>Column 2</i> <i>References</i>	<i>Column 3</i> <i>Extent of revocation</i>
The National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2007	S.S.I. 2007/139	The whole Regulations
The National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2007	S.S.I. 2007/317	The whole Regulations

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide for the making and recovery of charges for drugs and appliances (other than dental or optical appliances) supplied under or by virtue of the National Health Service (Scotland) Act 1978 (“the Act”).

The National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001 (“the 2001 Regulations”) were consolidated (with some modifications) by the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2007 (“the 2007 Regulations”) which were amended by the National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2007.

These Regulations make some further modifications to the 2007 Regulations. In view of the recent consolidation, and to assist the reader, the modifications have been effected by revoking the 2007 Regulations and making new regulations incorporating these modifications.

Some changes have been made to the scheme operating under the 2007 Regulations as noted below.

There are no changes to the rates of charge.

Regulation 1 provides that the Regulations shall come into force on 1st October 2007.

Regulation 2 defines the meaning of terms used in the Regulations.

New definitions have been added of—

- (a) “the revoked 2007 Regulations”; and
- (b) “pharmacist independent prescriber”.

The definition of “prescriber” has been amended to include “pharmacist independent prescriber” in anticipation of the proposed introduction of pharmacist independent prescribing in Scotland.

Regulation 3 provides that chemists who provide pharmaceutical services to patients shall make and recover charges in respect of the supply of drugs and appliances except where a declaration of entitlement to exemption is completed in respect of a patient.

Regulation 4 provides that doctors who provide certain pharmaceutical services to patients shall make and recover charges in respect of the supply of drugs and appliances and are to remit the sum recovered in charges to the relevant Health Board.

Regulation 5 provides that a Health Board which supplies hospital out-patients with drugs or appliances shall make and recover charges in respect of drugs or appliances supplied to the out-patients.

Regulation 6 provides that a Health Board shall make and recover a charge from a patient in respect of the supply of a fabric support or wig.

Regulation 7 provides for exemptions from charges for certain patients including those under the age of 16 or those who have a listed medical condition, or where the patient has an exemption certificate. An additional category of exemption has been added (paragraph (1)(g)) for persons to whom drugs specified in Schedule 4 (drugs to treat tuberculosis) are supplied.

Regulation 8 provides for pre-payment certificates in respect of charges for drugs and appliances and for the circumstances in which a claim for refund of the cost of a certificate can be made. Paragraph (1) has been amended to provide that the application form for a certificate is to be sent to the address specified in the form. Paragraph (3) has been amended to specify the permitted validity dates of the certificate. Paragraphs (6), (8) and (11) have been amended to clarify that the

amount of a refund shall be calculated by reference to the amount paid for the certificate, or the appropriate specified fraction of that amount.

Regulation 9 enables a person who was eligible for exemption from charges at the time of payment to claim a refund of those charges. Such claims shall be made on a form provided for the purpose and shall be accompanied by appropriate evidence in support of the claim. The claim form is available from Community Pharmacists.

Regulation 10(1) revokes the regulations which have been consolidated by these Regulations.

Regulation 10(2) makes transitional provisions.

Schedule 1 sets out the charges for elastic hosiery.

Schedule 2 sets out the charges for tights.

Schedule 3 sets out the charges for fabric supports and wigs.

A new Schedule 4 has been added specifying the drugs used to treat tuberculosis for which exemption from charges is provided in regulation 7(1)(g).

Schedule 5 lists the regulations revoked by these Regulations.

2007 No. 389

NATIONAL HEALTH SERVICE

The National Health Service (Charges for Drugs and
Appliances) (Scotland) (No. 2) Regulations 2007

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