SCOTTISH STATUTORY INSTRUMENTS

2008 No. 27

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

"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;

⁽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).

- "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);
- "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

^{(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.

(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
 - (iii) a prescriber,

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

⁽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.

"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-
 - (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,

⁽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.

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.

⁽²⁴⁾ S.S.I. 2004/142.

⁽²⁵⁾ S.S.I. 2004/163.