

2007 No. 208

NATIONAL HEALTH SERVICE

**The National Health Service (Pharmaceutical Services)
(Scotland) Amendment Regulations 2007**

<i>Made</i> - - - -	<i>6th March 2007</i>
<i>Laid before the Scottish Parliament</i>	<i>8th March 2007</i>
<i>Coming into force</i> - -	<i>1st April 2007</i>

The Scottish Ministers in exercise of the powers conferred by sections 27(1) and (2), 105(7), 106 and 108(1) of the National Health Service (Scotland) Act 1978(a) and of all other powers enabling them in that behalf, hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2007 and shall come into force on 1st April 2007.

Amendment of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995

2.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995(b) are amended as follows.

(2) In regulation 2(1) (interpretation and application)—

(a) insert each of the following definitions in the appropriate alphabetical place—

““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;

(a) 1978 c.29; section 27(1) was amended by the Health Services Act 1980 (c.53) (“the 1980 Act”), section 20(2), the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), Schedule 9, paragraph 19(7)(a), the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 3, the National Health Services (Primary Care) Act 1997 (c.46), Schedule 2, Part 1, paragraph 44, and the Health and Social Care Act 2001 (c.15), section 44(2); section 27(2) was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(3) and amended by the 1990 Act, Schedule 9, paragraph 19(7)(b); section 105(7) was amended by the 1980 Act, Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 9, Part I, paragraph 24 and the Health Act 1999 (c.8), Schedule 4, paragraph 60; section 108(1) contains definitions of “prescribed” and “regulations” relevant to the exercise of the statutory powers under which these Regulations are made. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

(b) S.I. 1995/414, as amended by S.I. 1996/840 and 1504, 1997/696, 1998/2224 and 3031, S.S.I. 1999/57, 2001/70, 2002/111, 2003/296, 2004/39 and 212, S.I. 2004/1771, 2005/327 and 618, 2006/143, 245 and 320, and S.I. 2007/289.

“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;

“ePharmacy service” means the electronic system provided by the Agency by which electronic prescription forms are transmitted;

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

(b) for the definition of “prescription form” substitute–

““prescription form” means–

(a) a form–

(i) on which the provision of pharmaceutical services may be ordered by–

(a) a Board;

(b) a dentist pursuant to the provisions of his or her terms of service;

(c) a dentist performing personal dental services in accordance with a pilot under Part I of the National Health Service (Primary Care) Act 1997(b); or

(d) 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 or 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 a 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.”.

(3) For paragraph 3(1) (provision of pharmaceutical services) of Schedule 1(c), substitute–

“(1) Subject to the other provisions of these Regulations where–

(a) any person presents a non-electronic prescription form which contains–

(i) an order for drugs, not being scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber; or

(ii) an order for a drug specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug which can only be ordered for

(a) 2000 c.7.

(b) 1997 c.46.

(c) Schedule 1, paragraph 3(1) was amended by S.I. 1996/1504 and S.S.I. 2001/70.

specified patients and specified purposes in the provision of primary medical services under a general medical services contract signed by and endorsed on its face with the reference “SLS” by a prescriber; or

(iii) an order for a restricted availability appliance, signed by and endorsed on its face with the reference “SLS” by a prescriber; or

(iv) an order for listed drugs signed by a dentist; or

(b) subject to sub-paragraph (1B), the pharmacist receives from the ePharmacy service an electronic prescription form which contains an order of a kind specified in sub-sub-paragraph (a)(i) to (iv) and the patient named on the form, or a person on the patient’s behalf, requests the provision of drugs or appliances in accordance with that prescription and completes and signs a declaration of entitlement to exemption or a statement that a charge has been paid,

a pharmacist shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as the pharmacist supplies in the normal course of business and any drugs so specified shall be in a suitable container.”.

(4) Insert new sub-paragraphs (1B) and (1C) in paragraph 3 of Schedule 1 as follows–

“(1B) A pharmacist shall not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971(a), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(b).

(1C) A pharmacist may refuse to supply drugs or appliances ordered on a prescription form where–

(a) the pharmacist or other person is subjected to or threatened with violence by the person presenting the prescription form or requesting the provision of drugs or appliances in accordance with an electronic prescription form, or by any person accompanying that person; or

(b) the person presenting the prescription form or requesting the provision of drugs or appliances in accordance with an electronic prescription form, or any other person accompanying that person, commits or threatens to commit a criminal offence.”.

(5) Paragraph 3(3A) of Schedule 1(c) is amended as follows–

(a) in sub-sub-paragraph (a)–

(i) after “presenting a” insert “non-electronic”;

(ii) for “National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001(d) (“the 2001 Regulations”)” substitute “National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2007(e) (“the 2007 Regulations”)”; and

(iii) after “2003,” insert “or a declaration of entitlement to such exemption or remission in relation to an electronic prescription form,”,

(b) after sub-sub-paragraph (a), insert a new sub-sub-paragraph (aa) as follows–

“(aa) sub-sub-paragraph (a) shall not apply in respect of claims for exemption under regulation 7(1)(a) or (c) of the 2007 Regulations where–

(i) the prescription form is an electronic prescription form and the person’s date of birth is specified in the electronic prescription form; or

(ii) the prescription form is a non-electronic prescription form and the person’s date of birth has been printed by means of a computer on the non-electronic prescription form.”.

(a) 1971 c.38.

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

(c) Paragraph 3(3A) of Schedule 1 was inserted by S.I. 1998/303.

(d) S.S.I. 2001/430, amended by S.S.I. 2002/100, 2003/130, 295, 2004/66, 212, S.I. 2004/1771, S.S.I. 2005/124, 326, 617, 2006/149 and 246.

(e) S.S.I. 2007/139.

- (c) in sub-sub paragraph (c)–
 - (i) for “the prescription form” substitute “a non-electronic prescription form”;
 - (ii) after “supply form” where it first appears insert “, or declaration of entitlement to exemption in relation to an electronic prescription form”,
 - (iii) after “patient’s” insert “non-electronic”; and
 - (iv) after “supply form” where it second appears insert “or that patient’s declaration of entitlement to exemption in relation to an electronic prescription form”.
 - (d) in sub-sub paragraphs (b) and (c) for “the 2001 Regulations” substitute “the 2007 Regulations”; and
 - (e) in sub-paragraphs (4) and (6) for “the Misuse of Drugs Regulations 1985(a)” substitute “the Misuse of Drugs Regulations 2001(b)”.
- (6) Paragraph 3(11) of Schedule 1(c) is amended as follows–
- (a) before “prescription” where it first appears insert “non-electronic”;
 - (b) for “sub-paragraph (1)” substitute “sub-paragraph (1)(a), or in accordance with an electronic prescription form received in accordance with sub-paragraph (1)(b)”;
 - (c) for “Schedule 5 to the Misuse of Drugs Regulations 1985” substitute “Schedule 4 or 5 to the Misuse of Drugs Regulations 2001”.

LEWIS MACDONALD

Authorised to sign on behalf of the Scottish Ministers

St Andrew’s House,
Edinburgh
6th March 2007

(a) S.I. 1985/2066.
(b) S.I. 2001/3998.
(c) Paragraph 3(11) of Schedule 1 was amended by S.I. 1996/1504.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995 (“the principal Regulations”) which regulate the provision of pharmaceutical services under the National Health Service (Scotland) Act 1978.

Regulation 2(2) inserts into the principal Regulations definitions of “advanced electronic signature”, “electronic communication”, “electronic prescription form”, “electronic signature”, “e-Pharmacy Service” and “non-electronic prescription form” and substitutes a new definition of “prescription form”, to provide for the electronic transmission of prescriptions.

Regulation 2(3) substitutes a new sub-paragraph 3(1) to Schedule 1 of the principal Regulations to provide that a pharmacist shall dispense drugs ordered on an electronic prescription form, as well as on a non-electronic prescription form. Sub-sub paragraph (a)(iv) now refers only to an order for listed drugs signed by a dentist, and omits the previous reference in sub-paragraph 1(a) of the principal Regulations to “drugs, not being scheduled drugs”.

Regulation 2(4) inserts into Schedule 1–

- (i) a new sub-paragraph 3(1B) to restrict the provision of controlled drugs ordered on an electronic prescription form; and
- (ii) a new sub-paragraph 3(1C) to give a pharmacist the right to refuse to supply drugs and appliances in specified circumstances.

Regulation 2(5)(b) amends the principal Regulations to provide that evidence of exemption on the grounds of age need not be produced if the patient’s date of birth is computer printed on a prescription form.

Regulation 2(5) makes various other amendments to the principal Regulations as a consequence of the introduction of electronic prescription forms and the revocation of the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001, and their replacement by the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2007.

Regulation 2(6) amends paragraph 3(11) of Schedule 1 in consequence of the introduction of electronic prescription forms.

References in the principal Regulations to the Misuse of Drugs Regulations 1985 have been replaced by references to the Misuse of Drugs Regulations 2001.

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