

2020 No. 420

NATIONAL HEALTH SERVICE

**The National Health Service (Pharmaceutical Services)
(Scotland) Amendment Regulations 2020**

Made - - - - - *8th December 2020*

Laid before the Scottish Parliament *10th December 2020*

Coming into force in accordance with regulation 1(2) and (3)

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 27, 28A, 105(7) and 106(a) of the National Health Service (Scotland) Act 1978(a) and all other powers enabling them to do so.

Citation and commencement

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2020.

(2) Subject to paragraph (3) these Regulations come into force on 24 January 2021.

(3) Regulation 4(2), (3) and (4) come into force on 12 February 2021.

Amendment of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

2. The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(b) are amended in accordance with regulations 3 to 5.

(a) 1978 c.29. Section 27 was amended by the Health Services Act 1980 (c.53) (“the 1980 Act”), section 20(2), the National Health Service (Amendment) Act 1986 (c.66), section 3(3), the National Health Service and Community Care Act 1990 (c.19), section 66(1) and schedule 9, paragraph 19(7), the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 3, the National Health Service (Primary Care) Act 1997 (c.46), schedule 2, paragraph 44, the Health and Social Care Act 2001 (c.15), section 44(2) and (3), the Health and Social Care Act 2012 (c.7), sections 213(7) and 220(2), S.I. 1987/2202, S.I. 2003/1590, S.I. 2004/1771, S.I. 2005/2011 and S.I. 2010/231, and is to be read with the Health and Medicines Act 1988 (c.49), section 17; section 28A was inserted by the Health Act 1999 (c.8) (“the 1999 Act”), section 57 and amended by the Primary Medical Services (Scotland) Act 2004 (asp 1), schedule, paragraph 1(9); and section 105(7) was amended by the 1980 Act, schedule 6, paragraph 5 and schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), section 29(1) and schedule 9, paragraph 24 and the 1999 Act, schedule 4, paragraph 60. Section 108(1) contains definitions of “prescribed” and “regulations” relevant to the exercise of the statutory power 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.S.I. 2009/183. Relevantly amended by S.I. 2012/1916, S.S.I. 2009/209, S.S.I. 2014/73, S.S.I. 2018/67 and S.S.I. 2019/284.

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

- (a) after the definition of “optometrist independent prescriber”, insert—
 - ““pandemic treatment protocol” means a protocol that—
 - (a) relates to the supply of a prescription only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of a disease being imminently, pandemic and a serious risk, or potentially a serious risk, to human health, and
 - (b) is approved in accordance with regulation 247 of the Human Medicines Regulations 2012(a) (exemption for supply in the event or anticipation of pandemic disease),”, and
- (b) after the definition of “provisional pharmaceutical list”, insert—
 - ““PTP” means a pandemic treatment protocol,”.

4.—(1) Paragraph 4 (provision of pharmaceutical services) of schedule 1 (terms of service for pharmacists and pharmacy contractors) is amended as follows.

(2) In sub-paragraph (2)—

- (a) in head (a)—
 - (i) for “chronic medication service”, where it appears for the first time, substitute “Medicines: Care and Review Service”, and
 - (ii) for “chronic medication service”, where it appears for the second time, substitute “service to assist patients with drugs, medicines and appliances and the management of long term illnesses, diseases or health conditions”,
- (b) after head (a), insert—
 - “(aa) “prison” means—
 - (i) a prison within the meaning of section 43 of the Prisons (Scotland) Act 1989(b),
 - (ii) a remand centre within the meaning of section 19(1)(a) of that Act, or
 - (iii) a young offenders institution within the meaning of section 19(1)(b) of that Act(c),”,
- (c) in head (b)—
 - (i) after “doctor” in each place it occurs, insert “, pharmacist independent prescriber or independent nurse prescriber other than a supplementary prescriber”,
 - (ii) in sub-head (i), for “2”, substitute “3”,
 - (iii) in sub-head (iii)—
 - (aa) after “receive”, insert “those”, and
 - (bb) after “3 months,”, insert “or where that patient receives primary medical services in prison,”, and
 - (iv) in the text after sub-head (iii), from “registered” to the end of head (b), substitute “a long-term illness, disease or health condition that requires ongoing management over a period of a year or longer,”, and
- (d) in head (c)(ii)—
 - (i) for “the”, where it appears before “pharmacy contractor”, substitute “a”, and
 - (ii) omit from “with whom”, to the end of sub-head (ii).

(a) S.I. 2012/1916. Relevantly amended by S.I. 2013/235 and S.I. 2020/1125.

(b) 1989 c.45.

(c) Section 19 was amended by the Criminal Justice (Scotland) Act 2003 (asp 7), section 23.

- (3) After sub-paragraph (2), insert—
- “(2A) A pharmacy contractor must ensure that drugs or appliances ordered on a serial prescription are not supplied to a patient unless the patient has registered with that pharmacy contractor for the provision of the Medicines: Care and Review Service.”
- (4) In sub-paragraph (3)—
- (a) for “has”, substitute “is”, and
 - (b) for “chronic medication service”, substitute “Medicines: Care and Review Service”.
- (5) In sub-paragraph (11)—
- (a) for “ordered on a prescription form or a serial prescription”, substitute “in accordance with these Regulations”,
 - (b) in head (a)—
 - (i) omit “presenting the prescription form or serial prescription or”, and
 - (ii) for “an electronic prescription form or serial prescription”, substitute “these Regulations”, and
 - (c) in head (b)—
 - (i) omit “presenting the prescription form or serial prescription, or”, and
 - (ii) for “an electronic prescription form or serial prescription”, substitute “these Regulations”.
- (6) In sub-paragraph (23), for “(33)”, substitute “(43)”.
- (7) After sub-paragraph (38), insert—
- “(39) A pharmacist may supply a prescription only medicine in accordance with a PTP where—
- (a) a PTP has effect in respect of the prescription only medicine,
 - (b) the requirements specified in the PTP are satisfied, and
 - (c) the pharmacist is able to supply the prescription only medicine with reasonable promptness.
- (40) A pharmacist may refuse to supply a prescription only medicine in accordance with a PTP where in the pharmacist’s professional judgement it is unreasonable or inappropriate to do so.
- (41) Where a pharmacist supplies a prescription only medicine in accordance with a PTP the pharmacist must—
- (a) include in the dispensing label on the packaging of the prescription only medicine, for the patient’s benefit, information to the effect that the prescription only medicine is being supplied in accordance with a PTP, identifying the particular PTP, and
 - (b) supply the prescription only medicine in a suitable container.
- (42) A pharmacist may provide pharmaceutical services in accordance with the terms of a protocol approved by the Scottish Ministers under regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations) of the Human Medicines Regulations 2012(a) where the conditions specified in that regulation are satisfied.
- (43) A pharmacist may provide pharmaceutical services in response to an announcement of the Secretary of State and arrangements made in accordance with regulation 10A (directions of a practitioner while a disease is, or in anticipation of a disease being imminently, pandemic etc.) or 15(5) (form of prescriptions) of the Misuse of Drugs Regulations 2001(b).”.

(a) Regulation 247A was relevantly amended by S.I. 2020/1125.

(b) S.I. 2001/3998. Relevantly amended by S.I. 2020/468.

5. For paragraph 10(8) (method of payment) of schedule 1 (terms of service for pharmacists and pharmacy contractors), substitute—

“(8) No pharmacy contractor will be paid in respect of the supply of drugs or appliances—

- (a) indicated on a prescription form or serial prescription,
- (b) in terms of regulation 225 (emergency sale etc by pharmacist: at patient’s request) of the Human Medicines Regulations 2012(a),
- (c) in terms of a Patient Group Direction issued by a Health Board in accordance with regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012(b),
- (d) in accordance with the terms of a protocol approved by the Scottish Ministers under regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations) of the Human Medicines Regulations 2012(c),
- (e) in accordance with a SSP or a Scottish SSP,
- (f) in accordance with a PTP, or
- (g) in response to an announcement by the Secretary of State and arrangements made in accordance with regulation 10A (directions of a practitioner while a disease is, or in anticipation of a disease being imminently, pandemic etc.) or 15(5) (form or prescriptions) of the Misuse of Drugs Regulations 2001(d),

unless that supply takes place at a registered pharmacy included in the pharmaceutical list in respect of that pharmacy contractor.”.

JEANE FREEMAN

A member of the Scottish Government

St Andrew’s House,
Edinburgh
8th December 2020

(a) Relevantly amended by S.I. 2014/323.
(b) Relevantly amended by S.I. 2013/235, S.R. (NI) 2015 No 354 and S.I. 2020/1125.
(c) Relevantly amended by S.I. 2020/1125.
(d) Relevantly amended by S.I. 2020/468.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (“the 2009 Regulations”) to make changes to the chronic medication service which is to be re-named the “Medicines: Care and Review Service”. These Regulations also amend the 2009 Regulations to allow pharmacists to provide pharmaceutical services in certain circumstances while a disease is, or in anticipation of a disease being, imminently pandemic.

Regulation 3 amends regulation 2(1) of the 2009 Regulations to include definitions of “pandemic treatment protocol” and “PTP”.

Regulation 4(2)(a) and (4)(b) amend paragraph 4(2)(a) and (3) of schedule 1 of the 2009 Regulations to substitute references to the “chronic medication service” for the “Medicines: Care and Review Service” and add a description of the service.

Regulation 4(2)(b) inserts a new head (aa) into paragraph 4(2) of schedule 1 of the 2009 Regulations to include a definition for “prison”.

Regulation 4(2)(c) amends the definition of “serial prescriber” in paragraph 4(2)(b) of schedule 1 of the 2009 Regulations to:

- extend the definition by inserting “pharmacist independent prescriber” and “independent nurse prescriber other than a supplementary prescriber”,
- exclude patients receiving primary medical services in prison, and
- remove the requirement that the patient has to be registered with a pharmacy contractor for the provision of the chronic medication service and to include a new requirement that the patient has a long-term illness, disease or health condition that requires ongoing management over a period of a year or longer.

Regulation 4(2)(d) amends the definition of “serial prescription” in paragraph 4(2)(c) of schedule 1 of the 2009 Regulations. An electronic copy of the prescription form transmitted through the ePharmacy service to a pharmacy contractor no longer has to be transmitted to the pharmacy contractor the patient has registered with for the provision of the chronic medication service.

Regulation 4(3) inserts a new sub-paragraph (2A) in paragraph 4 of schedule 1 of the 2009 Regulations which requires pharmacy contractors to ensure that drugs or appliances ordered on a serial prescription are not supplied to a patient unless the patient has registered with that pharmacy contractor for the Medicines: Care and Review Service.

Regulation 4(5) amends paragraph 4(11) of schedule 1 of the 2009 Regulations. Paragraph 4(11) currently sets out circumstances in which a relevant pharmacist may refuse to supply drugs or appliances and is limited to those drugs or appliances ordered on a prescription form or serial prescription. Regulation 4(5) extends the application of this provision to the supply of drugs or appliances under the 2009 Regulations generally.

Regulation 4(7) inserts new sub-paragraphs (39) to (43) in paragraph 4 of schedule 1 of the 2009 Regulations. Sub-paragraphs (39) to (41) set out the requirements for pharmacists supplying prescription only medicines in accordance with a pandemic treatment protocol. Sub-paragraph (42) allows a pharmacist to provide pharmaceutical services in accordance with the terms of a protocol approved by the Scottish Ministers under regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations) of the Human Medicines Regulations 2012. Sub-paragraph (43) allows a pharmacist to provide pharmaceutical services in response to an announcement of the Secretary of State and arrangements made in accordance with regulation 10A (directions of a practitioner while a disease is, or in anticipation of a disease being imminently, pandemic etc.) or 15(5) (form of prescriptions) of the Misuse of Drugs Regulations 2001.

Regulation 5 replaces paragraph 10(8) of schedule 1 of the 2009 Regulations to consolidate the provision and to set out the circumstances in which a pharmacy contractor will not be paid in

respect of the supply of drugs and appliances unless supply takes place at a registered pharmacy included in the pharmaceutical list in respect of that pharmacy contractor.

Regulation 4(2)(c)(ii), (2)(c)(iii)(aa), (4)(a) and (6) make minor and consequential amendments to the 2009 Regulations.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.

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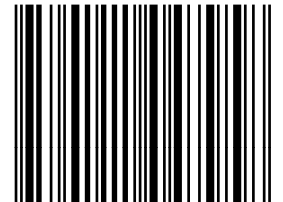
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