STATUTORY RULES OF NORTHERN IRELAND

2022 No. 31

HEALTH AND PERSONAL SOCIAL SERVICES

The Pharmaceutical Services (Amendment) Regulations (Northern Ireland) 2022

Made - - - -	*8th February 2022*
Coming into operation	*1st March 2022*

The Department of Health(**1**), in conjunction with the Department of Finance(**2**), makes the following Regulations in exercise of the powers conferred by Articles 63(1) and (2), 106(b) and 107(6) of the Health and Personal Social Services (Northern Ireland) Order 1972(**3**).

In accordance with Article 63(3) of that Order, the Department of Health has consulted with such organisations as appear to it to be representative of the pharmaceutical profession.

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Pharmaceutical Services (Amendment) Regulations (Northern Ireland) 2022 and shall come into operation on 1st March 2022.

(2) In the Regulations "the Pharmaceutical Regulations" means the Pharmaceutical Services Regulations (Northern Ireland) 1997(**4**).

Amendment of regulation 2 of the Pharmaceutical Regulations

2.—(1) Regulation 2(1) of the Pharmaceutical Regulations (interpretation) is amended as follows.

(2) After "appropriate non-proprietary name" insert —

""authorisation" means permission to supply a drug in accordance with a PTP;".

(3) After "the Order" insert —

""paramedic independent prescriber" means a person—

(**1**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c. 5 (N.I.), s. 1(5)
(**2**) Formally the Department of Finance and Personnel; see 2016 c. 5 (N.I.)
(**3**) S.I. 1972/1265 (N.I. 14); the relevant amending instruments are S.I. 1978/1907 (N.I. 26) Article 14; S.I. 1986/2023 (N.I. 20) Articles 5(1) and (2); S.I. 1991/194 (N.I. 1) Articles 3(1) and (2), 34 and Part II of Schedule 5; S.I. 1992/2671 (N.I. 18) Article 3; S.I. 1997/1177 (N.I. 7) Article 29; S.I. 2003/431 (N.I. 9) Article 47; and 2008 c. 2 (N.I.) section 10
(**4**) S.R. 1997 No. 381; relevant amending instruments are S.R. 1998 No.95, S.R. 1999 Nos. 100, 254 and 405, S.R. 2001 No. 222, S.R. 2002 Nos. 92 and 397, S.R. 2003 No. 447, S.R. 2005 No. 231, S.R. 2009 Nos. 191 and 320, S.R. 2010 No. 72, S.R. 2014 No. 170, S.R. 2016 No. 104 and S.R. 2019 No. 186

(a) who is registered in Part 8 of the register maintained under Article 5 of the Health and Social Work Professions Order 2001; and

(b) against whose name in that register is recorded an annotation signifying that person is qualified to order drugs, medicines or appliances as a paramedic independent prescriber;".

(4) For the definition of "prescriber" substitute—

""prescriber" means a doctor, dentist, a chiropodist or podiatrist independent prescriber, an independent nurse prescriber, an optometrist independent prescriber, a paramedic independent prescriber, a pharmacist independent prescriber, a physiotherapist independent prescriber, a therapeutic radiographer independent prescriber or a supplementary prescriber;".

(5) After "the Prescription of Drugs Regulations" insert—

""PTP" means a pandemic treatment protocol, which is a protocol—

(a) relating 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 it being imminently, pandemic; and

(b) approved in accordance with regulation 247 of the Human Medicines Regulations 2012(**5**) (exemption for supply in the event or anticipation of pandemic disease);".

(6) For the definition of "relevant register" substitute—

""relevant register" means—

(a) in relation to a nurse, the Nursing and Midwifery Register;

(b) in relation to a paramedic, the register maintained under Article 5 of the Health and Social Work Professions Order 2001; and

(c) in relation to a pharmacist, the register maintained under Article 10(1) (the Register of Pharmacists) of the Pharmacists and Pharmacy Technicians Order 2007 or the register maintained in pursuance of Articles 6 (the registers) and 9 (the register) of the Pharmacy (Northern Ireland) Order 1976; ".

(7) In the definition of "supplementary prescriber"—

(a) at the end of sub-paragraph (a)(iv)(bb) and (cc), omit "or" at both places where it occurs; and

(b) after sub-paragraph (a)(iv)(cc) insert "(dd) dietitians; or";

(8) In the definition of "terms of service", omit "and";

(9) After "terms of service" insert —

""therapeutic radiographer independent prescriber" means a person—

(a) who is a registered radiographer; and

(b) against whose name is recorded in the relevant register –

(i) an entitlement to use the title "therapeutic radiographer", and

(ii) an annotation signifying that the person is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber; and".

Amendment of Schedule 2 to the Pharmaceutical Regulations

3.—(1) Schedule 2 to the Pharmaceutical Regulations is amended in accordance with paragraphs (2) and (3) as follows.

(**5**) S.I. 2012/1916; regulation 247 has been amended by S.I. 2013/235 and S.I. 2020/1125

(2) In Part 2 (terms of service for chemists), after paragraph 5B(**6**) (supply in accordance with a SSP) insert—

"**Supply in accordance with a PTP**

5C.—(1) Subject to the following provisions of this paragraph, where—

(a) a chemist receives, via a secure service, an authorisation that amounts to an order for the supply of a drug in accordance with a PTP; and

(b) the person who is to be supplied with that drug in pursuance of that order, or someone acting on that person's behalf, requests the provision of the drug in accordance with that order,

the chemist must, with reasonable promptness, provide the drug so ordered.

(2) If the person who is to be supplied with the drug as mentioned in sub paragraph 1(b), or someone acting on that person's behalf asks the chemist to do so—

(a) the chemist must give an estimate of the time when the drug will be ready; and

(b) if the drug is not ready by then, the chemist must give a revised estimate of the time when it will be ready (until it is ready).

(3) Sub-paragraphs (1) and (2) apply to the provision of a drug in accordance with a PTP as they apply to the provision of a drug in accordance with a prescription form or a repeatable prescription (or an associated batch issue).

(4) Where the chemist provides a drug under this paragraph, the chemist must include a dispensing label on the packaging of the product and include in the label (in addition to the particulars required or permitted by Part 2 of Schedule 26 to the Human Medicines Regulations 2012), for the benefit of the person who is to be supplied with that drug, information to the effect that the product is being supplied in accordance with a PTP, identifying the particular PTP.

(5) The chemist may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP, where—

(a) the chemist reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

(b) providing it would be contrary to the chemist's clinical judgement;

(c) the chemist or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying that person; or

(d) the person who requests the provision of the drug, or any person accompanying that person, commits or threatens to commit a criminal offence.

(6) The chemist must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where the chemist is not satisfied that it is in accordance with the PTP,

but if the chemist does refuse to do so, the chemist, using their clinical judgement, must provide the person who requests, or on whose behalf is requested, the provision of the drug, with appropriate advice as necessary, about alternative sources of treatment.".

(3) In Part 3 (terms of service for doctors who provide pharmaceutical services), after paragraph 15A(**7**) insert—

(**6**) Paragraph 5B was inserted by Regulation 4(2) of S.R. 2019 No. 186
(**7**) Paragraph 15A was inserted by Regulation 4(3) of S.R. 2019 No. 186

"**Supply in accordance with a PTP**

15B.—(1) Subject to the following provisions of this paragraph, where—

(a) a dispensing doctor receives, via a secure service, an authorisation that amounts to an order for the supply of a drug in accordance with a PTP; and

(b) the person who is to be supplied with that drug in pursuance of that order, or someone acting on that person's behalf requests the provision of the drug in accordance with that order,

the dispensing doctor must, with reasonable promptness, provide the drug so ordered.

(2) If the person who is to be supplied with that drug in pursuance of that order, or someone acting on that person's behalf asks the dispensing doctor to do so—

(a) the dispensing doctor must give an estimate of the time when the drug will be ready; and

(b) if the drug is not ready by then, the dispensing doctor must give a revised estimate of the time when it will be ready (until it is ready).

(3) Sub-paragraphs (1) and (2) apply to the provision of a drug in accordance with a PTP as they apply to the provision of a drug in accordance with a prescription form or a repeatable prescription (or an associated batch issue).

(4) Where the dispensing doctor provides a drug under this paragraph, the dispensing doctor must include a dispensing label on the packaging of the product and include in the label (in addition to the particulars required or permitted by Part 2 of Schedule 26 to the Human Medicines Regulations 2012), for the benefit of the person who is to be supplied with that drug, information to the effect that the product is being supplied in accordance with a PTP, identifying the particular PTP.

(5) The dispensing doctor may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP, where—

(a) the dispensing doctor reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

(b) providing it would be contrary to the dispensing doctor's clinical judgement;

(c) the dispensing doctor or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying that person; or

(d) the person who requests the provision of the drug, or any person accompanying that person, commits or threatens to commit a criminal offence.

(6) The dispensing doctor must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where the dispensing doctor is not satisfied that it is in accordance with the PTP,

but if the dispensing doctor does refuse to do so, the dispensing doctor, using their clinical judgement, must provide the person who requests, or on whose behalf is requested, the provision of the drug, with appropriate advice as necessary, about alternative sources of treatment.".

Sealed with the Official Seal of the Department of Health on 8th February 2022.

Cathy Harrison
A senior officer of the Department of Health

Sealed with the Official Seal of the Department of Finance on 8th February 2022.

Barry Armstrong
A senior officer of the Department of Finance

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Pharmaceutical Services Regulations (Northern Ireland) 1997 ("the Pharmaceutical Regulations") which govern the arrangements for the provision of pharmaceutical services under the Health and Personal Social Services (Northern Ireland) Order 1972. The changes arise out of new arrangements for the independent prescribing of drugs and appliances by registered paramedics and therapeutic radiographers and the inclusion of registered dietitians as supplementary prescribers.

Regulation 2 inserts new definitions of "authorisation", "paramedic independent prescriber" and "therapeutic radiographer independent prescriber" into regulation 2 of the Pharmaceutical Regulations. It also substitutes new definitions of "prescriber" and "relevant register" in this regulation and amends the definition of "supplementary prescriber" to include dietitians. Finally it inserts a new definition of "PTP" (pandemic treatment protocol) into this regulation which is part of new measures that are being introduced as part of the response to the coronavirus pandemic, related to which is the expansion of the national programme for immunisation against influenza.

Regulation 3 amends Schedule 2 to the Pharmaceutical Regulations to make provision to allow chemists and dispensing doctors to supply in accordance with a "PTP", which allows for the supply, without a prescription, of prescription only medicines used for the prevention or treatment of diseases that are, or in anticipation of them being imminently, pandemic. There are also supplementary provisions related to this requirement dealing with matters such as dispensing.