STATUTORY RULES OF NORTHERN IRELAND

2022 No. 116

HEALTH AND PERSONAL SOCIAL SERVICES

The Pharmaceutical Services (Amendment No. 2) Regulations (Northern Ireland) 2022

Made - - - -	*16th March 2022*
Coming into operation -	*1st April 2022*

The Department of Health(**a**) makes the following Regulations in exercise of the powers conferred by Articles 63(1) and (2) and 106(b) of the Health and Personal Social Services (Northern Ireland) Order 1972(**b**).

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 No. 2) Regulations (Northern Ireland) 2022 and shall come into operation on 1st April 2022.

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

Amendment of the Pharmaceutical Regulations

2.—(1) Regulation 2 of the Pharmaceutical Regulations (interpretation) is amended in accordance with paragraphs (2) to (4).

(2) In paragraph (1)—

(a) omit the definition of "Board";

(b) in the definition of "dispensing doctor", for "the Board" substitute "the Department";

(c) after the definition of "Drug Tariff", insert—

""FPSIAP" means the Family Practitioner Services Independent Appeal Panel established under regulation 3 of the Health and Social Care (Family Practitioner Services Independent Appeal Panel) Regulations (Northern Ireland) 2022(**d**);";

(**a**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c. 5 (N.I.), s. 1(5)

(**b**) S.I. 1972/1265 (N.I. 14). Article 63 is amended amended by paragraph 33 of Schedule 1 to the Health and Social Care Act (Northern Ireland) 2022 (2022 c.3 (N.I.)). Other 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

(**c**) 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, S.R. 2019 No. 186 and S.R. 2022 No. 31

(**d**) S.R. 2022 No. 109

(d) in the definitions of "Local Dental Committee", "Local Medical Committee" and "Local Pharmaceutical Committee" for "a Board" substitute "the Department";

(e) in the definition of "patient list", for "a Board" substitute "the Department"; and

(f) in the definition of "repeatable prescriber", for "the Regional Board" substitute "the Department".

(3) In paragraph (1A)(**a**) omit "who are in a Board's area".

(4) For paragraph (4) substitute—

"(4) In these Regulations, "emergency requiring the flexible provision of pharmaceutical services" means an emergency to the effect that, as a result of the threatened damage to human welfare caused by illness or which may be caused by illness, the Department must for a specified period—

(a) exercise, or

(b) where a discretion is conferred, consider exercising,

one or more of the functions under regulation 6A, 12(7A) or paragraph 4A of Schedule 2 subject to any conditions or limitations.".

3. In regulation 4(2)(a) of the Pharmaceutical Regulations (additional professional services) for "the Board" substitute "the Department".

4.—(1) Regulation 4A(**b**) of the Pharmaceutical Regulations (repeat dispensing services) is amended in accordance with paragraphs (2) and (3).

(2) In paragraph (2)(b) omit "of a Board".

(3) In paragraph (3), for "the Board" substitute "the Department".

5.—(1) Regulation 6 of the Pharmaceutical Regulations (pharmaceutical list) is amended in accordance with paragraphs (2) to (8).

(2) In paragraph (1)—

(a) for "Each Board" substitute "The Department"; and

(b) omit "within the Board's area".

(3) In paragraph (2)—

(a) omit "within the Board's area," in both places where it occurs; and

(b) for "the Board" where it last occurs, substitute "the Department".

(4) In paragraph (3), for "the Board" substitute "the Department".

(5) In paragraph (4), for "the Board" in both places where it occurs, substitute "the Department".

(6) In paragraphs (4A), (4B), (4C), (4D)(**c**), (5), (7), (8), (9), (10) and (11) for "the Board" in each place where it occurs, substitute "the Department".

(7) In paragraph (12)—

(a) for "the Board" substitute "the Department"; and

(b) omit "in the Board's area".

(8) In paragraph (13), for "the Board" substitute "the Department".

6. In regulation 6A(**d**) of the Pharmaceutical Regulations (temporary relocations and additional premises during an emergency requiring the flexible provision of pharmaceutical services)—

(a) for "Regional Board" in each place where it occurs, substitute "the Department"; and

(b) in paragraph (2)(a) omit "in the direction given".

(**a**) Paragraph (1A) was inserted by S.R. 1999 No. 100
(**b**) Regulation 4A was inserted by S.R. 2005 No. 231
(**c**) Paragraphs (4A), (4B), (4C) and (4A) were inserted into regulation 6 by S.R. 2001 No. 222
(**d**) Regulation 6A was inserted by S.R. 1997 No. 547

7. In regulation 7 of the Pharmaceutical Regulations (removal from the pharmaceutical list) for "the Board" in each place where it occurs, substitute "the Department".

8. In regulation 8 of the Pharmaceutical Regulations (scheme for securing proper pharmaceutical services), for "The Board" substitute "The Department".

9. In regulation 9 of the Pharmaceutical Regulations (standards of and payments for, drugs and appliances), for "the Board" in each place where it occurs, substitute "the Department".

10. Regulation 10 of the Pharmaceutical Regulations (payments to suspended chemists), for "The Board" substitute "The Department".

11. In regulation 10A(**a**) of the Pharmaceutical Regulations (reward scheme), for "the Board" in each place where it occurs, substitute "the Department".

12.—(1) Regulation 12 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors) is amended in accordance with paragraphs (2) to (4).

(2) For "the Board", "a Board", "A Board" or "the Regional Board" in each place where it occurs, substitute "The Department" or where appropriate, "the Department".

(3) In paragraph (5), for "the Department" substitute "the FPSIAP".

(4) In paragraphs (12), (13) and (14), for "The Department" or "the Department" in each place where it occurs, substitute "the FPSIAP".

13. In regulations 12B and 12C(**b**) (dispensing doctor lists), for "A Board" or "the Board" in each place where it occurs, substitute "The Department" or where appropriate, "the Department".

14.—(1) Regulation 14 (publication of particulars) is amended in accordance with paragraphs (2) and (3).

(2) For "The Board" and "the Board" in each place where it occurs, substitute "The Department" or where appropriate, "the Department".

(3) In paragraph (3) omit "the Department,".

15.—(1) Regulation 16 (claims and overpayments) is amended in accordance with paragraphs (2) to (4).

(2) In paragraph (2) omit ", except to the extent that the Department, on the application of the Board, directs otherwise,".

(3) For "the Board" or "the Regional Board" in each place where it occurs, substitute "the Department".

(4) In paragraph (2)(b) for "the Department" substitute "the FPSIAP".

16.—(1) Regulation 18 (transitional provisions in respect of drugs or appliances supplied in accordance with SSPs) in amended in accordance with paragraph (2).

(2) In paragraph (1)(b)—

(a) for "the Board" substitute "the Department; and

(b) for "on the Board's behalf" substitute "on the Department's behalf".

17.—(1) Schedule 2 to the Pharmaceutical Regulations is amended in accordance with paragraphs (2) to (4).

(2) For "the Board", "that Board" "that Board's", "a Board" or "the Regional Board" in each place where it occurs, substitute "the Department".

(3) In paragraph 1(1)(c)(ii), for "the Department" substitute "the FPSIAP".

(4) In Part 2 (terms of service for chemists)—

(**a**) Regulation 10A was inserted by S.R. 1999 No. 254

(**b**) Regulations 12B and 12C were inserted by S.R. 2001 No. 222 and further amended by S.R. 2005 No. 231

(a) in paragraph 4(1),(8),(9) and (10) (premises and hours), for "the Department" or where appropriate, "The Department" in each place where it occurs, substitute "the FPSIAP" or where appropriate, "The FPSIAP";

(b) in paragraph 4(14)(b), for "the Department's determination" substitute "the FPSIAP's determination";

(c) in paragraph 4(15)(b), for "the Department" substitute "the FPSIAP";

(d) in paragraph 4(19), for "the Department" substitute "the FPSIAP";

(e) in paragraph 4(21)(b), for "the Department's decision" substitute "the FPSIAP's decision";

(f) for paragraph 4(23) substitute—

"(23) If the Department makes arrangements under Article 63A(1)(a) or (b) of the Order for a pharmacist to be available to any person for consultation outside the hours referred to in sub-paragraph (22) no direction shall be made under sub-paragraph (22), unless the requirements of sub-paragraph (23A) have been complied with.";

(g) in paragraph 4(26), for "the Department" substitute "the FPSIAP"; and

(h) in paragraph 4(28)(b), for "the Department's decision" substitute "the FPSIAP's decision".

18. In Schedule 3 to the Pharmaceutical Regulations, for "Health and Social Services Board", "the Health and Social Services Board" or "the Board" in each place where it occurs, substitute "the Department of Health" and in each place where it occurs, omit "in the Board's area".

19.—(1) Schedule 4 to the Pharmaceutical Regulations is amended in accordance with paragraphs (2) to (5).

(2) In Part 1 (procedure on applications)—

(a) in paragraph 1(notification of applications)—

(i) in sub-paragraph (1)—

(aa) for "to which regulation 6(9) applies" substitute "to which applications under regulation 6(3), (4), or (9) apply;

(bb) in head (c) omit "in the Board's area" and for "the Board" substitute "the Department;

(cc) omit head (d);

(ii) omit sub-paragraph (2); and

(iii) in sub-paragraph (3) omit "or (2)";

(b) in paragraph 2 (determination of applications)—

(i) for "the Board" or "The Board" in each place where it occurs, substitute "the Department" or where appropriate, "The Department";

(ii) in sub-paragraph (1), for "an application to which regulation 6(9) applies" substitute "application to which regulation 6(3), (4), or (9) applies";

(c) in paragraph 3 (notification of decisions) substitute—

"**Notification of decisions**

3. In the case of an application to which regulation 6(3), (4), or (9) applies, the Department shall, within 14 days of having been notified in accordance with paragraph 11(5), give to the applicant and any person who has made representations to the Department in accordance with paragraph 1(1) or (2), notice of its decision on the application, together with the reasons therefor and any right of appeal under paragraph 4.";

(d) in paragraph 4 (appeals) substitute—

"**Appeals**

4.—(1) Where the Department has determined an application to which regulation 6(3), (4), or (9) applies, the applicant or any person who was given notice of the application under paragraph l(1)(c) or l(2)(c) and who has made representations to the Department in accordance with paragraph 1(1) or 1(2) may appeal against the decision of the Department on the application, and notice of any such appeal shall be received by the Department within 21 days from the date on which notification of the Department's decision was sent to him.

(2) Any notice of appeal under this paragraph shall contain a concise statement of the facts and contentions upon which the appellant intends to rely.

(3) The Department shall refer a notice of appeal under this paragraph to the chairman of the National Appeal Panel appointed in accordance with Part IV.

(4) If the chairman of the National Appeal Panel, after considering the notice of appeal, is of the opinion that the notice discloses no reasonable grounds of appeal or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it forthwith, in which case he shall notify the Department accordingly.

(5) In any other case the National Appeal Panel shall be convened in accordance with Part IV and shall thereafter determine the appeal.".

(3) In Part 2 (pharmacy practices committee)—

(a) for "The Board" or "the Board" in each place where it occurs, substitute "The Department" or where appropriate, "the Department";

(b) in paragraph 7 for "a member" substitute "an officer"; and

(c) in paragraph 8 omit ", and shall provide the Department with a copy of such lists".

(4) In Part 3 (procedure at meetings of the pharmacy practices committee) for "the Board" in each place where it occurs, substitute "the Department".

(5) In Part 4 (National Appeal Panel)—

(a) for paragraph 14 (nominees for the national appeal panel) substitute—

"**Appointments and Nominees to the National Appeal Panel**

14.—(1) The Department shall appoint lay persons for the National Appeal Panel in accordance with the provisions set out in regulation 5 of the Health and Social Care (Family Practitioner Services Independent Appeal Panel) Regulations (Northern Ireland) 2022(**a**).

(2) The Department shall request the Pharmaceutical Society of Northern Ireland and such organisation which is, in the opinion of the Department, representative of the general body of chemists, to submit to the Department their nominees for the National Appeal Panel.".

(b) in paragraph 15 (chairman and vice-chairman of national appeal panel) omit "all Boards,".

(c) for paragraph 16 (membership) substitute—

"**Membership**

16.—(1) In any case in which paragraph 4(6) applies, the Department shall arrange to convene in accordance with this paragraph the National Appeal Panel, the members of which shall be drawn from—

(a) the lists maintained in accordance with paragraph 8; and

(b) the persons appointed and nominated in accordance with paragraph 14.

(**a**) S.R. 2022 No. 109

(2) A member of the National Appeal Panel shall not be an official of the Department or the Regional Business Services Organisation or a member of the Pharmacy Practices Committee which considered the application.

(3) The National Appeal Panel shall consist of 9 members of whom—

(a) one shall be chairman appointed in accordance with paragraph 15;

(b) one shall be vice-chairman and likewise be appointed as such in accordance with paragraph 15;

(c) 4 shall be pharmacists one of whom has been nominated by the Pharmaceutical Society of Northern Ireland and the other 3 by such organisation which is, in the opinion of the Department, representative of the general body of chemists; and of those 4 members only 2 shall be persons whose names are, or who are employees of persons whose names are, included in the pharmaceutical list; and

(d) 3 shall have been appointed by the Department in accordance with paragraph 14, but none shall be a pharmacist or a person, or employee of a person, whose name is included in the pharmaceutical list, or be a doctor who is required to supply drugs and appliances under regulation 12; and not more than one of those 3 shall be a doctor, dentist or ophthalmic optician.".

(d) In paragraph 20 (decisions by the national appeal panel)—

(i) for "the Board" or "The Board" in each place where it occurs, substitute "the Department" or where appropriate, "The Department"; and

(ii) in sub-paragraph (2) omit "to whom the application was made".

20. In Schedule 5 (pharmaceutical committee) for "the Boards", "a Board" and "that Board", in each place where it occurs substitute "the Department".

Sealed with the Official Seal of the Department of Health on 16th March 2022.

L.S.

Cathy Harrison
A senior officer of the Department of Health

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 are consequential to the Health and Social Care Act (Northern Ireland) 2022 (2022 c. 3 (N.I.)).