STATUTORY INSTRUMENTS

2016 No. 1077

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016

Made - - - -	*8th November 2016*
Laid before Parliament	*10th November 2016*
Coming into force - -	*5th December 2016*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 89(1), 94(1), 126(2), 128A, 129(2), (4) and (6), 130(1), 172(1) and 272(7) and (8) of the National Health Service Act 2006(**1**).

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 and come into force on 5th December 2016.

(2) In these Regulations, "the principal Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**2**).

(**1**) 2006 c.41. Section 89 of the National Health Service Act 2006 ("the 2006 Act") has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 28(1) and 202(2), and Schedule 4, paragraph 34. Section 94 of the 2006 Act has been amended by the 2006 Act, section 28(2), and Schedule 4, paragraph 38. Section 126 of the 2006 Act has been amended by the 2012 Act, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63. Section 128A of the 2006 Act was inserted by the Health Act 2009 (c. 21) ("the 2009 Act"), and amended by the 2012 Act, section 206(1). Section 129 of the 2006 Act has been amended by: the 2009 Act, sections 26 and 27, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Section 130 of the 2006 Act has been amended by the 2012 Act, section 207(10), and Schedule 4, paragraph 47, and by S.I. 2010/22. By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England. *See also* section 275(1) of the 2006 Act, which contains definitions of "prescribed" and "regulations" that are relevant to the powers being exercised.

(**2**) S.I. 2013/349.

PART 2

Amendments relating to consolidation applications

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations(**3**) (interpretation), in paragraph (1)—

(a) after the definition of "chiropodist or podiatrist independent prescriber" insert—

> ""consolidation application" means an application pursuant to regulation 26A(1);"; and

(b) in the definition of "excepted application", after "Part 4" insert "or a consolidation application to which regulation 26A(2) does not apply".

Amendment of regulation 6 of the principal Regulations

3. In regulation 6 of the principal Regulations (subsequent assessments), after paragraph (3) insert —

"(4) Where chemist premises are removed from a pharmaceutical list as a consequence of the grant of a consolidation application, if in the opinion of the relevant HWB the removal does not create a gap in pharmaceutical services provision that could be met by a routine application—

(a) to meet a current or future need for pharmaceutical services; or

(b) to secure improvements, or better access, to pharmaceutical services,

the relevant HWB must publish a supplementary statement explaining that, in its view, the removal does not create such a gap, and any such statement becomes part of its pharmaceutical needs assessment.".

Amendment of regulation 10 of the principal Regulations

4. In regulation 10 (pharmaceutical lists and EPS lists), in paragraph (6), after "these Regulations" add ", and must notify it of changes to the lists that are relevant to the carrying out of its functions".

Amendment of regulation 18 of the principal Regulations

5. In regulation 18 of the principal Regulations(**4**) (unforeseen benefits applications: additional matters to which the NHSCB must have regard), in paragraph (2), after sub-paragraph (f) insert—

"(g) whether it is satisfied that the application presupposes that a gap in pharmaceutical services provision has been or is to be created—

(i) by the removal of chemist premises from a pharmaceutical list as a consequence of the grant of a consolidation application, and

(ii) since the last revision of the relevant HWB's pharmaceutical needs assessment other than by way of a supplementary statement.".

Amendment of regulation 19 of the principal Regulations

6. In regulation 19 of the principal Regulations (applications to which regulation 17 or 18 applies: consequences of additional matters), in paragraph (5), after "18(2)(a)" insert "or (g)".

(**3**) Amended by S.I. 2015/137, 570, 1862 and 1879 and 2016/696.
(**4**) Amended by S.I. 2014/417.

New regulation 26A of the principal Regulations

7. After regulation 26 of the principal Regulations(**5**) (change of ownership applications), insert —

"**Consolidation onto an existing site**

26A.—(1) A person already included in a pharmaceutical list may make an application pursuant to this paragraph ("a consolidation application") in respect of the consolidation onto the site (S1) of listed chemist premises in the area of the relevant HWB (HWB1) of the provision of pharmaceutical services provided at or from S1 and other listed chemist premises (S2) in the area of HWB1.

(2) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to a consolidation application by a person already included in a pharmaceutical list for inclusion in respect of premises not already listed in relation to that person.

(3) Subject to paragraph (4), a consolidation application—

(a) must be made by the person (P1) included in the pharmaceutical list in relation to S1; and

(b) if different persons are listed in relation to S1 and S2, must include as part of the application an application by P1 to change the ownership of S2.

(4) If different persons are listed in relation to S1 and S2, and the person (P2) listed in relation to S2 is seeking to become the person listed in relation to S1, a consolidation application—

(a) must be made by P2; and

(b) must include as part of the application an application by P2 to change the ownership of S1.

(5) The NHSCB must refuse a consolidation application—

(a) if it is satisfied that granting the application would create a gap in pharmaceutical services provision that could be met by a routine application—

(i) to meet a current or future need for pharmaceutical services, or

(i) to secure improvements, or better access, to pharmaceutical services; or

(b) if either S1 or S2 are distance selling premises or appliance contractor premises.

(6) In the case of an application to which paragraph (3) applies, the NHSCB must refuse the application unless it is satisfied—

(a) if the NHSCB intends to commission from P1 at or from S1 enhanced services which P2 provides at or from S2 but which P1 has not been providing at or from S1, that the provision of those services will not be interrupted except for such period as the NHSCB may for good cause allow;

(b) in the case of an application to which paragraph (3)(b) applies, that—

(i) P2 consents to the change of ownership of S2, and

(ii) P1 and P2 consent to S2 ceasing to be listed chemist premises as a consequence of the application; and

(c) in the case of an application to which paragraph (3)(b) does not apply, that P1 consents to S2 ceasing to be listed chemist premises as a consequence of the application.

(**5**) Amended by S.I. 2014/417.

(7) In the case of an application to which paragraph (4) applies, the NHSCB must refuse the application unless it is satisfied—

(a) that P2 is proposing to carry on at S1, in place of P1, the business in the course of which P1 is providing pharmaceutical services at S1;

(b) that P2 is undertaking to provide the same pharmaceutical services as those that P1 is providing (whether or not P2 is also to provide other services that P2 is providing at S2);

(c) that the provision of pharmaceutical services at S1 is not to be interrupted, except for such period as the NHSCB may for good cause allow;

(d) if the NHSCB intends to commission from P2 at or from S1 enhanced services which P2 provides at or from S2 but which P1 has not been providing at or from S1, that the provision of those services will not be interrupted except for such period as the NHSCB may for good cause allow; and

(e) that—

(i) P1 consents to the change of ownership of S1, and

(ii) P1 and P2 consent to S2 ceasing to be listed chemist premises as a consequence of the application.

(8) If two or more consolidation applications are being considered together, as regards the issue of a gap in provision, as mentioned in paragraph (5)(a), each application may be refused on the basis of the cumulative effect on provision of all the applications being considered together.".

Amendment of regulation 31 of the principal Regulations

8. In regulation 31 of the principal Regulations(**6**) (refusal: same or adjacent premises), in paragraph (1), after "excepted application" insert ", other than a consolidation application,".

Amendment of regulation 67 of the principal Regulations

9. In regulation 67 of the principal Regulations (conditions as to voluntary closure of premises)—

(a) in paragraph (1)—

(i) after "paragraph (3)" insert "or (5)", and

(ii) after "of ownership application" insert "or a consolidation application";

(b) in paragraph (3), after "a relocation application," insert "which is not part of a consolidation application,"; and

(c) after paragraph (4), insert—

"(5) If C has consented to—

(a) particular listed chemist premises no longer being listed by the NHSCB; or

(b) being removed from a pharmaceutical list for the area of a HWB,

in the context of a consolidation application, paragraph (6) applies.

(6) In the circumstances described in paragraph (5), in the context of an application —

(a) to which regulation 26A(3) applies, if it is granted—

(i) C who is the person listed in relation to S2 for the purposes of regulation 26A(3)(b) must give notice of C's intention to cease the

(**6**) Amended by S.I. 2014/417.

provision of pharmaceutical services at the same time as C who is P1 for the purposes of regulation 26A(3) issues a notice in accordance with paragraph 34A of Schedule 2; but

(ii) C who is P1 for the purposes of regulation 26A(3) need not issue a notice under this regulation;

(b) to which regulation 26A(4) applies, if it is granted—

(i) C who is the person listed in relation to S1 for the purposes of regulation 26A(4) must give notice of C's intention to cease the provision of pharmaceutical services at the same time as C who is P2 for the purposes of regulation 26A(4) issues a notice in accordance with paragraph 34A of Schedule 2; but

(ii) C who is P2 for the purposes of regulation 26A(4) need not issue a notice under this regulation.".

Amendment of regulation 75 of the principal Regulations

10. In regulation 75 of the principal Regulations(**7**) (voluntary or automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure)—

(a) in paragraph (1), after "change of ownership application" insert "or a consolidation application"; and

(b) in paragraph (2), after "to new chemist premises" insert "other than as a consequence of a consolidation application".

Amendment of paragraph 9 of Schedule 2 to the principal Regulations

11. Paragraph 9 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – undertakings) is renumbered paragraph 9(1), and after sub-paragraph (1) insert—

"(2) In relation to a consolidation application, if the NHSCB intends to commission from the applicant enhanced services provided at or from the closing premises, and notifies the applicant of that intention, the applicant is required to provide the undertaking referred to in sub-paragraph (1)(d) in relation to those services, whether or not the applicant is on notice of that intention at the time the applicant makes the consolidation application.".

Amendment of paragraph 18 of Schedule 2 to the principal Regulations

12. In paragraph 18 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – applications requiring notification), in sub-paragraph (b), for "or 26(2)" substitute ", 26(2) or 26A".

Amendment of paragraph 19 of Schedule 2 to the principal Regulations

13. In paragraph 19 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – notification procedure for notifiable applications), after sub-paragraph (4) insert—

"(5) A relevant HWB that is notified under sub-paragraph (1)(h) in relation to a consolidation application must make representations in writing about the application under sub-paragraph (4) which (in addition to any other matter about which they may wish to make representations) indicate whether, if the application were granted, in the opinion of

(**7**) Amended by S.I. 2016/296.

the relevant HWB the proposed removal of premises from its pharmaceutical list would or would not create a gap in pharmaceutical services provision that could be met by a routine application—

(a) to meet a current or future need for pharmaceutical services; or

(b) to secure improvements, or better access, to pharmaceutical services.".

Amendment of paragraph 28 of Schedule 2 to the principal Regulations

14. In paragraph 28 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – notification of decisions on routine and excepted applications), in sub-paragraph (3)(b), for "or 26(2)" substitute ", 26(2) or 26A".

Amendment of paragraph 29 of Schedule 2 to the principal Regulations

15. In paragraph 29 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – template notice of commencement to be included with a notice of decision), before "The NHSCB must" insert "Subject to paragraph 29A,".

New paragraph 29A of Schedule 2 to the principal Regulations

16. In Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed) after paragraph 29 (template notice of commencement to be included with a notice of decision) insert—

"**Template notice of consolidation**

29A.—(1) This paragraph applies as regards a notice of decision under paragraph 28 in respect of a consolidation application that is granted, in relation to the person who is—

(a) P1 for the purposes of regulation 26A (P1), if regulation 26A(3) applied to that application; or

(b) P2 for the purposes of regulation 26A (P2), if regulation 26A(4) applied to that application.

(2) The NHSCB must send with the notice of decision sent to P1 or P2 a template of a notice of consolidation, for P1 or P2 to send to it under paragraph 34A, in which P1 or P2 is to provide the following information (some of which the NHSCB may have included in the template that it sends)—

(a) the date of the grant of the application;

(b) the address of the premises at which pharmaceutical services are no longer to be provided ("the closing premises");

(c) the date on which pharmaceutical services are to cease being provided at the closing premises;

(d) the address of the premises at which pharmaceutical services are to continue to be provided ("the continuing premises");

(e) the registration number of the continuing premises with the General Pharmaceutical Council;

(f) confirmation that reasonable steps have been taken to advise any patients who have nominated the person listed in relation to the closing premises as their nominated dispensing contractor that their nomination will transfer to the person listed in relation to the continuing premises, if the Electronic Prescription Service is available through those premises, unless they change their nomination;

(g) the date on which the consolidation is to take effect;

(h) a signature on behalf of P1 or P2 (whichever has been sent the template) and the date of the notice.".

Amendment of paragraph 34 of Schedule 2 to the principal Regulations

17. In paragraph 34 of Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – taking effect of listing decisions: general), in sub-paragraph (1), before "As regards any application" insert "Except where paragraph 34A applies,".

New paragraph 34A of Schedule 2 to the principal Regulations

18. In Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed) after paragraph 34 insert—

"**Taking effect of decisions relating to business consolidations**

34A.—(1) This paragraph applies as regards a consolidation application that is granted, in relation to the person who is—

(a) P1 for the purposes of regulation 26A (P1), if regulation 26A(3) applied to that application; or

(b) P2 for the purposes of regulation 26A (P2), if regulation 26A(4) applied to that application.

(2) The NHSCB may only change a pharmaceutical list to give effect to that decision if P1 or P2 gives the NHSCB a valid notice of consolidation, in the correct form, informing the NHSCB of the date on which the consolidation is to take effect in the next 14 days.

(3) A notice of consolidation under this paragraph is in the correct form if it—

(a) includes the information required under paragraph 29A; and

(b) is in the same format as the version of the notice sent by the NHSCB with the notice of decision under paragraph 28.

(4) A notice of consolidation is invalid unless it is sent to the NHSCB within—

(a) 6 months of the date on which the applicant was sent the notice of the NHSCB's decision under paragraph 28 granting the application;

(b) such longer period—

(i) not exceeding a further 3 months as the NHSCB may allow, or

(ii) if—

(aa) the grant is appealed by a person with third party appeal rights, or

(bb) P1 or P2 appeals successfully against a decision not to allow a longer period under paragraph (i),

as the Secretary of State may allow when the appeal is determined,

(5) A notice of consolidation ceases to have effect if the Secretary of State receives a valid notice of appeal from a person with third party appeal rights relating to the grant to which the notice of consolidation relates.

(6) Once, having regard to sub-paragraph (4), a valid notice of consolidation can no longer be sent in relation to the grant of a consolidation application, the grant of that application lapses.".

Amendment of paragraph 36 of Schedule 2 to the principal Regulations

19. In Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and the procedures to be followed), in paragraph 36 (appeals to the Secretary of State by the applicant)—

(a) in sub-paragraph (1)(e), after "paragraph 34(4)(c)(i)" insert "or 34A(4)(b)(i)"; and

(b) in sub-paragraph (2), for "paragraph" substitute "sub-paragraph".

Amendment of paragraph 10 of Schedule 3 to the principal Regulations

20. In Schedule 3 (appeals to the Secretary of State), in paragraph 10 (notification of decisions and any subsequent action by the NHSCB)—

(a) after sub-paragraph (1) insert—

"(1A) If the Secretary of State has—

(a) granted or confirmed the grant of a consolidation application; or

(b) allowed or refused an appeal against a decision as mentioned in paragraph 36(1)(b) in respect of an extension period under paragraph 34A(4)(b)(i),

the Secretary of State must notify the relevant HWB (under this sub-paragraph or sub-paragraph (1)(d)), and must include with that notification a statement of the reasons for the Secretary of State's decision and the Secretary of State's findings of fact."; and

(b) in sub-paragraph (2)—

(i) in paragraph (a), after "paragraph 29" insert "or a notice of consolidation referred to in paragraph 29A", and

(ii) in paragraph (b), for "and 34" substitute ", 34 and 34A", and for "paragraph (3)" substitute "sub-paragraph (1)".

PART 3

Amendments relating to therapeutic radiographer independent prescribers and dietitian supplementary prescribers

Further amendment of regulation 2 of the principal Regulations

21. In regulation 2 of the principal Regulations(**8**) (interpretation), in paragraph (1)—

(a) in the definition of "prescriber", for "or an optometrist independent prescriber;" substitute ", an optometrist independent prescriber or a therapeutic radiographer independent prescriber;";

(b) in paragraph (b)(i) of the definition of "supplementary prescriber", after "chiropodists and podiatrists," insert "dietitians,"; and

(c) after the definition of "supplementary prescriber" insert—

""therapeutic radiographer independent prescriber" means a radiographer—

(a) who is registered in Part 11 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(**9**); and

(b) against whose name in that register is recorded—

(**8**) Amended by S.I. 2015/137, 570, 1862 and 1879 and 2016/696.
(**9**) S.I. 2002/254; article 5 has been amended by S.I. 2009/1182. This Order was so renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).

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

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

Amendment of regulation 2 of the National Health Service (Charges for Drugs and Appliances) Regulations 2015

22. In regulation 2 of the National Health Service (Charges for Drugs and Appliances) Regulations 2015(**10**) (interpretation), in paragraph (1)—

(a) in the definition of "prescriber", for "or an optometrist independent prescriber;" substitute ", an optometrist independent prescriber or a therapeutic radiographer independent prescriber;";

(b) in paragraph (b)(i) of the definition of "supplementary prescriber", after "chiropodists and podiatrists," insert "dietitians,"; and

(c) before the definition of "the Travel Expenses and Remission of Charges Regulations" insert—

""therapeutic radiographer independent prescriber" means a radiographer—

(a) who is registered in Part 11 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(**11**); and

(b) against whose name in that register is recorded—

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

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

Amendment of the National Health Service (General Medical Services Contracts) Regulations 2015

23. In regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015(**12**) (interpretation), in paragraph (1)—

(a) in the definition of "prescriber"—

(i) omit the "and" at the end of paragraph (f),

(ii) in paragraph (g), for "prescriber," substitute "prescriber; and", and

(iii) after paragraph (g) insert—

"(h) a therapeutic radiographer independent prescriber,"; and

(b) in the definition of "supplementary prescriber", in sub-paragraph (b)(iv)—

(i) omit "or" at the end of sub-paragraph (bb), and

(ii) after sub-paragraph (cc) insert the following sub-paragraph—

"(dd) dietitians, or"; and

(c) after the definition of "temporary resident" insert—

""therapeutic radiographer independent prescriber" means a radiographer—

(**10**) S.I. 2015/570; regulation 2 has been amended by S.I. 2015/1879 and 2016/686.
(**11**) S.I. 2002/254; article 5 has been amended by S.I. 2009/1182. This Order was so renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).
(**12**) S.I. 2015/1862; amended by S.I. 2016/696.

(a) who is registered in Part 11 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—

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

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

Amendment of the National Health Service (Personal Medical Services Agreements) Regulations 2015

24. In regulation 3 of the National Health Service (Personal Medical Services Agreements) Regulations 2015(**13**) (interpretation), in paragraph (1)—

(a) in the definition of "prescriber"—

(i) omit the "and" at the end of paragraph (f),

(ii) in paragraph (g), for "prescriber," substitute "prescriber; and", and

(iii) after paragraph (g) insert—

"(h) a therapeutic radiographer independent prescriber,";

(b) in the definition of "supplementary prescriber", in sub-paragraph (b)(iv)—

(i) omit "or" at the end of sub-paragraph (bb), and

(ii) after sub-paragraph (cc) insert the following sub-paragraph—

"(dd) dietitians, or"; and

(c) after the definition of "temporary resident" insert—

""therapeutic radiographer independent prescriber" means a radiographer—

(a) who is registered in Part 11 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—

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

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

PART 4

Amendments relating to emergency supplies of drugs

Amendment of paragraph 28 of Schedule 4 to the principal Regulations

25. In Schedule 4 to the principal Regulations (terms of service of NHS pharmacists), in paragraph 28(**14**) (clinical governance), in sub-paragraph (2)(a)(ii), after "advanced services" insert ", other than an advanced service in respect of the supply of drugs in accordance with regulation 225

(**13**) S.I. 2015/1879; amended by S.I. 2016/696.
(**14**) Amended by S.I. 2015/58.

of the Human Medicines Regulations 2012(**15**) (emergency sale etc by pharmacist: at patient's request),".

Amendment of regulation 3 of the National Health Service (Charges for Drugs and Appliances) Regulations 2015

26. In regulation 3 of the National Health Service (Charges for Drugs and Appliances) Regulations 2015(**16**) (supply of drugs and appliances by chemists)—

(a) in paragraph (3)—

(i) omit "either",

(ii) omit "or" at the end of sub-paragraph (a),

(iii) insert "; or" at the end of sub-paragraph (b), and

(iv) after sub-paragraph (b) insert the following sub-paragraph—

"(c) where the person has been supplied with a drug—

(i) in accordance with regulation 225 of the Human Medicines Regulations 2012(**17**) (emergency sale etc by pharmacist: at patient's request), and

(ii) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act(**18**) (arrangements for additional pharmaceutical services) or, if the drug is supplied under arrangements for the provision of local pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions,

provide a declaration that the relevant charge has been paid on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012 and issued by a chemist.";

(b) in paragraph (5)(a)—

(i) omit "or" at the end of paragraph (iii), and

(ii) after paragraph (iii) insert the following paragraph—

"(iiia) in cases involving the supply of a drug—

(aa) in accordance with regulation 225 of the Human Medicines Regulations 2012, and

(bb) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act or, if the drug is supplied under arrangements for the provision of local pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions,

on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012 and issued by a chemist, or"; and

(c) in paragraph 5(b)—

(i) omit "or" at the end of paragraph (iii), and

(**15**) S.I. 2012/1916; regulation 225 has been amended by S.I. 2014/490.
(**16**) S.I. 2015/570; regulation 2 has been amended by S.I. 2015/1879 and 2016/325.
(**17**) S.I. 2012/1916; regulation 225 has been amended by S.I. 2014/490.
(**18**) Section 127 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 64.

(ii) after paragraph (iii) insert the following paragraph—

"(iiia) in cases involving the supply of a drug—

(aa) in accordance with regulation 225 of the Human Medicines Regulations 2012, and

(bb) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act or, if the drug is supplied under arrangements for the provision of local pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions,

on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012 and issued by a chemist, or".

Signed by authority of the Secretary of State for Health.

David Mowat
Parliamentary Under-Secretary of State,
Department of Health

8th November 2016

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations principally amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations"). The 2013 Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical services and local pharmaceutical services.

The 2013 Regulations provide for pharmaceutical services provision by, amongst others, retail pharmacy businesses, and for pharmaceutical lists to be held by the National Health Service Commissioning Board ("the NHSCB") of the retail pharmacy businesses entitled to provide pharmaceutical services, which are kept by reference to the areas of the Health and Wellbeing Board ("HWB") of a local authority.

Retail pharmacy businesses that are included in a particular pharmaceutical list may wish to consolidate the services provided on two or more sites onto a single site. Such consolidations could require a change in the ownership of one of the businesses in question. Part 2 of these Regulations puts in place a process to facilitate such consolidations.

Applications to consolidate will be dealt with as "excepted applications" under the 2013 Regulations, which means in general terms they will not be assessed against the local plan known as the pharmaceutical needs assessment ("PNA") produced by the HWB. Instead, they will follow a simpler procedure, the key to which is whether or not a gap in pharmaceutical service provision would be created by the consolidation. Some provision is also made in respect of continuity of services – for example, if the NHSCB intends to commission from the applicant "enhanced services" (additional pharmaceutical services, such as minor ailments schemes, that are commissioned locally) that have been provided at or from the closing premises, the applicant is required to provide undertakings to continue to provide those services (regulation 11). If the NHSCB is satisfied that the consolidation would create a gap in pharmaceutical services provision, it must refuse the application (regulation 7). The opinion of the HWB on this issue must be given when the application is notified locally and representations are sought (regulations 12 and 13). If the application is granted and pharmacy premises are removed from the relevant pharmaceutical list, if the HWB does not consider that a gap in service provision is created as a consequence, it must publish a supplementary statement published alongside its pharmaceutical needs assessment recording its view (regulation 3). Also, if the NHSCB does grant the application, it must then refuse any further applications known as "unforeseen benefits applications" by other chemists seeking inclusion in the pharmaceutical list, if the applicant is seeking to rely on the consolidation as a reason for saying there is now a gap in provision, at least until the next revision of the PNA (regulations 5 and 6).

Various supplementary amendments are made in relation to the new process, or to align the existing processes with the new process, including in relation to the undertakings to be given by applicants (regulation 11), enabling businesses to relocate onto an existing site in this particular context (regulation 8), notification by the NHSCB of decisions on consolidation applications (regulation 15), the notices to be sent by pharmacy businesses when premises close or open (regulations 9, 10 and 15 to 18), the NHSCB's responsibilities to notify HWBs of changes to lists (regulation 4), and in relation to appeals (regulations 19 and 20).

Part 3 of these Regulations makes provision for the prescribing and dispensing, as part of NHS primary care services of prescriptions written by therapeutic radiographer independent prescribers and dietitians who are entitled to prescribe as supplementary prescribers – and for prescription charges to be levied in respect of such prescriptions (regulations 21 to 24).

Part 4 of these Regulations makes provision which allows prescription charges to be levied by providers of pharmaceutical or local pharmaceutical services who undertake emergency supplies of medicines at the request of a patient in accordance with specified types of arrangements with the NHSCB for the making of such supplies (regulation 26). However, providers of pharmaceutical services on pharmaceutical lists who have such arrangements are not obliged to publicise them as part of their clinical governance programme (regulation 25). Clinical governance programmes are not required terms of local pharmaceutical services contracts.