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.