This Statutory Instrument has been made, in part, as a consequence of defects in SI 2013/349 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2014 No. 417

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014

Made - - - -	*25th February 2014*
Laid before Parliament	*4th March 2014*
Coming into force - -	*1st April 2014*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126, 129 and 272(7) and (8) of, and paragraph 3(3)(h) of Schedule 12 to, the National Health Service Act 2006(**1**).

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 and come into force on 1st April 2014.

Interpretation

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 126 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 213(7)(k) and 220(7), and Schedule 4, paragraph 63. Section 129 of the 2006 Act has been amended by the Health Act 2009 (c. 21), sections 26 and 27 and Schedule 6, by the 2012 Act, section 207(1) to (9) and Schedule 4, paragraph 66, by the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121, and by S.I. 2010/231. Paragraph 3 of Schedule 12 to the 2006 Act has been amended by the Health Act 2009, section 29(14) and (15), and by the 2012 Act, Schedule 4, paragraph 93(4). 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.

Amendment of regulation 13 of the principal Regulations

3. In regulation 13 of the principal Regulations (current needs: additional matters to which the NHSCB must have regard), for paragraph (1) substitute the following paragraph—

"(1) If—

(a) the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the current need has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act(**3**) (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).".

Amendment of regulation 15 of the principal Regulations

4. In regulation 15 of the principal Regulations (future needs: additional matters to which the NHSCB must have regard), for paragraph (1) substitute the following paragraph—

"(1) If—

(a) the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the future need has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2(b) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).".

Amendment of regulation 17 of the principal Regulations

5. In regulation 17 of the principal Regulations (improvements or better access to the current service: additional matters to which the NHSCB must have regard), for paragraph (1) substitute the following paragraph—

"(1) If—

(a) the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).".

(**3**) Section 129(2A) was inserted by the Health Act 2009 (c. 21), section 26(3), and has been amended by the Health and Social Care Act 2012 (c. 7), section 207(4), and Schedule 4, paragraph 66(5).

Amendment of regulation 18 of the principal Regulations

6. In regulation 18 of the principal Regulations (unforeseen benefits applications: additional matters to which the NHSCB must have regard), in paragraph (2)(b), at the end of paragraph (ii), for "and" substitute "or".

Amendment of regulation 20 of the principal Regulations

7. In regulation 20 of the principal Regulations (future improvements or better access: additional matters to which the NHSCB must have regard), for paragraph (1) substitute the following paragraph—

"(1) If—

(a) the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, in the future to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(b) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).".

Amendment of regulation 24 of the principal Regulations

8. In regulation 24 of the principal Regulations (regulations that do not result in significant change to pharmaceutical services provision)—

(a) in paragraph (1)(c), for "is satisfied that granting the application would not cause" substitute "is not of the opinion that granting the application would cause";

(b) in paragraph (2)(d), for "is satisfied that granting the application would not cause" substitute "is not of the opinion that granting the application would cause"; and

(c) in paragraph (3)—

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

(ii) insert "; or" at the end of sub-paragraph (c), and

(iii) after sub-paragraph (c) insert the following sub-paragraph—

"(d) are distance selling premises, unless—

(i) the premises to which the applicant is seeking to relocate are also distance selling premises, and

(ii) if the application was one to which regulation 25(1) applied, it would not be refused pursuant to regulation 25(2).".

Amendment of regulation 26 of the principal Regulations

9. In regulation 26 of the principal Regulations (change of ownership applications)—

(a) in paragraph (2)—

(i) in sub-paragraph (d), for "if Y had" substitute "had Y", and

(ii) in sub-paragraph (e), for "if" substitute "in a case where"; and

(b) after paragraph (2) insert the following paragraphs—

"(3) An application pursuant to paragraph (1) must be refused if it relates to distance selling premises, unless the application, if made pursuant to regulation 25(1), would not be refused pursuant to regulation 25(2).

(4) An application pursuant to paragraph (2) must be refused if the existing pharmacy premises from which the applicant is seeking to relocate are distance selling premises, unless the premises to which the applicant is seeking to relocate are also distance selling premises (and this is in addition to the requirement that arises by virtue of paragraph (2)(d) that the application, if made pursuant to regulation 25(1), would not be refused pursuant to regulation 25(2)).".

Amendment of regulation 31 of the principal Regulations

10. In regulation 31 of the principal Regulations (refusal: same or adjacent premises), for paragraph (1) substitute the following paragraph—

"(1) A routine or excepted application must be refused where paragraph (2) applies.".

Amendment of regulation 32 of the principal Regulations

11. In regulation 32 of the principal Regulations (deferrals arising out of LPS designations), for paragraph (1) substitute the following paragraph—

"(1) A routine application must be refused where paragraph (2) applies to the relevant premises.".

Amendment of regulation 33 of the principal Regulations

12. In regulation 33 of the principal Regulations (refusal of applications for inclusion in a pharmaceutical list on fitness grounds)—

(a) before paragraph (1), insert the following paragraph—

"(A1) In this regulation, "A" means, where an application for inclusion in a pharmaceutical list is made by a person who is—

(a) an individual, the individual making the application;

(b) a partnership, any partner in the partnership making the application; or

(c) a body corporate—

(i) except for the purposes of paragraphs (1)(a) and (b) and (3)(h)(i), the body corporate making the application, and

(ii) except for the purposes of paragraph (2)(b) and (e), any director or superintendent of the body corporate making the application.";

(b) in paragraph (1)—

(i) omit "(A)", and

(ii) in sub-paragraphs (a) and (b), omit "(or where A is a body corporate, any director or superintendent of A)";

(c) in paragraphs (2)(c)(i) and (ii) and (d)(i) and (ii), and (3)(g) and (h), omit "(and where A is a body corporate, any director or superintendent of A)"; and

(d) in paragraph (3)(g) and (h), omit "(and where A is a body corporate, any director or superintendent of A)".

Amendment of regulation 34 of the principal Regulations

13. In regulation 34 of the principal Regulations (deferral of consideration of applications for inclusion in a pharmaceutical list on fitness grounds)—

(a) before paragraph (1), insert the following paragraph—

"(A1) In this regulation, "A" means, where an application for inclusion in a pharmaceutical list is made by a person who is—

(a) an individual, the individual making the application;

(b) a partnership, any partner in the partnership making the application; or

(c) a body corporate—

(i) except for the purposes of paragraph (1)(b), (c)(ii), (e), (g), (i) and (k), the body corporate making the application, and

(ii) any director or superintendent of the body corporate making the application."; and

(b) in paragraph (1)—

(i) omit "(A)",

(ii) in sub-paragraph (a)—

(aa) omit "(or where A is a body corporate, in respect of A or any director or superintendent of A)", and

(bb) for "A's removal from its pharmaceutical list, if A" substitute "the person's removal from the pharmaceutical list, if the person",

(iii) in sub-paragraph (b), for "A's removal from its pharmaceutical list, if A" substitute "the person's removal from the pharmaceutical list, if the person",

(iv) in sub-paragraph (c)—

(aa) in paragraph (i), omit "(or where A is a body corporate, any director or superintendent of A's)",

(bb) in paragraph (ii), omit "(or where A is a body corporate, any director or superintendent of A)", and

(cc) for "A from the pharmaceutical list if A" substitute "the person from the pharmaceutical list if the person",

(v) in sub-paragraphs (d), (j) and (k), omit "(and where A is a body corporate, any director or superintendent of A)",

(vi) in sub-paragraph (e), omit "(or where A is a body corporate, any director or superintendent of A)",

(vii) in sub-paragraph (f)—

(aa) omit "(or where A is a body corporate, by A or any director or superintendent of A)", and

(bb) for "A from the pharmaceutical list if A" substitute "the person from the pharmaceutical list if the person",

(viii) in sub-paragraph (g)—

(aa) omit "(or where A is a body corporate, any director or superintendent of A)", and

(bb) for "A from the pharmaceutical list if A" substitute "the person from the pharmaceutical list if the person",

(ix) in sub-paragraph (h)—

(aa) omit "(and where A is a body corporate, any director or superintendent of A)", and

(bb) for "A from the pharmaceutical list if A" substitute "the person from the pharmaceutical list if the person",

(x) in sub-paragraph (i)—

(aa) omit "(and where A is a body corporate, any director or superintendent of A)", and

(bb) for "A from the pharmaceutical list if A" substitute "the person from the pharmaceutical list if the person", and

(xi) in sub-paragraph (l)(ii), for "A" substitute "the applicant".

Amendment of regulation 40 of the principal Regulations

14. In regulation 40 of the principal Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), after paragraph (3) insert the following paragraphs—

"(4) Paragraph (2)(b) does not apply where the NHSCB is satisfied that there are reasonable grounds for believing the person making the refused application was motivated (wholly or partly) by a desire for that application to be refused.

(5) The refusal of an application pursuant to paragraph (2)(b), or regulation 40(2)(b) of the 2012 Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), is to be ignored for the purposes of the calculation of a 5 year period pursuant to paragraph (2)(b).".

Amendment of regulation 64 of the principal Regulations

15. In regulation 64 of the principal Regulations (distance selling premises: specific conditions), for paragraph (1) substitute—

"(1) Paragraph (2) applies where—

(a) an application in respect of distance selling premises is granted under these Regulations; or

(b) an application was granted under the 2005 Regulations or 2012 Regulations in respect of premises which were, for the purposes of the Regulations under which the application was granted, distance selling premises.".

Transitional provision in relation to the application of regulation 64(3)(c) of the principal Regulations

16.—(1) Regulation 64(3)(c) of the principal Regulations (distance selling premises: specific conditions) does not apply to distance selling premises—

(a) which before 1st April 2014 were located, otherwise than in breach of the condition set out in regulation 64(3)(c) of the principal Regulations, on the same site or in the same building as the premises of a provider of primary medical services with a patient list; or

(b) where—

(i) before 1st April 2014 an application was granted under the principal Regulations to relocate the retail pharmacy business or appliance contractor business at those premises to the same site or into the same building as the premises of a provider of primary medical services with a patient list, and

(ii) on or after 1st April 2014 that business relocated to that same site or into that same building, and so the premises are distance selling premises of that business.

(2) Expressions used in this regulation which are defined in regulation 2 of the principal Regulations (interpretation) have the meanings given in that regulation.

Amendment of Schedule 2 to the principal Regulations

17. In Schedule 2 to the principal Regulations (applications in respect of pharmaceutical lists and procedures to be followed)—

(a) in paragraph 7 (additional information to be included with routine applications), in sub-paragraph (1)(b), for "Trust," substitute "Trust),";

(b) in the heading of paragraph 13 (which relates to the functions of the NHSCB in relation to fitness information relevant to applications, where it already holds fitness information that may be relevant to future applications), for "applications from bodies corporate" substitute "applications: aggregation of information";

(c) in paragraph 31 (conditional grant of applications where the address of the premises is unknown), after sub-paragraph (3) insert the following sub-paragraph—

"(3A) For the purposes of paragraph (3), premises are not within the range of possible locations covered by the estimate referred to in sub-paragraph (1)(b) if the granted application would have been refused pursuant to regulation 31 if the address of those premises had been included in that application instead of the estimate."; and

(d) in paragraph 32 (changes to the premises specified in an application after its grant but before the listing of the premises), after sub-paragraph (3) insert the following sub-paragraph—

"(3A) A notification under sub-paragraph (2) is not valid if the granted application would have been refused pursuant to regulation 31 if the address of those premises had been included in that application instead of the address mentioned in sub-paragraph (1)(b).".

Amendment of Schedule 4 to the principal Regulations

18. In Schedule 4 to the principal Regulations (terms of service of NHS pharmacists), in paragraph 12(5)(b) (additional requirements in relation to specified appliances), for from "the telephone number" to "on line" substitute "telephone or website contact details for providers of NHS services that may be consulted for advice regarding specified appliances during those periods".

Amendment of Schedule 5 to the principal Regulations

19. In Schedule 5 to the principal Regulations (terms of service of NHS appliance contractors), in paragraph 11(5)(b) (additional requirements in relation to specified appliances), for from "the telephone number" to "on line" substitute "telephone or website contact details for providers of NHS services that may be consulted for advice regarding specified appliances during those periods".

Amendment of Schedule 9 to the principal Regulations

20. In Schedule 9 to the principal Regulations (transitional provisions), in paragraph 11 (giving effect to listing decisions: pharmaceutical lists and dispensing doctor lists)—

(a) in sub-paragraph (1)(a), for "in pharmaceutical" substitute "in a pharmaceutical"; and

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

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

25th February 2014

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Regulations 3, 4, 5 and 7 restructure regulations 13(1), 15(1), 17(1) and 20(1) of the 2013 Regulations, which relate to pharmaceutical list applications in respect of needs for, or improvements or better access to, pharmaceutical services (or to pharmaceutical services of a specified type) which are identified in pharmaceutical needs assessments ("PNAs"). Pharmaceutical lists are lists of permitted providers of pharmaceutical services held by the National Health Service Commissioning Board ("NHSCB") and PNAs are assessments of pharmaceutical services provision, including of potential gaps in service provision, produced by the Health and Wellbeing Boards of local authorities. The changes clarify the drafting, with no intended substantive effect.

Regulation 6 amends regulation 18 of the 2013 Regulations, which relates to pharmaceutical list applications where the applicant is seeking to offer what were unforeseen benefits at the time the relevant PNA was produced. The 2013 Regulations identify three desirable characteristics of such applications and the amendment makes it clear that the list of these three is disjunctive, so that the NHSCB needs only to have particular regard to the desirability of one of these three when considering an unforeseen benefits application.

Pharmaceutical list applications that offer either benefits identified in a PNA or unforeseen benefits are together known as "routine applications". Pharmaceutical list applications that offer neither of these types of benefit generally have to be refused by the NHSCB, but there are a number of types of "excepted application" which can be granted even if they do not offer these types of benefit, one of which is applications for relocations that do not result in significant change to pharmaceutical services provision locally. Regulation 8(a) and (b) amend the threshold criteria in regulation 24 of the 2013 Regulations for granting these applications so that the requirement is that the NHSCB is not of the opinion that granting the application would cause significant detriment to proper planning, rather than the NHSCB positively needing to satisfy itself that granting the application would not cause significant detriment to proper planning.

The threshold criteria for this type of relocation application are also changed so that, if the relocation is of distance selling premises (typically, internet pharmacies), the NHSCB must be satisfied that the general conditions that apply for the granting of new distance selling premises applications also apply to the grant of applications for relocations of distance selling premises that do not result in significant change to pharmaceutical services provision locally (regulation 8(c)).

Change of ownership applications are another type of "excepted application", and regulation 9(b) amends the threshold criteria in regulation 26 of the 2013 Regulations for granting these applications (which may sometimes be combined with a relocation application) so that if the application relates to distance selling premises, the NHSCB must be satisfied that the general conditions that apply to the grant of new distance selling premises applications also apply to the grant of change of ownership applications for distance selling premises.

The changes in regulation 8(c) and 9(b) are also reflected in a change to regulation 64 of the 2013 Regulations, which sets the conditions of entry in pharmaceutical lists for distance selling premises. The change is to make sure that, going forward, the specific conditions of entry that apply to distance

selling premises apply to all distance selling premises, not simply those distance selling premises that have resulted from the grant of an application pursuant regulation 25 of the 2013 Regulations and the provisions that preceded it (regulation 15).

It is possible, however, that prior to 1st April 2014, distance selling premises may have relocated, or been given permission to relocate, under the previous arrangements to the same site as a provider of primary medical services with a patient list. A transitional provision is included in these Regulations so that, if that has indeed happened, the term of service that would prevent the distance selling premises being on the same site as a provider of primary medical services with a patient list is disapplied (regulation 16).

Some pharmaceutical list applications have needed to be refused if the proposed premises were part of the same site as the premises of an existing provider of pharmaceutical services, and regulation 10 amends regulation 31 of the 2013 Regulations so that this restriction now applies to all types of pharmaceutical list applications.

Applications for new NHS chemist premises sometimes include a best estimate of where the new premises are to be located, rather than an exact location, and in some cases where an exact location is given, change of that exact location is permissible after the application has been granted. Regulation 17(c) and (d) amend paragraphs 31 and 32 of Schedule 2 to the 2013 Regulations to provide that, when an exact location, or a different exact location, is given after an application has been granted, that location also cannot be part of the same site as the premises of an existing provider of pharmaceutical services.

Regulation 11 amends regulation 32 of the 2013 Regulations so that a designation of an area or premises under Part 13 of the Regulations – which is a potential preliminary for a tendering exercise for a contract to provide local pharmaceutical services – now acts as a ground for deferring all types of routine applications in the area, or for the premises, covered by the designation – not just some types of routine applications.

Applications for entry on a pharmaceutical list may be deferred or refused on some specified grounds relating to the fitness of the potential provider of pharmaceutical services to be a provider of such services. Previously, the refusal and deferral provisions applied only to potential providers who were individuals or bodies corporate, but regulations 12 and 13 amend regulations 33 and 34 of the 2013 Regulations so that these refusal and deferral provisions now also apply to the partners in applications from partnerships. The changes to regulations 33 and 34 of the 2013 Regulations also correct drafting errors.

Regulation 14 amends regulation 40 of the 2013 Regulations, which includes a rule requiring the refusal of applications for new pharmacies in certain rural areas for a period of five years, where dispensing services are provided in the relevant location by dispensing doctors, if an application for a pharmacy within 1.6 kilometres of the proposed new pharmacy has been refused in the previous five years. The changes prevent a new five year period being triggered within an existing five year period by an application for a new pharmacy that has to be refused because of the rule. It also requires the NHSCB to decline to apply the rule if it is satisfied that the pharmacy application was motivated wholly or partly by a desire for the application to be refused, thus triggering a five year bar on further applications.

Providers of pharmaceutical services that provide certain types of specialist appliances may provide telephone care lines for users of the appliances during their normal opening hours. Regulations 18 and 19 amend provisions in Schedules 4 and 5 of the 2013 Regulations to provide that those providers must ensure that, during out of hours periods, if advice is not available to those users via those telephone lines, contact details are given via those telephone lines for alternative sources of NHS advice. Previously, contact details had to be given of NHS Direct National Health Service Trust, which is to be abolished.

Regulations 9(a), 17(a) and (b) and 20 correct drafting errors in the 2013 Regulations.