

2015 No. 58

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Pharmaceutical and Local
Pharmaceutical Services) (Amendment and Transitional
Provision) Regulations 2015**

<i>Made</i> - - - -	<i>23rd January 2015</i>
<i>Laid before Parliament</i>	<i>30th January 2015</i>
<i>Coming into force</i> - -	<i>1st March 2015</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126, 129, 130, 132, 139(9), 145(1) and 272(7) and (8) of, and paragraphs 2(2)(b) and 3 of Schedule 12 to, the National Health Service Act 2006(a).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015 and come into force on 1st March 2015.

(2) In these Regulations, “the principal Regulations” means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(b).

Amendment of regulation 25 of the principal Regulations

2. In regulation 25 of the principal Regulations (distance selling premises applications), in paragraph (1)(b), omit “also”.

(a) 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) (“the 2009 Act”), 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. Section 130 of the 2006 Act has been amended by the 2012 Act, section 207(10), and by S.I. 2010/22; section 132 of the 2006 Act has been amended by the 2012 Act, Schedule 4, paragraph 69, by the Protection of Freedoms Act 2012, Schedule 9, paragraph 122, and by S.I. 2007/289 and 2010/22 and 231. Paragraph 2 of Schedule 12 to the 2006 Act has been amended by the 2009 Act, section 29(12), and by the 2012 Act, section 207(12), and Schedule 4, paragraph 93(3). Paragraph 3 of Schedule 12 to the 2006 Act has been amended by the 2009 Act, 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.

(b) S.I. 2013/349.

Amendment of regulation 32 of the principal Regulations

3. In regulation 32 of the principal Regulations^(a) (deferrals arising out of LPS designations), in paragraph (1), for “must be refused” substitute “may be deferred”.

Amendment of regulation 103 of the principal Regulations

4. In regulation 103 of the principal Regulations (LPS schemes: health service body status), in paragraph (6), for sub-paragraph (a) substitute the following sub-paragraph—

- “(a) paragraph (4)(b), where C or the NHSCB—
- (i) has referred any matter to the NHS dispute resolution procedure before C ceases to be a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with paragraph 21(1)(a) of Schedule 7, after C ceases to be a health service body,
- C is to continue to be treated as a health service body (and accordingly the scheme or agreement is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute;”.

Amendment of regulation 109 of the principal Regulations

5. In regulation 109 of the principal Regulations (LPS pilot schemes: health service body status), in paragraph (4)—

- (a) for sub-paragraph (a) substitute the following sub-paragraph—
- “(a) paragraph (2)(b), where P or the NHSCB—
- (i) has referred any matter to the NHS dispute resolution procedure before P ceases to be a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with the terms of the scheme, after it ceases to be a health service body,
- P is to continue to be regarded as a health service body (and accordingly the scheme is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute;”;
- (b) in sub-paragraph (b), for “C is” substitute “P is”.

Amendment of Schedule 2 to the principal Regulations

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

- (a) in paragraph 4 (fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list), after sub-paragraph (9) insert the following sub-paragraph—
- “(10) Details of any case in which an application by C1 or C2 has lapsed by virtue of regulation 35(8).”; and
- (b) in paragraph 6 (applications seeking listing of premises that are already, or are in close proximity to, listed chemist premises), omit sub-paragraphs (a) and (b).

(a) Amended by S.I. 2014/417.

(b) To which there are amendments not relevant to these Regulations.

Amendment of Schedule 3 to the principal Regulations

7. In Schedule 3 to the principal Regulations (appeals to the Secretary of State), in paragraph 5 (notification of appeals relating to decisions under Part 8 of the Regulations), in sub-paragraph (2)(a), for “regulation 50(6)” substitute “regulation 50(7)”.

Amendment of Schedule 4 to the principal Regulations

8.—(1) Schedule 4 to the principal Regulations(a) (terms of service of NHS pharmacists) is amended as follows.

(2) In paragraph 10 (further activities to be carried on in connection with the provision of dispensing services), in sub-paragraph (1), after paragraph (d) insert the following paragraph—

“(da) ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—

(i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and

(ii) requires regular medicine in respect of that medical condition,

including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on;”.

(3) In paragraph 28 (clinical governance), in sub-paragraph (2), for paragraph (b) substitute—

“(b) an audit programme, which in each financial year includes at least one clinical audit specified by P, and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB’s arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB’s arrangements for the receiving and processing of data from the audit;”.

Amendment of Schedule 7 of the principal Regulations

9. In Schedule 7 to the principal Regulations (mandatory terms for LPS schemes), in paragraph 21 (dispute resolution: non-NHS contracts), for sub-paragraph (1) substitute the following sub-paragraph—

“(1) In the case of an LPS scheme that is not an NHS contract, any dispute arising out of or in connection with the scheme, except matters dealt with under the complaints procedure pursuant to paragraph 25, may be referred for consideration and determination to the Secretary of State—

(a) if it relates to a period when the contractor was treated as a health service body, by the contractor or by the NHSCB; or

(b) in any other case, by the contractor or, if the contractor agrees in writing, by the NHSCB.”.

Transitional provision relating to LPS schemes and pilot schemes in respect of which legal proceedings have commenced before 1st March 2015

10.—(1) Paragraph (2) applies as regards any dispute which relates to a matter arising before 1st March 2015 under—

(a) To which there is an amendment not relevant to these Regulations.

- (a) an LPS scheme; or
- (b) a pilot scheme within the meaning given in section 134(2) of the National Health Service Act 2006^(a) (pilot schemes),

which is not an NHS contract.

(2) If legal proceedings relating to the dispute have commenced before 1st March 2015—

- (a) regulation 103(6)(a) of the principal Regulations (LPS schemes: health service body status);
- (b) regulation 109(4)(a) of the principal Regulations (LPS pilot schemes: health service body status); and
- (c) paragraph 21(1) of Schedule 7 to the principal Regulations (mandatory terms for LPS schemes – dispute resolution: non-NHS contracts),

have affect in relation to that dispute as if the amendments made by regulations 4, 5(a) and 9 had not come into force.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State
Department of Health

23rd January 2015

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, under Part 7 of the National Health Service Act 2006 for the provision of pharmaceutical services and local pharmaceutical services (apart from the terms of service of piloted services).

The National Health Service Commissioning Board (“NHSCB”) holds lists, known as pharmaceutical lists, of approved providers of pharmaceutical services. These lists are kept by reference to local authority areas. An amendment is made to regulation 25 of the 2013 Regulations to make it clear that an applicant for new distance selling premises who is already included in a particular pharmaceutical list but who is seeking replacement premises in the same local authority area is subject to the requirements in respect of distance selling premises applications in regulation 25 (regulation 2).

Under regulation 99 of the 2013 Regulations, the NHSCB may designate premises or a neighbourhood for the purpose of giving priority in that place to the development of schemes for the provision of local pharmaceutical services (a form of contractual arrangement for the provision of pharmaceutical services that is separate from the pharmaceutical list system). The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417) erroneously amended regulation 32 of the 2013 Regulations so that the NHSCB was required to refuse pharmaceutical list applications that related to a neighbourhood or premises covered by such a designation, rather than simply giving the NHSCB the power to defer such an application. Regulation 3 corrects that error.

A local pharmaceutical services contractor may choose to be a “health service body” and so for their contract to be an NHS contract – and if they do, they may also choose to cease to be such a body and so for their contract to cease to be an NHS contract. Where a local pharmaceutical services contractor does choose to cease to be a health service body, the amendments made by these Regulations have the effect of providing that all disputes relating to the period when their

(a) Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8, and by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 71(3).

contract was an NHS contract are to be dealt with via the NHS dispute resolution procedure (regulation 4, 5(a) and 9). An exception is made in a transitional provision which provides, in effect, that if a dispute was already the subject of legal proceedings before these Regulations came into force, that dispute is to be determined in accordance with the relevant legislation as it applied at that time (regulation 10). Before these Regulations came into force, disputes under a local pharmaceutical services contract that was not an NHS contract, but which related to a time when the contract was an NHS contract, could only be dealt with via the NHS dispute resolution procedure (if they had not been referred to that procedure when the contract was an NHS contract) with the contractor's consent.

Regulations 5(b) and 7 correct drafting errors.

Applicants for inclusion in a pharmaceutical list may be granted subject to a condition that relates to the applicant's fitness to provide pharmaceutical services. If that condition is appealed by the applicant, and the appeal is lost, the application may lapse if a required notification is not given by the applicant. In respect of cases where the applicant makes a subsequent pharmaceutical list application, the application procedures are amended so that the applicant must make reference in the new application to the earlier lapsed application (regulation 6(a)). The pharmaceutical list applications procedures are also amended so that in all cases where the applicant is seeking the listing of premises that are the same as, or in close proximity to, premises that are already listed, the applicant must explain why they believe the application should not be refused under regulation 31 of the 2013 Regulations, which prevents the granting of applications where the proposed and existing premises should be treated as the same site (regulation 6(b)).

The terms of service of providers of pharmaceutical services on pharmaceutical lists that dispense both drugs and some appliances are amended so that they are required to give appropriate advice about the benefits of repeat dispensing to specified categories of patients. In addition, their audit programme requirements are amended so that rather than in all cases having to undertake two clinical audits, they are required to undertake a clinical audit of their choice, and either a clinical or policy based audit as specified by the NHSCB (regulation 8).

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