
STATUTORY INSTRUMENTS

2013 No. 349

**The National Health Service (Pharmaceutical and
Local Pharmaceutical Services) Regulations 2013**

PART 9

**Conditional inclusion in pharmaceutical lists: certain specific
conditions that do not relate to fitness or performance**

Distance selling premises: specific conditions

64.—(1) If an application in respect of distance selling premises—

- (a) to which regulation 25(1) applies is granted;
- (b) to which regulation 25(1) of the 2012 Regulations (distance selling premises applications) applied was granted; or
- (c) to which regulation 13(1)(d) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted,

paragraph (2) applies.

(2) The inclusion in the pharmaceutical list of the person (X) listed in relation to—

- (a) those distance selling premises; or
- (b) if there has been a relocation of the retail pharmacy business or appliance contractor business at those distance selling premises to other premises, those other premises,

is subject to the conditions set out in paragraph (3).

(3) Those conditions are—

- (a) X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;
- (b) the means by which X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;
- (c) the listed chemist premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
- (d) in the case of pharmacy premises, the pharmacy procedures for the premises must be such as to secure—
 - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and X or X's staff; and

- (e) nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that—
 - (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
 - (ii) X is likely to refuse, for reasons other than those provided for in X's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from X is limited to other categories of patients).
- (4) The NHSCB may not vary or remove the conditions set out in paragraph (3).

Core opening hours conditions

65.—(1) If an application to which regulation 13(1)(b) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted, the inclusion in the pharmaceutical list of the person listed in relation to—

- (a) the premises that were listed as a consequence of that application; or
- (b) if there has been a relocation of the retail pharmacy business or appliance contractor business at those premises to other premises, those other premises,

is subject to the condition set out in paragraph (2) (“the 100 hours condition”).

(2) The condition is that the premises must be kept open for at least 100 hours per week for the provision of pharmaceutical services.

(3) The NHSCB may not vary or remove the 100 hours condition.

(4) Where, in the course of making a routine application or an excepted application to which regulation 24 or 26(2) applies—

- (a) for inclusion in a pharmaceutical list as mentioned in regulation 10(2)(a), or from a person already included in such a list to relocate to different pharmacy premises or to open, within the area of the relevant HWB, additional pharmacy premises—
 - (i) an NHS pharmacist undertook to provide pharmaceutical services at the proposed pharmacy premises for a specified number of core opening hours each week which is more than 40 (other than as a consequence of a 100 hours condition),
 - (ii) the NHS pharmacist and the NHSCB agreed that pharmaceutical services are to be provided at the proposed pharmacy premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, and
 - (iii) the application was granted having regard to that undertaking and that agreement, when it includes the premises in a pharmaceutical list, the NHSCB must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed; or
- (b) for inclusion in a pharmaceutical list as mentioned in regulation 10(2)(b), or from a person already included in such a list to relocate to different appliance contractor premises or to open, within the area of the relevant HWB, additional appliance contractor premises—
 - (i) an NHS appliance contractor undertook to provide pharmaceutical services at proposed appliance contractor premises for a specified number of core opening hours

each week which is more than 30 (other than as a consequence of a 100 hours condition),

(ii) the NHS appliance contractor and the NHSCB agreed that pharmaceutical services are to be provided at the appliance contractor premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 30) at set times and on set days, and

(iii) the application was granted having regard to that undertaking and that agreement, when it includes the premises in a pharmaceutical list, the NHSCB must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed.

(5) Where the NHSCB has—

(a) invited an NHS chemist to increase the total number of core opening hours during which the NHS chemist is to provide pharmaceutical services at listed chemist premises; and

(b) thereafter agreed with the NHS chemist—

(i) an increased number of core opening hours, and

(ii) if the NHS chemist—

(aa) is an NHS pharmacist, that pharmaceutical services are to be provided at the pharmacy premises during any additional opening hours (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, and

(bb) is an NHS appliance contractor, that pharmaceutical services are to be provided at the appliance contractor premises during any additional opening hours (that is, the hours which are the difference between the total number of hours specified and 30) at set times and on set days,

the NHSCB must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during any additional opening hours at the set times and on the set days so agreed.

(6) Except as provided for under paragraph (5) and subject to paragraph (7), the NHSCB may only vary a direction given under paragraph (4) or (5), or regulation 65(4) or (5) of the 2012 Regulations (core opening hours conditions), in accordance with paragraph 25 or 26 of Schedule 4 or paragraph 15 or 16 of Schedule 5.

(7) A direction given under paragraph (4) or (5), or regulation 65(4) or (5) of the 2012 Regulations, must not be varied within 3 years of the direction being given.

Conditions relating to providing directed services

66.—(1) Where, immediately before these Regulations came into force, the inclusion in the pharmaceutical list of an NHS chemist (C1) was subject to a condition imposed in relation to listed chemist premises by virtue of regulation 13(3)(b) of the 2005 Regulations (exemption from the necessary or expedient test), including such a condition as varied in accordance with regulation 14 of the 2005 Regulations⁽¹⁾ (variation of directed services in respect of exempted premises) or regulation 66(2) and (3) of the 2012 Regulations (conditions relating to providing directed services), it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises—

(1) Prior to its revocation, regulation 14 was amended by [S.I. 2006/3373](#).

- (a) if, before these Regulations came into force, C1 had not been requested by a Primary Care Trust to provide the directed services specified as regards C1 for the purposes of that condition, that they must provide those directed services at those premises, where requested to do so by the NHSCB unless thereafter the NHSCB ceases to commission those services; or
 - (b) if, before these Regulations came into force, C1 was providing, or had been requested by a Primary Care Trust to provide, the directed services specified as regards C1 for purposes of that condition, that they must provide those directed services at those premises unless the NHSCB does not continue to commission those services.
- (2) The person listed in relation to the premises may apply to the NHSCB to vary the directed services specified for the purposes of the condition imposed by virtue of paragraph (1), or to remove the condition, but only if at least 3 years have elapsed—
- (a) since the condition was imposed by virtue of the 2005 Regulations; and
 - (b) during that period neither a Primary Care Trust nor the NHSCB has requested that the services be provided at the premises in respect of which the condition was imposed,
- but otherwise the NHSCB may not vary or remove the condition imposed by virtue of paragraph (1).
- (3) If, pursuant to an application under paragraph (2), the NHSCB does vary the directed services specified for the purposes of the condition imposed by virtue of paragraph (1) in respect of any premises, it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises that they must—
- (a) provide the directed services specified as regards C1 as a consequence of the application—
 - (i) if the NHSCB commissions the services within 3 years of the date on which the condition is imposed by virtue of these Regulations, and
 - (ii) unless thereafter the NHSCB ceases to commission the services; and
 - (b) not withhold agreement to a service specification for those services unreasonably.
- (4) Where, in the course of making a routine or excepted application under these Regulations or the 2012 Regulations, an NHS chemist undertook—
- (a) to provide the directed services mentioned in the application, if a Primary Care Trust or the NHSCB commissioned the services within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates;
 - (b) if the directed services were commissioned, to provide the services in accordance with an agreed service specification; and
 - (c) not to withhold agreement to a service specification unreasonably,
- the inclusion in the pharmaceutical list of the person (C2) listed in relation to the premises that were listed as a consequence of that application is subject to the condition set out in paragraph (5).
- (5) The condition is that, at those premises, C2 must—
- (a) provide the directed services mentioned in the application (whether or not C2 was the applicant); and
 - (b) not withhold agreement to a service specification for those services unreasonably,
- if the Primary Care Trust or the NHSCB commissions the services from C2 within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates, unless thereafter the NHSCB ceases to commission the services (if it has commissioned them) or does not continue to commission services (that is, if only the Primary Care Trust, and not the Board, has commissioned them).

(6) Where a Primary Care Trust or the NHSCB specifies that a requirement to provide directed services arising out of a condition imposed by virtue of this regulation is to take effect by a specified date, the requirement takes effect—

- (a) on that date; or
- (b) on the date on which provision of the directed service is commenced,

whichever is the sooner.

(7) The NHSCB may not vary or remove the condition imposed by virtue of paragraphs (3) to (5).

Conditions relating to voluntary closure of premises

67.—(1) Except in the circumstances described in paragraph (3), where an NHS chemist (C) wishes, other than as a consequence of a change of ownership application—

- (a) to withdraw from a pharmaceutical list, or
- (b) for particular listed chemist premises no longer to be listed in relation to C,

C must comply with paragraph (2).

(2) C must notify the NHSCB of C's wish—

- (a) unless sub-paragraph (b) applies, at least 3 months in advance of the date on which pharmaceutical services are no longer to be provided;
- (b) at least—
 - (i) 6 months in advance of that date, if in respect of C the 100 hours condition is imposed as regards those premises, or
 - (ii) 30 days in advance of that date, if—
 - (aa) a condition is imposed under regulation 35,
 - (bb) C appeals that condition to the First-tier Tribunal,
 - (cc) on appeal, the First-tier Tribunal confirms the imposition of that condition or imposes another condition, and
 - (dd) within 30 days of being informed of the decision of the First-tier Tribunal, C notifies the NHSCB that C wishes to withdraw from the pharmaceutical list within a shorter period of not less than 30 days,

unless either it is impracticable for C to do so, in which case C must notify the NHSCB as soon as it is practicable for C to do so, or the NHSCB agrees to a shorter notification period.

(3) If C has consented to—

- (a) particular listed chemist premises no longer being listed in relation to C by the NHSCB; or
- (b) being removed from the pharmaceutical list for the area of a HWB,

in the context of a relocation application, paragraph (4) applies.

(4) In the circumstances described in paragraph (3), C must, where the relocation application is granted, when C gives notice to the NHSCB of C's intention to commence the provision of pharmaceutical services at the new premises (in accordance with paragraph 34 of Schedule 2), give notice to the NHSCB of when, before C commences the provision of pharmaceutical services at the new premises, C is to cease to provide pharmaceutical services at the existing premises.

Conditions relating to local resolution of disputes over terms of service

68.—(1) It is a condition of the inclusion of each NHS chemist (C) in a pharmaceutical list by the NHSCB that C makes every reasonable effort to communicate and co-operate with the NHSCB

with a view to resolving any dispute between C and the NHSCB relating to C's compliance with the terms of service under which C provides pharmaceutical services for the NHSCB.

(2) The NHSCB may not vary or remove the condition imposed by virtue of paragraph (1).