STATUTORY INSTRUMENTS

2012 No. 1909

The National Health Service (Pharmaceutical Services) Regulations 2012

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; or
 - (b) 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) A Primary Care Trust 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) A Primary Care Trust 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 Primary Care Trust, 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 originally imposed by virtue of the 2005 Regulations),
 - (ii) the NHS pharmacist and the Primary Care Trust 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 its pharmaceutical list, the Primary Care Trust 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
 - (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 Primary Care Trust, additional appliance contractor premises—

the additional opening hours at the set times and on the set days so agreed;

(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 originally imposed by virtue of the 2005 Regulations),

- (ii) the NHS appliance contractor and the Primary Care Trust 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 its pharmaceutical list, the Primary Care Trust 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 a Primary Care Trust 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 Primary Care Trust 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), a Primary Care Trust may only vary a direction given under paragraph (4) or (5) 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) 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), it is a condition of the inclusion in the pharmaceutical list of the person listed in relation to those premises—
 - (a) if, before these Regulations came into force, C1 had not been requested by the 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 Primary Care Trust;

- (b) if, before these Regulations came into force, C1 was providing, or had been requested by the 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.
- (2) The person listed in relation to the premises may apply to a Primary Care Trust 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 the Primary Care Trust has not requested that the services be provided at the premises in respect of which the condition was imposed,

but otherwise the Primary Care Trust may not vary or remove the condition imposed by virtue of paragraph (1).

- (3) If, pursuant to an application under paragraph (2), the Primary Care Trust 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, if the Primary Care Trust commissions the services within 3 years of the date on which the condition is imposed by virtue of these Regulations;
 - (b) not withhold agreement to a service specification for those services unreasonably.
- (4) Where, in the course of making a routine or excepted application, an NHS chemist undertook—
 - (a) to provide the directed services mentioned in the application, if the Primary Care Trust 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; and
 - (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 to withhold agreement to a service specification for those services unreasonably,

if the Primary Care Trust 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.

- (6) Where a Primary Care Trust 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) A Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust that C wishes to withdraw from its pharmaceutical list within a shorter period of not less than 30 days,

unless it is impracticable for C to do so in which case C must notify the Primary Care Trust as soon as it is practicable for C to do so.

- (3) If C has consented to—
 - (a) particular listed chemist premises no longer being listed in relation to C by a Primary Care Trust (PCT1); or
- (b) being removed from the pharmaceutical list of PCT1,

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—
 - (a) if C is relocating to the area of a different Primary Care Trust (PCT2)—
 - (i) notify PCT1 of the grant as soon as is practicable after C is notified of the grant by PCT2, and
 - (ii) when C gives notice to PCT2 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 PCT1 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; and
 - (b) if C is relocating within the area of PCT1, when C gives notice to PCT1 of C's intention to commence the provision of pharmaceutical services at the new premises (in accordance with paragraph 34 of Schedule 2), also give notice to PCT1 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 a Primary Care Trust (PCT1) that C makes every reasonable effort to communicate and co-operate with PCT1 with a view to resolving any dispute between C and PCT1 relating to C's compliance with the terms of service under which C provides pharmaceutical services for PCT1.
- (2) A Primary Care Trust may not vary or remove the condition imposed by virtue of paragraph (1).