#### STATUTORY INSTRUMENTS

# 2013 No. 349

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

#### PART 4

# **Excepted applications**

## Applications from NHS chemists in respect of providing directed services

23. Section 129(2A) of the 2006 Act(1) (regulations as to pharmaceutical services) does not apply to an application by a person already included in a pharmaceutical list for inclusion in that list also in respect of services that are directed services that are not already listed in relation to that person.

## Relocations that do not result in significant change to pharmaceutical services provision

- **24.**—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application from a person already included in a pharmaceutical list to relocate to different premises in the area of the relevant HWB (HWB1) if—
  - (a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
  - (b) in the opinion of the NHSCB, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
    - (i) in any part of the area of HWB1, or
    - (ii) in a controlled locality in the area of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;
  - (c) the NHSCB is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB1;
  - (d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, the NHSCB chooses to commission them); and
  - (e) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow).
- (2) Section 129(2A) of the 2006 Act does not apply to an application from a person already included in a pharmaceutical list for the area of a HWB (HWB2) for inclusion in the pharmaceutical

<sup>(1)</sup> 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).

list for the area of a neighbouring HWB (HWB3), or inclusion in the pharmaceutical list for the area of HWB3 also in respect of other premises than those already listed in relation to that person, if—

- (a) the purpose of the application is to relocate to different premises;
- (b) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises (P1), the location of the new premises (P2) is not significantly less accessible:
- (c) in the opinion of the NHSCB, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of HWB3's area; or
  - (ii) in a controlled locality in the area of a neighbouring HWB (including HWB2), where that controlled locality is within 1.6 kilometres of P2;
- (d) the NHSCB is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB3;
- (e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, the NHSCB chooses to commission them);
- (f) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow); and
- (g) the applicant consents to—
  - (i) where the applicant has only one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of the applicant's name from that pharmaceutical list, or
  - (ii) where the applicant has more than one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of P1 from being listed in relation to the applicant in that pharmaceutical list,

with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.

- (3) An application pursuant to this regulation must be refused if the existing pharmacy premises from which the applicant is seeking to relocate (P3)—
  - (a) were listed in relation to an NHS pharmacist as a result of an application to which regulation 13(1)(a) of the 2005 Regulations(2) (exemption from the necessary or expedient test) applied, and—
    - (i) P3 are located in an area that, immediately before the 2012 Regulations came into force, was an approved retail area (within the meaning given in regulation 15 of the 2005 Regulations (approved retail areas)), and
    - (ii) the applicant proposes to relocate from P3 to premises that are outside that area;
  - (b) were listed in relation to an NHS pharmacist as a result of an application to which regulation 13(1)(c) of the 2005 Regulations applied, unless—
    - (i) the provider, or where there is more than one provider all the providers, of primary medical services at the one-stop primary care centre (within the meaning given in regulation 16 of the 2005 Regulations(3) (new one-stop primary care centres)) at

<sup>(2)</sup> Prior to its revocation, the heading of regulation 13 was amended by S.I. 2009/2205.

<sup>(3)</sup> Prior to its revocation, regulation 16 was amended by S.I. 2005/1501.

- which P3 are located are relocating with the applicant to a new discrete site or building,
- (ii) at that new discrete site or building primary medical services are or are to be provided by one or more providers of primary medical services with a patient list of, or patient lists with a combined total of, 18,000 patients, and
- (iii) at that site or building the services of a broad range of health care professionals are or will be regularly and frequently provided (together, where appropriate, with other health or social services); or
- (c) have been listed in relation to the applicant for a period of less than 12 months prior to the application, and—
  - (i) that listing arose out of the applicant relocating to P3 from other pharmacy premises,
  - (ii) that relocation arose out of the grant of an application—
    - (aa) that was an excepted application by virtue of this regulation or regulation 24 of the 2012 Regulations (relocations that do not result in significant change to pharmaceutical services provision), or
    - (bb) to which regulation 6 or 7 of the 2005 Regulations(4) (which related to minor relocations) applied, and
  - (iii) the applicant is unable to satisfy the NHSCB that relocation from P3 is necessary for reasons that the NHSCB accepts are good cause.

#### Distance selling premises applications

- **25.**—(1) Section 129(2A) of the 2006 Act(**5**) (regulations as to pharmaceutical services) does not apply to an application—
  - (a) for inclusion in a pharmaceutical list by a person not already included; or
  - (b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

- (2) The NHSCB must refuse an application to which paragraph (1) applies—
  - (a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and
  - (b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely 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 the applicant or the applicant's staff.

<sup>(4)</sup> Prior to their revocation, regulations 6 and 7 were both amended by S.I. 2005/1501 and 2006/3373.

<sup>(5)</sup> 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).

#### Change of ownership applications

- **26.**—(1) Section 129(2A) of the 2006 Act(6) (regulations as to pharmaceutical services) does not apply to an application from a person who is not included in a pharmaceutical list for inclusion in the list, or from a person included in a pharmaceutical list for inclusion in that list also in respect of other premises than those already listed in relation to that person, if—
  - (a) the applicant (X) is undertaking to provide pharmaceutical services at premises—
    - (i) that are already listed chemist premises, and
    - (ii) at which another person (Y) is providing pharmaceutical services;
  - (b) X is proposing to carry on at the listed chemist premises, in place of Y, the business in the course of which Y is providing pharmaceutical services at those premises;
  - (c) X is undertaking to provide the same pharmaceutical services as those that Y is providing; and
  - (d) the provision of pharmaceutical services at the premises will not be interrupted (except for such period as the NHSCB may for good cause allow).
- (2) Section 129(2A) of the 2006 Act does not apply to an application from a person who is not included in a pharmaceutical list for the area of a HWB (HWB1) for inclusion in that list, or from a person included in a pharmaceutical list for inclusion in that list also in respect of other premises than those already listed in relation to that person, if—
  - (a) the applicant (X) is undertaking to provide the pharmaceutical services that another person (Y)—
    - (i) is providing at listed chemist premises ("Y's premises"), whether in the area of HWB1 or a neighbouring HWB, or
    - (ii) has provided at Y's premises but Y is no longer able to provide pharmaceutical services at those premises for reasons that the NHSCB accepts are good cause;
  - (b) X is proposing to carry on, in place of Y, the business in the course of which Y is providing, or has provided, pharmaceutical services at Y's premises;
  - (c) X is undertaking to provide the same pharmaceutical services as Y is providing or has provided at Y's premises, but at different premises ("X's premises");
  - (d) if Y had applied to move to X's premises, that application would have been granted under regulation 24; and
  - (e) if pharmaceutical services—
    - (i) are being provided at Y's premises, the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow) by the move of the business from Y's premises to X's premises, or
    - (ii) are not being provided at Y's premises, the provision of pharmaceutical services will commence at X's premises within the period that the NHSCB considers is an acceptable period for the interruption of the provision of pharmaceutical services by the business that X is taking over.

#### Applications for temporary listings arising out of suspensions

- **27.**—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—
  - (a) for temporary inclusion in a pharmaceutical list by a person not already included; or

<sup>(6)</sup> 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).

(b) by a person already included in a pharmaceutical list for temporary inclusion in that list in respect of services, or services and premises, other than those already listed in relation to that person,

from a person (X) who proposes to provide pharmaceutical services which are not being provided because the person listed in relation to them (Y) is suspended from the pharmaceutical list.

- (2) The NHSCB must refuse an application to which paragraph (1) applies—
  - (a) unless it is satisfied that—
    - (i) Y has nominated X as the person to provide those services for the duration of Y's suspension and consents to X doing so,
    - (ii) X will provide the same pharmaceutical services as those that Y provided or had undertaken to provide before the suspension, and
    - (iii) there is no direct or indirect connection between X and Y (including such a connection through a third party) the nature of which makes it unlikely that X will be able to exercise an appropriate degree of autonomy;
  - (b) if Y is a body corporate and X—
    - (i) is an employee of Y,
    - (ii) is, or was at the time of the suspension or of the originating events, a director or superintendent of Y,
    - (iii) is a body corporate in which Y or an employee of Y is a majority shareholder,
    - (iv) is a body corporate in which a majority shareholder of Y is, or was at the time of the suspension or of the originating events, a director or superintendent of X,
    - (v) is a body corporate which has a director or superintendent who is an employee of Y, or
    - (vi) is a body corporate which has as a director or superintendent someone who is, or was at the time of the suspension or of the originating events, a director or superintendent of Y;
  - (c) if Y is an individual and X—
    - (i) is an employee of Y,
    - (ii) is a body corporate of which Y or an employee of Y is a director or superintendent,
    - (iii) is a body corporate in which Y or an employee of Y is a majority shareholder, or
    - (iv) is a body corporate which has a director or superintendent who is an employee of Y; or
  - (d) if Y is a partnership and X—
    - (i) is or has been a member or employee of Y,
    - (ii) is a body corporate of which a member or employee of Y is or has been a director, superintendent or majority shareholder, or
    - (iii) is a partnership of which X, or a member or employee of X, is or has been a member.
- (3) If an application to which—
  - (a) paragraph (1)(a) applies is granted, the applicant must only be included in the pharmaceutical list for a fixed period;
  - (b) paragraph (1)(b) applies is granted, the premises or services must only be listed in relation to the applicant for a fixed period.
- (4) The fixed periods referred to in paragraph (3) must be no longer than—
  - (a) the period of Y's suspension; or

(b) until Y notifies the NHSCB, with effect from a specified date (which must be at least 2 working days after the date of the notification), that Y no longer consents to X providing the services that X is providing because of Y's suspension from the pharmaceutical list.

# Applications from persons exercising a right of return to a pharmaceutical list

- **28.**—(1) Section 129(2A) of the 2006 Act(7) (regulations as to pharmaceutical services) does not apply to an application—
  - (a) for inclusion in a pharmaceutical list by a person not already included; or
  - (b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in the circumstances set out in paragraph (2).

- (2) Those circumstances are—
  - (a) it has been determined in accordance with—
    - (i) regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(8) (right of return to pharmaceutical lists),
    - (ii) regulation 15 of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(9) (right of return to pharmaceutical lists), or
    - (iii) regulation 108,

that the applicant is to be given a right of return to a pharmaceutical list;

- (b) the applicant is seeking to exercise that right after ceasing to provide local pharmaceutical services under the LPS scheme as a consequence of entering into which, or of the variation of which, the applicant was given the right of return; and
- (c) the granting of the right of return arose out of the provision of the local pharmaceutical services which the applicant is ceasing to provide.
- (3) The NHSCB must refuse an application to which paragraph (1) applies, unless—
  - (a) the change from providing local pharmaceutical services to providing pharmaceutical services will not give rise to any interruption in the receipt and dispensing of prescriptions by the applicant (except for such period as the NHSCB may for good cause allow); and
  - (b) any conditions in the relevant determination of the right of return are satisfied.

# Temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists

- **29.**—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application for a temporary amendment to a pharmaceutical list in the following circumstances—
  - (a) there is an emergency requiring the flexible provision of pharmaceutical services; or
  - (b) there is a temporary suspension in the provision of pharmaceutical services at listed chemist premises (P1) for a reason (for example, fire or flooding) that is beyond the control of the NHS chemist (C) listed in relation to P1.

<sup>(7)</sup> 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).

<sup>(8)</sup> S.I. 2002/2016. These Regulations are revoked by Schedule 10.

<sup>(9)</sup> S.I. 2006/552. These Regulations are revoked by Schedule 10.

- (2) In the circumstances described in paragraph (1)(a), the NHSCB may make a temporary amendment to an entry in a pharmaceutical list, but—
  - (a) only for a specified period (which must not be longer than the specified period of the emergency given by the Secretary of State) which the NHSCB may extend or curtail in appropriate circumstances; and
  - (b) the applicant may revert to the applicant's overridden entry in the pharmaceutical list before the end of the period specified by the NHSCB, on giving the NHSCB at least 24 hours notice.
- (3) In the circumstances described in paragraph (1)(b), the NHSCB may make a temporary amendment to the entry of C in the relevant pharmaceutical list in order to allow C to provide the services that C ordinarily provided at P1 at other premises nearby (P2), at the days on which and times at which those services were ordinarily provided at P1, for a period specified by the NHSCB.
- (4) A period specified under paragraph (3) must not be longer (initially) than 6 months, and the NHSCB may under that paragraph—
  - (a) if it has good cause to do so, extend the period specified under that paragraph (but not beyond 12 months from the date on which C starts to provide the services in question from P2); or
  - (b) curtail the period specified,

in appropriate circumstances.

- (5) For the period specified under paragraph (3), but subject to paragraph (6) and regulation 118, P2 instead of P1 are to be treated as listed in relation to C for the purposes of these Regulations (albeit that the premises actually listed in relation to C are P1).
- (6) The applicant may revert to the applicant's overridden entry in the pharmaceutical list before the end of the period specified by under paragraph (3), on giving the NHSCB at least 24 hours notice.
- (7) Planned refurbishment is not a "reason beyond the control" of C for the purposes of paragraph (1)(b).
- (8) There is no right of appeal under these Regulations in respect of a decision of the NHSCB under this regulation.