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STATUTORY INSTRUMENTS

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**2013 No. 349**

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

**PART 3**

General matters relating to pharmaceutical lists and applications in respect of them

**Pharmaceutical lists**<sup>F1</sup> ...

**10.**—(1) In respect of the area of each HWB, the NHSCB must prepare, maintain and publish 2 lists of persons (if there are any), other than medical practitioners or dental practitioners, who undertake to provide pharmaceutical services from premises situated in that area.

(2) Those lists (which are pharmaceutical lists) are—

- (a) a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs; and
- (b) a list of persons who undertake to provide pharmaceutical services only by way of the provision of appliances.

(3) Those lists must include—

- (a) the address of the premises in the area of the HWB at which the listed person has undertaken to provide pharmaceutical services (“the listed chemist premises”);
- (b) the days on which and times at which, at those premises, the listed person is to provide those services during the core opening hours and any supplementary opening hours of the premises.

<sup>F2</sup>(4) .....

<sup>F3</sup>(5) .....

(6) The NHSCB must ensure that each HWB has access to the pharmaceutical lists<sup>F4</sup>... that it holds which is sufficient to enable the HWB to carry out its functions under these Regulations<sup>F5</sup>, and must notify it of changes to the lists that are relevant to the carrying out of its functions].

(7) Schedule 2, which has effect, contains provisions with regard to—

(a) the information to be supplied by a person—

- (i) seeking inclusion in a pharmaceutical list who is not already included in it, or
- (ii) who is included in a pharmaceutical list and who is seeking—
  - (aa) to open, within the area of the relevant HWB, additional premises from which to provide the same or different pharmaceutical services,
  - (bb) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or
  - (cc) to provide, from the person's listed chemist premises, services that are in addition to those already listed in relation to that person; and

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- (b) the procedure to be followed by persons as mentioned in sub-paragraph (a) when making a routine application or an excepted application; and
- (c) other related matters.

(8) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under Parts 2 to 5 and Schedule 2 (as it does in relation to appeals against decisions under Parts 7, 8, 10 and 12).

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| <p><b>F1</b> Words in <a href="#">reg. 10</a> heading omitted (1.10.2022) by virtue of <a href="#">The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930)</a>, regs. 1(2), <b>4(2)</b></p> <p><b>F2</b> <a href="#">Reg. 10(4)</a> omitted (1.10.2022) by virtue of <a href="#">The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930)</a>, regs. 1(2), <b>4(1)(a)</b></p> <p><b>F3</b> <a href="#">Reg. 10(5)</a> omitted (1.10.2022) by virtue of <a href="#">The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930)</a>, regs. 1(2), <b>4(1)(a)</b></p> <p><b>F4</b> Words in <a href="#">reg. 10(6)</a> omitted (1.10.2022) by virtue of <a href="#">The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930)</a>, regs. 1(2), <b>4(1)(b)</b></p> <p><b>F5</b> Words in <a href="#">reg. 10(6)</a> added (5.12.2016) by <a href="#">The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077)</a>, regs. 1(1), <b>4</b></p> |
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### Terms of service of NHS chemists: general

**11.—(1)** The arrangements under which an NHS pharmacist undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights or obligations—

- (a) that are included in these Regulations, including—
  - (i) the terms of service set out in Schedule 4 (which accordingly has effect), and
  - (ii) any obligation that is only applicable in prescribed cases, if the NHS pharmacist is a person to whom the obligation is applicable;
- (b) that are included in the Drug Tariff, in so far as those rights or obligations relate to NHS pharmacists and are applicable in the case of the NHS pharmacist;
- (c) where the NHSCB makes an arrangement with the NHS pharmacist for the provision of any directed services, that are included in that arrangement; and
- (d) that are—
  - (i) included in regulations under section 225 of the 2007 Act<sup>M1</sup> (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and
  - (ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider,

as varied, where applicable, in accordance with regulation 35 or Chapter 6 of Part 7 of the 2006 Act.

(2) The arrangements under which an NHS appliance contractor undertakes to provide pharmaceutical services (and so their terms of service) are to include any provisions affecting their rights or obligations—

- (a) that are included in these Regulations, including—
  - (i) the terms of service set out in Schedule 5 (which accordingly has effect), and
  - (ii) any obligation that is only applicable in prescribed cases, if the NHS appliance contractor is a person to whom the obligation is applicable;

- (b) that are included in the Drug Tariff, in so far as those rights or obligations relate to NHS appliance contractors and are applicable in the case of the NHS appliance contractor;
- (c) where the NHSCB makes an arrangement with the NHS appliance contractor for the provision of any directed services, that are included in that arrangement; and
- (d) that are—
  - (i) included in regulations under section 225 of the 2007 Act <sup>M2</sup> (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and
  - (ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider,

as varied, where applicable, in accordance with regulation 35 or Chapter 6 of Part 7 of the 2006 Act.

[<sup>F6</sup>(3) A term of service of an NHS chemist that would otherwise be part of the arrangements mentioned in paragraphs (1) and (2) is temporarily not part of those arrangements, in the particular circumstances mentioned in sub-paragraph (c)(ii) and during the period mentioned in sub-paragraph (c)(iii), in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
  - (i) pandemic, and
  - (ii) a serious risk or potentially a serious risk to human health,the NHSCB with the agreement of the Secretary of State has made an announcement in respect of the prioritisation of services to be provided in, or in any part of, England as part of the health service;
- (b) the prioritisation is in order to assist in the management of the serious risk or potentially serious risk to human health;
- (c) as part of the announcement, the NHSCB with the agreement of the Secretary of State has issued advice to the effect that NHS chemists are not to comply with a specified term of service—
  - (i) in the area to which the announcement relates,
  - (ii) in the circumstances specified in the announcement, and
  - (iii) during the period specified in the announcement; and
- (d) the NHS chemist is situated in the area to which the announcement relates and compliance with the term of service (it being the specified term of service) would, but for the effect of this paragraph, be a requirement of the NHS chemist's terms of service.]

**F6** [Reg. 11\(3\) inserted \(27.3.2020\) by The National Health Service \(Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.\) Regulations 2020 \(S.I. 2020/351\), regs. 1\(2\), 6](#)

**Marginal Citations**

- M1** Section 225 has been amended by the [Health and Social Care Act 2012 \(c. 7\), section 186\(6\) to \(10\), Schedule 14, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.](#)
- M2** Section 225 has been amended by the [Health and Social Care Act 2012 \(c. 7\), section 186\(6\) to \(10\), Schedule 14, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.](#)

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### **Routine applications for inclusion in or amendments to a pharmaceutical list**

**12.** In these Regulations, a “routine application” is any application, other than an excepted application, by a person—

- (a) for inclusion in a pharmaceutical list who is not already included in it; or
- (b) who is included in a pharmaceutical list and who is seeking—
  - (i) to open, within the area of the relevant HWB, additional premises from which to provide the same or different pharmaceutical services,
  - (ii) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or
  - (iii) to provide, from the person's listed chemist premises, services that are in addition to those already listed in relation to that person.

### **Current needs: additional matters to which the NHSCB must have regard**

**13.**—<sup>F7</sup>(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 (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).]

(2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to meet the current need mentioned in paragraph (1) that the applicant is offering to meet;
- (b) whether it is satisfied that another application offering to meet the current need mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (c) whether it is satisfied that an appeal relating to another application offering to meet the current need mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (d) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the needs for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;
- (e) whether it is satisfied that—
  - (i) granting the application would only meet the current need mentioned in paragraph (1) in part, and
  - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
- (f) whether—
  - (i) it is satisfied that granting the application would only meet the current need mentioned in paragraph (1) in part, but

- (ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
  - (g) whether it is satisfied that—
    - (i) the current need mentioned in paragraph (1) was for services other than essential services, and
    - (ii) granting the application would result in an increase in the availability of essential services in the area of the relevant HWB;
  - (h) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the current need mentioned in paragraph (1) has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;
  - (i) whether the application needs to be deferred or refused by virtue of any provision of Parts 5 to 7.
- (3) For the purposes of paragraph (2)(h), a need is to be treated as due to be met if—
- (a) the person (P) undertaking to meet that need is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice; or
  - (b) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet commenced the provision of those services.

**F7** [Reg. 13\(1\)](#) substituted (1.4.2014) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment and Transitional Provision\) Regulations 2014 \(S.I. 2014/417\)](#), regs. 1, 3

### **Current needs: consequences of additional matters**

- 14.**—(1) If the NHSCB is satisfied as mentioned in regulation 13(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to meet the current need mentioned in regulation 13(1) that the applicant is offering to meet; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to meet the current need mentioned in regulation 13(1) that the applicant is offering to meet,
- but it must not defer consideration of the application for longer than 6 months.
- (2) If the NHSCB is satisfied as mentioned in regulation 13(2)(b), it may defer consideration of the application until it can be considered at the same time as the other application.
- (3) If the NHSCB is satisfied as mentioned in regulation 13(2)(c), it may defer consideration of the application until after the appeal has reached its final outcome.
- (4) If the NHSCB is satisfied as mentioned in regulation 13(2)(d) or (e), it must refuse the application.
- (5) If the NHSCB is satisfied as mentioned in regulation 13(2)(f) to (h), it may only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in the area of the relevant HWB.

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## Future needs: additional matters to which the NHSCB must have regard

### 15.—<sup>F8</sup>(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).]

### (2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to meet the future need mentioned in paragraph (1) that the applicant is offering to meet;
- (b) whether it is satisfied that it would be desirable to defer consideration of the application until some or all of the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 have arisen (should they arise);
- (c) whether it is satisfied that another application offering to meet the future need mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (d) whether it is satisfied that an appeal relating to another application offering to meet the future need mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before determining the applicant's application;
- (e) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;
- (f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the needs, or future needs, for pharmaceutical services in the area of the relevant HWB that are such that—
  - (i) the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 will not, or are now unlikely to, arise (in whole or in part), and
  - (ii) granting the application would not secure improvements, or better access, to pharmaceutical services in that area;
- (g) whether it is satisfied that—
  - (i) granting the application would only meet the future need mentioned in paragraph (1) in part, and
  - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
- (h) whether —
  - (i) it is satisfied that granting the application would only meet the future need mentioned in paragraph (1) in part, but
  - (ii) it considers that, if the application were granted, it would not be unlikely, in the reasonably foreseeable future, that the remainder of that need would be met;
- (i) whether it is satisfied that—

- (i) the future need mentioned in paragraph (1) was for services other than essential services, and
  - (ii) granting the application would result in an increase in the availability of essential services in the area of the relevant HWB;
  - (j) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the future need mentioned in paragraph (1) has been met by another person who is providing, or is due to be met by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;
  - (k) whether the application needs to be deferred or refused by virtue of any provision of Parts 5 to 7.
- (3) For the purposes of paragraph (2)(j), a future need is to be treated as due to be met if—
- (a) the person (P) undertaking to meet that need is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice;
  - (b) the grant of P's application to meet that need is subject to a condition imposed by virtue of paragraph 33(2) of Schedule 2; or
  - (c) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet commenced the provision of those services.

**F8** [Reg. 15\(1\)](#) substituted (1.4.2014) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment and Transitional Provision\) Regulations 2014 \(S.I. 2014/417\)](#), regs. 1, 4

### **Future needs: consequences of additional matters**

- 16.—**(1) If the NHSCB is satisfied as mentioned in regulation 15(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to meet the future need mentioned in regulation 15(1) that the applicant is offering to meet; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to meet the future need mentioned in regulation 15(1) that the applicant is offering to meet,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(2) If the NHSCB is satisfied as mentioned in regulation 15(2)(b), it may defer consideration of the application for such period as is reasonable in the circumstances, having regard to when the future circumstances specified in accordance with paragraph 2(b) of Schedule 1 are likely to arise.

(3) If the NHSCB is satisfied as mentioned in regulation 15(2)(c), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the NHSCB is satisfied as mentioned in regulation 15(2)(d), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the NHSCB is satisfied as mentioned in regulation 15(2)(e) to (g), it must refuse the application.

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(6) If the NHSCB is satisfied as mentioned in regulation 15(2)(h) to (j), it may only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in the area of the relevant HWB.

**Improvements or better access to the current service: additional matters to which the NHSCB must have regard**

17.—<sup>F9</sup>(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).]

(2) Those matters are—

- (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;
- (b) whether it is satisfied that another application offering to secure the improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (c) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (d) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;
- (e) whether it is satisfied that—
  - (i) granting the application would only secure the improvements or better access mentioned in paragraph (1) in part, and
  - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;
- (f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;
- (g) whether it is satisfied that—
  - (i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and
  - (ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB;



- (h) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- (3) For the purposes of paragraph (2)(f), the improvements or better access is to be treated as due to be secured by another person who has undertaken to provide services if—
  - (a) the person (P) undertaking to secure the improvements or better access is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet given that notice;
  - (b) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services.

**F9** Reg. 17(1) substituted (1.4.2014) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment and Transitional Provision\) Regulations 2014 \(S.I. 2014/417\)](#), regs. 1, 5

#### **Unforeseen benefits applications: additional matters to which the NHSCB must have regard**

- 18.—(1)** If—
- (a) the NHSCB receives a routine application and is required to determine whether it is satisfied that granting the application, 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 were or was not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1,
- in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act<sup>M3</sup> (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).
- (2)** Those matters are—
- (a) whether it is satisfied that granting the application would cause significant detriment to—
    - (i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB, or
    - (ii) the arrangements the NHSCB has in place for the provision of pharmaceutical services in that area;
  - (b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—
    - (i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also the NHSCB's duties under sections 13I and 13P of the 2006 Act<sup>M4</sup> (duty as to patient choice and duty as respects variation in provision of health services)),
    - (ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also the NHSCB's duties under section 13G of the 2006 Act<sup>M5</sup> (duty as to reducing inequalities)), [<sup>F10</sup>or]
    - (iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act<sup>M6</sup> (duty to promote innovation)),

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granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published;

- (c) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access that the applicant is offering to secure;
- (d) whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
- (e) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
- (f) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- [<sup>F11</sup>(g) whether it is satisfied that the application presupposes that a gap in pharmaceutical services provision has been or is to be created—
  - (i) by the removal of chemist premises from a pharmaceutical list as a consequence of the grant of a consolidation application, and
  - (ii) since the last revision of the relevant HWB's pharmaceutical needs assessment other than by way of a supplementary statement.]

(3) The NHSCB need only consider whether it is satisfied in accordance with paragraphs (2)(c) to (e) if it has reached at least a preliminary view (although this may change) that it is satisfied in accordance with paragraph (2)(b).

**F10** Word in reg. 18(2)(b)(ii) substituted (1.4.2014) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment and Transitional Provision\) Regulations 2014 \(S.I. 2014/417\)](#), regs. 1, 6

**F11** Reg. 18(2)(g) inserted (5.12.2016) by [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2016 \(S.I. 2016/1077\)](#), regs. 1(1), 5

#### Marginal Citations

**M3** 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).

**M4** Sections 13I and 13P were inserted by the [Health and Social Care Act 2012](#), section 23(1).

**M5** Sections 13G was inserted by the [Health and Social Care Act 2012](#), section 23(1).

**M6** Sections 13K was inserted by the [Health and Social Care Act 2012 \(c. 7\)](#), [section 23\(1\)](#).

#### Applications to which regulation 17 or 18 applies: consequences of additional matters

- 19.—(1) If the NHSCB is satisfied as mentioned in regulation 17(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or

- (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

- (2) If the NHSCB is satisfied as mentioned in regulation 18(2)(c), it may—
  - (a) defer determination of the application;
  - (b) invite applications from other persons to offer to secure the improvements or better access that the applicant is offering to secure; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(3) If the NHSCB is satisfied as mentioned in regulation 17(2)(b) or 18(2)(d), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the NHSCB is satisfied as mentioned in regulation 17(2)(c) or 18(2)(e), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the NHSCB is satisfied as mentioned in regulation 17(2)(d) to (g) or 18(2)(a) [<sup>F12</sup>or (g)], it must refuse the application.

(6) If the NHSCB is satisfied as mentioned in regulation 18(2)(b), it may grant the application notwithstanding that the improvements or better access were or was not included in the relevant pharmaceutical needs assessment.

**F12** Words in [reg. 19\(5\)](#) inserted (5.12.2016) by [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2016 \(S.I. 2016/1077\)](#), regs. 1(1), 6

### **Future improvements or better access: additional matters to which the NHSCB must have regard**

**20.**—<sup>F13</sup>(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).]

- (2) Those matters are—
  - (a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the future

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- improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;
- (b) whether it would be desirable to defer consideration of the application until some or all of the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 have arisen (should they arise);
  - (c) whether it is satisfied that another application offering to secure the future improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;
  - (d) whether it is satisfied that an appeal relating to another application offering to secure the future improvements or better access mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;
  - (e) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;
  - (f) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the profile or future profile of pharmaceutical services in the area of the relevant HWB that are such that the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 will not, or are now unlikely to, arise (in whole or in part);
  - (g) whether it is satisfied that—
    - (i) granting the application would only secure the future improvements or better access mentioned in paragraph (1) in part, and
    - (ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;
  - (h) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, the future improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;
  - (i) whether it is satisfied that—
    - (i) the future improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and
    - (ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB;
  - (j) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.
- (3) For the purposes of paragraph (2)(h), the improvements or better access is to be treated as due to be secured by another person who has undertaken to provide services if—
- (a) the person (P) undertaking to secure the improvements or better access is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to meet that need, but P has not yet given that notice;
  - (b) the grant of P's application to secure the improvements or better access is subject to a condition imposed by virtue of paragraph 33(2) of Schedule 2; or

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- (c) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services.

**F13** Reg. 20(1) substituted (1.4.2014) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment and Transitional Provision\) Regulations 2014 \(S.I. 2014/417\)](#), regs. 1, 7

### **Future improvements or better access: consequences of additional matters**

- 21.—(1) If the NHSCB is satisfied as mentioned in regulation 20(2)(a), it may—
- (a) defer determination of the application;
  - (b) invite applications from other persons to offer to secure the future improvements or better access mentioned in regulation 20(1) that the applicant is offering to secure; and
  - (c) consider, at the same time as the applicant's application, any application it receives—
    - (i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or
    - (ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the future improvements or better access mentioned in regulation 20(1) that the applicant is offering to secure,

but it must not, pursuant to this paragraph, defer consideration of the application for longer than 6 months.

(2) If the NHSCB is satisfied as mentioned in regulation 20(2)(b), it may defer consideration of the application for such period as is reasonable in the circumstances, having regard to when the future circumstances specified in accordance with paragraph 4(b) of Schedule 1 are likely to arise.

(3) If the NHSCB is satisfied as mentioned in regulation 20(2)(c), it may defer consideration of the application until it can be considered at the same time as the other application.

(4) If the NHSCB is satisfied as mentioned in regulation 20(2)(d), it may defer consideration of the application until after the appeal has reached its final outcome.

(5) If the NHSCB is satisfied as mentioned in regulation 20(2)(e) to (i), it must refuse the application.

### **[<sup>F14</sup>PNA based applications for new premises offering additional or different opening hours**

21A.—(1) Paragraph (2) applies where the NHSCB receives a routine application which is in respect of premises not already listed, where—

- (a) the applicant's stated intention (in accordance with paragraph 7(1)(a) of Schedule 2) is to meet a need, or secure improvements or better access, identified in the relevant pharmaceutical needs assessment (whether current or future gaps in provision); and
- (b) the need is, or the improvements are or the better access is, in respect of the days on which or the times at which essential services are provided in the area of the relevant HWB.

(2) In determining whether or not it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to whether granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB.

(3) If the NHSCB is satisfied that granting the application would result in the undesirable increase in availability mentioned in paragraph (2), it must refuse the application.]

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**F14** [Reg. 21A](#) inserted (1.1.2022) by [The National Health Service \(Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services\) \(Coronavirus\) \(Further Amendments\) Regulations 2021 \(S.I. 2021/1346\)](#), regs. 1(2)(b), 5

**Refusal of routine applications that are based on neither a pharmaceutical needs assessment nor unforeseen benefits**

**22.**—(1) If the NHSCB receives a routine application to which regulation 19(6) does not apply, the NHSCB must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would—

- (a) meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or
  - (b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.
- (2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is—
- (a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that the NHSCB takes its decision to grant or refuse the application, unless in the opinion of the NHSCB (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment; or
  - (b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated.

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**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

- blanket amendment words substituted by [S.I. 2023/1071 Sch. para. 1](#)