
WELSH STATUTORY INSTRUMENTS

2020 No. 1073

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

PART 5

Applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to pharmaceutical lists

Applications to be included in or make amendment to a pharmaceutical list

15.—(1) A person may submit an application to a Local Health Board where that person—

- (a) wishes to be included in a pharmaceutical list maintained by the Local Health Board,
- (b) is already included in a pharmaceutical list maintained by the Local Health Board but wishes, within the Local Health Board's area, to—
 - (i) open additional premises from which to provide the same or different pharmaceutical services,
 - (ii) relocate to different premises and at those premises to provide the same or different pharmaceutical services, or
 - (iii) provide from the listed premises pharmaceutical services that are of a different description to those pharmaceutical services already listed in relation to that person, or
- (c) is already included in a pharmaceutical list maintained by a neighbouring Local Health Board but wishes to relocate to different premises in the area of the Local Health Board to which the application is made and, at those premises, to provide the same or different pharmaceutical services.

(2) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 1 of Schedule 2.

(3) Subject to regulation 60 (home Local Health Board), a person making an application under paragraph (1)(a) must provide the information and undertakings specified in Part 2 of Schedule 2.

(4) If a Local Health Board considers that an application does not contain all of the information required under paragraphs (2) and (3)—

- (a) it may request the missing relevant information or documentation from the applicant, and
- (b) the applicant must, within the period reasonably specified by the Local Health Board in the request under sub-paragraph (a)—
 - (i) provide any information or documentation reasonably requested,
 - (ii) notify the Local Health Board that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or

- (iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the Local Health Board of that and seek a review by the Local Health Board of the reasonableness of the request.
- (5) If an applicant refuses to comply with a request under paragraph (4)(a)—
- (a) within the period—
 - (i) reasonably specified by the Local Health Board under paragraph (4)(b), or
 - (ii) ending on the date specified by the applicant in accordance with paragraph (4)(b)(ii), if the Local Health Board is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,
 unless sub-paragraph (b) applies, the application is to be treated as withdrawn;
 - (b) in circumstances where the applicant has, in accordance with paragraph (4)(b)(iii), sought a review by the Local Health Board of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—
 - (i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the Local Health Board for the provision of that information or documentation, or
 - (ii) need not be provided by the applicant, the request of the Local Health Board is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.
- (6) The Local Health Board may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application.
- (7) An application to be included in a pharmaceutical list by a person not already included must be refused if the applicant is an individual who qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom, unless that person satisfies the Local Health Board they have the level of knowledge of English which, in the interests of that individual and the persons making use of the pharmaceutical services to which the application relates, is necessary for the provision of those pharmaceutical services in the area of the Local Health Board.
- (8) All applications made under regulation 15(1) will be determined in accordance with regulation 16 (determination of applications to be included in or to make amendment to a pharmaceutical list) except for applications to which—
- (a) regulation 19 (applications involving relocation within a Local Health Board’s area),
 - (b) regulation 20 (applications involving relocation between neighbouring Local Health Board areas),
 - (c) regulation 21 (applications involving temporary relocation), or
 - (d) regulation 22 (applications involving a change of ownership),
- applies and which are determined in accordance with those regulations.
- (9) Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications made under this Part.

Determination of applications to be included in or to make amendment to a pharmaceutical list

16.—(1) Where the premises specified in an application are not in a controlled locality, the Local Health Board may grant the application only if it is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant

Local Health Board and which have been included in the pharmaceutical needs assessment of that Local Health Board in accordance with Schedule 1.

(2) Where the premises specified in an application are in a controlled locality but not in a reserved location (as defined in regulation 17(4) and (5)), the Local Health Board may—

- (a) refuse the application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality within which the premises specified in the application are situated (the “prejudice test”), and
- (b) where the application has not been refused under the prejudice test, grant the application only if it is satisfied that it meets a need identified in the pharmaceutical needs assessment of the relevant Local Health Board.

(3) The prejudice test does not apply to the Local Health Board’s determination of an application where the premises specified in an application are situated in a reserved location.

(4) A Local Health Board must refuse an application in which the applicant does not meet a need that is identified in the pharmaceutical needs assessment of the relevant Local Health Board.

(5) In determining an application under this regulation, which has been made in accordance with regulation 15(1), (except where the application is made by a person who has been granted preliminary consent pursuant to regulation 18 which is valid in accordance with regulation 18(5)), or in accordance with regulation 18 where the applicant is not already included in that Local Health Board’s pharmaceutical list, a Local Health Board may—

- (a) defer consideration of the application on fitness grounds in accordance with regulation 36 (deferral of applications on fitness grounds),
- (b) refuse the application on fitness grounds in accordance with regulation 37 (refusal of applications on fitness grounds), or
- (c) impose conditions on the grant of the application in accordance with regulation 38 (conditional inclusion on fitness grounds).

Locations in controlled localities that are reserved locations

17.—(1) A Local Health Board must determine whether premises specified in an application submitted to it under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) or premises or the relevant location from which the applicant wishes to provide pharmaceutical services, specified in an application submitted to it under regulation 18 (applications for preliminary consent and effect of preliminary consent) that are in a controlled locality are also in a reserved location.

(2) Where it has been determined by the Local Health Board, or on appeal by the Welsh Ministers (under paragraph (1) and Schedule 4 respectively) or pursuant to regulation 11 of, or Part 2 of Schedule 3 to, the 2013 Regulations, in relation to premises or a relevant location, from which pharmaceutical services are to be or are being provided, that those premises are or the relevant location is in a reserved location, the person included in the pharmaceutical list in relation to those premises, or that relevant location, may make an application in writing to the Local Health Board to make a further determination as to whether, on the date of the application, those premises are, or that relevant location is, in a reserved location.

(3) For the purposes of this regulation the “relevant location” means, where the location of the premises from which the pharmaceutical services are to be provided is specified in writing by the applicant before the Local Health Board makes its determination, that location, and where that location is not so specified, the best estimate the Local Health Board is able to make of where those premises may be.

(4) Subject to paragraph (5), a reserved location is a location in a controlled locality in respect of which the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location of the premises is less than 2,750 persons.

(5) A location is not a reserved location under paragraph (4) if the Local Health Board considers that if a pharmacy were to operate from the location, the extent to which it would be used would be similar to or greater than might be expected if the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location were equal to or more than 2,750 persons.

(6) Where in making a further determination applied for in accordance with paragraph (2) the Local Health Board determines that those premises are, or the relevant location is, not in a reserved location, or there is an appeal against a determination by the Local Health Board and it is determined on appeal that the premises are not, or that the relevant location is not, in a reserved location—

- (a) the Local Health Board may determine that the premises are, or the relevant location is, to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Local Health Board itself), dispensing services or pharmaceutical services in any controlled locality, or
- (b) if the Local Health Board considered that the provision of primary medical services by a provider of primary medical services (other than one employed by the Local Health Board), pharmaceutical services by a NHS pharmacist or NHS appliance contractor, local pharmaceutical services provided under a pilot scheme or pharmaceutical services provided by a doctor is likely to be adversely affected by a determination that the premises are not in a reserved location, it may make such determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 26 (or equivalent under the GMS Regulations) for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients.

Applications for preliminary consent and effect of preliminary consent

18.—(1) A person who wishes to be granted the right to be included in a pharmaceutical list maintained by the Local Health Board on a subsequent application under regulation 15(1)(a) or 15(1)(b)(i) (applications to be included in or make amendment to a pharmaceutical list) may submit an application to a Local Health Board for preliminary consent under this regulation.

(2) An application made under this regulation must be made in writing and must provide the information and undertakings set out in—

- (a) Part 1 of Schedule 2, and
- (b) subject to regulation 60 (home Local Health Board), Part 2 of Schedule 2.

(3) A Local Health Board must determine an application for preliminary consent as if it were an application made pursuant to regulation 15(1)(a) or 15(1)(b)(i).

(4) A preliminary consent will be valid for a period of 6 months from the date on which it is granted, which is the later of either—

- (a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 3, or
- (b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers give notice of their decision on the appeal under paragraph 8 of Schedule 4.

(5) A Local Health Board must grant a subsequent application made under regulation 15(1)(a) or 15(1)(b)(i) by a person who has been granted preliminary consent if—

- (a) the date on which the application was received by the Local Health Board is within the period specified in paragraph (4),

- (b) the pharmaceutical services specified in the application are the same as those that were specified in the application for preliminary consent, and
- (c) the premises specified in the application are in the same location as the premises or a location that is relevant to a need identified in the pharmaceutical needs assessment of the Local Health Board.

(6) Where sub-paragraphs (a) and (b) in respect of paragraph (5) are satisfied but the premises specified in the application have a different location from that in respect of which preliminary consent was granted, the Local Health Board must treat the application as though it were an application made pursuant to regulation 15(1)(b)(ii).

(7) The grant of an application under paragraph (5) must be subject to any conditions that were imposed by the Local Health Board, or the Welsh Ministers on appeal, in relation to the final grant of the corresponding preliminary consent.

(8) In determining an application under this regulation from a person who is not already included in the Local Health Board's pharmaceutical list (apart from an application from a person who has a valid preliminary consent in accordance with paragraph (4)), a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 36 (deferral of application on fitness grounds),
- (b) refuse the application on fitness grounds under regulation 37 (refusal of applications on fitness grounds), or
- (c) impose conditions on the grant of the application under regulation 38 (conditional inclusion on fitness grounds).

Applications involving relocation within a Local Health Board's area

19.—(1) A person who has made an application under regulation 15(1)(a) (applications to be included in or make amendment to a pharmaceutical list) may at any time after making the application, but before the end of the relevant period (as defined in regulation 23 (procedure following grant of an application)), notify the Local Health Board that they wish to change the premises from which they intend to provide pharmaceutical services specified in the application and the Local Health Board may amend the premises specified in the original application if it is satisfied that—

- (a) the change is a relocation,
- (b) the pharmaceutical services specified in the application that would have been provided at the premises specified in the original application will be provided at the new premises, and
- (c) the relocation still meets the need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment.

(2) A Local Health Board may grant an application made by a person under regulation 15(1)(b)(ii) to relocate from listed premises to new premises at which the person intends to provide pharmaceutical services, if it is satisfied that—

- (a) the relocation is to meet a need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment and—
 - (i) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),
 - (ii) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation), and
 - (iii) would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a

- person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises, or
- (b) the relocation is not to meet a need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment but—
- (i) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,
 - (ii) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises,
 - (iii) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),
 - (iv) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation), and
 - (v) would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises.

(3) A person who has had an application granted under this regulation may not, within 12 months of the date of the grant of the application (as defined in regulation 23(3)(a)), submit another application for determination pursuant to this regulation or regulation 20.

Applications involving relocation between neighbouring Local Health Board areas

20.—(1) A Local Health Board may grant an application made by a person under regulation 15(1) (c) (applications to be included in or make amendment to a pharmaceutical list) to relocate from listed premises in the area of neighbouring Local Health Board to new premises in the area of the Local Health Board to which the application is made, and at those premises the person intends to provide pharmaceutical services, if—

- (a) the Local Health Board, to which the application is made, is satisfied that—
 - (i) the change is a relocation to meet a need identified in the relevant pharmaceutical needs assessment of the Local Health Board,
 - (ii) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,
 - (iii) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),
 - (iv) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation),
 - (v) the application would not, if granted, result in a significant change in the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises, and

- (b) the person consents to the removal of the premises from the pharmaceutical list maintained by the Local Health Board in whose area the current listed premises are located with effect from the date on which the provision of pharmaceutical services from the new premises commences.

(2) A person who has had an application granted pursuant to this regulation may not, within 12 months of the date of the grant of the application (as defined in regulation 23(3)(a)), submit another application for determination under this regulation or regulation 19.

Applications involving temporary relocation

21.—(1) A Local Health Board may make a temporary amendment to an entry in a pharmaceutical list by granting an application made by a person under regulation 15(1)(b)(ii) (applications to be included in or make amendment to a pharmaceutical list) to relocate to different premises on a temporary basis if it is satisfied that—

- (a) the circumstances in which the application is made require the flexible provision of pharmaceutical services,
- (b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the temporary premises is not significantly less accessible,
- (c) the same pharmaceutical services will be provided at the temporary premises as are provided at the listed premises, and
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) A temporary amendment to an entry in the pharmaceutical list will have effect from the date on which the Local Health Board approved the application made to it and will be valid for such period of up to 6 months and any further periods of up to 3 months each that the Local Health Board considers necessary.

(3) A person may revert to the overridden entry in the pharmaceutical list maintained by the Local Health Board before the end of the period determined by the Local Health Board under paragraph (2) on giving the Local Health Board at least 7 days' notice in writing.

(4) Where, in accordance with this regulation, an entry in a pharmaceutical list is overridden by a temporary amendment, any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed for other reasons) and if, as a result of those proceedings the overridden arrangements require amendment before the end of the temporary amendment, the reversion to the overridden arrangements is to be to the original overridden amendments as amended as a result of those proceedings.

Applications involving a change of ownership

22.—(1) A Local Health Board must grant an application made by a person under regulation 15(1) (a), (b)(i) or (ii) (applications to be included in or make amendment to a pharmaceutical list) who intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by another person who is included in a pharmaceutical list maintained by the Local Health Board under regulation 10 (preparation and maintenance of pharmaceutical lists) if the Local Health Board is satisfied that—

- (a) the premises are already included in a pharmaceutical list maintained by the Local Health Board,
- (b) the same pharmaceutical services will continue to be provided from the premises, and
- (c) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) In determining an application under this regulation which has been made under regulation 15(1)(a) (except where the application has been made by a person who has been granted preliminary consent under regulation 18 which is valid in accordance with regulation 18(5)), or under regulation 18 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 36 (deferral of applications on fitness grounds),
- (b) refuse the application on fitness grounds under regulation 37 (refusal of applications on fitness grounds), or
- (c) impose conditions on the grant of the application under regulation 38 (conditional inclusion on fitness grounds).

Procedure following grant of an application

23.—(1) Following the date of the grant of an application made under regulation 15 (applications to be included in or make amendment to a pharmaceutical list), a Local Health Board must not include a person in a pharmaceutical list or amend a pharmaceutical list unless—

- (a) the condition in paragraph (2) is satisfied, and
- (b) the requirements of regulation 38 (conditional inclusion on fitness grounds), if any, are met as regards the imposition of conditions on any person.

(2) A person will be included in the relevant pharmaceutical list or the relevant pharmaceutical list will be amended as appropriate if, not less than 14 days before the end of the relevant period, that person notifies the Local Health Board in writing, providing the information specified in Part 3 of Schedule 2, that they will within the next 14 days commence the provision at the premises of the pharmaceutical services that were specified in the application.

(3) For the purposes of this regulation and, where relevant, regulation 24—

- (a) “the date of the grant of an application” is the date which is the later of either—
 - (i) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 3, or
 - (ii) the date of the determination of any appeal that is brought against the decision of the Local Health Board, and
- (b) “the relevant period” is—
 - (i) the period of 6 months from the date of the grant of an application, or
 - (ii) such further period in addition to that specified in paragraph (i) not exceeding 3 months that the Local Health Board may for good reason allow.

Application to extend the relevant period

24.—(1) A person may make an application to the Local Health Board to extend the relevant period no later than 5 months after the date of the grant of an application.

(2) In accordance with regulation 23(3)(b)(ii) a person may apply for an extension of up to 3 months.

(3) An application to the Local Health Board under this regulation must be made in writing and must provide reasons why an extension of the relevant period is sought.

(4) Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications made under this regulation.

(5) For the purposes of this regulation, “person” means the person who would be entitled to provide notification to a Local Health Board in accordance with regulation 23(2) of commencement of provision of pharmaceutical services.

Appeals

25.—(1) Schedule 4 makes provision for appeals to the Welsh Ministers in respect of decisions of Local Health Boards made under this Part, save for those regulations listed in paragraph (2).

(2) There is no right of appeal in respect of a decision of a Local Health Board—

- (a) to make or not to make, or to extend, a temporary amendment to a pharmaceutical list under regulation 21 (applications involving temporary relocation), or
- (b) to extend or not to extend the relevant period under regulation 24 (application to extend the relevant period).