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WELSH STATUTORY INSTRUMENTS

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**2020 No. 1073**

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

**PART 6**

Applications by doctors for inclusion in or amendment to dispensing doctors lists

**Arrangements for the provision of pharmaceutical services by doctors**

**26.**—(1) A Local Health Board may make an arrangement with a doctor who falls within paragraph (8) for the doctor to provide pharmaceutical services to a patient included on the doctor's patient list or the patient list of a provider of primary medical services by whom the doctor is employed or engaged, if the patient—

- (a) would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy because of distance or inadequacy of means of communication, and the conditions in paragraph (2) are satisfied,
- (b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy, and the conditions specified in paragraph (4) are satisfied, or
- (c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination and the conditions specified in paragraph (4) are satisfied.

(2) The conditions referred to in paragraph (1)(a) are—

- (a) the patient has made a request in writing to the Local Health Board for the doctor to provide them with pharmaceutical services for the reasons specified in paragraph (1)(a), and
- (b) the Local Health Board is satisfied that the patient would have serious difficulty in obtaining any necessary drugs or appliances for those reasons.

(3) In making an arrangement with a doctor for the doctor to provide a patient under paragraph (1) (a) with pharmaceutical services from practice premises, the Local Health Board must give reasonable notice in writing to the doctor of when the arrangement is to take effect unless the doctor satisfies the Local Health Board that—

- (a) the doctor does not normally provide pharmaceutical services to patients, or
- (b) the patient would not have serious difficulty in obtaining drugs and appliances from a pharmacy because of distance or inadequacy of means of communication.

(4) The conditions referred to in paragraph (1)(b) and (c) are that—

- (a) outline consent has been granted to the doctor or the provider of primary medical services by whom the doctor is employed or engaged,
- (b) premises approval has been granted in relation to the premises from which the doctor will provide pharmaceutical services to that patient,

- (c) the outline consent and premises approval has taken effect under regulation 31 (taking effect of outline consent and premises approval), and
  - (d) any conditions imposed under these Regulations in connection with the grant of outline consent or premises approval are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to patients under paragraph (1)(b) or (c).
- (5) References in paragraph (4) to outline consent, premises approval and conditions imposed include references to those in effect under the 2013 Regulations.
- (6) A doctor with whom an arrangement has been made to provide pharmaceutical services to a patient under this regulation may, with the consent of the patient, instead of providing the drugs or appliances order them by issuing a prescription to the patient.
- (7) Where an arrangement for a doctor to provide pharmaceutical services to a patient was in effect immediately before these Regulations came into force, that arrangement will have effect as though made under this regulation notwithstanding that the conditions in paragraph (4) are not satisfied.
- (8) A doctor falls within this paragraph if they are—
- (a) a GMS contractor or an APMS contractor,
  - (b) engaged or employed by a GMS contractor or an APMS contractor, or
  - (c) is engaged by a Local Health Board for the purposes of providing primary medical services to a LHBMS practice.
- (9) A doctor may appeal to the Welsh Ministers against a decision of a Local Health Board under paragraph (3). The appeal must be made in writing within 30 days beginning with the date on which notice of the decision was sent to the doctor and must contain a concise statement of the grounds of appeal.
- (10) The Welsh Ministers must, on receipt of any notice of appeal under paragraph (9), send a copy of that notice to the Local Health Board and the relevant GMS contractor or APMS contractor, and the Local Health Board and the relevant GMS contractor or APMS contractor may, within 30 days from the date on which the Welsh Ministers sent a copy of the notice of appeal, make representations in writing to the Welsh Ministers.
- (11) The Welsh Ministers may determine an appeal pursuant to paragraph (9) in such manner as they see fit, taking into consideration the preliminary matters in Part 1 of Schedule 4.
- (12) The Welsh Ministers must, upon determination by them of any appeal under paragraph (9), give notice of their decision in writing, together with the reasons for it, to the appellant, to the Local Health Board, and to the relevant GMS contractor or APMS contractor.

### **Necessary services for temporary patients**

**27.** A doctor who provides pharmaceutical services to patients on a patient list by arrangement made with a Local Health Board under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) may provide necessary pharmaceutical services to a person who has been accepted by the doctor as a temporary patient.

### **Provision of pharmaceutical services for immediate treatment or personal administration**

- 28.—**(1) Subject to paragraph (2), a doctor whose name is included in a medical performers list may—
- (a) provide to a patient any appliance or drug, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained, and

(b) provide to a patient any appliance or drug, not being a Scheduled drug, which the doctor personally administers or applies to the patient.

(2) A doctor may only provide a restricted availability appliance if it is for a person or a purpose specified in the Drug Tariff.

### **Discontinuation of arrangements for the provision of pharmaceutical services by doctors**

**29.**—(1) A Local Health Board must give reasonable notice in writing to a doctor that they must discontinue the provision of pharmaceutical services to a patient under an arrangement pursuant to regulation 26 where the patient no longer falls within regulation 26(1)(a), (b) or (c).

(2) A notice given under paragraph (1)—

(a) is subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under paragraph 6 of Schedule 3, paragraph 13 of Schedule 3 or regulation 17(6), and

(b) must not be given—

(i) pending any appeal against a decision of the Local Health Board to postpone the making of or the termination of the arrangement, or

(ii) where paragraph 5 of Schedule 3 applies.

### **Outline consent and premises approval**

**30.**—(1) A doctor who is a provider of primary medical services or who is engaged or employed by a provider of primary medical services and who wishes to make an arrangement with a Local Health Board to provide pharmaceutical services to patients under regulation 26(1)(b) or (c) (arrangements for the provision of pharmaceutical services by doctors) must submit an application in writing to the Local Health Board for—

(a) consent, specifying the area in which the doctor wishes to provide pharmaceutical services (“outline consent”), and

(b) approval of any practice premises from which the doctor wishes to dispense (“premises approval”).

(2) A doctor who has outline consent which has taken effect under regulation 31 (taking effect of outline consent and premises approval) may submit an application for premises approval only in relation to—

(a) additional practice premises from which to provide pharmaceutical services, or

(b) practice premises to which the doctor wishes to relocate from listed premises.

(3) 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 4 of Schedule 2

(4) A Local Health Board must return an application if it does not contain all of the information required under paragraph (3).

(5) The Local Health Board—

(a) must refuse outline consent in relation to any part of the area specified in the application which is not in a controlled locality or which is within 1.6 kilometres of any pharmacy;

(b) must refuse premises approval in relation to any premises specified in the application which are within 1.6 kilometres of any pharmacy;

(c) must refuse an 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”);

- (d) where an application has not been refused under the prejudice test, must refuse the application unless 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 locality and which has been included in the relevant pharmaceutical needs assessment and which the doctor has applied for outline consent;
- (e) may, where the Local Health Board has considered two or more applications together and in relation to each other, refuse one or more of them (notwithstanding that it would, if determining the applications in isolation, grant them) where the number of applications is such that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any controlled locality.

(6) Any refusal of an application outlined at paragraph (5)(a) to (e) may relate to all or any part of the area within the controlled locality, or, as the case may be, all or some of the premises for which approval is sought.

(7) Subject to any specific requirements that are contained within this Part, Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications under this Part.

(8) An application under this regulation is granted on the date which is the later of—

- (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 15 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 gave notice of their decision on the appeal under paragraph 8 of Schedule 4.

### **Taking effect of outline consent and premises approval**

**31.**—(1) When granting an application made under regulation 30 (outline consent and premises approval), the Local Health Board must determine the date on which outline consent and premises approval are to take effect.

(2) Where there are no outstanding pharmacy applications (as defined in paragraph (11)) outline consent and premises approval take effect on the date on which the application is granted.

(3) Where there are outstanding pharmacy applications on the day before the application under regulation 30 is granted, the date on which outline consent and premises approval take effect is to be determined in accordance with paragraphs (4) to (9).

(4) The Local Health Board must in respect of an application to which paragraph (3) applies notify the doctor who made the application under regulation 30, and the Welsh Ministers if the application is subject to appeal, of—

- (a) any outstanding pharmacy applications,
- (b) the withdrawal of outstanding pharmacy applications,
- (c) the provisional date (as defined in paragraph (11)) on which the doctor can request the Local Health Board to determine that outline consent and premises approval should come into effect, and
- (d) the lapse of the doctor’s application for outline consent and premises approval if, before the provisional date, the provision of pharmaceutical services is commenced from the premises which were the subject of an outstanding pharmacy application which has been granted.

(5) On, or as soon as reasonably practicable after, the provisional date, the Local Health Board must notify the doctor who made the application under regulation 30 that—

- (a) the doctor may within 3 months of the Local Health Board’s notification submit a request in writing to the Local Health Board asking it to determine whether the outline consent and premises approval should come into effect, and
- (b) the Local Health Board must determine the request as soon as practicable and in accordance with paragraphs (6) and (7).

(6) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are practice premises, the Local Health Board must determine that the outline consent and premises approval in respect of those premises will come into effect on that date.

(7) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are not practice premises outline consent and premises approval will lapse.

(8) The Local Health Board must notify its determination under paragraph (5) to the applicant and those persons to whom notice of the application under regulation 30 was required to be given under paragraph 8 of Schedule 3.

(9) Where the Local Health Board has determined that outline consent and premises approval will lapse by virtue of paragraph (7) or that the provisional date is to be extended under paragraph (11), the doctor who made the application under regulation 30 may appeal to the Welsh Ministers.

(10) If, in the circumstances outlined in paragraph (9), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

- (a) 6(3)(b) and (c),
- (b) 7(1) and (3), and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

(11) In this regulation—

“outstanding pharmacy application” (“*cais am fferyllfa yn yr arfaeth*”) means an application made under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) or regulation 18 (applications for preliminary consent and effect of preliminary consent)—

- (a) where the premises specified in that application are within 1.6 kilometres of the premises for which premises approval has been sought, and
- (b) which has either—
  - (i) been made but not yet determined, including on appeal, or
  - (ii) has been granted as defined in regulation 23 (procedure following grant of an application) but the provision of pharmaceutical services from those premises has not been commenced;

“provisional date” (“*dyddiad dros dro*”) means the day after the end of a period of 1 year or such further period not exceeding 3 months as the Local Health Board may determine (and it must notify the doctor who made the application under regulation 30 of any extension) beginning with the date on which the application is granted in accordance with regulation 30(9).

### **Lapse of outline consent and premises approval**

**32.**—(1) Outline consent will cease to have effect—

- (a) where the provision of dispensing services has not commenced within 12 months of outline consent or premises approval taking effect under regulation 31 (taking effect of outline consent and premises approval),
  - (b) where more than 12 months have elapsed since the last provision of dispensing services,
  - (c) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval, or
  - (d) where outline consent has lapsed under regulation 31.
- (2) Premises approval will cease to have effect in relation to—
- (a) listed premises which have permanently ceased to be practice premises,
  - (b) listed premises which have not been used for dispensing by any doctor authorised to dispense from those premises for 6 months or such longer period as the Local Health Board may for good cause allow,
  - (c) listed premises where the doctor under whose name those premises are listed in the dispensing doctors list has notified the Local Health Board that all the doctors who have authority to dispense from those premises have ceased to do so,
  - (d) listed premises where there is no doctor with premises approval in respect of them remaining on the dispensing doctor list, or
  - (e) listed premises which were granted premises approval under regulation 35(3), where no practice amalgamation takes place within the period specified in regulation 35(7).
- (3) Premises approval will cease to have effect where the related outline consent ceases to have effect.

**Premises approval: change of premises before outline consent takes effect**

**33.—(1) Where—**

- (a) outline consent has been granted but has not yet taken effect under regulation 31 (taking effect of outline consent and premises approval), and
- (b) before the provisional date defined in regulation 31(11) the doctor intends to change the practice premises from which they wish to provide pharmaceutical services,

the doctor may apply in writing to the Local Health Board providing the information set out in Part 4 of Schedule 2 for the Local Health Board to determine whether premises approval should be given in relation to the new premises, and the Local Health Board must make the determination in accordance with paragraph (2).

(2) If the Local Health Board is satisfied that the change of premises is a minor relocation it may grant the premises approval for those new premises, but if it is not so satisfied, premises approval for the new premises must be refused.

(3) The Local Health Board must notify those persons to whom notice of the application made under regulation 30 (outline consent and premises approval) was required to be given of its determination under paragraph (2).

(4) The determination by the Local Health Board under paragraph (2) may be appealed by the applicant to the Welsh Ministers.

(5) If, in the circumstances outlined in paragraph (4), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

- (a) 6(3)(b) and (c),
- (b) 7(1) and (3), and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

(6) In this regulation—

“minor relocation” means a relocation of practice premises where—

- (a) the pharmaceutical services specified in the application that would have been provided at the practice premises specified in the original application will be provided at the new practice premises, and
- (b) the location of the new practice premises would not be significantly less accessible for the patients who access the practice premises specified in the original application.

### **Premises approval: additional and new premises after outline consent has taken effect**

**34.**—(1) A doctor who has outline consent which has taken effect and who wishes to be granted premises approval for premises in addition to those premises in respect of which premises approval has been given (“additional premises”) may apply in writing providing the information set out in Part 4 of Schedule 2 to all of the appropriate Local Health Boards and the application will be determined by the relevant Local Health Board in accordance with paragraph (2).

(2) An application for additional premises must be determined by the relevant Local Health Board in accordance with regulation 30 (outline consent and premises approval) and regulation 31 (taking effect of outline consent and premises approval).

(3) For the purposes of this regulation—

- (a) the “appropriate Local Health Boards” are those Local Health Boards that hold the dispensing doctor lists on which the doctor making the application is included, and
- (b) the “relevant Local Health Board” is the Local Health Board in whose area the additional premises are situated.

(4) A doctor wishing to be granted premises approval in relation to premises (“new premises”) where they wish to dispense instead of listed premises may apply to all the appropriate Local Health Boards providing the information set out in Part 4 of Schedule 2 and the application will be determined by the relevant Local Health Board in accordance with paragraphs (5) and (6).

(5) In the case of an application for new premises, the relevant Local Health Board must give notice of the application in accordance with paragraph 9 of Schedule 3 and the content of the notification must comply with paragraph 10 of that Schedule.

(6) In the case of an application for new premises the relevant Local Health Board must—

- (a) grant an application, where it is satisfied that—
  - (i) for the patients that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible, and
  - (ii) granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical or dispensing services to any part of the controlled locality in which the new premises are located, or
- (b) in any case, determine the application as if it were an application for premises approval made under regulation 30(1)(b).

(7) A Local Health Board must, unless it has good cause not to do so, refuse an application under paragraph (1) or (4) if an application made by the doctor has been granted under paragraph (6)(a) during the 12 months before the application was submitted under paragraph (1) or (4).

(8) The Local Health Board must notify its determination under paragraph (2) or paragraph (6)(b) to the persons to whom notice of the application is required to be given in accordance with regulation 30 and paragraph 8 of Schedule 3.

(9) The Local Health Board must notify its determination under paragraph (6)(a) to those persons to whom notification is required to be given in accordance with paragraph 15 of Schedule 3.

(10) A determination by the Local Health Board under paragraph (2), (6)(a) or (6)(b) may be appealed to the Welsh Ministers by the persons listed in paragraph 6(1) of Schedule 4.

(11) Subject to paragraph (12), the premises approval for the additional or new premises will take effect from the date of notification of the grant of premises approval, which is—

- (a) where no appeal is made against the decision of the Local Health Board, the date after the expiry of 30 days beginning with the date on which notice of that decision is given under paragraph (8) or paragraph (9), or
- (b) where such an appeal is made, the date on which the Welsh Ministers give notice of their decision on that appeal.

(12) Where—

- (a) the premises approval is granted in relation to additional premises, and
- (b) in relation to the premises for which the approval is granted there, at the date of the grant, outstanding pharmacy applications (as defined in regulation 31(11)),

the premises approval will take effect on the date which is the day after the end of a period of 1 year, or such further period (not exceeding 3 months) as the Local Health Board may for good cause allow, from the final resolution of any outstanding pharmacy application.

(13) The Local Health Board may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new premises where the Local Health Board considers it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant locality and which has been included in the relevant pharmaceutical needs assessment and in respect of which the doctor has applied for outline consent, and renew any such temporary approval granted, and where it does so it must—

- (a) notify those persons to whom notice of the application under regulation 30 (outline consent and premises approval) was required to be given under paragraph 8 of Schedule 3 and the applicants in relation to the outstanding pharmacy applications,
- (b) state the period during which the temporary premises approval is to apply, and
- (c) include those premises in the dispensing doctor list in relation to that doctor.

(14) Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding 3 months.

(15) The determination by the Local Health Board under paragraph (13) may be appealed by the applicant to the Welsh Ministers.

(16) If, in the circumstances outlined in paragraph (15), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

- (a) 6(3)(b) and (c),
- (b) 7(1) and (3), and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

### **Premises approval: practice amalgamations**

**35.—**(1) A practice amalgamation occurs where two or more providers of primary medical services amalgamate as a single provider of primary medical services as a result of which two or more patient lists are combined.



(2) Following a practice amalgamation, if the practice premises of the single provider of primary medical services are all premises that immediately prior to the practice amalgamation were listed premises, the premises approvals for those premises and the related outline consents will continue to have effect.

(3) Following a practice amalgamation, if paragraph (2) does not apply but one or more of the doctors coming together as the single provider of primary medical services had, immediately prior to amalgamation, premises approval for premises—

(a) if any of those premises become practice premises of the single provider of primary medical services—

(i) the premises approvals for the premises and the related outline consents will continue to have effect, and

(ii) any applications for premises approvals for other practice premises must be treated as applications for additional premises under regulation 34 (premises approval: additional and new premises after outline consent has taken effect);

(b) if none of those premises become practice premises of the single provider of primary medical services—

(i) a doctor may submit an application for premises approval for premises under regulation 30 (outline consent and premises approval) and have that application treated as a relocation from listed premises of a doctor who was part of the practice amalgamation, and

(ii) any applications for premises approval in respect of other practice premises of the single provider of primary medical services are to be treated as applications for additional premises under regulation 34.

(4) An application mentioned in paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

(a) any premises approval in effect at the date of the practice amalgamation will have effect from the date of the amalgamation as if it were a temporary premises approval under regulation 34(13) for a period stated by the Local Health Board not exceeding 1 year, and

(b) the new practice will have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Local Health Board not exceeding 1 year.

(5) When the practice amalgamation takes effect the doctors must notify all Local Health Boards in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to paragraph (7), where an application made under paragraph (3) was granted before the practice amalgamation takes place, premises approval will take effect from the date of the practice amalgamation.

(7) Where an application was made under paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of 1 year beginning with the date that premises approval was granted under that paragraph, that grant will lapse.

(8) Where an application under paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the doctors who had premises approval prior to making the application, and any other doctor in the new practice after that date will have residual premises approval.

(9) For the purposes of this regulation, “residual premises approval” means premises approval to provide pharmaceutical services—

- (a) from premises in respect of which the doctor or another doctor in the practice had premises approval at the time of the application in relation to the practice amalgamation, and
- (b) to a patient falling within regulation 26(1) to whom the doctor making the application provides pharmaceutical services, but excluding any such patient who ceases to be a patient mentioned in regulation 26(1)(b) or (c).

(10) For the purposes of paragraph (9), regulation 26(1)(b) or (c) is to be read as if the words “and the conditions specified in paragraph (4) are satisfied” were omitted.

(11) Where a Local Health Board has determined an application for premises approval under paragraph (3), the persons who may make an appeal to the Welsh Ministers will be determined in accordance with—

- (a) regulation 34 in respect of an application under paragraph (3)(a)(ii) or (b)(ii), or
- (b) regulation 30 in respect of an application under paragraph (3)(b)(i).

(12) Where a Local Health Board has determined an application under paragraph (4), the applicant may make an appeal to the Welsh Ministers.

(13) If, in the circumstances outlined in paragraph (12), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

- (a) 6(3)(b),
- (b) 7(1) and (3), and
- (c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.