
WELSH STATUTORY INSTRUMENTS

2009 No. 1491

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2009

Substitution of regulation 12 of the principal Regulations

11. For regulation 12 of the principal Regulations (determination of applications in respect of controlled localities), substitute the following regulation—

“Determination of applications in respect of controlled localities

12.—(1) Where a Local Health Board receives an application which it is required, by virtue of regulation—

- (a) 11ZA;
- (b) 11;
- (c) 14(3);
- (d) 21;
- (e) 21D; and
- (f) 21E,

to determine in accordance with the provisions of this regulation, it must send a notice of the application and a copy of the application to any person specified in paragraph (2).

(2) The Local Health Board must send a notice of the application and a copy of the application referred to in paragraph (1) to—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;
- (c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted;
- (d) any person (except itself) who is a provider of primary medical services within the area of the Local Health Board or whose name is included in the dispensing doctor list of the Local Health Board, who might, in the opinion of the Local Health Board, be significantly affected if the application were granted;
- (e) any Local Health Board or Primary Care Trust any part of whose area is within 2 kilometres of the premises;
- (f) any Community Health Council serving the area of the Local Health Board or of any Local Health Board notified under sub-paragraph (e);
- (g) any other patient, consumer or community groups in the area of the Local Health Board that the Local Health Board considers has an interest in the provision of pharmaceutical services in the area;
- (h) any other Local Health Board part of whose area is or might form part of a reserved location; and

- (i) where the determination is required to be made by regulation 21, any other Local Health Board part of whose area is within 1.6 kilometres of the premises from which the doctor wishes to dispense.
- (3) Where a Local Health Board or Primary Care Trust is sent a copy of an application under paragraph (2)(e) it must, as soon as practicable, send a copy to—
- (a) the Local Pharmaceutical Committee for its area;
 - (b) the Local Medical Committee for its area;
 - (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Local Health Board or Primary Care Trust, be significantly affected if the application were granted;
 - (d) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Local Health Board or Primary Care Trust, be significantly affected if the application were granted;
 - (e) any Community Health Council serving its area;
 - (f) any relevant local involvement network; and
 - (g) any other patient, consumer or community groups in the area of the Local Health Board or the Primary Care Trust that that Local Health Board or Primary Care Trust considers has an interest in the provision of pharmaceutical services in the area.
- (4) Any person to whom a Local Health Board or Primary Care Trust has sent a copy of the application may, within 45 days of the date on which that copy was sent to him or her, make representations in writing to the Local Health Board to which the application was made.
- (5) Any person who considers that he or she might be affected by the decision may, within such reasonable time as the Local Health Board to whom the application was made may allow, make representations in writing to it.
- (6) Subject to regulation 11, when determining any application to which regulation 4(4) applies, a Local Health Board must have regard in particular to—
- (a) whether or not any pharmaceutical services specified in the application are already provided in the neighbourhood by persons included in a pharmaceutical list; and
 - (b) any information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application; and
 - (c) any representations received by the Local Health Board from—
 - (i) any person specified in paragraph (2)(a), (b) or (f) or paragraph (3)(a) or (b),
 - (ii) a chemist who was notified of the application pursuant to paragraph (2)(c) or (3)(c), or
 - (iii) any other Local Health Board or Primary Care Trust which was notified of the application pursuant to paragraph (2)(e).
- (7) Subject to paragraph (14) and to regulation 11 and 21D(4), the Local Health Board may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.
- (8) In any case where the Local Health Board decides to hear oral representations, it must give the applicant and any person from whom it has received representations under

paragraph (4) or (5) not less than 14 days notice of the time and place at which the representations are to be heard.

(9) The Local Health Board may invite any other person to give oral evidence as it thinks fit.

(10) The applicant and any person mentioned in paragraph (8) may be assisted at any such hearing in the presentation of his or her representations by some other person, but no person is entitled to be heard in the capacity of counsel or solicitor.

(11) The procedure by which representations are heard will be such as the Local Health Board may determine;

(12) No person—

- (a) who provides or assists in providing pharmaceutical services under Part 7 of the 2006 Act;
- (b) who is a GMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a GMS contractor, or is employed or engaged by a GMS contractor;
- (c) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, or voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;
- (d) who is employed or engaged by a Local Health Board for the purposes of providing primary medical services within an LHBMS practice,

is able to take part in any decision under this regulation.

(13) The Local Health Board may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it must inform the applicants and the persons to whom copies of the applications were sent under this regulation.

(14) The Local Health Board —

- (a) must refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any locality;
- (b) must refuse an application under regulation 21 in relation to any part of the area specified in the application—
 - (i) which is not in a controlled locality, or
 - (ii) which is within 1.6 kilometres of any pharmacy;
- (c) must refuse an application under regulation 21 in relation to any premises from which the doctor wishes to be authorised to dispense and which are within 1.6 kilometres of any pharmacy; and
- (d) may refuse an application to which paragraph (13) applies (notwithstanding that it would, if determining that application in isolation, grant it) 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 locality,

and any refusal of such an application 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.

(15) The determination of an application by the Local Health Board under this regulation is subject to paragraph (14) and to regulation 4(4) and 21D(4).

(16) When an application is granted by the Local Health Board it must consider whether the provision of primary medical services by any provider of such services (except itself) or pharmaceutical services by any chemist is likely to be adversely affected in consequence of that grant.

(17) Where the Local Health Board considers that the provision of primary medical services by a provider of such services (except itself) or pharmaceutical services by any chemist is likely to be adversely affected in consequence of the grant of an application under this regulation, it may determine to impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

(18) Save where regulation 21A(4) applies, an application granted in accordance with the provisions of this regulation will not be treated as finally granted for the purpose of these Regulations until the end of the period for bringing an appeal under regulation 13 or until the determination of any such appeal, whichever is the later, and “final grant” is to be construed accordingly.

(19) Subject to paragraph (20), a Local Health Board must not consider under this regulation—

- (a) any application for outline consent under regulation 21 where, during the relevant period, an application made under that regulation (or any corresponding provision or directions relating to dispensing services) in respect of the same area has been finally refused;
- (b) any application to which regulation 11 or 14 applies where the location of the premises at which the pharmacist intends to provide pharmaceutical services is in a controlled locality and—
 - (i) is in an area in respect of which an application under regulation 21 (or any corresponding provision of directions relating to dispensing services) was finally granted during the relevant period, or
 - (ii) is within 1.6 kilometres of the location of premises in respect of which an application to which regulation 11 or 14 applies was finally refused during the relevant period;
- (c) any request by a chemist under regulation 11ZA(5) for a determination as to whether premises are in a reserved location, where the application in relation to the premises was refused by operation of regulation 12(14) during the relevant period; or
- (d) any application by a doctor for outline consent or premises approval for premises in respect of which outline consent has been refused by operation of regulation 12(14) during the relevant period.

(20) A Local Health Board may at any time consider an application to which paragraph (19) applies where it is satisfied that, since the date of the refusal or, as the case may be, grant referred to in paragraph (19)(a) or (b), or, where there has been more than one such refusal or grant during the relevant period, the last such refusal or grant, there has been a substantial change of circumstances affecting the controlled locality.

(21) In this regulation “relevant period” means the period of 5 years immediately preceding the making of the application.

(22) The Local Health Board must, as soon as practicable after making the determination and in any event within four months beginning with the date of receipt of the application unless the Local Health Board has good cause to require a longer period, give notice in writing—

- (a) of its decision and the reasons for that decision to—
 - (i) the applicant,
 - (ii) the Local Pharmaceutical Committee,
 - (iii) the Local Medical Committee,
 - (iv) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted,
 - (v) any person (except itself) who is a provider of primary medical services within the area of the Local Health Board or whose name is included in the dispensing doctor list of the Local Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted,
 - (vi) any other Local Health Board or Primary Care Trust to which notice was sent pursuant to paragraph (2)(e), (h) or (i), and
 - (vii) any other person who has made representations under the provisions of paragraph (4) or (5); and
- (b) the rights of appeal under regulation 13 to—
 - (i) the applicant, and
 - (ii) any person who gave evidence under the provisions of paragraph (4).

(23) Any Local Health Board or Primary Care Trust which is notified under paragraph (22)(a)(vi) must, as soon as practicable, give notice in writing of the decision and reasons for it to—

- (a) the Local Pharmaceutical Committee for its area;
- (b) the Local Medical Committee for its area;
- (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of the Local Health Board or Primary Care Trust, be significantly affected if the application were granted;
- (d) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of the Local Health Board or Primary Care Trust, be significantly affected if the application were granted.”.