WELSH STATUTORY INSTRUMENTS

## 2020 No. 1073

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

### PART 2

#### Pharmaceutical needs assessments

#### Pharmaceutical needs assessments

**3.**—(1) The statement of the needs for pharmaceutical services which each Local Health Board is required to publish by virtue of section 82A of the 2006 Act(1), whether it is the statement of its first assessment or of any revised assessment, is referred to in these Regulations as a "pharmaceutical needs assessment".

(2) The pharmaceutical services to which each pharmaceutical needs assessment must relate are all the pharmaceutical services that may be provided under arrangements made by a Local Health Board for—

- (a) the provision of pharmaceutical services by a person on a pharmaceutical list,
- (b) the provision of local pharmaceutical services under a pilot scheme, or
- (c) the dispensing of drugs and appliances with a person on a dispensing doctors list (but not other NHS services that may be provided under arrangements made by a Local Health Board with a dispensing doctor).

#### **Commencement Information**

I1 Reg. 3 in force at 1.10.2020, see reg. 1(2)(b)

#### Information to be contained in pharmaceutical needs assessments

**4.**—(1) Each pharmaceutical needs assessment must contain the information set out in Schedule 1.

(2) Each Local Health Board must, so far as is practicable, keep up to date the map which it includes in its pharmaceutical needs assessment pursuant to paragraph 5 of Schedule 1 (without needing to republish the whole assessment or publish a supplementary statement).

#### **Commencement Information**

I2 Reg. 4 in force at 1.10.2020, see reg. 1(2)(b)

#### Date by which the first pharmaceutical needs assessment is to be published

**5.** Each Local Health Board must publish its first pharmaceutical needs assessment within 12 months of the date on which these Regulations come into force.

#### **Commencement Information**

I3 Reg. 5 in force at 1.10.2020, see reg. 1(2)(b)

#### Subsequent assessments

**6.**—(1) After it has published its first pharmaceutical need assessment, each Local Health Board must publish a statement of its revised assessment—

- (a) no later than 5 years after its previous publication of a pharmaceutical needs assessment, or
- (b) at any point within 5 years of its previous publication of a pharmaceutical needs assessment, having regard to any other needs assessments the Local Health Board is under a statutory duty to publish.

(2) A Local Health Board must make a revised assessment as soon as is reasonably practicable after identifying changes, which are of a significant extent, since the publication of its pharmaceutical needs assessment which are relevant to the granting of applications referred to in section 83 of the 2006 Act, unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

(3) Pending the publication of a statement of a revised assessment, a Local Health Board may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its pharmaceutical needs assessment (which becomes part of the assessment), where—

- (a) the changes are relevant to the granting of applications referred to in section 83 of the 2006 Act, and
- (b) the Local Health Board—
  - (i) is satisfied that making a revised assessment would be a disproportionate response to those changes, or
  - (ii) is in the course of making a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent detriment to the provision of pharmaceutical services in its area.

(4) Where a Local Health Board publishes a supplementary statement in accordance with paragraph (3), the Local Health Board must notify those bodies listed in regulation 7(1) of its publication as soon as reasonably practicable.

#### **Commencement Information**

I4 Reg. 6 in force at 1.10.2020, see reg. 1(2)(b)

#### **Consultation on pharmaceutical needs assessments**

7.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must consult on the contents of the assessment with the following—

(a) the Local Pharmaceutical Committee for Wales,

- (b) the Local Medical Committee for its area (including one for its area and that of one or more other Local Health Boards relevant to the assessment);
- (c) the persons on its pharmaceutical lists,
- (d) any pilot scheme pharmacy with whom the Local Health Board has made arrangements for the provision of any local pharmaceutical services,
- (e) the persons on its dispensing doctors list (if it has one),
- (f) any person with whom the Local Health Board has made arrangements for the provision of dispensing services,
- (g) any provider of primary medical services in its area,
- (h) [<sup>F1</sup>the Citizen Voice Body] and any other group representing patients, consumers or a community in its area which in the opinion of the Local Health Board has an interest in the provision of pharmaceutical services in its area,
- (i) any Regional Partnership Board for its area,
- (j) any local authority for its area,
- (k) any NHS Trust in its area, and
- (l) any neighbouring Local Health Board.

(2) A draft of the proposed pharmaceutical needs assessment must be published on the website of the Local Health Board for a minimum of 60 days.

(3) The Local Health Board must, no later than 24 hours after the draft pharmaceutical needs assessment is published in accordance with paragraph (2), notify the persons listed in paragraph (1) that—

- (a) a draft of the proposed pharmaceutical needs assessment has been published on the website of the Local Health Board, and
- (b) the date by which any consultation response must be provided to the Local Health Board.

(4) If a person listed in paragraph (1) requests a copy of the draft pharmaceutical needs assessment in hard copy form, the Local Health Board must as soon as is practicable, and in any event within 14 days, supply a hard copy of the draft to that person (free of charge).

(5) Where a Local Health Board is notified in accordance with paragraph (3) and there is a Local Medical Committee for its area that is different to the Local Medical Committee consulted under paragraph (1)(b), the Local Health Board notified—

- (a) must consult that Committee before making its response to the consultation, and
- (b) must have regard to any representation received from the Committee when making its response to the consultation.
- F1 Words in reg. 7(1)(h) substituted (1.4.2023) by The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Consequential, Supplementary and Incidental Amendments and Revocations) (Secondary Legislation) Regulations 2023 (S.I. 2023/299), regs. 1(2), 9(3)

#### **Commencement Information**

I5 Reg. 7 in force at 1.10.2020, see reg. 1(2)(b)

#### Matters for consideration when making assessments

**8.**—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must have regard, in so far as it is practicable to do so, to the following matters—

- (a) any assessment or further assessment of relevant needs prepared under section 82A of the 2006 Act—
  - (i) where it relates to the area of the Local Health Board, and
  - (ii) which has not been superseded by a further assessment under that section,
- (b) the demography of its area,
- (c) any different needs of different localities within its area,
- (d) the pharmaceutical services provided under arrangements with any neighbouring Local Health Board which affect the need for pharmaceutical services in its area, and
- (e) any dispensing services or other NHS services provided in or outside its area (which are not covered by sub-paragraph (d)) which affect the need for pharmaceutical services in its area.

(2) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must take account of the likely future needs—

- (a) to the extent necessary to make a proper assessment of the matters mentioned in paragraph 3 of Schedule 1, and
- (b) having regard to changes to the number of people in its area who will require pharmaceutical services.

#### **Commencement Information**

I6 Reg. 8 in force at 1.10.2020, see reg. 1(2)(b)

#### Publication of pharmaceutical needs assessments

9.—(1) A Local Health Board must publish on its website—

- (a) the pharmaceutical needs assessment for its area,
- (b) any subsequent assessment made pursuant to regulation 6(1), and
- (c) any supplementary statement made pursuant to regulation 6(3).

(2) If a Local Health Board receives a request for a copy of any of the documents in paragraph (1) in hard copy form, the Local Health Board must, as soon as is practicable and in any event within 14 days, supply a hard copy (free of charge).

#### **Commencement Information**

I7 Reg. 9 in force at 1.10.2020, see reg. 1(2)(b)

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, PART 2.