

## SCHEDULE 1 **E+W**

Regulation 4

### Information to be contained in pharmaceutical needs assessments

#### **Current provision of pharmaceutical services **E+W****

1. A statement of the pharmaceutical services that the Local Health Board has identified as services that are provided—

- (a) in the area of the Local Health Board and which are necessary to meet the need for pharmaceutical services in its area,
- (b) outside the area of the Local Health Board but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the Local Health Board has identified such services), or
- (c) in or outside the area of the Local Health Board and, whilst not being services of the types described in sub-paragraph (a) or (b), they nevertheless affect the assessment by the Local Health Board of the need for pharmaceutical services in its area.

#### **Commencement Information**

**I1** Sch. 1 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### **Other NHS services **E+W****

2. A statement of any NHS services provided or arranged by the Local Health Board, another Local Health Board, a dispensing doctor or NHS Trust to which the Local Health Board has had regard in its assessment, which affect the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

#### **Commencement Information**

**I2** Sch. 1 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### **Gaps in provision of pharmaceutical services **E+W****

3. A statement of the pharmaceutical services that the Local Health Board has identified (if it has) as services that are not provided in the area of the Local Health Board but which the Local Health Board is satisfied—

- (a) need to be provided (whether or not they are located in the area of the Local Health Board) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;
- (b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the Local Health Board) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

#### **Commencement Information**

**I3** Sch. 1 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**How the assessment was carried out** **E+W**

4. An explanation of how the assessment has been carried out, and in particular—
- (a) how it has determined what are the localities in its area,
  - (b) how it has taken into account (where applicable)—
    - (i) the different needs of different localities in its area, and
    - (ii) the different needs of members of different groups in its area who share a common attribute in respect of one, or more than one, of the following characteristics—
      - (aa) age,
      - (bb) gender,
      - (cc) proposed, commenced or completed reassignment of gender,
      - (dd) disability,
      - (ee) race,
      - (ff) religion or belief, and
      - (gg) sexual orientation;
  - (c) a report on the consultation that it has undertaken.

**Commencement Information**

**I4** Sch. 1 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Map of provision** **E+W**

5. A map that identifies the premises at which pharmaceutical services and dispensing services are provided in the area of the Local Health Board.

**Commencement Information**

**I5** Sch. 1 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**SCHEDULE 2** **E+W**

Regulations 15, 18, 23, 30, 33 and 34

Information to be included in applications to provide pharmaceutical services

**PART 1** **E+W**

Application for inclusion in or for amendment to a pharmaceutical list

*Information required from all applicants*

**Details of the application** **E+W**

1. Name of the Local Health Board to which the application is made.

**Commencement Information**

**I6** Sch. 2 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

2. Type of consent applied for (full or preliminary).

**Commencement Information**

**I7** Sch. 2 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

3. Type of application (for example: new inclusion; relocation within a Local Health Board's area; relocation between neighbouring Local Health Board areas; relocation; change of ownership; preliminary consent).

**Commencement Information**

**I8** Sch. 2 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Details of the applicant** **E+W**

4. Name and address of the applicant.

**Commencement Information**

**I9** Sch. 2 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

5. If the applicant is an individual or a partnership carrying on a retail pharmacy business, the applicant's or each partner's registration number in the General Pharmaceutical Council register.

**Commencement Information**

**I10** Sch. 2 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

6. If the applicant is a body corporate carrying on a retail pharmacy business, the name and registration number of the applicant's superintendent in the General Pharmaceutical Council register.

**Commencement Information**

**I11** Sch. 2 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Details of the premises and opening hours** **E+W**

7. The address of the premises from which the applicant applies to provide pharmaceutical services; or the location of the premises from which the applicant intends to provide pharmaceutical services if the application is for preliminary consent.

**Commencement Information**

**I12** Sch. 2 para. 7 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. (See end of Document for details)

8. Whether the applicant is currently in possession of the premises or whether, for example, the premises are under construction or negotiation.

**Commencement Information**

I13 Sch. 2 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

9. The days on which the pharmacy will be open for the provision of pharmaceutical services and the opening hours on those days.

**Commencement Information**

I14 Sch. 2 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Pharmaceutical services to be provided** E+W

10. Confirmation that all essential services will be provided and, if applicable, which appliances the applicant undertakes to supply.

**Commencement Information**

I15 Sch. 2 para. 10 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

11. Details of directed services that the applicant applies to provide.

**Commencement Information**

I16 Sch. 2 para. 11 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

12. If the application is to provide pharmaceutical services of a different description to those currently provided at the listed premises, details of those services.

**Commencement Information**

I17 Sch. 2 para. 12 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

*Information relating to applications to be included in, or amend, a pharmaceutical list*

13. Where regulation 16 applies to the determination of an application, the applicant must state the reasons why the applicant considers the application will meet a need identified in the relevant pharmaceutical needs assessment of the Local Health Board in which the premises specified in the application are situated.

**Commencement Information**

I18 Sch. 2 para. 13 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

*Information relating to the prejudice test*

14. Where the prejudice test in regulation 16 applies to the determination of an application, the applicant must state the reasons why they consider that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

**Commencement Information**

**I19** Sch. 2 para. 14 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

*Information relating to applications involving relocations*

15. Where the applicant applies to relocate (whether within the Local Health Board's area under regulation 19, between neighbouring Local Health Board areas under regulation 20 or on a temporary relocation basis under regulation 21) the applicant must provide details of the proposed relocation including the address of the applicant's existing listed premises.

**Commencement Information**

**I20** Sch. 2 para. 15 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

16. Where the application involves a relocation between neighbouring Local Health Board area under regulation 20 the applicant must state—

- (a) the name of the Local Health Board where the existing premises are located,
- (b) that the applicant consents to the removal of their name from the pharmaceutical list maintained by the Local Health Board in whose area the existing premises are located and in respect of those existing listed premises with effect from the date on which the provision of pharmaceutical services from the new premises will commence, and
- (c) how the applicant intends to meet a need identified in the pharmaceutical needs assessment of the neighbouring Local Health Board, if the application involves a relocation to meet such a need.

**Commencement Information**

**I21** Sch. 2 para. 16 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

17. The applicant must provide details of whether—

- (a) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is significantly less accessible,
- (b) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises, and
- (c) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

**Commencement Information**

**I22** Sch. 2 para. 17 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. (See end of Document for details)

18. If the application is for a temporary relocation, the applicant must state the circumstances that require a temporary relocation.

**Commencement Information**

**I23** Sch. 2 para. 18 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

*Information relating to applications involving a change of ownership*

19. Name of the person included in the pharmaceutical list currently providing pharmaceutical services from the premises.

**Commencement Information**

**I24** Sch. 2 para. 19 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

20. The applicant must provide details of whether—

- (a) the same pharmaceutical services will continue to be provided from the premises, and
- (b) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

**Commencement Information**

**I25** Sch. 2 para. 20 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

*Applicant's undertaking*

21. The applicant must give an undertaking that if the application is granted the applicant will provide the pharmaceutical services, and if applicable supply the appliances, at the premises in respect of which the application is granted in accordance with the applicable terms of service.

**Commencement Information**

**I26** Sch. 2 para. 21 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**PART 2** **E+W**

Information and undertakings for applications for inclusion in a pharmaceutical list

**Applicant's details** **E+W**

22.—(1) An applicant (other than an applicant which is a body corporate) must provide the following information—

- (a) full name,
- (b) gender,
- (c) date of birth,
- (d) address and telephone number,

- (e) a declaration that they are a registered pharmacist, and
  - (f) professional registration number and date of first registration in the register.
- (2) An applicant which is a body corporate must provide the following information—
- (a) full name,
  - (b) company registration number,
  - (c) registered office and telephone number relating to that office,
  - (d) a declaration that it is a person who is or who will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968,
  - (e) registration number in the Register of Premises maintained by the General Pharmaceutical Council, and
  - (f) details of any relevant list from which it has been removed or contingently removed, or to which it has been refused admission or in which it has been conditionally included, on fitness grounds, with an explanation as to why.

#### Commencement Information

**I27** Sch. 2 para. 22 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Investigation, proceedings and convictions **E+W**

**23.** An applicant must supply in writing information as to whether they, or where the applicant is a body corporate any of its directors or its superintendent—

- (a) has any criminal convictions in the United Kingdom,
- (b) has been bound over following a criminal conviction in the United Kingdom,
- (c) has accepted a police caution in the United Kingdom,
- (d) has in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 (penalty as alternative to prosecution),
- (f) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales, or is subject to a penalty which would be the equivalent of being bound over or cautioned,
- (g) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board,
- (h) has been subject to any investigation into their professional conduct by any licensing, regulatory or other body, where the outcome was adverse,
- (i) is currently subject to any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) is or has been where the outcome was adverse, the subject of any investigation into their professional conduct in respect of any current or previous employment,
- (k) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to removal from any relevant list,

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (l) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (m) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list kept by another Local Health Board or equivalent body, or has been or is currently suspended from such a list, on fitness grounds, and if so, why and the name of that Local Health Board or equivalent body, or
- (n) is, or ever has been, subject to a national disqualification, and, if so, the applicant must give details including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings, and any outcome.

#### Commencement Information

**I28** Sch. 2 para. 23 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**24.** If the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is, has been in the preceding 6 months, or was at the time of the originating events, a director or superintendent of a body corporate, they must in addition supply information in writing to the Local Health Board as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom,
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board,
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse,
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from any relevant list,
- (g) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list, or has been or is currently suspended from such a list, on fitness grounds, or
- (i) is or ever has been, subject to a national disqualification, and if so, the applicant must give the name and registered office of the body corporate and details, including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings and any outcome.

#### Commencement Information

**I29** Sch. 2 para. 24 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Pharmaceutical qualifications, referees etc. **E+W**

**25.** Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply details of their pharmaceutical qualifications (including where obtained) and chronological details of their



professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why they were dismissed from any post.

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**Commencement Information**

**I30** Sch. 2 para. 25 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**26.** Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply names and addresses of two referees who are willing to provide references in respect of two recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, a full explanation and alternative referees.

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**Commencement Information**

**I31** Sch. 2 para. 26 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**27.** Where the applicant is a body corporate, the name and address of each director and superintendent of the body corporate must be supplied.

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**Commencement Information**

**I32** Sch. 2 para. 27 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**28.** The applicant must supply the name of any Local Health Board (or equivalent body) in whose pharmaceutical list the applicant, and where the applicant is a body corporate, any director or superintendent of the applicant, is included, and particulars of any outstanding applications (including deferred applications) for inclusion in, or preliminary consent to be included in, any pharmaceutical list of a Local Health Board (or equivalent body) with the name of the Local Health Board (or body) in question.

.....  
**Commencement Information**

**I33** Sch. 2 para. 28 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**29.** If the applicant is the director or superintendent of a body corporate that is included in any relevant list, or which has an outstanding application (including a deferred application) for inclusion in any relevant list, the applicant must supply the name of the Local Health Board or equivalent body in question, and the name and registered office of any such body corporate.

.....  
**Commencement Information**

**I34** Sch. 2 para. 29 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Undertakings** **E+W**

**30.—(1)** The applicant must give a written undertaking to notify the Local Health Board within 7 days of any material changes to the information provided in the application until—

- (a) their name is entered on the pharmaceutical list,

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (b) the period specified in regulation 23(2) for them to notify the Local Health Board that they will commence the provision of the pharmaceutical services in respect of which the application was made has expired,
  - (c) they withdraw the application, or
  - (d) in the case of an applicant who has been granted preliminary consent under regulation 18, the period during which the preliminary consent has effect in accordance with regulation 18(5) has expired.
- (2) The applicant must give a written undertaking to notify the Local Health Board if they are included or apply to be included in a relevant list.

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**Commencement Information**

**I35** Sch. 2 para. 30 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 3 **E+W**

### Notification of commencement date

#### **Information to be provided prior to the commencement of the provision of pharmaceutical services **E+W****

- 31.** The applicant must provide the following information—
- (a) name of the applicant,
  - (b) date of grant of application,
  - (c) premises specified in the application from which the pharmaceutical services will be provided,
  - (d) confirmation that the premises are registered with the General Pharmaceutical Council (including reference number),
  - (e) details of the pharmaceutical services to be provided,
  - (f) date on which the provision of pharmaceutical services will commence,
  - (g) name and registration number of the registered pharmacist in charge at the premises, and
  - (h) an undertaking that the applicant will, in accordance with the application granted by the Local Health Board, provide the pharmaceutical services from the premises in accordance with the terms of services.

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**Commencement Information**

**I36** Sch. 2 para. 31 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 4 **E+W**

### Applications for outline consent and premises approval

#### **Details of the application **E+W****

- 32.** Name of the Local Health Board to which the application is made.

**Commencement Information**

**I37** Sch. 2 para. 32 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**33.** Type of application (outline consent, premises approval or both).

**Commencement Information**

**I38** Sch. 2 para. 33 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Details of the applicant** **E+W**

**34.** Name and address of the applicant.

**Commencement Information**

**I39** Sch. 2 para. 34 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**35.** The General Medical Council reference number under which the applicant is included in the List of Registered Medical Practitioners maintained by the General Medical Council.

**Commencement Information**

**I40** Sch. 2 para. 35 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Application for outline consent** **E+W**

**36.** Description and map of the area within which the applicant wishes to provide pharmaceutical services.

**Commencement Information**

**I41** Sch. 2 para. 36 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**37.** Address of any pharmacy within the area described and delineated under paragraph 36.

**Commencement Information**

**I42** Sch. 2 para. 37 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Application for premises approval** **E+W**

**38.** The address of the practice premises from which the applicant applies to provide pharmaceutical services and whether those practice premises are listed premises in relation to a different area.

**Commencement Information**

**I43** Sch. 2 para. 38 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

39. Distance between those premises and the nearest pharmacy (and the address of that pharmacy).

**Commencement Information**

**I44** Sch. 2 para. 39 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

40. Whether the application is for premises approval for additional premises or to relocate to new premises (and if the latter the distance from the new premises to the premises in respect of which the applicant currently has premises approval).

**Commencement Information**

**I45** Sch. 2 para. 40 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

41. Whether the application arises because a practice amalgamation has taken place or will be taking place and, if so, the names of the doctors or contractors participating in the amalgamation.

**Commencement Information**

**I46** Sch. 2 para. 41 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

42. If outline consent has already been granted a description and map of the area in respect of which consent has been granted.

**Commencement Information**

**I47** Sch. 2 para. 42 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

43. Details of any other medical practice premises which have been granted premises approval or in respect of which an application has already been made but not yet determined by the Local Health Board.

**Commencement Information**

**I48** Sch. 2 para. 43 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Pharmaceutical services to be provided** **E+W**

44. The pharmaceutical services to be provided and the opening hours and days on which those services will be provided.

**Commencement Information**

**I49** Sch. 2 para. 44 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Prejudice test **E+W**

45. The reasons why the applicant considers that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

#### Commencement Information

**I50** Sch. 2 para. 45 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Meeting identified needs **E+W**

46. The reasons why the applicant considers it is necessary to grant the application in order to meet a need identified in a relevant pharmaceutical needs assessment.

#### Commencement Information

**I51** Sch. 2 para. 46 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Applicant's undertaking **E+W**

47. The applicant must give an undertaking that if the application is granted and outline consent and premises approval is in effect the applicant will provide the pharmaceutical services from the practice premises in respect of which the application is granted in accordance with the terms of service.

#### Commencement Information

**I52** Sch. 2 para. 47 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## SCHEDULE 3 **E+W**

Regulations 13, 15 and 30

Procedures to be followed by Local Health Boards  
to determine applications under the Regulations

## PART 1 **E+W**

### Preliminary matters

#### General principles **E+W**

1.—(1) Except in so far as these Regulations provide to the contrary, a Local Health Board may determine an application submitted to it in such manner as it thinks fit.

(2) A Local Health Board must follow the procedure in regulation 15(4) in respect of an application submitted to it which does not contain all of the information that an applicant is required to provide in accordance with Schedule 2.

(3) A Local Health Board may if it thinks fit consider two or more applications together and in relation to each other but where it intends to do so it must give notice of that intention in writing to—

- (a) the respective applicants, and
- (b) where the application is one in respect of which notice must be given under paragraph 8, any other person that must be given notice of that application.

(4) Where in accordance with sub-paragraph (3) a Local Health Board considers two or more applications to which regulation 16(2) applies together and in relation to each other, it may refuse an application (notwithstanding the fact that it would if determining the application in isolation grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the application are situated.

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**Commencement Information**

**I53** Sch. 3 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Timetable for determining applications** E+W

**2.** A Local Health Board must endeavour to determine an application as soon as is practicable after its receipt.

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**Commencement Information**

**I54** Sch. 3 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Persons prohibited from taking part in decision-making on applications** E+W

**3.—(1)** No person is to take part in determining an application if they—

- (a) are a person who is included in the pharmaceutical list or dispensing doctor list maintained by the Local Health Board, or are an employee of such a person,
- (b) are a shareholder, director or company secretary of a company which runs a retail pharmacy business in the area of the Local Health Board,
- (c) are a provider of primary medical services in the area of the Local Health Board,
- (d) are an APMS contractor in the area of the Local Health Board, or is an officer, trustee or other person concerned with the management of a company, society or voluntary organisation or other body which is an APMS contractor, or is employed or engaged by such an APMS contractor, or
- (e) are employed or engaged by the Local Health Board for the purposes of providing primary medical services within an LHBMS practice.

(2) No other person is to take part in determining an application if, because of an interest or an association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

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**Commencement Information**

**I55** Sch. 3 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 2 **E+W**

### Determination of controlled localities

#### Notice of proposed determination in respect of controlled localities **E+W**

4.—(1) If a Local Health Board decides that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 13(3) (areas that are controlled localities), the Local Health Board must take no action in relation to that application other than to notify the applicant of that fact and of its right of appeal against that decision under regulation 14 (appeals).

(2) In all other cases, before making a determination under regulation 13(2) a Local Health Board must give a written notice of proposed determination to—

- (a) the Local Medical Committee in its area,
- (b) the Local Pharmaceutical Committee in its area,
- (c) [<sup>F1</sup>the Citizen Voice Body], and
- (d) any person included in a pharmaceutical list maintained by the Local Health Board and any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established who, in the opinion of the Local Health Board, may be affected by the determination.

(3) A notice of proposed determination must inform the person notified of their right to make representations (or in the case of a Local Medical Committee or Local Pharmaceutical Committee being notified that applied for the determination any further representations) in writing on the proposed determination within 30 days of the date on which the notice was sent to them.

#### Textual Amendments

- F1** Words in Sch. 3 para. 4(2)(c) 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(4)(a)**

#### Commencement Information

- I56** Sch. 3 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Deferral of applications **E+W**

5. Where a Local Health Board has issued a notice of proposed determination it must defer consideration of any application submitted under Part 5 or Part 6 of these Regulations but not determined by it if the application could be affected by the proposed determination until—

- (a) it has determined whether or not the locality is or is part of a controlled locality and the period for bringing an appeal relating to that determination has ended, or
- (b) the date of the determination of any such appeal.

#### Commencement Information

- I57** Sch. 3 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Imposition of conditions **E+W**

6. Where a Local Health Board determines whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it—

- (a) must consider whether the provision of—
  - (i) primary medical services by a provider of such services (other than itself),
  - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
  - (iii) local pharmaceutical services provided under a pilot scheme, or
  - (iv) pharmaceutical services by a doctor,
 is likely to be adversely affected as a consequence of that determination, and
- (b) may, where it is of the opinion that any of those services are likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision under the GMS Regulations for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

#### Commencement Information

**I58** Sch. 3 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Notification of determination and action following determination **E+W**

7.—(1) Once a Local Health Board has determined the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it must—

- (a) as soon as practicable after reaching a determination give notice in writing to those notified under paragraph 4(2) informing them of—
    - (i) the determination and the reasons for it,
    - (ii) any conditions that it has imposed under paragraph 6, and
    - (iii) any rights of appeal under Schedule 4, and
  - (b) as soon as practicable after the relevant date—
    - (i) delineate precisely on a map the boundaries of the controlled locality or remove the delineated boundary of a locality that has ceased to be a controlled locality,
    - (ii) give a doctor that is affected reasonable notice of any conditions that have been imposed under paragraph 6 as a result of the determination, and
    - (iii) proceed to determine any applications that have been deferred under paragraph 5.
- (2) For the purposes of this paragraph, “the relevant date” is the later of—
- (a) the date on which the period for bringing an appeal relating to the determination ends, or
  - (b) the date of the determination of any such appeal.

#### Commencement Information

**I59** Sch. 3 para. 7 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)



## PART 3 **E+W**

### Applications for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

#### Notice of certain applications **E+W**

8.—(1) This paragraph applies to applications for—

- (a) inclusion in, or to make an amendment to, a—
  - (i) pharmaceutical list made under Part 5 of these Regulations, except for applications under regulation 22 (applications involving a change of ownership), and
  - (ii) dispensing doctor list made under Part 6 of these Regulations,
- (b) an extension of the relevant time period under regulation 24, and
- (c) a further determination as to whether premises are, or a relevant location is, in a reserved location under regulation 17(2).

(2) The Local Health Board to which the application was submitted must give notice in writing of the application in accordance with paragraph 9.

(3) Those notified of an application may within 30 days of the date on which the notification was sent to them, make representations on the application, in writing, to the Local Health Board to which the application was submitted, except for applications made pursuant to regulation 21 (applications involving temporary relocation).

#### Commencement Information

**I60** Sch. 3 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Persons and bodies to be notified **E+W**

9.—(1) The persons and bodies that must be notified by a Local Health Board are—

- (a) the Local Pharmaceutical Committee,
- (b) the Local Medical Committee,
- (c) any person—
  - (i) included in a pharmaceutical list maintained by it, or
  - (ii) who has been granted preliminary consent for inclusion in a pharmaceutical list, whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,
- (d) any provider of local pharmaceutical services under a pilot scheme in the area for which the Local Health Board is established whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,
- (e) <sup>F2</sup>the Citizen Voice Body],
- (f) any patient group, consumer group or community group in the area of the Local Health Board that it considers has a significant interest in the provision of pharmaceutical services in the area,
- (g) where the premises specified in the application are in a controlled locality, any person (except itself) who is a provider of primary medical services within the Local Health Board's area or who is included in the dispensing doctor list maintained by the Local

**Changes to legislation:** There are currently no known outstanding effects for the *The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020*. (See end of Document for details)

Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,

- (h) any Local Health Board or equivalent body any part of whose area is within 2 kilometres of the premises or the location of the premises specified in the application, and
- (i) in the case of an application made under regulation 20 (applications involving relocation between neighbouring Local Health Board areas), the Local Health Board from whose area the applicant wishes to relocate.

(2) A Local Health Board that provided the notification under sub-paragraph (1)(h) must—

- (a) within 14 days of receiving the notification give notice in writing to the persons and bodies specified in sub-paragraph (1)(a) to (g) that are within or that serve the area for which the Local Health Board is established, and
- (b) notify the Local Health Board that provided the notification under sub-paragraph (1) that it has provided the notification required by sub-paragraph (2)(a).

(3) An equivalent body notified under sub-paragraph (1)(h) may request the Local Health Board to give notification to such persons in the area for which the equivalent body is established whose interests might in the opinion of the equivalent body, be significantly affected if the application is granted and the Local Health Board must comply with any such request.

#### Textual Amendments

**F2** Words in Sch. 3 para. 9(1)(e) 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(4)(b)**

#### Commencement Information

**I61** Sch. 3 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Content of notification **E+W**

**10.** A notification of an application under paragraph 8 must—

- (a) inform the person or body notified—
  - (i) of their right to make representations on the application under paragraph 8(3),
  - (ii) the circumstances in which the Local Health Board may require an oral hearing to be held under paragraph 11, and
  - (iii) if the Local Health Board intends to consider the application together with and in relation to any other application, of that intention,
- (b) provide a copy of the application submitted by the applicant to enable the person or body notified to make informed representations with regard to whether or not the application should be granted, and
- (c) where regulation 17(1) applies to an application under paragraph 8(1)(a) inform the person or body notified that the Local Health Board will be determining whether the premises or relevant location specified in the application that are in a controlled locality are also in a reserved location.

#### Commencement Information

**I62** Sch. 3 para. 10 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Oral hearings **E+W**

**11.**—(1) In the case of an application falling within paragraph 8, a Local Health Board may require an oral hearing to be held if it considers it is necessary to hear oral representations before determining such an application.

(2) If the Local Health Board does decide to hold an oral hearing, it must—

(a) give not less than 14 days' notice of the time and place of the hearing to—

(i) the applicant, and

(ii) any person who has made representations on the application under paragraph 8(3),

(b) advise the applicant who has been given notice of the hearing, and

(c) advise those notified that they may make oral representations relating to the application at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) A Local Health Board may determine the procedure to be followed at the oral hearing.

(5) A Local Health Board is not bound by any recommendations arising from an oral hearing.

### Commencement Information

**I63** Sch. 3 para. 11 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Information to which a Local Health Board must have regard **E+W**

**12.** In determining an application falling within paragraph 8, a Local Health Board must have regard, in particular, to—

(a) any representations received by the Local Health Board under paragraph 8(3),

(b) any recommendations arising from an oral hearing, if one is held under paragraph 11,

(c) the relevant pharmaceutical needs assessment and relevant locality, and

(d) any other information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application.

### Commencement Information

**I64** Sch. 3 para. 12 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Imposition of conditions **E+W**

**13.**—(1) This sub-paragraph applies where a Local Health Board decides to grant an application falling within—

(a) paragraph 8(1)(a)(i) where the premises specified in the application are in a controlled locality, or

(b) paragraph 8(1)(a)(ii).

(2) Where sub-paragraph (1) applies, a Local Health Board—

(a) must consider whether the provision of—

- (i) primary medical services by a provider of such services (other than itself),
- (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
- (iii) local pharmaceutical services provided under a pilot scheme, or
- (iv) pharmaceutical services by a doctor,

is likely to be adversely affected as a consequence of its decision to grant the application, and

- (b) may, where it is of the opinion that the provision of any of those services listed in subparagraph (2)(a) is likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant list.

#### Commencement Information

**I65** Sch. 3 para. 13 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Notification of decisions: applications for inclusion in or to make an amendment to a pharmaceutical list **E+W**

**14.**—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(i), give notice in writing of its decision (including the questions of the imposition of conditions under paragraph 13 and the determination of a reserved location under regulation 17(1)) to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) In the case of an application which is determined under regulation 22 (applications involving a change of ownership), a Local Health Board must as soon as practicable after reaching a decision give notice in writing in accordance with paragraph 9.

(3) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

#### Commencement Information

**I66** Sch. 3 para. 14 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists **E+W**

**15.**—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(ii), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13) to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

**Commencement Information**

**I67** Sch. 3 para. 15 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Notification of decisions: applications under regulation 24 for extension of the relevant period** **E+W**

**16.**—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(b), give notice in writing of its decision to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) Any notification of a decision under this paragraph must include a statement of the reasons for the decision.

**Commencement Information**

**I68** Sch. 3 para. 16 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Notification of decisions: applications under regulation 17(2)** **E+W**

**17.**—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(c), give notice in writing of its decision to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

**Commencement Information**

**I69** Sch. 3 para. 17 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Action following determination in respect of reserved locations** **E+W**

**18.**—(1) After determining an application under regulation 17(2) or making a determination in accordance with regulation 17(1), as soon as practicable after the relevant date, the Local Health Board must delineate precisely on a map the boundaries of any reserved location that it has determined, or remove the delineated boundary of a location that has ceased to be a reserved location, as the case may be.

(2) For the purposes of this paragraph, “the relevant date” is the later of—

- (a) the date on which the period for bringing an appeal relating to the determination ends, or
- (b) the date of the determination of any such appeal.

**Commencement Information**

**I70** Sch. 3 para. 18 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

SCHEDULE 4 **E+W**

Regulations 14, 25, 35 and 54

Appeals to the Welsh Ministers

PART 1 **E+W**

Preliminary matters

**General principles** **E+W**

1. Except in so far as these Regulations provide to the contrary, the Welsh Ministers may determine an appeal submitted to them in such manner as they think fit and may, in particular—

- (a) consider all information available to them which, in their opinion, is relevant to the determination of an appeal;
- (b) consider two or more appeals together and in relation to each other (but they are not obliged to do so where the Local Health Board has determined two or more applications together and in relation to each other) but where they intend to do so they must give notice of that intention to each appellant and those given notice of each appeal in accordance with this Schedule;
- (c) where in accordance with sub-paragraph (b) the Welsh Ministers consider two or more appeals to which regulation 15(2) applies together and in relation to each other, they may refuse an appeal (notwithstanding the fact that they would if determining the appeal in isolation grant it) where the number of appeals is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the appeal are situated;
- (d) remit an appeal submitted to them to a Local Health Board for re-determination in cases where the information that the applicant is required to provide in accordance with Schedule 2 was incomplete;
- (e) dismiss an appeal if they are of the opinion that the notice of appeal—
  - (i) is not valid because it does not comply with the requirements of this Schedule,
  - (ii) does not disclose any reasonable grounds of appeal, or
  - (iii) is otherwise vexatious or frivolous.

**Commencement Information**

**I71** Sch. 4 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Oral hearings **E+W**

2.—(1) The Welsh Ministers may require an oral hearing to be held if they consider that it is necessary to hear oral representations before determining an appeal submitted to them.

(2) If the Welsh Ministers decide to hold an oral hearing, they must—

- (a) appoint one or more persons to hear and to report to them on the appeal,
- (b) give not less than 14 days' notice of the time and place of the hearing to the appellant and to any person sent a copy of the notice of appeal under paragraph 4 or 7,
- (c) advise the appellant who has been given notice of the hearing, and
- (d) advise those notified that they may make oral representations relating to the appeal at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) The person or persons appointed by the Welsh Ministers to hear the appeal may determine the procedure to be followed at the hearing.

(5) The Welsh Ministers are not bound by any recommendations arising from an oral hearing.

### Commencement Information

I72 Sch. 4 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 2 **E+W**

### Appeals against decisions determining controlled localities

#### Right of appeal to the Welsh Ministers **E+W**

3.—(1) Where a Local Health Board has decided that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 13(3) (areas that are controlled localities), the applicant may submit a notice of appeal against that decision to the Welsh Ministers.

(2) Where a Local Health Board has determined under regulation 13(2) whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality, the persons entitled to submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee,
- (b) the Local Pharmaceutical Committee, and
- (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 3.

(3) Where a Local Health Board has determined that it should or should not postpone the making or termination of arrangements, as mentioned in paragraph 6(b) of Schedule 3, those that may submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee,
  - (b) the Local Pharmaceutical Committee, and
  - (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 3.
- (4) A notice of appeal is valid if—
- (a) it is submitted by a person with the right of appeal under sub-paragraph (1), (2) or (3),
  - (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal, and
  - (c) it contains a statement of the grounds of appeal.

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**Commencement Information**

**I73** Sch. 4 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Notification of appeals** E+W

**4.—(1)** The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(1) send a copy of the notice to the Local Health Board.

(2) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(2) or 3(3) send a copy of the notice to—

- (a) the Local Health Board, and
- (b) those persons to whom the Local Health Board has given notice of its determination under paragraph 7(1) of Schedule 3.

(3) Those sent a copy of the notice of appeal under sub-paragraphs (1) to (3) must, at the same time, be informed by the Welsh Ministers—

- (a) that they may within 30 days of the date on which the notice of appeal was sent to them, make representations on the appeal in writing to the Welsh Ministers, and
- (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held.

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**Commencement Information**

**I74** Sch. 4 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Decision on appeals** E+W

**5.—(1)** The Welsh Ministers must after reaching a decision on an appeal submitted under paragraph 3 give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 4.

(2) The Welsh Ministers—

- (a) must, where they allow an appeal against a decision by a Local Health Board that an application cannot be considered by virtue of regulation 13(3), either—
  - (i) themselves determine the question of whether or not the particular locality is or is part of a controlled locality, or



- (ii) remit the question to the Local Health Board for determination,
- (b) may, where the Local Health Board, on determining the application, considered the imposition of conditions under paragraph 6 of Schedule 3, themselves consider whether to impose conditions,
- (c) may, where the Local Health Board, on determining the application, has not considered the imposition of conditions under paragraph 6 of Schedule 3 either—
  - (i) themselves consider whether to impose conditions, or
  - (ii) remit the question to the Local Health Board for determination,
- (d) may, where the Local Health Board, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 26 (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, themselves postpone, for such period as they think fit, the making or termination of such arrangements, or
- (e) must, where the Local Health Board, did not consider the question whether to postpone the making or termination of arrangements under regulation 26 (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, remit the question to the Local Health Board for determination.

**Commencement Information**

**I75** Sch. 4 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 3 **E+W**

### Appeals against decisions for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

#### **Right of appeal to the Welsh Ministers** **E+W**

**6.—(1)** For applications to which paragraph 8(1)(a) and (c) of Schedule 3 apply, the persons entitled to submit a notice of appeal against the decision of the Local Health Board to the Welsh Ministers are—

- (a) the applicant;
- (b) any of the following who made representations on the application to the Local Health Board under paragraph 8(3) of Schedule 3—
  - (i) any person included in a pharmaceutical list,
  - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
  - (iii) any provider of local pharmaceutical services under a pilot scheme, and
  - (iv) where the premises specified in an application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.

**(2)** In the case of an application determined under regulation 22 (applications involving a change of ownership), the persons entitled to submit a notice of appeal to the Welsh Ministers are—

- (a) the applicant, and
- (b) any of the following who were, under paragraph 14(2) of Schedule 3, given notice of the Local Health Board's decision on the application—
  - (i) any person included in a pharmaceutical list,
  - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
  - (iii) any provider of local pharmaceutical services under a pilot scheme, and
  - (iv) where the premises specified in the application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.
- (3) A notice of appeal is valid if—
  - (a) it is submitted by a person with the right of appeal under sub-paragraph (1) or (2),
  - (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal, and
  - (c) it contains a statement of the grounds of appeal which do not amount to a challenge to the legality or reasonableness of a pharmaceutical needs assessment, or to the fairness of the process by which the Local Health Board undertook that assessment.

**Commencement Information**

**I76** Sch. 4 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Notification of appeals** E+W

- 7.—(1) The Welsh Ministers must, on receipt of a notice of appeal submitted under paragraph 6(1), send a copy of the notice to—
- (a) the applicant, if the applicant has not submitted the notice of appeal,
  - (b) the Local Health Board, and
  - (c) those notified of and who made representations on the application under paragraph 8(3) of Schedule 3.
- (2) The Welsh Ministers must, on receipt of a notice of appeal submitted under paragraph 6(2), send a copy of the notice to—
- (a) the applicant, if the applicant has not submitted the notice of appeal,
  - (b) the Local Health Board, and
  - (c) those given notification of the Local Health Board's decision under paragraph 14(2) of Schedule 3.
- (3) The persons to whom a copy of the notice of appeal is sent under this paragraph must, at the same time, be informed by the Welsh Ministers—
- (a) that they may, within 30 days of the date on which the notice of appeal was sent to them, make representations on the appeal in writing to the Welsh Ministers,
  - (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held, and
  - (c) where the Welsh Ministers intend to consider two or more appeals together and in relation to each other, of that intention.

**Commencement Information**

**I77** Sch. 4 para. 7 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Decision on appeals** **E+W**

- 8.**—(1) On determining an appeal made under paragraph 6, the Welsh Ministers must either—
- (a) allow the appeal, or
  - (b) confirm the decision of the Local Health Board.
- (2) In the case where the premises specified in an application that is subject to appeal are in a controlled locality, the Welsh Ministers—
- (a) may, where the Local Health Board, on determining the application, considered whether to impose conditions under paragraph 13 of Schedule 3 or regulation 17(6)(b), themselves consider whether to impose conditions to postpone, for such period as they think fit, the making or termination of such arrangements, or
  - (b) must, where the Local Health Board on determining the application has not considered whether to impose conditions under paragraph 13 of Schedule 2 or regulation 17(6)(b) either—
    - (i) themselves consider whether to impose conditions, or
    - (ii) remit the question to the Local Health Board for determination.
- (3) The Welsh Ministers must after reaching a decision on an appeal, including the imposition of conditions under sub-paragraph (2), give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 7.

**Commencement Information**

**I78** Sch. 4 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Effect of decisions by the Welsh Ministers** **E+W**

- 9.** For the purposes of these Regulations, the Welsh Ministers' decision becomes the Local Health Board's decision on the matter (but no further appeal to the Welsh Ministers on that decision is possible, unless the Welsh Ministers' decision is overruled by a court).

**Commencement Information**

**I79** Sch. 4 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

SCHEDULE 5 **E+W**

Regulation 12

Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provisions of drugs

PART 1 **E+W**

General

**Interpretation** **E+W**

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

**Commencement Information**

**I80** Sch. 5 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Incorporation of provisions** **E+W**

2. Any provisions of the following affecting the rights and obligations of NHS pharmacists who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations,
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services),
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
  - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and,
  - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board<sup>[F3.]</sup>

<sup>F4</sup>(d) .....

**Textual Amendments**

- F3** Sch. 5 para. 2(c)(ii): full stop 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(5)(a)**
- F4** Sch. 5 para. 2(d) omitted (1.4.2023) by virtue of [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(5)(b)**

#### Commencement Information

**I81** Sch. 5 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### [<sup>F5</sup>2A. Code of practice on access to premises

An NHS pharmacist who provides pharmaceutical services must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act.)]

#### Textual Amendments

**F5** Sch. 5 para. 2A inserted (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\(3\)\(b\), 9\(5\)\(c\)](#)

## PART 2 **E+W**

### Essential services

#### Essential services **E+W**

3. For the purposes of this Schedule, “essential services” means—
- the services described in this Part, and
  - the activities described in this Part to be carried out in connection with those services.

#### Commencement Information

**I82** Sch. 5 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Dispensing services **E+W**

4. An NHS pharmacist must, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting a prescription for that drug or appliance signed by a prescriber in pursuance of their functions in the health service in Wales, England, Scotland or Northern Ireland.

#### Commencement Information

**I83** Sch. 5 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Dispensing of drugs and appliances **E+W**

5.—(1) Subject to the following provisions of this Part, where a person presents on a prescription form—

- an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,

- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by, and endorsed on its face with the reference “SLS” by a prescriber, or
- (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference “SLS” by a prescriber,

an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the prescriber in the prescription form, provide the drugs so ordered, and such of the appliances so ordered they supply in the normal course of business.

(2) Subject to the following provisions of this Part, where any person—

(a) presents a non-electronic repeatable prescription which contains—

- (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(1), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(2) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a repeatable prescriber,
- (ii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
- (iii) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference “SLS” by a repeatable prescriber,

and also presents an associated batch issue, or

(b) requests the provision of drugs or appliances in accordance with an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iii),

an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the repeatable prescriber in the repeatable prescription, provide the drugs so ordered, and such of the appliances so ordered as they supply in the normal course of their business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances is to be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

#### Commencement Information

**184** Sch. 5 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Supply in accordance with a SSP **E+W**

6.—(1) This sub-paragraph applies where—

- (a) a person requests a drug or appliance from an NHS pharmacist in accordance with a prescription form or repeatable prescription, and
- (b) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or

(1) [1971 c. 38](#). See section 2(1)(a) of that Act which defines “controlled drug” for the purposes of that Act.

(2) [S.I. 2001/3998](#).

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, the NHS pharmacist must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, the NHS pharmacist may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

- (a) the NHS pharmacist is able to do so with reasonable promptness,
- (b) to do so is in accordance with the SSP, and
- (c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a registered pharmacist who is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where an NHS pharmacist, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

- (a) the registered pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription), and
- (b) if the patient to or for whom the product is provided is on a patient list, and the supply—
  - (i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012 (sale etc. by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or
  - (ii) is of any other type, and the Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS pharmacist must notify the provider of primary medical services on whose patient list the patient is, of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(5) Where—

- (a) sub-paragraph (1) applies,
- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 5(1) and (2) are to be read as requirements to act within a reasonable timescale.

#### Commencement Information

**185** Sch. 5 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Urgent supply without a prescription **E+W**

7.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist to provide a drug or appliance.

(2) The NHS pharmacist may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—

- (a) in the case of a request for a drug, the drug is neither—
  - (i) a Scheduled drug, nor
  - (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
  - (i) give the NHS pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
  - (ii) give the NHS pharmacist an electronic prescription form or electronic repeatable prescription complying with the ETP service within 72 hours of the request being made.

#### Commencement Information

**186** Sch. 5 para. 7 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Preliminary matters before providing ordered drugs or appliances **E+W**

8.—(1) If the person presenting the prescription form or repeatable prescription, or requesting the provision of drugs or appliances in accordance with a repeatable prescription, asks the NHS pharmacist to do so—

- (a) the NHS pharmacist must give an estimate of the time when the drugs or appliances will be ready, and
  - (b) if they are not ready by then, the NHS pharmacist must give a revised estimate of the time when they will be ready (and so on).
- (2) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription—
- (a) the NHS pharmacist must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
    - (i) entitlement to exemption under regulation 8(1) (exemptions) of the Charges Regulations, or
    - (ii) entitlement to remission of such charges under regulation 5 of the Remission of Charges Regulations (remissible NHS charges),



to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of sub-paragraphs (a) to (f) of regulation 5(2) of the Remission of Charges Regulations, and at the time of the declaration such evidence is already available to the NHS pharmacist, and

- (b) if no satisfactory evidence, as required by paragraph (a), is produced to the NHS pharmacist, the NHS pharmacist must endorse the form on which the declaration is made to that effect.

(3) Sub-paragraph (2) applies to the provision of a drug or appliance in accordance with a SSP as it does to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes, the prescription for product reimbursement purposes, as mentioned in paragraph 6(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).

#### Commencement Information

**187** Sch. 5 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Providing ordered drugs or appliances **E+W**

**9.**—(1) Where an NHS pharmacist is presented with a prescription form or a repeatable prescription, the NHS pharmacist must only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and endorsed as described in paragraph 5(1) or (2), and
- (b) in accordance with the order and any directions given by the prescriber on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(3) and the following provisions of this Part.

(2) Drugs or appliances so ordered must be provided either by or under the direct supervision of a registered pharmacist.

(3) Where the pharmacist referred to in sub-paragraph (2) is employed by an NHS pharmacist, the registered pharmacist must not be someone—

- (a) who is disqualified from inclusion in a relevant list, or
- (b) who is suspended from the General Pharmaceutical Council Register.

(4) If the order is for, or a product to be provided in accordance with a SSP is, an appliance of a type requiring measuring and fitting (for example a truss), the NHS pharmacist must make all necessary arrangements—

- (a) for measuring the person named on the prescription form or repeatable prescription for the appliance, and
- (b) for fitting the appliance.

(5) If the order is for, or a product to be provided in accordance with a SSP is, a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with the standard or formula specified therein.

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(3) [1985 c. 72.](#)

(6) If the order—

- (a) is an order for a drug, but
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971 other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,

and does not prescribe its quantity, strength or dosage, an NHS pharmacist may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care they consider to be appropriate and, subject to sub-paragraph (7), in such quantity as they consider to be appropriate for a course of treatment for a period not exceeding 5 days.

(7) Where an order to which sub-paragraph (6) applies is for—

- (a) an oral contraceptive substance;
- (b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs, or
- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, the NHS pharmacist may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by an NHS pharmacist in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile,
- (b) effervescent or hygroscopic,
- (c) a liquid preparation for addition to bath water,
- (d) a coal tar preparation,
- (e) a viscous preparation, or
- (f) packed at the time of its manufacture in a calendar pack or special container,

the NHS pharmacist must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) In this paragraph, “special container” means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(10) Where a drug is ordered by a prescriber, or is to be provided in accordance with a SSP is, in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a marketing authorisation holder for the drug, the NHS pharmacist must provide the drug in an original pack (or in original packs) of that size which have been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

- (a) it is not possible for the NHS pharmacist to obtain such a pack (or packs) with reasonable promptness in the normal course of business, or
- (b) it is not practicable for the NHS pharmacist to provide such a pack (or packs) in response to the order (for example because of patient needs or the method of administration of the drug).

(11) Except as provided in sub-paragraph (12), an NHS pharmacist must not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, an NHS pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph must apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) An NHS pharmacist must provide any drug which they are required to provide under paragraph 5, or provides under paragraph 6, in a suitable container.

(15) Where an NHS pharmacist provides a drug or appliance under paragraph 6, the NHS pharmacist must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.

#### Commencement Information

**I88** Sch. 5 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Refusal to provide drugs or appliances ordered **E+W**

**10.**—(1) An NHS pharmacist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the NHS pharmacist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because they reasonably believe the form has been stolen or forged),
- (b) it appears to the NHS pharmacist that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the NHS pharmacist's clinical judgement,
- (c) the NHS pharmacist or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription, or by any person accompanying that person, or
- (d) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) An NHS pharmacist must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) An NHS pharmacist must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description, and
- (b) alternative provision has already taken place in accordance with the SSP.

(4) An NHS pharmacist may refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested drug or appliance, or
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description,
- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is unable to provide the drug or appliance within a reasonable timescale,

but if the NHS pharmacist does refuse to do so, they must provide the patient or the person requesting the drug or appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

(5) An NHS pharmacist must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the NHS pharmacist has no record of that prescription,
- (b) the NHS pharmacist does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to them,
- (c) it is not signed by a repeatable prescriber,
- (d) to do so would not be in accordance with any intervals specified in the prescription,
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously,
- (f) the repeatable prescription was signed more than 1 year previously,
- (g) the expiry date on the repeatable prescription has passed, or
- (h) the NHS pharmacist has been informed by the repeatable prescriber that the prescription is no longer required.

(6) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that they make such a request), an NHS pharmacist must only provide the drugs and appliances so ordered if they are satisfied—

- (a) that the patient in respect of whom the prescription was written—
  - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
  - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment,
- (b) that the medication regimen of, or manner of utilisation of the appliance by, the patient in respect of whom the prescription was written has not altered in a way which indicates the need or desirability of reviewing the patient's treatment, and
- (c) there have been no changes to the health of the patient in respect of whom the prescription was written which indicate the need or desirability of reviewing the patient's treatment.

#### **Commencement Information**

**I89** Sch. 5 para. 10 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Further activities to be carried out in connection with the provision of dispensing services** **E**  
**+W**

- 11.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist must—
- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—
    - (i) to enable them to utilise the drugs or appliances appropriately, and
    - (ii) to meet the patient’s reasonable needs for general information about the drugs or appliances,
  - (b) provide appropriate advice to persons to whom they provide drugs or appliances on—
    - (i) the safe keeping of the drugs or appliances, or
    - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction,
  - (c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need,
  - (d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
    - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
    - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question,
  - (e) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when the drug or appliance becomes available,
  - (f) keep and maintain records—
    - (i) of drugs and appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient,
    - (ii) in appropriate cases, of advice given and any interventions or referrals made (in particular of clinically significant interventions in cases involving repeatable prescriptions), and
    - (iii) of notes provided under paragraph (e),
  - (g) undertake appropriate training in respect of repeat prescribing, having regard to any recommendations in respect of such training set out in the Drug Tariff,
  - (h) if they take possession of a repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue,
  - (i) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied),
  - (j) destroy any surplus batch issues relating to drugs or appliances—
    - (i) which are not required, or
    - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 10,
  - (k) ensure that where a person is refused drugs or appliances pursuant to paragraph 10(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice,
  - (l) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification,

- (m) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 10(4),
- (n) when providing appliances, provide a patient with a written note of the NHS pharmacist's name, address and telephone number, and
- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 12.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, an NHS pharmacist is unable (having regard to any relevant SSP) to provide an appliance, or stoma appliance customisation is required and the NHS pharmacist is unable to provide that, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

#### Commencement Information

**I90** Sch. 5 para. 11 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Additional requirements in relation to specified appliances **E+W**

**12.**—(1) This paragraph sets out the additional requirements referred to in paragraph 11(1)(o) relating to the provision of specified appliances.

(2) An NHS pharmacist who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS pharmacist must offer to deliver the specified appliance to the patient's home,
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient,
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content, and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS pharmacist must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance, or
- (b) if the NHS pharmacist believes it is appropriate to do so, must—
  - (i) refer the patient to a prescriber, or
  - (ii) offer the patient an appliance use review service.

(4) If the NHS pharmacist is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the NHS pharmacist must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS pharmacist.

(5) Where an NHS pharmacist provides a telephone care line in respect of the dispensing of any specified appliance, the NHS pharmacist must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line, or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales<sup>(4)</sup>, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

“expert clinical advice” (“*cyngor clinigol arbenigol*”), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

“out of hours periods” (“*cyfnodau y tu allan i oriau*”), in relation to a pharmacy, means the periods outside the periods during which the NHS pharmacist—

- (a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 22(1) or 26(1), or
- (b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 22(2).

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#### Commencement Information

**I91** Sch. 5 para. 12 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Disposal service in respect of unwanted drugs **E+W**

**13.** An NHS pharmacist must, to the extent paragraph 14 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs provided to the NHS pharmacist for disposal.

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#### Commencement Information

**I92** Sch. 5 para. 13 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Basic procedure in respect of unwanted drugs **E+W**

**14.—(1)** Subject to sub-paragraph (2), where a person presents to an NHS pharmacist or any of the NHS pharmacist’s staff any drugs provided for a patient in, and which have been kept in—

- (a) a private household, or
- (b) a residential care home,

the NHS pharmacist must accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) An NHS pharmacist must not be required to accept any drugs for disposal unless the Local Health Board in whose pharmaceutical list the NHS pharmacist is included has made arrangements with the NHS pharmacist for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the NHS pharmacist must—

- (a) where required to do so by the Local Health Board or by a waste disposal contractor retained by the Local Health Board, separate solid drugs or ampoules, liquids and aerosols from each other,

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(4) NHS Direct Wales telephone number 0845 46 47, website address [www.nhsdirect.wales.nhs.uk](http://www.nhsdirect.wales.nhs.uk).

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (b) store the drugs in containers provided by the Local Health Board, or by a waste disposal contractor retained by the Local Health Board for the purpose of storing drugs of that description, and
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and must co-operate with any suitable arrangements that the Local Health Board has in place for regular collection of the drugs from the NHS pharmacist's premises by or on behalf of the Local Health Board.

#### Commencement Information

**I93** Sch. 5 para. 14 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Further activities to be carried out in connection with the disposal of unwanted drugs **E**

**+W**

- 15.** In connection with the services provided under paragraph 13, an NHS pharmacist must—
- (a) ensure that they and any of their staff, are aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks, and
  - (b) ensure that they and any of their staff have readily available and close to any place where waste drugs are stored appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

#### Commencement Information

**I94** Sch. 5 para. 15 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Promotion of healthy lifestyles **E+W**

**16.** An NHS pharmacist must, to the extent paragraphs 17 and 18 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

#### Commencement Information

**I95** Sch. 5 para. 16 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Prescription linked intervention **E+W**

- 17.—(1)** Where a person using a pharmacy—
- (a) presents a prescription form or repeatable prescription to an NHS pharmacist, and
  - (b) it appears to the NHS pharmacist that the person—
    - (i) has diabetes,
    - (ii) is at risk of coronary heart disease or high blood pressure, or
    - (iii) smokes or is overweight,



the NHS pharmacist must, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets), and
- (b) by referring the person to other sources of information or advice.

(3) An NHS pharmacist must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person who has been given the advice.

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**Commencement Information**

**I96** Sch. 5 para. 17 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Public health campaigns** **E+W**

**18.** An NHS pharmacist must, at the request of the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, ensure that—

- (a) they, and any of their staff, participate, in the manner reasonably requested by the Local Health Board, in up to six campaigns in each calendar year to promote public health messages to users of the NHS pharmacist's pharmacy, and
- (b) where requested to do so by the Local Health Board, record the number of people that have been provided information as part of one of those campaigns.

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**Commencement Information**

**I97** Sch. 5 para. 18 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Signposting** **E+W**

**19.** An NHS pharmacist must, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

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**Commencement Information**

**I98** Sch. 5 para. 19 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Service outline in respect of signposting** **E+W**

**20.—(1)** Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the NHS pharmacist's pharmacy—

- (a) requires advice, treatment or support that the NHS pharmacist cannot provide, but
- (b) another provider, of which the NHS pharmacist is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

the NHS pharmacist must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, an NHS pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the NHS pharmacist's normal course of business, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

#### Commencement Information

**I99** Sch. 5 para. 20 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Support for self-care **E+W**

**21.** An NHS pharmacist must, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

#### Commencement Information

**I100** Sch. 5 para. 21 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Service outline in respect of support for self-care **E+W**

**22.—(1)** Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using the NHS pharmacist's pharmacy would benefit from advice from the NHS pharmacist to help the person manage a medical condition (including, in the case of a carer, to help the carer in assisting in the management of another person's medical condition), the NHS pharmacist must provide advice to the person using the pharmacy as regards managing the medical condition, including as appropriate advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines, and
- (b) on changes to the patient's lifestyle.

(2) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

**Commencement Information**

**I101** Sch. 5 para. 22 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## PART 3 **E+W**

### Pharmacy opening hours

#### Pharmacy opening hours: general **E+W**

**23.**—(1) An NHS pharmacist must ensure that pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services—

- (a) for not less than 40 hours each week, or
- (b) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that the NHS pharmacist provides those services at set times and on set days, at the times and on the days so set, or
- (c) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week, at set times and on set days, at the times and on the days so set, or
- (d) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week—
  - (i) for the total number of hours each week required by virtue of that direction, and
  - (ii) as regards the additional hours for which the NHS pharmacist is required to provide pharmaceutical services by virtue of that direction, at the days on which and the times at which the NHS pharmacist is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of pharmaceutical services for a set period, where it has received 3 months' notice of the proposed suspension from the NHS pharmacist.

(2) An NHS pharmacist must notify the Local Health Board in whose pharmaceutical list the NHS pharmacist is included of other hours during which the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to in these Regulations as “supplementary opening hours”).

(3) At each of the premises from which an NHS pharmacist has undertaken to provide pharmaceutical services, the NHS pharmacist must exhibit—

- (a) a notice specifying the times at which the premises are open for the provision of drugs and appliances, and
- (b) at times when the premises are not open, a notice based on information provided by the Local Health Board, legible from outside the premises, specifying the addresses of other

NHS pharmacists included in the pharmaceutical list and the times at which drugs and appliances may be obtained from those addresses.

(4) An NHS pharmacist must, on request, submit a return to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included setting out—

- (a) the times at which pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services (including the times at which the NHS pharmacist is providing pharmaceutical services when they are not obliged to do so by virtue of sub-paragraph (1)), and
- (b) the pharmaceutical services which the NHS pharmacist ordinarily provides at each of those premises.

(5) Where an NHS pharmacist changes—

- (a) the days on which or the times at which pharmaceutical services are to be provided at premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or
- (b) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

the NHS pharmacist must supply the Local Health Board on whose pharmaceutical list the NHS pharmacist is included with a return informing it of the change.

(6) Where an NHS pharmacist has submitted a return under sub-paragraph (4) or (5) in respect of any premises, or where the NHS pharmacist has set out in an application under these Regulations for inclusion in the pharmaceutical list the days on which and the times at which pharmaceutical services will be provided at the premises to which the application relates if the application is granted—

- (a) the NHS pharmacist must ensure that pharmaceutical services are provided at the premises to which the return or application relates on the days and at the times set out in the return or application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (5)), and
- (b) the NHS pharmacist must not change—
  - (i) the days on which or the times at which pharmaceutical services are to be provided at those premises, or
  - (ii) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

as set out in that return or application, for a period of at least 3 months after that return or application was received by the Local Health Board.

(7) Where an NHS pharmacist is prevented by illness or other reasonable cause from complying with their obligations under sub-paragraph (1), they must, where practicable, make arrangements with one or more other NHS pharmacists whose premises are situated in the neighbourhood for the provision of pharmaceutical services during that time.

(8) Where there is a temporary suspension in the provision of pharmaceutical services for a reason beyond the control of the NHS pharmacist, the NHS pharmacist will not be in breach of sub-paragraphs (1), (2) and (3) provided that—

- (a) the NHS pharmacist notifies the Local Health Board on whose pharmaceutical list the NHS pharmacist is included of that suspension as soon as practicable, and
- (b) the NHS pharmacist uses all reasonable endeavours to resume provision of pharmaceutical services as soon as practicable.

(9) Planned refurbishment of a pharmacy is neither a “reasonable cause” for the purposes of sub-paragraph (7), nor a “reason beyond the control of the NHS pharmacist” for the purposes of sub-paragraph (8).

(10) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it must be deemed that the pharmacy was open on that day at the times at which it would ordinarily have been open on that day of the week.

(11) In this Part—

“additional hours” (“*oriau ychwanegol*”) for which an NHS pharmacist is to be required to provide pharmaceutical services are those hours during which the NHS pharmacist would not be providing pharmaceutical services, were the NHS pharmacist subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d);

“existing direction” (“*cyfarwyddyd presennol*”) means one that has been made in accordance with this Part or one that was in existence on the date that these Regulations come into force.

#### Commencement Information

**I102** Sch. 5 para. 23 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### **Matters to be considered when issuing directions in respect of pharmacy opening hours** E

+W

**24.**—(1) Where a Local Health Board issues a direction setting any times or days under this Part, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that the pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1) the Local Health Board may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the NHS pharmacist is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS pharmacist may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in the neighbourhood is likely to be adequate to meet the need for such services at times when the NHS pharmacist is not providing pharmaceutical services.

(4) The Local Health Board may only direct that an NHS pharmacist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that the NHS pharmacist will receive reasonable remuneration in respect of the additional hours for which they are required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as a consequence of regulation 42 in respect of those hours is “reasonable remuneration” for these purposes).

#### Commencement Information

**I103** Sch. 5 para. 24 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### **Determination of pharmacy opening hours instigated by the Local Health Board** E+W

**25.**—(1) Where it appears to the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the times at which a pharmacy is or will be open for the provision of pharmaceutical services will not, or no longer meet, the needs of—

(a) people in the neighbourhood, or

(b) other likely users of that pharmacy,

for pharmaceutical services, it may carry out an assessment as to whether to issue a direction requiring the NHS pharmacist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1), the Local Health Board must—

- (a) give notice to the NHS pharmacist of any proposed changes to the times at which or the days on which the pharmacy is to be open, and
- (b) allow the NHS pharmacist 30 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5),
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph, or
- (c) either—
  - (i) revoke (without replacing it) any existing direction setting the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, or
  - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 23(1)(a), the pharmacy must be open for not less than 40 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
  - (i) the total number of hours each week for which the NHS pharmacist must provide pharmaceutical services at the pharmacy, and
  - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 40 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(6) The Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services at the pharmacy, it must include with the notification a statement in writing of—

- (a) the reasons for the change, and

(b) the NHS pharmacist's right of appeal under sub-paragraph (7).

(7) An NHS pharmacist may, within 30 days of receiving notification under sub-paragraph (6) appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the times at which or the days on which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if they have not appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (6), or
- (b) if they have appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (9).

#### Commencement Information

**I104** Sch. 5 para. 25 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Determination of pharmacy opening hours instigated by the NHS pharmacist **E+W**

**26.**—(1) An NHS pharmacist may apply to a Local Health Board on whose pharmaceutical list the NHS pharmacist is included for it to change the days on which or the times at which the NHS pharmacist is obliged to provide pharmaceutical services at the NHS pharmacist's pharmacy in a way that—

- (a) reduces the total number of hours for which the NHS pharmacist is obliged to provide pharmaceutical services each week, or
- (b) keeps the total number of hours the same.

(2) Where an NHS pharmacist makes an application under sub-paragraph (1), as part of that application the NHS pharmacist must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part,
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (5) and (6), or

- (c) either—
- (i) revoke (without replacing it) any existing direction in respect of the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, where this has the effect of granting the application under this paragraph or granting it only in part, or
  - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 23(1)(a), the pharmacy must be open for not less than 40 hours each week.
- (5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of a pharmacy that is required to be open—
- (a) for more than 40 hours each week, it must set out in that direction—
    - (i) the total number of hours each week for which the NHS pharmacist is required to provide pharmaceutical services at the pharmacy, and
    - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and the times at which the NHS pharmacist is required to provide those services during those additional hours,but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or
  - (b) for less than 40 hours each week, it must set out in that direction the days on which and the times at which pharmaceutical services are to be provided at that pharmacy.
- (6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).
- (7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (4)(c)(i), it must consult the Local Pharmaceutical Committee before determining the application.
- (8) A Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS pharmacist a statement in writing setting out—
- (a) the reasons for the refusal or, as the case may be, for granting the application only in part, and
  - (b) the NHS pharmacist's right of appeal under sub-paragraph (9).
- (9) An NHS pharmacist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.
- (10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).
- (11) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.
- (12) If the days on which or times at which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—
- (a) if they have not appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (8), or



- (b) if they have appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (11).

**Commencement Information**

**I105** Sch. 5 para. 26 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services** **E+W**

**27.**—(1) Notwithstanding the provisions of this Schedule, during an emergency requiring the flexible provision of pharmaceutical services, the Local Health Board in whose pharmaceutical list the NHS pharmacist is included may, on application from the NHS pharmacist, permit the NHS pharmacist a temporary change to the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS pharmacist gives at least 24 hours' notice of the change or closure, and  
(b) the reasons given by the NHS pharmacist for the request are, in the opinion of the Local Health Board, adequate reasons.

(2) The Local Health Board need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that the NHS pharmacist's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to the NHS pharmacist.

**Commencement Information**

**I106** Sch. 5 para. 27 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**PART 4** **E+W**

**Clinical governance and complaints**

**Clinical governance** **E+W**

**28.**—(1) An NHS pharmacist must, in connection with all the pharmaceutical services that the NHS pharmacist provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in an acceptable system of clinical governance.

- (2) A system of clinical governance is “acceptable” if it provides for—  
(a) compliance with the clinical governance components set out in sub-paragraph (3), and  
(b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.
- (3) The clinical governance components comprise of the following—  
(a) a patient and public involvement programme, which includes—

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (i) a requirement that the NHS pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of the NHS pharmacist’s pharmacy,
- (ii) a requirement that the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy,
- (iii) a requirement that where the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy (whether the NHS pharmacist is producing their own publicity material or advertising services in material published by another person), the NHS pharmacist does so in a manner which makes clear that those services are funded as part of the health service,
- (iv) a requirement that the NHS pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS pharmacist intends to take,
- (v) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
- (vi) an approved complaints system (which meets the requirements of this Part),
- <sup>F6</sup>(vii) . . . . .
- (viii) a requirement that the NHS pharmacist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, <sup>F7</sup>...
- (ix) monitoring arrangements for compliance with the Equality Act 2010(5), [<sup>F8</sup>and]
- [<sup>F9</sup>(x) a requirement that the NHS pharmacist must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act),]
- (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
- (c) a risk management programme, which includes—
  - (i) arrangements for ensuring that all stock is handled in an appropriate way,
  - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
  - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
    - (aa) a patient safety incident log, and
    - (bb) a near-miss log,
  - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and [<sup>F10</sup>NHS England],

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(5) 2010 c. 15.

- (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
  - (vi) appropriate waste disposal arrangements (in addition to those required under paragraphs 14 and 15) for clinical and confidential waste,
  - (vii) a clinical governance lead person for each pharmacy, appointed as such by the NHS pharmacist (or that is the NHS pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
  - (viii) appropriate child protection procedures, and
  - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974<sup>(6)</sup>,
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS pharmacist—
- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
  - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
  - (iii) to people caring for themselves or their families,

and arrangements for ensuring that the NHS pharmacist, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 11(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question,

- (e) a staffing and staff management programme, which includes—
- (i) arrangements for appropriate induction training for staff, including any locum,
  - (ii) appropriate training for all staff in respect of any role they are asked to perform,
  - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
  - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of pharmaceutical, or other NHS, services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
  - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
  - (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum, who, arising out of their employment with the NHS pharmacist—
    - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996<sup>(7)</sup> (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
    - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe

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<sup>(6)</sup> 1974 c. 37.

<sup>(7)</sup> 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,

- (f) an information governance programme, which provides for—
- (i) compliance with approved procedures for information management and security, and
  - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—
- (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised, and
  - (ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

#### Textual Amendments

- F6** Sch. 5 para. 28(3)(a)(vii) omitted (1.4.2023) by virtue of [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(5)(d)**
- F7** Word in Sch. 5 para. 28(3)(a)(viii) omitted (1.4.2023) by virtue of [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(3)(b), **9(5)(e)**
- F8** Word in Sch. 5 para. 28(3)(a)(ix) inserted (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(3)(b), **9(5)(f)**
- F9** Sch. 5 para. 28(3)(a)(x) inserted (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(3)(b), **9(5)(g)**
- F10** Words in Sch. 5 para. 28(3)(c)(iv) substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), regs. 1(1), **103(4)**

#### Commencement Information

- I107** Sch. 5 para. 28 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Professional standards **E+W**

**29.** An NHS pharmacist must provide pharmaceutical services and exercise any professional judgments in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

#### Commencement Information

- I108** Sch. 5 para. 29 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Inducements **E+W**

**30.**—(1) An NHS pharmacist or their staff must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of the person presenting an order for drugs or appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a compliance aid or a home delivery service is not a “gift or reward” for the purposes of sub-paragraph (1).

(3) In the case of the provision of appliances, neither an NHS pharmacist nor any person employed or engaged by that NHS pharmacist must accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 11(2)(b), 12(4) or 20(2)(b), or
- (b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 11(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

### Commencement Information

**1109** Sch. 5 para. 30 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Duty to provide information about fitness to practice matters as they arise **E+W**

**31.**—(1) Subject to paragraph 32, an NHS pharmacist, and where the NHS pharmacist is part of a body corporate each of its directors, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS pharmacist or a director—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,
- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(8)</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992<sup>(9)</sup> (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them,

<sup>(8)</sup> 1995 c. 46.

<sup>(9)</sup> 1992 c. 5.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness grounds,

and if so, the NHS pharmacist must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 32, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate,
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse,
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list, or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

#### Commencement Information

**I110** Sch. 5 para. 31 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Home Local Health Board of bodies corporate **E+W**

**32.** Where an NHS pharmacist is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 31 and 35(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 60). When the NHS pharmacist provides the information to its home Local Health Board, it must also provide the home Local Health Board with

details of all the other Local Health Boards in whose pharmaceutical lists the NHS pharmacist is included.

**Commencement Information**

**I111** Sch. 5 para. 32 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Complaints** **E+W**

**33.** An NHS pharmacist must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011<sup>(10)</sup>, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

**Commencement Information**

**I112** Sch. 5 para. 33 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**PART 5** **E+W**

Other terms of service

**Directed services** **E+W**

**34.** An NHS pharmacist with whom a Local Health Board on whose pharmaceutical list the NHS pharmacist is included makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

**Commencement Information**

**I113** Sch. 5 para. 34 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Information to be supplied** **E+W**

**35.—(1)** An NHS pharmacist must give notice to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about them in the pharmaceutical list which they have not otherwise notified in accordance with these Regulations,
- (b) in the case of an NHS pharmacist who is an individual, any change of private address, and
- (c) in the case of an NHS pharmacist that is a body corporate, any change to the address of its registered office.

(2) An NHS pharmacist must give the Local Health Board, if it so requests, the name of any pharmacist employed by them who is responsible for dispensing a particular prescription.

<sup>(10)</sup> S.I. 2011/704 (W. 108), amended by S.I. 2011/1706 (W. 192).

(3) Subject to sub-paragraph (6), an NHS pharmacist that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors and superintendent.

(4) Subject to sub-paragraph (6), if an NHS pharmacist that is a body corporate appoints a director or superintendent that was not listed on the NHS pharmacist's application for inclusion in a pharmaceutical list, the NHS pharmacist must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS pharmacist or the director or superintendent of an NHS pharmacist that is a body corporate must inform the Local Health Board—

(a) if the NHS pharmacist, or a body corporate of which they are a director or superintendent, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application, and

(b) if the NHS pharmacist becomes a director or superintendent of a body corporate which is in any of another Local Health Board's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS pharmacist is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS pharmacist also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

(a) in whose pharmaceutical list the NHS pharmacist is included, or

(b) to whom the NHS pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

(7) In this paragraph, "NHS performers or providers list" means—

(a) a pharmaceutical list, or

(b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

#### Commencement Information

**I114** Sch. 5 para. 35 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Withdrawal from pharmaceutical lists **E+W**

**36.** Where an NHS pharmacist intends to withdraw from the pharmaceutical list, they must notify the Local Health Board of this at least 3 months in advance of that date, unless it is impracticable to do so in which case they must notify the Local Health Board as soon as it is practicable to do so.

#### Commencement Information

**I115** Sch. 5 para. 36 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)



## Charges for drugs and refunds **E+W**

**37.**—(1) Subject to regulations made under section 121 of the 2006 Act (charges for drugs, medicines or appliances, or pharmaceutical services) all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where an NHS pharmacist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the NHS pharmacist, the container and equipment remains the property of the NHS pharmacist.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents an NHS pharmacist with a valid claim for repayment, the NHS pharmacist must make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if it is duly made on Form WP57 0405 within 3 months of the date on which the charge was paid.

### Commencement Information

**I116** Sch. 5 para. 37 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Inspections and access to information **E+W**

**38.**—(1) An NHS pharmacist must allow persons authorised in writing by the Local Health Board in whose pharmaceutical list the NHS pharmacist is included to enter and inspect the NHS pharmacist's pharmacy at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS pharmacist is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by the NHS pharmacist for patient care and treatment, and
  - (ii) the management by the NHS pharmacist of the pharmaceutical services they provide,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given,
- (b) the Local Pharmaceutical Committee for the area where the pharmacy is situated has been invited to be present at the inspection, where this is requested by the NHS pharmacist,
- (c) the person authorised in writing carries written evidence of their authorisation, which they produce on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS pharmacist must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow the Local Health Board or person authorised by it access to any information which the Local Health Board or person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1), or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

#### Commencement Information

**I117** Sch. 5 para. 38 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Welsh language **E+W**

**39.**—(1) Where an NHS pharmacist provides pharmaceutical services through the medium of Welsh, the NHS pharmacist must notify the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in writing.

(2) An NHS pharmacist must make available a Welsh language version of any document or form for use by patients and/or members of the public, provided by the Local Health Board.

(3) Where an NHS pharmacist displays a new sign or notice in connection with pharmaceutical services, the text on the sign or notice must be in English and Welsh, and an NHS pharmacist may utilise the translation service offered by the Local Health Board for this purpose.

(4) An NHS pharmacist must encourage the wearing of a badge, provided by the Local Health Board, by those delivering pharmaceutical services who are Welsh speaking, to convey that they are able to speak Welsh.

(5) An NHS pharmacist must encourage those delivering pharmaceutical services to utilise information and/or attend training courses and events provided by the Local Health Board, so that they can develop—

- (a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and
- (b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.

(6) An NHS pharmacist must encourage those delivering pharmaceutical services to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

#### Commencement Information

**I118** Sch. 5 para. 39 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### SCHEDULE 6 **E+W**

Regulation 12

Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances

#### Incorporation of provisions **E+W**

**1.** Any provisions of the following affecting the rights and obligations of NHS appliance contractors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations;
- (b) the Drug Tariff in so far as it lists appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—

- (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and
- (ii) appeals to the Welsh Ministers from decisions of the Local Health Board<sup>[F11]</sup>.

<sup>F12</sup>(d) .....

**Textual Amendments**

- F11** Sch. 6 para. 1(c)(ii): full stop 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(6)(a)**
- F12** Sch. 6 para. 1(d) omitted (1.4.2023) by virtue of [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(6)(b)**

**Commencement Information**

- I119** Sch. 6 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

<sup>F13</sup>**1A.** Code of practice on access to premises

An NHS appliance contractor who provides pharmaceutical services must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act).]

**Textual Amendments**

- F13** Sch. 6 para. 1A inserted (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(3)(c), **9(6)(c)**

**Division of responsibilities between individuals and corporate bodies** **E+W**

**2.—(1)** To the extent that this Schedule imposes a requirement on an NHS appliance contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the NHS appliance contractor is a registered pharmacist—
  - (i) that registered pharmacist must comply with that requirement, or
  - (ii) if they employ or engage a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by the person whom they employ or engage, and
- (b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by a person whom it employs or engages,

and references in this Schedule to an NHS appliance contractor must be construed accordingly.

(2) Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, breach of that requirement must be deemed to be a breach by the body corporate of its terms of service.

**Commencement Information**

**I120** Sch. 6 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Dispensing services** **E+W**

**3.** An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances by health care professionals in pursuance of their functions.

**Commencement Information**

**I121** Sch. 6 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Dispensing of appliances** **E+W**

**4.—(1)** In this paragraph, “signed” includes signature with a prescriber’s advanced electronic signature.

**(2)** Subject to the provisions of this Schedule, where—

- (a)** any person presents a non-electronic prescription form which contains—
  - (i)** an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
  - (ii)** an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”, “Selected List Scheme” or “Drug Tariff”, or
- (b)** an NHS appliance contractor receives an electronic repeatable prescription complying with the ETP service which contains an order of a kind specified in paragraph **(a)(i)** and **(ii)** and—
  - (i)** any person requests the provision of an appliance in accordance with that prescription, or
  - (ii)** the NHS appliance contractor has previously arranged with the patient that they will dispense that prescription on receipt,

an NHS appliance contractor must, with reasonable promptness, provide such of the appliances so ordered as they supply in the normal course of business.

**(3)** For the purposes of this paragraph, a non-electronic repeatable prescription for appliances is to be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where—

- (a)** the NHS appliance contractor has that prescription in their possession, and
- (b)** that person presents, or the NHS appliance contractor has in their possession, an associated batch issue.

**Commencement Information**

**I122** Sch. 6 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Supply in accordance with a SSP** **E+W**

**5.—(1)** This sub-paragraph applies where—

- (a) a person requests an appliance from an NHS appliance contractor in accordance with a prescription form or repeatable prescription, and
  - (b) a SSP has effect in respect of—
    - (i) the requested appliance, or
    - (ii) appliances of a specified description, and the requested appliance is of that description.
- (2) Where sub-paragraph (1) applies, an NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.
- (3) Where sub-paragraph (1) applies, an NHS appliance contractor may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—
- (a) the NHS appliance contractor is able to do so with reasonable promptness,
  - (b) to do so is in accordance with the SSP, and
  - (c) the NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.
- (4) Where an NHS appliance contractor, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—
- (a) the NHS appliance contractor must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription), and
  - (b) if—
    - (i) the patient to or for whom the product is provided is on a patient list, and
    - (ii) the supply is of a type in relation to which the Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS appliance contractors, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,
- the NHS appliance contractor must notify the provider of primary medical services on whose patient list the patient is, of the supply in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription.
- (5) Where—
- (a) sub-paragraph (1) applies,
  - (b) an NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
  - (c) the NHS appliance contractor is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,
- the requirement to act with reasonable promptness in paragraph 4(2) is to be read as a requirement to act within a reasonable timescale.

#### Commencement Information

**I123** Sch. 6 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Urgent supply without a prescription **E+W**

**6.—(1)** This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor to provide an appliance.

**(2)** The NHS appliance contractor may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

- (a) give the NHS appliance contractor a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made, or
- (b) give the NHS appliance contractor an electronic prescription form complying with the ETP service within 72 hours of the request being made.

#### Commencement Information

**I124** Sch. 6 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Preliminary matters before providing appliances **E+W**

**7.—(1)** If the person specified in sub-paragraph (2) asks the NHS appliance contractor to do so—

- (a) the NHS appliance contractor must give an estimate of the time when the appliance will be ready, and
- (b) if it is not ready by then, the NHS appliance contractor must give a revised estimate of the time when it will be ready.

**(2)** A person specified in this sub-paragraph is a person—

- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription, or
- (b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

**(3)** Before providing an appliance in accordance with a prescription form or repeatable prescription—

- (a) the NHS appliance contractor must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3 of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
  - (i) entitlement to exemption under regulation 8 of the Charges Regulations (exemptions), or
  - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations and at the time of the declaration such evidence has already been made available to the NHS appliance contractor,

- (b) if, in the case of a non-electronic prescription form or a non-electronic repeatable prescription no satisfactory evidence, as required by paragraph (a), is produced to the NHS appliance contractor, the NHS appliance contractor must endorse the form on which the declaration is made to that effect, and
- (c) in the case of an electronic prescription form or an electronic repeatable prescription, the NHS appliance contractor must comply with any requirements of the ETP service to provide—
  - (i) a record of the exemption from or remission of charges claimed and whether satisfactory evidence was produced, as referred to in paragraph (a), and
  - (ii) in any case where a charge is due, confirmation that the relevant charge was paid.

(4) Sub-paragraph (3) applies to the provision of an appliance in accordance with a SSP as it applies to the provision of an appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes the prescription for product reimbursement purposes, as mentioned in paragraph 5(4)(a), is treated as being the prescription in accordance with which the appliance is provided (even though the supply is not in pursuance of that prescription).

#### Commencement Information

**I125** Sch. 6 para. 7 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Providing appliances **E+W**

**8.—(1)** Where an NHS appliance contractor is presented with a prescription form or a repeatable prescription, the NHS appliance contractor must only provide the appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4, and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985 and the following provisions of this Schedule.

(2) If the order is for, or a product to be provided in accordance with a SSP is, an appliance of a type requiring measuring and fitting by the NHS appliance contractor, the NHS appliance contractor must make all necessary arrangements for—

- (a) measuring the person named on the prescription form or repeatable prescription for the appliance, and
- (b) fitting the appliance.

(3) If the order is for, or a product to be provided in accordance with a SSP is, an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner’s Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

(4) Where an NHS appliance contractor provides an appliance under paragraph 5, the NHS appliance contractor must include with it in a written note, for the patient’s benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.

### Commencement Information

**I126** Sch. 6 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Refusal to provide appliances ordered **E+W**

**9.—(1)** An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) the NHS appliance contractor reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription,
- (b) it appears to the NHS appliance contractor that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to the clinical judgement of the NHS appliance contractor,
- (c) the NHS appliance contractor or other persons are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with a prescription form or repeatable prescription or by any person accompanying that person, or
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or electronic repeatable prescription or any other person accompanying that person, commits or threatens to commit a criminal offence.

**(2)** An NHS appliance contractor must refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested appliance, or
  - (ii) appliances of a specified description, and the requested appliance is of that description, and
- (b) alternative provision has already taken place in accordance with the SSP.

**(3)** An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
  - (i) the requested appliance, or
  - (ii) appliances of a specified description, and the requested appliance is of that description,
- (b) the NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS appliance contractor is unable to provide the appliance within a reasonable timescale,

but if the NHS appliance contractor does refuse to do so, they must provide the patient or the person requesting the appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

**(4)** An NHS appliance contractor must refuse to provide appliances ordered on a repeatable prescription where—



- (a) they have no record of that prescription,
  - (b) they do not, in the case of a non-electronic repeatable prescription, have any associated batch issue and no such batch issue is presented,
  - (c) it is not signed by a repeatable prescriber,
  - (d) to do so would not be in accordance with any intervals specified in the prescription,
  - (e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously,
  - (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously,
  - (g) the expiry date on the repeatable prescription has passed, or
  - (h) they have been informed by the repeatable prescriber that the prescription is no longer required.
- (5) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), an NHS appliance contractor must only provide the appliance ordered if satisfied that—
- (a) the patient to whom the prescription relates—
    - (i) is using and is likely to continue to use the appliance appropriately, and
    - (ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient’s treatment,
  - (b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient’s treatment, and
  - (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient’s treatment.

**Commencement Information**

**1127** Sch. 6 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Further activities to be carried out in connection with the provision of dispensing services** **E**  
**+W**

- 10.**—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor must—
- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
    - (i) to enable them to utilise the appliances appropriately, and
    - (ii) to meet the patients’ reasonable needs for general information about the appliances,
  - (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances,
  - (c) when providing appliances to a patient in accordance with a prescription form or repeatable prescription—
    - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

- (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question,
  - (d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available,
  - (e) provide a patient with a written note of the NHS appliance contractor's name, address and telephone number,
  - (f) keep and maintain records—
    - (i) of appliances provided, in order to facilitate the continued care of the patient,
    - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
    - (iii) of notes provided under paragraph (d),
  - (g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff,
  - (h) if the NHS appliance contractor takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue,
  - (i) if the NHS appliance contractor provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it may be dispensed,
  - (j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied),
  - (k) destroy any surplus batch issues relating to appliances—
    - (i) which are not required, or
    - (ii) where a patient is refused an appliance pursuant to paragraph 9,
  - (l) ensure that where a person is refused appliances pursuant to paragraph 9(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;
  - (m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification,
  - (n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 9(3), and
  - (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.
- (2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, an NHS appliance contractor is unable to provide an appliance, or stoma appliance customisation is required and the NHS appliance contractor is unable to provide that, the NHS appliance contractor must—
- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist, or
  - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

### Commencement Information

**1128** Sch. 6 para. 10 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Additional requirements in relation to specified appliances **E+W**

**11.**—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(o) relating to the provision of specified appliances.

(2) An NHS appliance contractor who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS appliance contractor must offer to deliver the specified appliance to the patient's home,
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient,
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content, and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS appliance contractor must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance, or
- (b) if the NHS appliance contractor believes it is appropriate to do so, must—
  - (i) refer the patient to a prescriber, or
  - (ii) offer the patient an appliance use review service.

(4) If the NHS appliance contractor is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), they must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS appliance contractor.

(5) Where an NHS appliance contractor provides a telephone care line in respect of the dispensing of any specified appliance, they must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line, or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph—

“expert clinical advice” (“*cyngor clinigol arbenigol*”), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

“out of hours periods” (“*cyfnodau y tu allan i oriau*”), in relation to each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, means the periods outside the periods during which the NHS appliance contractor is obliged to provide pharmaceutical services by virtue of paragraph 13.

### Commencement Information

**I129** Sch. 6 para. 11 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Signposting **E+W**

**12.**—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within their normal course of business, the NHS appliance contractor must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist, and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

(2) The NHS appliance contractor must, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS appliance contractor, and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

### Commencement Information

**I130** Sch. 6 para. 12 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Opening hours: general **E+W**

**13.**—(1) An NHS appliance contractor must ensure that pharmaceutical services are provided at each of the premises from which they have undertaken to provide pharmaceutical services—

- (a) for not less than 30 hours each week,
- (b) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 5 to the 2013 Regulations), that the NHS appliance contractor may provide pharmaceutical services at the premises for fewer than 30 hours per week, provided that those services are provided at set times and on set days, at the times and on the days so set,
- (c) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 5 to the 2013 Regulations), that the NHS appliance contractor must provide pharmaceutical services at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set, or
- (d) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed under this Schedule that the NHS appliance contractor must provide pharmaceutical services at the premises for more than 30 hours each week—
  - (i) for the total number of hours each week required by virtue of that direction, and

- (ii) as regards the additional hours for which the NHS appliance contractor is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which the NHS appliance contractor is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of pharmaceutical services for a set period, where it has received 3 months' notice of the proposed suspension.

(2) At each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, an NHS appliance contractor must exhibit a notice specifying the days on which and times at which the premises are open for the provision of appliances.

(3) An NHS appliance contractor must, on request, submit a return to the Local Health Board setting out—

- (a) the days on which and times at which pharmaceutical services are provided at each of the premises from which the NHS appliance contractor has undertaken to provide pharmaceutical services (including times at which they are providing pharmaceutical services when not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as “supplementary opening hours”), and
- (b) the pharmaceutical services which the NHS appliance contractor ordinarily provides at each of those premises.

(4) Where an NHS appliance contractor changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which they have undertaken to provide pharmaceutical services, or
- (b) the pharmaceutical services which they are ordinarily to provide at those premises,

the NHS appliance contractor must supply the Local Health Board with a return informing it of the change.

(5) Subject to sub-paragraph (6), where an NHS appliance contractor is prevented by illness or other reasonable cause from complying with its obligations under sub-paragraph (1) the NHS appliance contractor must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists or providers of local pharmaceutical services under a pilot scheme whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) An NHS appliance contractor may make an arrangement with a provider of local pharmaceutical services under a pilot scheme under sub-paragraph (5) only where that provider provides local pharmaceutical services which are of a similar description, and a similar extent to, the pharmaceutical services which the NHS appliance contractor ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by an NHS appliance contractor for a reason beyond its control, the NHS appliance contractor will not be in breach of sub-paragraphs (1) and (2), provided that the NHS appliance contractor—

- (a) notifies the Local Health Board of that suspension as soon as practicable, and
- (b) uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(8) Planned refurbishment of premises is neither a “reasonable cause” for the purposes of sub-paragraph (5) nor a “reason beyond its control” for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(10) In this Schedule, the “additional hours” for which an NHS appliance contractor is to be required to provide pharmaceutical services are those hours during which the NHS appliance contractor would not be providing pharmaceutical services, were the NHS appliance contractor subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d).

(11) Notwithstanding the provisions of paragraphs 14 to 17, during an emergency requiring the flexible provision of pharmaceutical services, a Local Health Board may, on application from an NHS appliance contractor, permit a temporary change to the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at the premises from which they have undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS appliance contractor gives at least 24 hours’ notice of the change or closure, and
- (b) the reasons given by the NHS appliance contractor for the request are, in the opinion of the Local Health Board, adequate reasons.

(12) The Local Health Board need not approve the request referred to in sub-paragraph (11), in advance of the change or closure, and if it does not do so but decides subsequently that the NHS appliance contractor’s reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to the NHS appliance contractor.

#### Commencement Information

**I131** Sch. 6 para. 13 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Matters to be considered when issuing directions in respect of opening hours **E+W**

**14.**—(1) Where a Local Health Board issues a direction setting any days or times under this Schedule, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Local Health Board—

- (a) must treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided, and
- (b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the person providing the pharmaceutical services is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS appliance contractor may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood are likely to be adequate to meet the need for such services at times when the NHS appliance contractor is not providing pharmaceutical services.

(4) A Local Health Board may only direct that an NHS appliance contractor must provide pharmaceutical services at premises for more than 30 hours in any week if a Local Health Board is satisfied that the NHS appliance contractor will receive reasonable remuneration in respect of the additional hours for which they are required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is “reasonable remuneration” for these purposes).

### Commencement Information

**I132** Sch. 6 para. 14 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Determination of opening hours instigated by the Local Health Board **E+W**

**15.**—(1) Where it appears to the Local Health Board, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of—

- (a) people in the neighbourhood, or
- (b) other likely users of the NHS appliance contractor's premises,

for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board must—

- (a) give notice to the NHS appliance contractor of any proposed changes to the days on which or times at which the premises are to be open, and
- (b) allow the NHS appliance contractor 60 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5), or
- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph, or
- (c) either—
  - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, or
  - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 13(1)(a), the premises must be open for not less than 30 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
  - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
  - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which they are required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Local Health Board must notify the NHS appliance contractor in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises, it must include with the notification a statement of—

- (a) the reasons for the change, and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (7).

(7) An NHS appliance contractor may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS appliance contractor in writing of a determination under sub-paragraph (8) and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which an NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if they have not appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive a notification under sub-paragraph (6), or
- (b) if they have appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive a notification under sub-paragraph (9).

#### Commencement Information

**I133** Sch. 6 para. 15 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Determination of opening hours instigated by the NHS appliance contractor **E+W**

**16.**—(1) An NHS appliance contractor may apply to a Local Health Board in writing with 90 days' notice for it to change the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at their premises, in a way that—

- (a) reduces the total number of hours for which the NHS appliance contractor is obliged to provide pharmaceutical services each week, or
- (b) keeps that total number of hours the same.

(2) Where an NHS appliance contractor makes an application under sub-paragraph (1), as part of that application they must provide the Local Health Board with such information as the Local



Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part,
- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, would meet the requirements of sub-paragraphs (5) and (6), or
- (c) either—
  - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, where this has the effect of granting the application under this paragraph or granting it only in part, or
  - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 13(1)(a), the premises must be open for not less than 30 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
  - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
  - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which they are required to provide those services during those additional hours,but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours, or

(b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (4)(c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the NHS appliance contractor of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS appliance contractor a statement setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part, and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (9).

(9) An NHS appliance contractor may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the NHS appliance contractor in writing of its determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if they have not appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive a notification under sub-paragraph (4), or
- (b) if they have appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive a notification under sub-paragraph (11).

#### Commencement Information

**I134** Sch. 6 para. 16 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Clinical governance **E+W**

**17.**—(1) An NHS appliance contractor must, in connection with all the services that they provide, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list they are included, in an acceptable system of clinical governance.

- (2) A system of clinical governance is “acceptable” if it provides for—
  - (a) compliance with the clinical governance components set out in sub-paragraph (3), and
  - (b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.
- (3) The clinical governance components comprise of the following—
  - (a) a patient and public involvement programme, which includes—
    - (i) a requirement that the NHS appliance contractor should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of each of the premises from which they provide pharmaceutical services,
    - (ii) a requirement that the NHS appliance contractor publicises the NHS services that are available at or from the premises from which the NHS appliance contractor provides such services,
    - (iii) a requirement that where the NHS appliance contractor publicises the NHS services that are available at or from premises from which the NHS appliance contractor provides such services (whether they are producing their own publicity material or advertising services in material published by another person), the NHS appliance

- contractor does so in a manner which makes clear that those services are funded as part of the health service,
- (iv) a requirement that the NHS appliance contractor should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS appliance contractor intends to take,
  - (v) monitoring arrangements for appliances owed to patients but which are out of stock,
  - (vi) an approved complaints system (which meets the requirements of this Part),
  - <sup>F14</sup>(vii) . . . . .
  - (viii) a requirement that the NHS appliance contractor co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, <sup>F15</sup>...
  - (ix) monitoring arrangements for compliance with the Equality Act 2010(11), [<sup>F16</sup>and]
  - [<sup>F17</sup>(x) a requirement that the NHS appliance contractor must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act),]
- (b) a clinical audit programme (normally of 5 days), which includes at least one premises-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is handled in an appropriate way,
  - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
  - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
    - (aa) a patient safety incident log, and
    - (bb) a near-miss log,
  - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and [<sup>F18</sup>NHS England],
  - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
  - (vi) appropriate waste disposal arrangements for clinical and confidential waste,
  - (vii) a clinical governance lead person for each of the premises from which the NHS appliance contractor provides NHS services, who is knowledgeable about both the procedures of the NHS appliance contractor and the other NHS services that are available in the locality,
  - (viii) appropriate child protection procedures, and

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(11) 2010 c. 15.

**Changes to legislation:** There are currently no known outstanding effects for the *The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020*. (See end of Document for details)

- (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974<sup>(12)</sup>,
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS appliance contractor—
  - (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
  - (ii) to people caring for themselves or their families,
 and arrangements for ensuring that the NHS appliance contractor, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question,
- (e) a staffing and staff management programme, which includes—
  - (i) arrangements for appropriate induction training for staff, including any locum,
  - (ii) appropriate training for all staff in respect of any role they are asked to perform,
  - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
  - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
  - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
  - (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum who, arising out of their employment with the NHS appliance contractor—
    - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996<sup>(13)</sup> (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
    - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,
- (f) an information governance programme, which provides for—
  - (i) compliance with approved procedures for information management and security, and
  - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—

<sup>(12)</sup> 1974 c. 37.

<sup>(13)</sup> 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

- (i) a system for maintaining cleanliness at the premises from which the NHS appliance contractor provides NHS services which is designed to ensure, in a proportionate manner, that the risk to people at the premises of healthcare acquired infection is minimised, and
- (ii) arrangements for there to be a clear separation between the areas of the premises which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

#### Textual Amendments

- F14** Sch. 6 para. 17(3)(a)(vii) omitted (1.4.2023) by virtue of [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(6)(d)**
- F15** Word in Sch. 6 para. 17(3)(a)(viii) omitted (1.4.2023) by virtue of [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(3)(c), **9(6)(e)**
- F16** Word in Sch. 6 para. 17(3)(a)(ix) inserted (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(3)(c), **9(6)(f)**
- F17** Sch. 6 para. 17(3)(a)(x) inserted (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(3)(c), **9(6)(g)**
- F18** Words in Sch. 6 para. 17(3)(c)(iv) substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), regs. 1(1), **103(5)**

#### Commencement Information

- I135** Sch. 6 para. 17 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Professional standards **E+W**

**18.** An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

#### Commencement Information

- I136** Sch. 6 para. 18 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Inducements **E+W**

**19.—(1)** Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor must give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of them presenting an order for appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a home delivery service is not a “gift or reward” for the purposes of sub-paragraph (1).

(3) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor may accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 11(4) or 12(1)(b), or
- (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 10(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription.

#### Commencement Information

**I137** Sch. 6 para. 19 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Duty to provide information about fitness to practise matters as they arise **E+W**

**20.**—(1) Subject to paragraph 21, an NHS appliance contractor, and where the NHS appliance contractor is a body corporate every director of the body corporate, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS appliance contractor or a director—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,
- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(14)</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992<sup>(15)</sup> (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them;
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness to practise grounds,

and if so, the NHS appliance contractor must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and

<sup>(14)</sup> 1995 c. 46.

<sup>(15)</sup> 1992 c. 5.

approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 21, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate,
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse,
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list, or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness to practise grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

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**Commencement Information**

**I138** Sch. 6 para. 20 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Home Local Health Board of bodies corporate** **E+W**

**21.** Where an NHS appliance contractor is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 20 and 24(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 60). When the NHS appliance contractor provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS appliance contractor is included.

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**Commencement Information**

**I139** Sch. 6 para. 21 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Complaints **E+W**

**22.** An NHS appliance contractor must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

### Commencement Information

**I140** Sch. 6 para. 22 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Directed services **E+W**

**23.** An NHS appliance contractor with whom a Local Health Board makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

### Commencement Information

**I141** Sch. 6 para. 23 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Information to be supplied **E+W**

**24.—(1)** An NHS appliance contractor must give written notice to the Local Health Board on whose pharmaceutical list the NHS appliance contractor is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about the NHS appliance contractor in the pharmaceutical list which the NHS appliance contractor has not otherwise notified to the Local Health Board in accordance with these Regulations,
- (b) in the case of an NHS appliance contractor who is an individual, any change of their private address, and
- (c) in the case of an NHS appliance contractor that is a body corporate, any change to the address of its registered office.

(2) An NHS appliance contractor must give the Local Health Board, if it so requests, the name of any registered pharmacist employed by the NHS appliance contractor who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS appliance contractor that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impractical, as soon as practicable thereafter) of any changes to the names and addresses of its directors.

(4) Subject to sub-paragraph (6), if an NHS appliance contractor that is a body corporate appoints a director or superintendent that was not listed on the NHS appliance contractor's application for inclusion in a pharmaceutical list, the NHS appliance contractor must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS appliance contractor or the director or superintendent of an NHS appliance contractor that is a body corporate must inform the Local Health Board—

- (a) if they, or a body corporate of which they are a director or superintendent, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application, and



- (b) if they become a director or superintendent of a body corporate which is on any of another Local Health Board's NHS performers or providers list, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS appliance contractor is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS appliance contractor also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS appliance contractor is included, or
- (b) to whom the NHS appliance contractor makes an application to be included in its pharmaceutical list, that requests it.

(7) In this paragraph, "NHS performers or providers list" means—

- (a) a pharmaceutical list, or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

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**Commencement Information**

**I142** Sch. 6 para. 24 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Withdrawal from pharmaceutical services** **E+W**

**25.** Where an NHS appliance contractor intends to withdraw from the pharmaceutical list in respect of particular premises, the NHS appliance contractor must notify the Local Health Board of this at least 3 months in advance of that date unless it is impracticable for the NHS appliance contractor to do so in which case the NHS appliance contractor must notify the Local Health Board as soon as it is practicable to do so.

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**Commencement Information**

**I143** Sch. 6 para. 25 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Charges for appliances** **E+W**

**26.** Subject to regulations made under section 121 of the 2006 Act, all appliances provided under these terms of service must be provided free of charge.

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**Commencement Information**

**I144** Sch. 6 para. 26 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Inspections and access to information** **E+W**

**27.—(1)** An NHS appliance contractor must allow persons authorised in writing by the Local Health Board to enter and inspect any premises the NHS appliance contractor uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS appliance contractor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
  - (i) the provision made by the NHS appliance contractor, in the course of providing pharmaceutical services, for patient care and treatment including any arrangement made with a person in respect of provision of appliances, and
  - (ii) the management by the NHS appliance contractor of the pharmaceutical services they provide, where the conditions in sub-paragraph (2) are satisfied.
- (2) The conditions are that—
  - (a) reasonable notice of the intended entry has been given,
  - (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the NHS appliance contractor,
  - (c) the person authorised in writing carries written evidence of their authorisation, which they produce on request, and
  - (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.
- (3) An NHS appliance contractor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow access to any information which the Local Health Board or that person reasonably requires—
  - (a) for the purposes mentioned in sub-paragraph (1), or
  - (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

**Commencement Information**

**I145** Sch. 6 para. 27 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Welsh language** **E+W**

**28.**—(1) Where an NHS appliance contractor provides pharmaceutical services through the medium of Welsh, the NHS appliance contractor must notify the Local Health Board on whose pharmaceutical list the NHS appliance contractor is included, in writing.

(2) An NHS appliance contractor must make available a Welsh language version of any document or form for use by patients and/or members of the public, provided by the Local Health Board.

(3) Where an NHS appliance contractor displays a new sign or notice in connection with pharmaceutical services, the text on the sign or notice must be in English and Welsh, and an NHS appliance contractor may utilise the translation service offered by the Local Health Board for this purpose.

(4) An NHS appliance contractor must encourage the wearing of a badge, provided by the Local Health Board, by those delivering pharmaceutical services who are Welsh speaking, to convey that they are able to speak Welsh.

(5) An NHS appliance contractor must encourage those delivering pharmaceutical services to utilise information and/or attend training courses and events provided by the Local Health Board, so that they can develop—

- (a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and

- (b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.
- (6) An NHS appliance contractor must encourage those delivering pharmaceutical services to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

**Commencement Information**

**I146** Sch. 6 para. 28 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

SCHEDULE 7 **E+W**

Regulation 12

Terms of service for doctors providing pharmaceutical services

**Interpretation** **E+W**

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the doctor has that prescription in their possession, and
- (b) that person presents, or the doctor has in their possession, an associated batch issue.

**Commencement Information**

**I147** Sch. 7 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

**Incorporation of provisions** **E+W**

2. Any provisions of the following affecting the rights and obligations of doctors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations,
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services),
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
  - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and
  - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board<sup>[F19]</sup>.

<sup>F20</sup>(d) .....

**Textual Amendments**

**F19** Sch. 7 para. 2(c)(ii): full stop 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(7)(a)**

**F20** Sch. 7 para. 2(d) omitted (1.4.2023) by virtue of [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(7)(b)**

#### Commencement Information

**I148** Sch. 7 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

[<sup>F21</sup>**2A.** Code of practice on access to premises

A doctor who provides pharmaceutical services must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act).]

#### Textual Amendments

**F21** Sch. 7 para. 2A inserted (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(3)(d), **9(7)(c)**

### Persons duly authorised to dispense on behalf of dispensing doctors **E+W**

3. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which they have duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement, and
- (b) that dispensing doctor must secure compliance with that requirement by that other person,

and references in this Schedule to a dispensing doctor are to be construed accordingly.

#### Commencement Information

**I149** Sch. 7 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Dispensing of drugs and appliances ordered by another prescriber **E+W**

4.—(1) Subject to the following provisions of this Schedule, where any person presents to a dispensing doctor a prescription form which contains—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor,
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by a prescriber other than the dispensing doctor, and including the reference “SLS”, or
- (c) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor and including the reference “SLS”,

and the dispensing doctor is authorised or required by virtue of regulation 26 (arrangements for the provision of pharmaceutical services by doctors) of these Regulations to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so

ordered, and such of the appliances so ordered as they supply in the normal course of their practice or business.

- (2) Subject to the following provisions of this Schedule, where—
- (a) any person presents to a dispensing doctor a non-electronic repeatable prescription which contains—
- (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under those Regulations), signed by a prescriber other than the dispensing doctor who is a repeatable prescriber,
  - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference “SLS”,
  - (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, or
  - (iv) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference “SLS”,
- and also presents a batch issue, or
- (b) the dispensing doctor receives an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—
- (i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or
  - (ii) the dispensing doctor has previously arranged with the patient that they will dispense that repeatable prescription on receipt,

and the dispensing doctor is authorised or required by regulation 26 to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as they supply in the normal course of their practice or business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances will be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the dispensing doctor has that prescription in their possession, and
- (b) that person presents, or the dispensing doctor has in their possession, an associated batch issue.

(4) Drugs and listed appliances provided under this paragraph must be provided in a suitable container.

#### Commencement Information

**I150** Sch. 7 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Dispensing of drugs and appliances ordered by the dispensing doctor **E+W**

**5.** In circumstances where paragraph 4 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of Part 6 of these Regulations to provide drugs or appliances to a person, the dispensing doctor must—

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (a) record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with a GMS contract which gives effect to <sup>F22</sup>paragraphs 49 and 50 of Schedule 3] to the GMS Regulations (other contract terms: prescribing),
- (b) provide those drugs or appliances in a suitable container,
- (c) provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph <sup>F23</sup><sup>F24</sup>55] of Schedule 3] to the GMS Regulations (restrictions on prescribing by medical practitioners) are satisfied, and
- (d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

#### Textual Amendments

- F22** Words in Sch. 7 para. 5(a) substituted (1.10.2023) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) Regulations 2023 \(S.I. 2023/953\)](#), reg. 1(2), **Sch. 5 para. 2(3)(a)(i)** (as amended by [S.I. 2023/1421](#), regs. 1, 20(f)(i))
- F23** Words in Sch. 7 para. 5(c) substituted (1.10.2023) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) Regulations 2023 \(S.I. 2023/953\)](#), reg. 1(2), **Sch. 5 para. 2(3)(a)(ii)**
- F24** Word in Sch. 7 para. 5(c) substituted (11.1.2024) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) \(Amendment\) Regulations 2023 \(S.I. 2023/1421\)](#), regs. 1, **23(3)(a)**

#### Commencement Information

- I151** Sch. 7 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Preliminary matters before providing ordered drugs or appliances **E+W**

**6.** Before providing drugs or listed appliances recorded on a prescription form in accordance with paragraph 4, or in the circumstances set out in paragraph 7—

- (a) the dispensing doctor must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations (supply of drugs and appliances by doctors) by virtue of either—
  - (i) entitlement to an exemption under regulation 8(1) of the Charges Regulations (exemptions), or
  - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),
 to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of remission by virtue of regulation 5(1)(e) or 5(2)(e) or (f) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor already has such evidence available to them, and
- (b) if no satisfactory evidence, as required by sub-paragraph (a) is produced to the dispensing doctor, the dispensing doctor must endorse the form on which the declaration is made to that effect.

#### Commencement Information

- I152** Sch. 7 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Provision of Scheduled drugs **E+W**

7.—(1) Subject to sub-paragraph (2), a dispensing doctor must not provide for a patient any Scheduled drug, except that, where the dispensing doctor or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, they may provide a drug which has the same specification notwithstanding that it is a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this Schedule prevents a dispensing doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

### Commencement Information

**I153** Sch. 7 para. 7 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## Refusal to provide drugs or appliances ordered **E+W**

8.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example, because the dispensing doctor reasonably believes that it has been stolen or forged), or
- (b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber), or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which they are otherwise authorised or required to provide by virtue of regulation 26, where—

- (a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription or repeatable prescription, or by any person accompanying that person, or
- (b) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) A dispensing doctor must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the dispensing doctor has no record of that prescription,
- (b) it is not signed by a repeatable prescriber,
- (c) to do so would not be in accordance with any intervals specified in the prescription,
- (d) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously,
- (e) if the repeatable prescription was signed more than 1 year previously,
- (f) the expiry date on the repeatable prescription has passed, or
- (g) where the dispensing doctor has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where the patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), a dispensing doctor may only provide the drugs or appliances ordered if satisfied—

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (a) that the patient to whom the prescription relates—
  - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
  - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient’s treatment,
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way that indicates the need or desirability of reviewing the patient’s treatment, and
- (c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient’s treatment.

#### Commencement Information

**I154** Sch. 7 para. 8 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Fees and charges **E+W**

9.—(1) The terms of a GMS contract giving effect to [<sup>F25</sup>regulations 21 and 22 of] the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in relation to prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services or provides any additional service associated with the dispensing of such drugs and appliances—

- (a) in accordance with this Schedule or an agreement with the Local Health Board, and
- (b) had the drug, appliance or additional service been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled by, by virtue of directions given by the Welsh Ministers under section 45 of the 2006 Act (GMS contracts: payments), to a payment—
  - (i) in respect of the drug or appliance, or
  - (ii) in respect of the additional service provision,

the Local Health Board will credit the dispensing doctor with the payment.

#### Textual Amendments

**F25** Words in Sch. 7 para. 9(1) substituted (1.10.2023) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) Regulations 2023 \(S.I. 2023/953\)](#), [reg. 1\(2\)](#), [Sch. 5 para. 2\(3\)\(b\)](#)

#### Commencement Information

**I155** Sch. 7 para. 9 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Complaints and concerns **E+W**

10.—(1) Where a dispensing doctor—

- (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to [<sup>F26</sup>paragraph [<sup>F27</sup>101] of Schedule 3] to the GMS Regulations (concerns and complaints);
- (b) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;



- (c) is employed or engaged by a Local Health Board for the purposes of providing pharmaceutical services within an LHBMS practice, the complaints procedure established by that LHBMS practice to deal with complaints in relation to the provision of primary medical services,

applies in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, a GMS contract which gives effect to [F28[F29 102] of Schedule 3] to the GMS Regulations (co-operation with investigations) also applies in relation to complaints or concerns notified about such matters.

#### Textual Amendments

- F26** Words in Sch. 7 para. 10(1)(a) substituted (1.10.2023) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) Regulations 2023 \(S.I. 2023/953\)](#), reg. 1(2), **Sch. 5 para. 2(3)(c)(i)**
- F27** Word in Sch. 7 para. 10(1)(a) substituted (11.1.2024) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) \(Amendment\) Regulations 2023 \(S.I. 2023/1421\)](#), regs. 1, **23(3)(b)(i)**
- F28** Words in Sch. 7 para. 10(2) substituted (1.10.2023) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) Regulations 2023 \(S.I. 2023/953\)](#), reg. 1(2), **Sch. 5 para. 2(3)(c)(ii)**
- F29** Word in Sch. 7 para. 10(2) substituted (11.1.2024) by [The National Health Service \(General Medical Services Contracts\) \(Wales\) \(Amendment\) Regulations 2023 \(S.I. 2023/1421\)](#), regs. 1, **23(3)(b)(ii)**

#### Commencement Information

- I156** Sch. 7 para. 10 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Inspections and access to information **E+W**

**11.**—(1) A dispensing doctor must allow persons authorised by the Local Health Board to enter and inspect any premises that they use for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
- (i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and
- (ii) the management by the dispensing doctor of the pharmaceutical services the dispensing doctor provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given,
- (b) the Local Medical Committee for the area in which the premises are situated has been invited to be present at the inspection, where this is requested by the dispensing doctor,
- (c) the person authorised in writing carries written evidence of their authorisation, which must be produced on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or that person access to any information which it or that person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1), or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

#### Commencement Information

**I157** Sch. 7 para. 11 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

#### Welsh language **E+W**

**12.**—(1) Where a dispensing doctor provides pharmaceutical services through the medium of Welsh, the dispensing doctor must notify the Local Health Board in writing.

(2) A dispensing doctor must make available a Welsh language version of any document or form for use by patients and/or members of the public, provided by the Local Health Board.

(3) Where a dispensing doctor displays a new sign or notice in connection with pharmaceutical services, the text on the sign or notice must be in English and Welsh, and a dispensing doctor may utilise the translation service offered by the Local Health Board for this purpose.

(4) Where a dispensing doctor is Welsh speaking, they are encouraged to wear a badge provided by the Local Health Board, to convey that the dispensing doctor is able to speak Welsh.

(5) A dispensing doctor is encouraged to utilise information and/or attend training courses and events provided by the Local Health Board, so that the dispensing doctor can develop—

- (a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and
- (b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.

(6) When delivering pharmaceutical services, a dispensing doctor is encouraged to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

#### Commencement Information

**I158** Sch. 7 para. 12 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

## SCHEDULE 8 **E+W**

Regulation 64

### Minor and consequential amendments

#### The National Health Service (Service Committees and Tribunal) Regulations 1992 **E+W**

**1.** In regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**16**) (interpretation)—

(16) [S.I. 1992/664.](#)

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

- (a) in paragraph (1), in the definition of “Pharmaceutical Regulations”, for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”, and
- (b) in paragraph (4)(c)(17), for “paragraph 33 of Schedule 4 to, or paragraph 21 of Schedule 5 to” substitute “paragraph 33 of Schedule 5 to, or paragraph 22 of Schedule 6 to”.

**Commencement Information**

**I159** Sch. 8 para. 1 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

**The National Health Service (Indicative Amounts) Regulations 1997** **E+W**

**2.** In regulation 1(2) of the National Health Service (Indicative Amounts) Regulations 1997 (citation, commencement and interpretation)(18), in the definition of “Drug Tariff”, for “regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

**Commencement Information**

**I160** Sch. 8 para. 2 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

**The National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001** **E+W**

**3.** In regulation 2 (prescribed functions of Health Authorities in Wales) of the National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001(19), in paragraph (2)(d)(20), for “regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

**Commencement Information**

**I161** Sch. 8 para. 3 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

**The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004** **E+W**

**4.—(1)** The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(21) are amended in accordance with this paragraph.

(2) In regulation 2(1) (interpretation)—

- (a) in the definition of “Drug Tariff”, for “regulation 41” substitute “regulation 55”, and

(17) Paragraph (4) was inserted by [S.I. 1996/703](#).

(18) [S.I. 1997/980](#), amended by [S.I. 2007/1112 \(W. 117\)](#).

(19) [S.I. 2001/1543 \(W. 108\)](#), amended by [S.I. 2007/1112 \(W. 117\)](#).

(20) Paragraph (2)(d) was inserted by [S.I. 2013/898 \(W. 102\)](#).

(21) [S.I. 2004/478 \(W. 48\)](#).

**Changes to legislation:** There are currently no known outstanding effects for the *The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020*. (See end of Document for details)

- (b) in the definition of “Pharmaceutical Regulations”, for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.
- (3) In Schedule 6 (other contractual terms)—
- (a) in paragraph 47 (provision of dispensing services)—
- (i) in sub-paragraphs (4)(b) and (9)(a), for “paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or paragraph 8(3) of Schedule 3 to”, in each place it occurs, substitute “paragraph 6 of Schedule 3, paragraph 13 of Schedule 3 or paragraph 8(3) of Schedule 4 to”, and
- (ii) in sub-paragraph (9)(b)(ii), for “Part 2 of Schedule 3 to” substitute “Part 2 of Schedule 4 to”,
- (b) in paragraph 48 (consent to dispense)—
- (i) in sub-paragraph (2)—
- (aa) for “regulation 24 of and Part 3 of Schedule 2 to” substitute “regulation 30 of, and Part 3 of Schedule 3 to,”, and
- (bb) for “regulation 24” substitute “regulation 30”,
- (ii) in sub-paragraph (4), for “regulation 24(9)” substitute “regulation 30(9)”,
- (iii) for sub-paragraph (5) substitute—
- “(5) Regulation 30 of the Pharmaceutical Regulations will apply as if modified as follows: in paragraph (1), for “to provide pharmaceutical services to patients under regulation 26(1)(b) or (c) (arrangements for the provision of pharmaceutical services by doctors)” there were substituted a reference to the provision of dispensing services to patients under paragraph 47.”, and
- (iv) for sub-paragraph (6) substitute—
- “(6) Part 3 of Schedule 3 to the Pharmaceutical Regulations will apply as if modified as follows: in paragraph 8(1)(a)(ii), for “dispensing doctor list made under Part 6 of these Regulations” there were substituted a reference to an application under sub-paragraph (1) of this paragraph.”, and
- (c) in paragraph 49(8)(22) (terms relating to the provision of dispensing services), in the words before paragraph (a), for “Schedule 6” substitute “Schedule 7”.

#### Commencement Information

**I162** Sch. 8 para. 4 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

### The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 **E+W**

5. In regulation 2(1) of the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(23), in the definition of “Drug Tariff”, for “regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)” substitute “regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)”.

(22) Sub-paragraph (8) was substituted by [S.I. 2013/898 \(W. 102\)](#).

(23) [S.I. 2007/121 \(W. 11\)](#). The definition of “Drug Tariff” was substituted by [S.I. 2007/1112 \(W. 117\)](#) and further amended by [S.I. 2013/898 \(W. 102\)](#).

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

**Commencement Information**

**I163** Sch. 8 para. 5 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

**The Single Use Carrier Bags Charge (Wales) Regulations 2010** **E+W**

**6.** In paragraph 1(3) of Schedule 1 to the Single Use Carrier Bags Charge (Wales) Regulations 2010(**24**), in the definitions of—

- (a) “independent nurse prescriber”,
- (b) “paramedic independent prescriber”,
- (c) “physiotherapist independent prescriber”,
- (d) “podiatrist or chiropodist independent prescriber”, and
- (e) “therapeutic radiographer independent prescriber”,

for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

**Commencement Information**

**I164** Sch. 8 para. 6 in force at 1.10.2020, see [reg. 1\(2\)\(c\)](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.