#### SCHEDULE 4

Regulation 11(1)(a)(i)

Terms of service of NHS pharmacists

# PART 1

# General

## Responsibilities of NHS pharmacists and pharmacy staff

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

- (a) if the NHS pharmacist is a registered pharmacist—
  - (i) that NHS pharmacist must comply with that requirement, or
  - (ii) if the NHS pharmacist employs or engages natural persons in connection with the provision of pharmaceutical services, the NHS pharmacist must either comply with that requirement or secure compliance with that requirement by—
    - (aa) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or
    - (bb) in other cases, by the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services; or
- (b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—
  - (i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or
  - (ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.
- (2) Where in this Schedule reference is made to an NHS pharmacist—
  - (a) being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or
  - (b) forming a view,

that reference is to be construed as a referring, as appropriate, to the NHS pharmacist (if a natural person) or to the NHS pharmacist's staff.

(3) References in this Schedule to an NHS pharmacist are to be construed in accordance with sub-paragraphs (1) and (2).

#### Breaches by directors and superintendents

**2.** Where this Schedule imposes a requirement on the director or superintendent of a body corporate that is on a pharmaceutical list, a breach of that requirement is to be deemed to be a breach by the body corporate of its terms of service.

# PART 2

# Essential services

### **Essential services**

- 3. For the purposes of these Regulations, "essential services" means-
  - (a) the services described in this Part; and
  - (b) the activities described in this Part to be carried out in connection with those services.

#### **Dispensing services**

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 prescriptions for drugs or appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

# Dispensing of drugs and appliances

- 5.—(1) In this Part, "signed" includes signature with a prescriber's advanced electronic signature.
- (2) Subject to the following provisions of this Part, where-
  - (a) any person presents to an NHS Pharmacist (P) a non-electronic prescription form which contains—
    - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,
    - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations <sup>MI</sup> (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or
    - (iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; <sup>F1</sup>...
  - (b) subject to sub-paragraph (4), P receives [<sup>F2</sup>as a nominated dispensing contractor] from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—
    - (i) any person requests the provision of drugs or appliances in accordance with that prescription, or
    - (ii) P has previously arranged with the patient that P will dispense that prescription on receipt[<sup>F3</sup>; or]
- [<sup>F4</sup>(c) any person—
  - (i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and
  - (ii) requests the provision of drugs or appliances in accordance with the related electronic prescription form,]

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

- (3) Subject to the following provisions of this Part, where-
  - (a) any person presents to P 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 <sup>M2</sup>, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 <sup>M3</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a 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 and including the reference "SLS",
- (iii) an order for appliances, not being restricted availability appliances, signed by a prescriber, or
- (iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference "SLS",

and also presents an associated batch issue; <sup>F5</sup>...

- (b) P receives [<sup>F6</sup>as a nominated dispensing contractor] from the Electronic Prescription Service 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) P has previously arranged with the patient that P will dispense that repeatable prescription on receipt[<sup>F7</sup>; or]
- [<sup>F8</sup>(c) any person—
  - (i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and
  - (ii) requests the provision of drugs or appliances in accordance with the related electronic repeatable prescription,]

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

(4) P must not provide under an electronic prescription form 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 [<sup>F9</sup>Schedules 2 to 5] to the Misuse of Drugs Regulations 2001.

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

- (a) P has that prescription in P's possession; and
- (b) that person presents, or P has in P's possession, an associated batch issue.

**F1** Word in Sch. 4 para. 5(2)(a) omitted (26.11.2018) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2)(a)(i)

<sup>F2 Words in Sch. 4 para. 5(2)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2) (a)(ii)</sup> 

- F3 Word in Sch. 4 para. 5(2)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2) (a)(iii)
- F4 Sch. 4 para. 5(2)(c) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2)(a)(iv)
- F5 Word in Sch. 4 para. 5(3)(a) omitted (26.11.2018) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2)(b)(i)
- F6 Words in Sch. 4 para. 5(3)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2) (b)(ii)
- F7 Word in Sch. 4 para. 5(3)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(2) (b)(iii)
- **F8** Sch. 4 para. 5(3)(c) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **7(2)(b)(iv)**
- **F9** Words in Sch. 4 para. 5(4) substituted (1.7.2015) by The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015 (S.I. 2015/915), regs. 1, **4(2)**

#### **Marginal Citations**

- M1 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.
- M2 1971 c.38; see section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.
- M3 S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

# [<sup>F10</sup>Supply in accordance with a SSP

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

- (a) any person requests a drug or appliance from an NHS pharmacist (P) 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
  - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, P 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, P 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) P 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 his or her 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 P, 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 thus 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 Secretary of State and the person who is, for the time being, the person consulted under section 165(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 its patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

P 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 his or her 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) P 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(2) and (3) are to be read as requirements to act within a reasonable timescale.]

F10 Sch. 4 para. 5A inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(2)

# [<sup>F11</sup>Supply in accordance with a PTP [<sup>F12</sup>or a PTPGD]

5B.—(1) Subject to the following provisions of this Part, where—

- (a) an NHS Pharmacist (P) receives, via a secure service approved by the NHSCB for this purpose, an electronic message that amounts to an order for the supply of a drug in accordance with a PTP [<sup>F13</sup> or a PTPGD]; and
- (b) a person who is entitled to be supplied with that drug in pursuance of that order requests the provision of the drug in accordance with that order,

P must, with reasonable promptness, provide the drug so ordered.

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<sup>F14</sup>(1A) Where P considers—

- (a) on the basis of a request for the supply of a drug in accordance with a PTP or a PTPGD that has been approved by the NHSCB as a basis for supply as part of pharmaceutical services;
- (b) having made the appropriate checks; and
- (c) having regard to what is reasonable and appropriate,

that a person is entitled to be supplied with the drug in accordance with the PTP or PTPGD as part of pharmaceutical services, P must, with reasonable promptness, provide the drug requested.]

(2) If a person who is entitled as mentioned in sub-paragraph (1)(b) [<sup>F15</sup>or (1A)] asks P to do so—

- (a) P must give an estimate of the time when the drug will be ready; and
- (b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready).

<sup>F16</sup>(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the drug (whether by P or otherwise) ordered pursuant to the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug ordered in accordance with such a PTP or PTPGD.

(4) Sub-paragraph (1A) does not apply where arrangements are in place for the provision of the drug (whether by P or otherwise) requested in accordance with the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug requested in accordance with such a PTP or PTPGD.]]

- F11 Sch. 4 para. 5B inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **6**
- **F12** Words in Sch. 4 para. 5B heading inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(2)(c)**
- **F13** Words in Sch. 4 para. 5B(1)(a) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(2)(a)**
- **F14** Sch. 4 para. 5B(1A) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(2)(b)**
- **F15** Words in Sch. 4 para. 5B(2) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(2)(c)**
- F16 Sch. 4 para. 5B(3)(4) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), 7(2)

# [<sup>F17</sup>Supply in accordance with a LPIV

5C.—(1) Subject to the following provisions of this Part, where—

- (a) an NHS Pharmacist (P) receives a LPIV; and
- (b) a person who is entitled to be supplied by P with a prescription item ordered on the LPIV requests the provision of the item in accordance with that LPIV,

P must, with reasonable promptness, provide the prescription item so ordered.

- (2) If a person who is entitled as mentioned in sub-paragraph (1)(b) asks P to do so—
  - (a) P must give an estimate of the time when the prescription item will be ready; and

(b) if they are not ready by then, P must give a revised estimate of the time when the item will be ready (until it is ready).

(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the item (whether by P or otherwise) ordered on the LPIV as part of a directed service which includes arrangements for the provision of such an item ordered on such a LPIV.]

**F17** Sch. 4 para. 5C inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), **7(3**)

## Urgent supply without a prescription

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

(2) P 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 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to-
  - (i) give P 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) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

## Preliminary matters before providing ordered drugs or appliances

7.—(1) If a person specified in sub-paragraph (2) asks an NHS pharmacist (P) to do so—

- (a) P must give an estimate of the time when the drugs or appliances will be ready; and
- (b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are 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 drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, P must ask any person who makes [<sup>F18</sup>or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription] that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) [<sup>F19</sup>or (2)] of the Charges Regulations <sup>M4</sup> (supply of drugs and appliances by chemists) by virtue of either—

(a) entitlement to exemption under [<sup>F20</sup>regulation 10(1)] of the Charges Regulations <sup>M5</sup> (exemptions); or

(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations <sup>M6</sup> (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 sub-paragraph (a), (c), (d), (e), (f) or (g) of [<sup>F20</sup>regulation 10(1)] 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 P already has such evidence available to P.

 $[^{F21}(3ZA)$  For the purposes of sub-paragraph (3), satisfactory evidence includes evidence derived from a check, known as a real time exemption check, of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under the Charges Regulations.]

 $[^{F22}(3A)$  In any case where no satisfactory evidence, as required by sub-paragraph (3), is produced to P, P must ensure before the drugs or appliances are provided that the person who was asked to produce that evidence is advised, in appropriate terms, that checks are routinely undertaken to ascertain entitlement to—

- (a) exemption under the Charges Regulations; or
- (b) remission of charges under the Remission of Charges Regulations,

where such entitlement has been claimed, as part of the arrangements for preventing or detecting fraud or error in relation to such claims.]

(4) If, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (3), is produced to P, P shall endorse the form on which the declaration is made to that effect.

(5) In the case of an electronic prescription, P must [<sup>F23</sup>ensure that the following information is duly entered into the records managed by [<sup>F24</sup>NHS England] that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (3))]—

- (a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—
  - (i) the exemption category specified in [<sup>F20</sup>regulation 10(1)] of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and
  - (ii) whether or not satisfactory evidence was produced to P as required by subparagraph (3);
- (b) in any case where a charge is due, confirmation that the relevant charge was paid; and
- (c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

[ $^{F25}(6)$  Sub-paragraphs (3) to (5) apply to the provision of a drug or appliance in accordance with a SSP as they apply 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 5A(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).]

**F18** Words in Sch. 4 para. 7(3) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(3)(a)

- F19 Words in Sch. 4 para. 7(3) substituted (1.4.2015) by The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570), reg. 1, Sch. 2 para. 5(4)(a)
- **F20** Words in Sch. 4 para. 7 substituted (1.4.2015) by The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570), reg. 1, Sch. 2 para. 5(4)(b)
- F21 Sch. 4 para. 7(3ZA) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(3)(b)
- F22 Sch. 4 para. 7(3A) inserted (E.) (1.7.2016) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016 (S.I. 2016/296), regs. 1(1)(b), 4(2)
- **F23** Words in Sch. 4 para. 7(5) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(3)(c)
- F24 Words in Sch. 4 para. 7(5) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), Sch. para. 47(3)(a) (with reg. 3)
- F25 Sch. 4 para. 7(6) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(3)

#### **Marginal Citations**

- M4 Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.
- M5 Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
- M6 Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

# Providing ordered drugs or appliances

**8.**—(1) Where an NHS pharmacist (P) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, P must only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); 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 M7 and the following provisions of this Part.

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

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

- (a) who is disqualified from inclusion in a relevant list; or
- (b) who is suspended from the GPhC register.

(4) If the order is for  $[^{F26}$ , 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), P must make all necessary arrangements for a registered pharmacist—

- (a) to measure the person named on the prescription form or repeatable prescription for the appliance; and
- (b) to fit the appliance.

(5) If the order is for  $[F^{27}$ , 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 any relevant standard or formula specified therein.

- (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 <sup>M8</sup> (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quantity, strength or dosage, P (in this context, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care P considers to be appropriate and, subject to sub-paragraph (7), in such quantity as P considers 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, P 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 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by P 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 special container,

P 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) Subject to sub-paragraph (11), where a drug is ordered by a prescriber on a prescription form or a repeatable prescription [<sup>F28</sup>, or is to be provided in accordance with a SSP,] in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a [<sup>F29</sup>UK] marketing authorisation holder for the drug, P must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a [<sup>F29</sup>UK] marketing authorisation holder, unless—

(a) it is not possible for P to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or

(b) it is not practicable for P 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) In the case of oral liquid methadone, P (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

- (a) each dose in a separate container;
- (b) an original pack (or original packs); or
- (c) the oral liquid methadone in some other way,

and P must then provide it in packaging that accords with that decision.

(12) P must only provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription if—

- (a) it is ordered as specified in sub-paragraph (13); or
- (b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations <sup>M9</sup> (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

(13) A Scheduled drug that is a drug with an appropriate non-proprietary name may be provided in response to an order on a prescription form or repeatable prescription for a drug ("the prescribed drug") that is not a Scheduled drug but which has the same non-proprietary name as the Scheduled drug if—

- (a) the prescribed drug is ordered by that non-proprietary name or by its formula;
- (b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and
- (c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

(14) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (13) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(15) P must provide any drug which P is required to provide under paragraph 5  $[^{F30}$  or 5C] $[^{F31}$ , or provides under paragraph 5A  $[^{F32}$  or 5B],] in a suitable container.

 $[^{F33}(16)$  Where P provides a drug or appliance under paragraph 5A, P 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.]

[ $^{F34}(17)$  Sub-paragraphs (5) to (10) apply to the provision of a drug in accordance with [ $^{F35}a$  LPIV,] a PTP [ $^{F36}$ or a PTPGD] as they apply to the provision of a drug in accordance with a prescription form or a repeatable prescription (or an associated batch issue).

(18) Where P provides a drug under paragraph 5B, P must include a dispensing label on the packaging of the product and include in the label (in addition to the particulars required or permitted by Part 2 of Schedule 26 to the Human Medicines Regulations 2012), for the patient's benefit, information to the effect that the product is being supplied in accordance with a PTP [<sup>F37</sup> or a PTPGD], identifying the particular PTP [<sup>F38</sup> or PTPGD].]

**F26** Words in Sch. 4 para. 8(4) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(4)(a)

**F27** Words in Sch. 4 para. 8(5) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(4)(b)

**F28** Words in Sch. 4 para. 8(10) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(4)(c)

- **F29** Word in Sch. 4 para. 8(10) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, Sch. 8 para. 11(2); 2020 c. 1, Sch. 5 para. 1(1)
- **F30** Words in Sch. 4 para. 8(15) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), 7(4)(a)
- **F31** Words in Sch. 4 para. 8(15) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(4)(d)
- **F32** Words in Sch. 4 para. 8(15) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 7(a)
- **F33** Sch. 4 para. 8(16) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(4)(e)
- F34 Sch. 4 para. 8(17)(18) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 7(b)
- **F35** Words in Sch. 4 para. 8(17) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), 7(4)(b)
- **F36** Words in Sch. 4 para. 8(17) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(3)(a)**
- **F37** Words in Sch. 4 para. 8(18) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(3)(b)(i)**
- **F38** Words in Sch. 4 para. 8(18) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(3)(b)(ii)**

#### **Marginal Citations**

- M7 1985 c.72.
- M8 S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.
- M9 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

# Refusal to provide drugs or appliances ordered

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

- (a) P reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because P reasonably believes it has been stolen or forged);
- (b) it appears to P 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 drugs or appliances would be contrary to P's (in practice, a registered pharmacist's) clinical judgement;
- (c) P or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;
- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or

a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or

- (e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—
  - (i) the remuneration of persons providing pharmaceutical services, and
  - (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless P (or the person who employs or engages P) is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) P 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.

 $[^{F39}(2A)$  P may refuse to provide a drug or appliance ordered on an electronic prescription if the access that P has to the Electronic Prescription Service is not such as to enable P to dispense that prescription promptly (or at all)  $[^{F40}$ , but where P does so, P must take all reasonable steps to ensure that the product ordered by the prescriber is supplied within a reasonable timescale, which may include (depending on what steps or combination of steps the circumstances require)—

- (a) providing details of other NHS pharmacists or LPS chemists whose premises are situated in the same area and who may be able to provide the product ordered by the prescriber;
- (b) urgent supply without a prescription in accordance with paragraph 6;
- (c) arranging for the urgent provision of a non-electronic prescription form by the prescriber.]]

 $[^{F41}(2B)$  P 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.

(2C) P 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 his or her 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) P is unable to provide the drug or appliance within a reasonable timescale,

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

- (3) P must refuse to provide drugs or appliances ordered on a repeatable prescription where—
  - (a) P has no record of that prescription (other than on the first occasion on which the prescription is presented);

- (b) P does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to P;
- (c) it is not signed by a 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 (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) P has been informed by the prescriber that the prescription is no longer required.

(4) Where a 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), P must only provide the drugs or appliances ordered if P is satisfied—

- (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, or 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.

 $[^{F42}(5)$  P may refuse to  $[^{F43}$  fulfil an order or a request] for a drug that is or is purportedly in accordance with  $[^{F44}a LPIV]$  a PTP  $[^{F45}or a PTPGD]$  where—

- (a) P reasonably believes it is not a genuine order [ $^{F46}$  or valid request] for the person who requests, or on whose behalf is requested, the provision of the drug;
- (b) providing it would be contrary to P's clinical judgement;
- (c) P or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying that person; or
- (d) the person who requests the provision of the drug, or any person accompanying that person, commits or threatens to commit a criminal offence.

(6) P must refuse to provide, pursuant to  $[^{F47}a \text{ LPIV},]$  a PTP  $[^{F48}\text{ or a PTPGD}]$ , an order  $[^{F49}\text{ or a request}]$  for a drug that is or is purportedly in accordance with  $[^{F50}\text{ the LPIV},]$  the PTP  $[^{F51}\text{ or PTPGD}]$  where P is not satisfied that it is in accordance with  $[^{F50}\text{ the LPIV},]$  the PTP  $[^{F51}\text{ or PTPGD}]$ .]

 $[^{F52}(7)$  P may refuse to provide a prescription item ordered on a prescription form or repeatable prescription where—

- (a) more than one prescription item has been ordered on the prescription form or repeatable prescription;
- (b) at least one of those prescription items is a listed HRT prescription item and at least one of those prescription items is not; and
- (c) the person named on the prescription form or repeatable prescription is claiming entitlement to exemption under regulation 10(1)(j) of the Charges Regulations

(exemptions) in respect of any of those prescription items which is a listed HRT prescription item.]

- **F39** Sch. 4 para. 9(2A) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(4)
- F40 Words in Sch. 4 para. 9(2A) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 8(a)
- F41 Sch. 4 para. 9(2B)(2C) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, 4(5)
- F42 Sch. 4 para. 9(5)(6) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 8(b)
- **F43** Words in Sch. 4 para. 9(5) substituted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(4)(a)(i)**
- **F44** Words in Sch. 4 para. 9(5) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), **7(5)(a)**
- **F45** Words in Sch. 4 para. 9(5) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(4)(a)(ii)**
- **F46** Words in Sch. 4 para. 9(5)(a) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(4)(a)(iii)**
- F47 Words in Sch. 4 para. 9(6) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), 7(5)(b)(i)
- F48 Words in Sch. 4 para. 9(6) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), 3(4)(b)(i)
- **F49** Words in Sch. 4 para. 9(6) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(4)(b)(ii)**
- **F50** Words in Sch. 4 para. 9(6) inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), **7(5)(b)(ii)**
- **F51** Words in Sch. 4 para. 9(6) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **3(4)(b)(iii)**
- **F52** Sch. 4 para. 9(7) inserted (1.4.2023) by The National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023 (S.I. 2023/171), regs. 1(1), **3**

#### Further activities to be carried out in connection with the provision of dispensing services

**10.**—(1) In connection with the services provided under paragraph 4, an NHS pharmacist (P) 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 patients to whom they provide drugs or appliances on-
  - (i) the safe keeping of the drugs or appliances, and
  - (ii) returning unwanted drugs or appliances to the pharmacy premises 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;
- [<sup>F53</sup>(da) ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—
  - (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and
  - (ii) requires regular medicine in respect of that medical condition,

including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on;]

- (e) provide a patient with a written note [<sup>F54</sup>(which may be in an electronic form)] of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;
- (f) keep and maintain records-
  - (i) of drugs and 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 sub-paragraph (e);
- <sup>F55</sup>(g) .....
  - (h) if P takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;
  - (i) if P provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can 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 drugs or appliances—
    - (i) which are not required, or

(ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;

- ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b),
   (2), (3) or (4), the patient is referred back to the prescriber for further advice;
- (m) 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;
- (n) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);
- (o) when providing appliances, provide a patient with a written note of P's name, address and telephone number; and
- (p) 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 the dispensing services under paragraph 4, P is unable [ $^{F56}$ (having regard to any relevant SSP)] to provide an appliance, or stoma appliance customisation is required and P is unable to provide that, P shall—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 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 P.
- **F53** Sch. 4 para. 10(1)(da) inserted (1.3.2015) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015 (S.I. 2015/58), regs. 1(1), **8(2)** (with reg. 10)
- **F54** Words in Sch. 4 para. 10(1)(e) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **9(a)**
- **F55** Sch. 4 para. 10(1)(g) omitted (9.11.2020) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **9(b)**
- **F56** Words in Sch. 4 para. 10(2) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **4(6)**

#### Additional requirements in relation to electronic prescribing

11.—(1) An NHS pharmacist (P) must, if requested to do so by any person—

 $^{F57}(a)$  ....

- (b) where the Electronic Prescription Service is [<sup>F58</sup>temporarily unavailable] through P's pharmacy premises, provide that person with contact details of at least 2 NHS pharmacists in the area at whose premises the service is available, if these details are known to P.
- (2) <sup>F59</sup>... P must, if requested to do so by any person, enter in that person's PDS patient details—
  - (a) where the person does not have a nominated dispensing contractor, [<sup>F60</sup>a nominated dispensing contractor]; or
  - (b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) Regulation 116(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

(5) If P is a nominated dispensing contractor for a person (X) but the nomination was made before P became the person listed in a pharmaceutical list in relation to the pharmacy premises nominated in X's PDS patient details, P must within 6 months of P becoming the person so listed—

- (a) explain to X that the ownership of the pharmacy premises has changed; and
- (b) ask X whether X wishes to maintain the nomination in respect of those pharmacy premises.

 $[^{F61}(6)$  If P dispenses an electronic prescription or makes an urgent supply without a prescription, P must send the form duly completed by or on behalf of the patient, if one is required under regulation 3(3)(b) or (c), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.]

- **F57** Sch. 4 para. 11(1)(a) omitted (9.11.2020) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **10(a)(i)**
- **F58** Words in Sch. 4 para. 11(1)(b) substituted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **10(a)(ii)**
- F59 Words in Sch. 4 para. 11(2) omitted (9.11.2020) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 10(b)
- F60 Words in Sch. 4 para. 11(2)(a) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 7(5)(a)
- **F61** Sch. 4 para. 11(6) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **7(5)(b)**

#### Additional requirements in relation to specified appliances

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

(2) An NHS pharmacist (P) 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) P 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 subparagraph (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), P 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 P 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 P is unable to provide an appliance use review service in accordance with sub-paragraph (3) (b)(ii), P must give the patient the contact details of at least 2 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 P.

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

- (a) advice is made available to patients through that telephone care line; or
- (b) [<sup>F62</sup>telephone or website contact details for providers of NHS services that may be consulted for advice regarding specified appliances during those periods], are made available to patients through that telephone care line.
- (6) For the purposes of this paragraph—

"expert clinical advice", 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", in relation to pharmacy premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

F62 Words in Sch. 4 para. 12(5)(b) substituted (1.4.2014) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 (S.I. 2014/417), regs. 1, 18

# Disposal service in respect of unwanted drugs

**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 presented to the NHS pharmacist for disposal.

# Basic procedure in respect of unwanted drugs

**14.**—(1) Subject to paragraph (2), where a person presents to an NHS pharmacist (P) any drugs provided for a patient in, and which have been kept in—

- (a) a private household; or
- (b) a children's home; or
- (c) a residential care home, that is to say an establishment which exists wholly or mainly for the provision of residential accommodation, together with board and personal care, for persons in need of personal care because of—
  - (i) old age,
  - (ii) mental or physical disability,
  - (iii) past or present dependence on alcohol or drugs,
  - (iv) any past illnesses, or

(v) past or present mental disorder,

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

(2) P is not required to accept any drugs for disposal unless the NHSCB has made arrangements for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, P must—

- (a) where required to do so by the NHSCB or by a waste disposal contractor retained by the NHSCB, separate solid drugs or ampoules, liquids and aerosols from each other;
- (b) store the drugs in containers provided by the NHSCB, or by a waste disposal contractor retained by the NHSCB, 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 shall co-operate with any suitable arrangements that the NHSCB has in place for regular collection of the drugs from P's pharmacy premises by or on behalf of the NHSCB.

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

15. In connection with the services provided under paragraph 13, an NHS pharmacist (P) must—

- (a) ensure that P (including P's staff) is 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 P (including P's staff) has readily available, and close to any place where waste drugs are stored, appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

# **Promotion of healthy lifestyles**

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.

## **Prescription linked intervention**

17.—(1) Where a person using a pharmacy—

- (a) presents a non-electronic prescription form or non-electronic repeatable prescription to an NHS pharmacist (P) or requests the provision of drugs or appliances in accordance with an electronic prescription; and
- (b) it appears to P that the person—

(i) has diabetes,

- (ii) is at risk of coronary heart disease, especially those with high blood pressure, or
- (iii) smokes or is overweight,

P 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) P 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 P; and
- (b) follow-up care for the person who has been given the advice.

# F63... Health campaigns

18. An NHS pharmacist (P) must, at the request of the NHSCB, ensure that—

- (a) P (including P's staff) participates, in the manner reasonably requested by the NHSCB, in up to 6 campaigns in each [<sup>F64</sup>financial] year to promote <sup>F65</sup>... health messages to users of P's pharmacy;
- (b) where requested to do so by the NHSCB, P records the number of people to whom P (including P's staff) has provided information as part of one of those campaigns [<sup>F66</sup>; and]
- [<sup>F67</sup>(c) where requested to do so by the NHSCB, P sends to the NHSCB by means of an electronic communication of the type specified in the request—
  - (i) the number recorded pursuant to sub-paragraph (b), and
  - (ii) information which is reasonably requested by the NHSCB, and which is in an anonymised form if it would otherwise identify any person to whom information was provided as part of the campaign, for the purposes of evaluating the effectiveness of the campaign and policy development.]
- **F63** Word in Sch. 4 para. 18 heading omitted (9.11.2020) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **11(2)**
- F64 Word in Sch. 4 para. 18(a) substituted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 11(3)(a)
- **F65** Word in Sch. 4 para. 18(a) omitted (9.11.2020) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **11(3)(b)**
- **F66** Word in Sch. 4 para. 18(b) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **11(4)**
- **F67** Sch. 4 para. 18(c) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **11(5)**

# Signposting

**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.

### Service outline in respect of signposting

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

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

P 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, P is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within P's normal course of business, P must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 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 P.

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

(4) P 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 P; and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

#### Support for self-care

**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.

# Service outline in respect of support for self-care

**22.**—(1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise the inappropriate use of health and social care services, that a person (X) using P's pharmacy would benefit from advice from P to help X manage a medical condition (including, in the case of a carer, to help X in assisting in the management of another person's medical condition), P must provide advice to X 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) P must, in appropriate cases, keep and maintain a record of any advice given under subparagraph (1), and of any drugs supplied when the advice was given, and that record shall be in a form that facilitates—

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

# [<sup>F68</sup>Home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.

**22A.**—(1) Before dispensing any item on a prescription form or supplying it in accordance with a serious shortage protocol, an NHS pharmacist (P) must provide a home delivery option to eligible patients in respect of the item where, as a consequence of a disease being or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from pharmacy premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

(2) If P's pharmacy premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from P's pharmacy, P must ascertain from—

(a) an eligible patient—

- (i) who has contacted P about the home delivery of prescription items, or
- (ii) who is a person whom P considered, on the basis of the nature of an item on a prescription form, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted P about the home delivery of prescription items,

whether or not the item could be supplied by a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which P must provide.

(3) Where paragraph (2) does not apply, if P's pharmacy premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from P's pharmacy, the home delivery option that P must provide must comprise—

- (a) P delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) P arranging for an item dispensed by P to be delivered by another NHS pharmacist or by an LPS contractor to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if P is unable to deliver the item or arrange for its delivery by another NHS pharmacist or by an LPS contractor, P arranging for the dispensing or supply of the item by another NHS pharmacist or by an LPS contractor who would be able to deliver the dispensed item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(4) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at P's pharmacy premises for the purposes of receiving dispensing services.

(5) Notwithstanding the foregoing provisions of this Part, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, P may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.

(6) Where arrangements are in place which enable an NHS pharmacist to make a delivery as mentioned in sub-paragraph (3)(a) or (b) as part of a directed service, the NHS pharmacist must deliver the item as part of that directed service.

(7) This paragraph does not apply to an NHS pharmacist in respect of distance selling premises.]

**F68** Sch. 4 para. 22A inserted (27.3.2020) by The National Health Service (Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/351), regs. 1(2), 9(2)

# [<sup>F69</sup>Home delivery of notified items while a disease is or in anticipation of a disease being imminently pandemic etc.

**22AA.**—(1) Before dispensing a notified item on a prescription form or supplying it in accordance with a serious shortage protocol, a PTP or a PTPGD, an NHS pharmacist (P) must provide a home delivery option to eligible patients in respect of that item.

(2) For the purposes of this paragraph, a "notified item" is an item that, as a consequence of a disease being or in anticipation of a disease being imminently—

- (a) pandemic; and
- (b) a serious risk or potentially a serious risk to human health,

is the subject of an announcement made by the NHSCB, with the agreement of the Secretary of State, to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are entitled to be provided with a home delivery option in respect of that item, if it is supplied to them as part of pharmaceutical services.

(3) Where P is to, or may be required to, dispense a notified item on a prescription form or supply it in accordance with a serious shortage protocol, a PTP or a PTPGD, P must ascertain from—

- (a) an eligible patient—
  - (i) who has contacted P about the home delivery of a notified item, or
  - (ii) who is a person whom P considered, on the basis of an order or request for a notifiable item, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted P about the home delivery of a notified item,

whether or not the item could be supplied via a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which P must provide.

(4) Where paragraph (3) does not apply, the home delivery option that P must provide must comprise—

- (a) P delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) P arranging for an item dispensed by P to be delivered by another NHS pharmacist or by an LPS contractor to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if P is unable to deliver the item or arrange for its delivery by another NHS pharmacist or by an LPS contractor, P arranging for the dispensing or supply of the item by another NHS pharmacist or by an LPS contractor who would be able to deliver the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(5) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at P's pharmacy premises for the purposes of being supplied with the notifiable item.

(6) Notwithstanding the foregoing provisions of this Part, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, P may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.

(7) Where arrangements are in place which enable an NHS pharmacist to make a delivery as mentioned in sub-paragraph (4)(a) or (b) as part of a directed service, the NHS pharmacist must deliver the item as part of that directed service.

(8) This paragraph does not apply to an NHS pharmacist in respect of distance selling premises.]

F69 Sch. 4 para. 22AA inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), 3(5)

# [<sup>F70</sup>Discharge medicines service

**22B.** An NHS pharmacist (P) must, to the extent that paragraph 22C requires and in the manner set out in that paragraph, provide advice, assistance and support to and in respect of a health service patient—

- (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or
- (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.
- **F70** Sch. 4 paras. 22B, 22C inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), **12**

### Service outline in respect of the discharge medicines service

**22C.**—(1) An NHS pharmacist (P) must have procedures in place (as part of its standard operating procedures) for checking at appropriate intervals on days on which P's pharmacy premises are open for business whether P has received any referrals, which are in the form and manner approved for this purpose by the NHSCB, for the services set out in this paragraph ("DMS referrals").

(2) If P receives a DMS referral in respect of a health service patient (X) requesting from P stage 1 of the service (as well as stages 2 and 3), P must, as soon as possible but in any event within 72 hours of receiving the DMS referral (excluding hours of days on which the pharmacy premises are not open for business), as stage 1 of the service—

- (a) review the actions requested, and act on those requested actions, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so;
- (b) use the information that P has or is able to access about X's medication regimen before the discharge or transfer to compare it (so far as is possible) with X's medication regimen on discharge or transfer;
- (c) check any prescriptions for X that P may be asked to dispense (including electronic repeatable prescriptions) or has part dispensed in order to assess whether, in P's clinical judgement, any changes are appropriate or there are any other issues of concern;

- (d) where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with—
  - (i) the staff of the hospital or other provider of NHS services that made the referral, and
  - (ii) any provider of primary medical services on whose patient list X is; and
- (e) keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).
- (3) This sub-paragraph applies—
  - (a) if P receives—
    - (i) in respect of X an electronic prescription for a medicinal product or is presented by X with a non-electronic prescription form, a non-electronic repeatable prescription or an EPS token in respect of a medicinal product, and
    - (ii) is on notice as a result of a DMS referral requesting from P stage 2 of the service (whether or not it is the referral mentioned in sub-paragraph (2)) that the prescription is the first prescription for a medicinal product to be dispensed by P to X following X's discharge from hospital or the transfer of X's care between different providers of NHS services; or
  - (b) in the following circumstances—
    - (i) P receives in respect of a health service patient (Y) an electronic prescription for a medicinal product or is presented by Y with a non-electronic prescription form, a non-electronic repeatable prescription or an EPS token in respect of a medicinal product,
    - (ii) P is on notice as a result of a DMS referral requesting from P stage 2 of the service (and potentially stage 3) that it is the first prescription for a medicinal product to be dispensed to Y following Y's discharge from hospital or the transfer of Y's care between different providers of NHS services (a different NHS pharmacist having provided stage 1 of the service in respect of Y), and
    - (iii) P is on notice that Y, or where appropriate a carer of Y, wishes P to provide the services described in sub-paragraphs (4) and (5) to or in respect of Y.

(4) Where sub-paragraph (3) applies, P must, as stage 2 of the service, prior to or as part of the process of dispensing the prescription—

- (a) review (or further review) the medication regimen of X or Y, using the information that P has or is able to access about that medication regimen, including from the prescription, in order to assess whether, in P's clinical judgement, appropriate account has been taken of any changes to X's or Y's medication regimen during X's or Y's stay in hospital or prior to the transfer of X's or Y's care between different providers of NHS services;
- (b) if any issues of concern are identified, raise these to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with any provider of primary medical services on whose patient list X or Y is; and
- (c) keep and maintain records of any actions taken as part of this stage of the process, as appropriate (in particular, to support delivery of stage 3 of the service).

(5) At the point at which P, in P's clinical judgement is to, or would normally, discuss the prescription as mentioned in paragraph (3)(a)(i) or (b)(i) with X or Y, or where appropriate with a carer of X or Y, P must, as stage 3 of the service—

(a) engage in a discussion with X or Y, or where appropriate a carer of X or Y, in a manner which is in accordance with P's duty of confidentiality to X or Y and which is—

- (i) to assess their understanding of what medicinal products X or Y should be taking, and
- (ii) to offer to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so advice, assistance and support in respect of X's or Y's medication regimen;
- (b) draw to X's or Y's attention (where appropriate via a carer of X or Y)-
  - (i) P's disposal service in respect of unwanted drugs, and
  - (ii) any other pharmaceutical services that P, in the exercise of P's clinical judgement, considers X or Y may benefit from following X's or Y's stay in hospital or the transfer of X's or Y's care between different providers of NHS services;
- (c) if any issues of concern are identified, raise these to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with any provider of primary medical services on whose patient list X or Y is; and
- (d) keep and maintain records, as appropriate-
  - (i) of the discussion pursuant to paragraphs (a) and (b), and of any raising of concerns and any actions taken, and
  - (ii) for service evaluation purposes.

(6) If the DMS referral requesting that P provides services under this paragraph includes circumstances in which P is not to provide, or is to cease to provide, services under this paragraph, P is not to, or is to cease to, provide services under this paragraph in those circumstances (for example, X's or Y's admission or re-admission to hospital).]

**F70** Sch. 4 paras. 22B, 22C inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 12

# PART 3

# Hours of opening

# Pharmacy opening hours: general

**23.**—(1) [<sup>F71</sup>Subject to paragraph 23A,] an NHS pharmacist (P) must ensure that pharmaceutical services are provided at P's pharmacy premises—

- (a) for 40 hours each week;
- (b) for not less than 100 hours each week, in the case of premises in respect of which a 100 hours condition applies;
- (c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;
- (d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set [<sup>F72</sup>, subject to any variation in respect of a rest break in accordance with subparagraph (7)(bd)]; or

- (e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours [<sup>F73</sup>, or the core opening hours where paragraph 26(4A) applied to the issuing of the direction]—
  - (i) for the total number of hours each week required by virtue of that direction, and
  - (ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction [<sup>F74</sup>, subject to any variation in respect of a rest break in accordance with sub-paragraph (7)(bd)],

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

(2) The hours during which pharmacy premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as "core opening hours".

(3) P must notify the NHSCB of other hours during which P's pharmacy premises are to be open, which are hours in addition to P's core opening hours (and which are referred to in these Regulations as "supplementary opening hours").

- (4) Unless P is a distance selling chemist, at P's pharmacy premises P must exhibit—
  - (a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances (including times at which P is providing pharmaceutical services during supplementary opening hours); and
  - (b) at times when the premises are not open, a notice based on information provided by the NHSCB, where practicable legible from outside the premises, specifying—
    - (i) the addresses of other NHS pharmacists and the days on which and times at which drugs and appliances may be obtained from those addresses, and
    - (ii) the addresses of LPS chemists in the area, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.
- (5) P must, on request, submit a return to the NHSCB setting out-
  - (a) the days on which and times at which pharmaceutical services are provided at P's pharmacy premises (including times at which P is providing pharmaceutical services during supplementary opening hours); and
  - (b) the pharmaceutical services which P ordinarily provides at those premises.
- (6) Where P changes—
  - (a) the supplementary opening hours of P's pharmacy premises; or
  - (b) the pharmaceutical services which P ordinarily provides at those premises,

P must supply the NHSCB with a return informing it of the change [<sup>F75</sup>before the change takes place].

(7) Where P has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and times at which pharmaceutical services are to be provided at P's pharmacy premises (for example, in a return under sub-paragraph (5) or (6) or in an application for inclusion in a pharmaceutical list)—

(a) P must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the times set out in the notification (unless the notification has been superseded by a return, or a further return, under sub-paragraph (6));
 F76....

- [<sup>F77</sup>(ba) P must not change the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours, except for making a change that—
  - (i) amounts to the inclusion of a rest break which is no longer than one hour, or a change to such a rest break—
    - (aa) on a Monday to Saturday, which starts at least 3 hours after the start of the pharmacy's opening hours and ends at least 3 hours before the end of the pharmacy's opening hours, or
    - (bb) on a Sunday, and

(ii) does not change the total number of P's core opening hours on a particular day,

otherwise than as provided for, and in accordance with the procedures set out in, paragraphs 25 and 26;

- (bb) P must not change P's supplementary opening hours in a way that reduces the time for which P's pharmacy is open before or after a rest break on a Monday to Saturday to less than 3 hours (if P wants to change the supplementary opening hours affected by this requirement, P must also change the time of the rest break);
- (bc) P must not change—
  - (i) the total number of P's supplementary opening hours in a way that either reduces or leaves the same the total number of P's supplementary opening hours, or
  - (ii) unless the change relates to an increase of the total number of supplementary opening hours, the days on which or the times at which pharmaceutical services are to be provided at P's premises during supplementary opening hours,

for a period of at least 5 weeks after the day on which that notification was received by NHS England, unless NHS England agrees otherwise; and

- (bd) P must not change the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours, in the case of making a change that—
  - (i) amounts to the inclusion of a rest break which is no longer than one hour, or a change to such a rest break—
    - (aa) on a Monday to Saturday, which starts at least 3 hours after the start of the pharmacy's opening hours and ends at least 3 hours before the end of the pharmacy's opening hours, or
    - (bb) on a Sunday, and

(ii) does not change the total number of P's core opening hours on a particular day,

for a period of at least 5 weeks after the day on which that notification was received by NHS England, unless NHS England agrees otherwise.]

[<sup>F78</sup>(7A) Paragraphs (ba) and (bd) of sub-paragraph (7) do not apply to changes to core opening hours of premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, and accordingly the core opening hours of such premises may only be changed in accordance with paragraph 25 or 26.]

<sup>F79</sup>(8) ..... <sup>F80</sup>(9) ....

(10) Where there is a temporary suspension in the provision of pharmaceutical services by P  $[^{F81}$  because of illness or another reason] beyond the control of P, P is not in breach of sub-paragraphs (1) and (7),  $[^{F82}$  or of paragraph 23A(5)(a),] provided that—

- (a) P notifies the NHSCB of that suspension as soon [<sup>F83</sup>as practicable, in the manner required by paragraph 29D(2)(a) and wherever possible before the start of the suspension;]
- [<sup>F84</sup>(aa) P uses all reasonable endeavours to implement the business continuity plan that P is required to have by virtue of paragraph 29D; and]
  - (b) P uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(11) Planned refurbishment of pharmacy premises is [<sup>F85</sup>not] a "reason beyond the control of P" for the purposes of sub-paragraph (10).

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

(13) For the purposes of this Part, "additional opening hours", where they are required, are hours during which P is required to provide pharmaceutical services pursuant to sub-paragraph (1) (e) which are in addition to the hours during which P would be required to provide pharmaceutical services, if P were subject instead to the condition set out in sub-paragraph (1)(a).

- F71 Words in Sch. 4 para. 23(1) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 9(2)(a)
- **F72** Words in Sch. 4 para. 23(1)(d) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **9(2)(b)**
- F73 Words in Sch. 4 para. 23(1)(e) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 9(2)(c)(i)
- F74 Words in Sch. 4 para. 23(1)(e)(ii) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 9(2)(c) (ii)
- **F75** Words in Sch. 4 para. 23(6) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **9(3)**
- **F76** Word in Sch. 4 para. 23(7)(a) omitted (25.5.2023) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 9(4)
- **F77** Sch. 4 para. 23(7)(ba)-(bd) substituted for Sch. 4 para. 23(7)(b) (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **9(4)**
- **F78** Sch. 4 para. 23(7A) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **9(5)**
- F79 Sch. 4 para. 23(8) omitted (31.7.2023) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), 9(6)
- **F80** Sch. 4 para. 23(9) omitted (31.7.2023) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **9(6)**
- **F81** Words in Sch. 4 para. 23(10) substituted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **9(7)(a)**
- **F82** Words in Sch. 4 para. 23(10) inserted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **9(7)(b)**
- **F83** Words in Sch. 4 para. 23(10)(a) substituted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **9**(7)(c)

- F84 Sch. 4 para. 23(10)(aa) inserted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), 9(7)(d)
- **F85** Word in Sch. 4 para. 23(11) substituted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **9(8)**

# [<sup>F86</sup>Local hours plans

**23A.**—(1) Where NHS England is satisfied that people in a particular area are experiencing, or are likely to experience, significant difficulty in accessing pharmaceutical services on a temporary basis for an identified period, NHS England may establish a local hours plan with the NHS pharmacists in that area that are willing to participate in a local hours plan for that area.

(2) NHS England must, prior to establishing a local hours plan, consult any local pharmaceutical committee for the area that comprises or includes the area of the plan, unless NHS England decides that it is not practicable to do so.

(3) NHS England must notify any local pharmaceutical committee for the area that comprises or includes the area of a local hours plan that it establishes of the contents of that plan and any changes to it, including where further NHS pharmacists join or any NHS pharmacists cease to participate in the plan.

(4) The local hours plan is to be of a specified duration, determined by NHS England, and is to contain the temporary opening hours agreed between NHS England and each of the participating NHS pharmacists (each participating NHS pharmacist agrees their own but not other participants' temporary opening hours).

(5) NHS pharmacists that have agreed to participate in a local hours plan-

- (a) must ensure that pharmaceutical services are provided at their pharmacy premises during the agreed temporary opening hours; and
- (b) may cease to participate in the plan and return to their core and supplementary opening hours, provided that, subject to sub-paragraph (8), they have given the notice period for doing so that they have each agreed with NHS England as part of the plan.

(6) NHS England may revise a local hours plan from time to time, including by allowing further NHS pharmacists to join, but any change to the plan that is a change to the temporary opening hours of an NHS pharmacist that is participating in the plan, or of their notice period as referred to in sub-paragraph (5)(b), must be agreed with that NHS pharmacist.

(7) A local hours plan ceases to have effect on the expiry of its specified duration, determined by NHS England in accordance with sub-paragraph (4), unless NHS England revises the specified duration, in which case the new specified duration becomes the specified duration of the plan, and further revisions are then also permissible pursuant to this sub-paragraph.

(8) If NHS England revises the specified duration of a local hours plan, an NHS pharmacist may cease to participate in the plan on the date that was the plan's expiry date, having given prior notice of their intention to do so, which may be of a shorter period than their agreed notice period where—

- (a) the NHS pharmacist does not wish to participate in the plan beyond the expiry date that has been extended;
- (b) the timing of the revision means it is not possible, or not reasonably practicable, for prior notice to be given for the agreed notice period; and
- (c) the NHS pharmacist gives notice of their intention to cease to participate in the plan on the date that was the plan's expiry date as soon as it is reasonably practicable for them to do so.

(9) While a local hours plan has effect, the core and supplementary opening hours that have temporarily been suspended may be changed in accordance with paragraphs 23(6) and (7), 25 and 26.]

**F86** Sch. 4 para. 23A inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **10** 

# Matters to be considered when issuing directions in respect of pharmacy premises core opening hours

**24.**— $[^{F87}(1)$  Subject to paragraph 26(2A), where NHS England issues a direction for setting any days or times for opening hours under this Part, or determines them without issuing a direction, it must in doing so seek to ensure that the days and times at which pharmacy premises are open for the provision of pharmaceutical services in the area in which the premises that are the subject of the direction are located are such as—

- (a) to maintain as necessary the existing level of service provision for the people in that area or other likely users of the pharmacy premises; or
- (b) to maintain a sustainable level of adequate service provision for the people in that area or other likely users of the pharmacy premises, in circumstances where maintaining the existing level of service provision is either unnecessary or not a realistically achievable outcome.]
- (2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—
  - (a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided; and
  - (b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.

(3) The NHSCB may only direct that an NHS pharmacist (P) 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 its area is likely to be adequate to meet the need for such services at times when P is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that P must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that P is to receive reasonable remuneration in respect of the additional opening hours for which P is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is "reasonable remuneration" for these purposes).

[<sup>F88</sup>(5) Sub-paragraph (4) does not apply in circumstances where the direction is in respect of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies.]

F87 Sch. 4 para. 24(1) substituted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 11(2)
F88 Sch. 4 para. 24(5) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), 11(3)

# Determination of pharmacy premises core opening hours instigated by the NHSCB

**25.**—(1) Where it appears to the NHSCB, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee for the area in which the premises are situated, that the days on which or times at which pharmacy premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—

- (a) people in its area; or
- (b) other likely users of the pharmacy premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS pharmacist (P) whose premises they are to provide pharmaceutical services at the pharmacy premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the NHSCB must-

- (a) give notice to P of any proposed changes to the days on which or times at which the pharmacy premises are to be open; and
- (b) allow P 30 days within which to make written representations to the NHSCB about the proposed changes.
- (3) When it determines the outcome of its assessment, the NHSCB must-
  - (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);
  - (b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5); or
  - (c) either—
    - (i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or
    - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of pharmacy premises that are to be 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 P must provide pharmaceutical services at the pharmacy, and
  - (ii) as regards the additional opening hours, the days on which and the times at which P is required to provide those services during those hours,

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

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

(5) The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring pharmacy premises 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 pharmacy premises to be open for either more or less than 40 hours each week).

(6) The NHSCB must notify P of any direction issued or any other action taken under subparagraph (3), and where it sets new days on which or times at which P is to provide pharmaceutical services at pharmacy premises, it must include with the notification a statement of—

(a) the reasons for the change; and

(b) P's right of appeal under paragraph (7).

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

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under paragraph (3).

(9) The Secretary of State shall notify P of the determination and shall in every case include with the notification a statement of the reasons for the determination.

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

- (a) if P has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (6); or
- (b) if P has appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (9).
- (11) This paragraph does not apply where regulation 65(5) to (7) applies.

# Determination of pharmacy premises core opening hours instigated by the NHS pharmacist

**26.**—(1) An NHS pharmacist (P) may apply to the NHSCB for it to change the days on which or times at which P is obliged to provide pharmaceutical services [<sup>F89</sup>during core opening hours] at P's pharmacy premises in a way that—

- (a) reduces the total number of hours for which P is obliged to provide pharmaceutical services at those premises each week <sup>F90</sup>...; or
- (b) keeps that total number of hours the same.

(2) [<sup>F91</sup>Except where sub-paragraph (2A) applies,] where P makes an application under subparagraph (1), as part of that application P must provide the NHSCB with such information as the NHSCB may reasonably request in respect of [<sup>F92</sup>the matters that NHS England must seek to ensure pursuant to paragraph 24(1)].

[<sup>F93</sup>(2A) In the case of an application for a direction under sub-paragraph (4) that has the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, the total number of core opening hours to 72 or above, but without changing any or all of the following—

- (a) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (b) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—
  - (i) is no longer than one hour, and
  - (ii) starts at least 3 hours after the start of the pharmacy's opening hours and ends at least 3 hours before the end of the pharmacy's opening hours; and
- (c) the total number of core opening hours on a Sunday,

NHS England must grant that application, and paragraph 24(1) does not apply to such an application.

(2B) In the case of a valid application for a direction under sub-paragraph (4) to which sub-paragraph (2A) applies, if—

(a) the date included in the application as the date on which P wishes to change P's core opening hours is five weeks or more after the day on which the application is received by NHS England; and

(b) NHS England has not determined the application by that date,

pending the determination of the application, P's core opening hours are the core opening hours that P requested in the application.]

(3) The NHSCB must determine the application within 60 days of receiving it (including any information required of P in accordance with sub-paragraph (2)).

- (4) When it determines the application, the NHSCB must-
  - (a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs [<sup>F94</sup>(4A),] (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 times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 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 times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 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.

F95

[<sup>F96</sup>(4A) NHS England must not issue a direction under sub-paragraph (4), or revoke without replacing it an existing direction under that sub-paragraph, if doing so would have the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies or has ever applied, or in respect of which a direction that replaced (at any distance in succession) a 100 hours condition applies, any or all of the following—

- (a) the total number of core opening hours to below 72;
- (b) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (c) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—
  - (i) is no longer than one hour, and
  - (ii) starts at least 3 hours after the start of the pharmacy's opening hours and ends at least 3 hours before the end of the pharmacy's opening hours; and
- (d) the total number of core opening hours on a Sunday,

and an application seeking such a change is not a valid application for the purposes of subparagraph (2B).

(4B) On and after 25th May 2023, NHS England must not issue a direction under subparagraph (4), or revoke without replacing it an existing direction under that sub-paragraph, pursuant to an application made before 25th May 2023 for a direction pursuant to this paragraph as it had effect before 25th May 2023, if doing so would have the effect of reducing, in the case of any premises in respect of which a 100 hours condition applies, any or all of the following—

- (a) the core opening hours on a Monday to Saturday at times between 5pm and 9pm;
- (b) the core opening hours on a Sunday at times between 11am and 4pm, other than by way of the inclusion of, or a change to, a rest break which—

(i) is no longer than one hour, and

- (ii) starts at least 3 hours after the start of the pharmacy's opening hours and ends at least 3 hours before the end of the pharmacy's opening hours; and
- (c) the total number of core opening hours on a Sunday.]

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of pharmacy premises that are to be 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 P must provide pharmaceutical services at the pharmacy premises, and
  - (ii) as regards any additional opening hours, the days on which and the times at which P is required to provide those services during those hours,

but [<sup>F97</sup>except in a case to which sub-paragraph (4A) applies,] it must not set out in that direction days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening hours; or

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

(6) The NHSCB must not issue a direction under sub-paragraph (4) that has the effect simply of requiring pharmacy premises 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 pharmacy premises to be open for either more or less than 40 hours each week).

(7) Where the NHSCB is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee for the area in which the pharmacy premises are situated before determining the application.

(8) The NHSCB must notify P of any direction issued or any other action taken under subparagraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send P 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) P's right of appeal under sub-paragraph (9).

(9) P may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State 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 Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

(11) The Secretary of State must notify the pharmacist of the determination and must include with the notification a statement of the reasons for the determination.

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

- (a) if P has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (4); or
- (b) if P has appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (11).
- (13) This paragraph does not apply where regulation 65(5) to (7) applies.

**F89** Words in Sch. 4 para. 26(1) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(2)(a)** 

- **F90** Words in Sch. 4 para. 26(1)(a) omitted (25.5.2023) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(2)(b)**
- **F91** Words in Sch. 4 para. 26(2) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(3)(a)**
- **F92** Words in Sch. 4 para. 26(2) substituted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(3)(b)**
- **F93** Sch. 4 para. 26(2A)(2B) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(4)**
- **F94** Word in Sch. 4 para. 26(4)(a) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(5)(a)**
- **F95** Words in Sch. 4 para. 26(4)(c) omitted (25.5.2023) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(5)(b)**
- **F96** Sch. 4 para. 26(4A)(4B) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(6)**
- **F97** Words in Sch. 4 para. 26(5)(a) inserted (25.5.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(2), **12(7)**

# Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

**27.**—(1) Notwithstanding the provisions of this Part, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS pharmacist ("P"), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at pharmacy premises, or permit temporary closure of those premises, if—

- (a) P gives at least 24 hours notice of the change or closure; and
- (b) the reasons given by P for the request are, in the opinion of the NHSCB, adequate reasons.

(2) The NHSCB need not approve the request in advance of the change or closure, but if it does not do so and decides subsequently that P's reasons are not, in its opinion, adequate reasons, then the days on which or times at which P 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 P.

# [<sup>F98</sup>Pharmacy opening hours: arrangements while a disease is or in anticipation of a disease being imminently pandemic etc.

**27A.**—(1) Notwithstanding the foregoing provisions of this Part, the core or supplementary opening hours of an NHS pharmacist (P) may be changed by the NHSCB where, as a consequence of a disease being, or in anticipation of a disease being imminently—

- (a) pandemic; and
- (b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, the NHSCB may, in the area to which the announcement relates and in the circumstances specified in the announcement, notify NHS pharmacists of changes to core and supplementary opening hours for the period specified in the announcement.

(2) Where paragraph (1) applies, where the NHSCB notifies P of changes to P's core or supplementary hours at P's pharmacy premises, those are P's core and supplementary opening hours for the period that the NHSCB specifies in the notification (unless the NHSCB notifies P of further changes to P's opening hours).]

**F98** Sch. 4 para. 27A inserted (27.3.2020) by The National Health Service (Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/351), regs. 1(2), 9(3)

## [<sup>F99</sup>Flexible provision of relevant immunisation services during a pandemic etc.

**27B.**—(1) Notwithstanding the forgoing provisions of this Part, in order to assist in the management of a serious risk or potentially serious risk to human health which arises as a consequence of a disease being, or in anticipation of a disease being imminently, pandemic, an NHS pharmacist (P) may, with the agreement of the NHSCB, limit for a specified period (within P's core and supplementary opening hours) the pharmaceutical services provided at or from P's pharmacy premises to relevant immunisation services.

(2) If the NHSCB has made an announcement to the effect that there are particular arrangements under this paragraph that it is prepared to agree, and P limits P's provision of pharmaceutical services to relevant immunisation services in a manner that is consistent with that announcement, it is to be assumed (in the absence of a contrary notification from the NHSCB to P) that P has the agreement of the NHSCB to those arrangements.

(3) In this paragraph, "relevant immunisation services" means directed services that provide for the administration of a medicinal product for vaccination or immunisation against coronavirus or influenza virus in accordance with—

- (a) a patient group direction that meets the conditions of regulation 233 of the Human Medicines Regulations 2012 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business); or
- (b) a protocol that meets the conditions of regulation 247A of the Human Medicines Regulations 2012 (protocols relating to coronavirus and influenza vaccinations and immunisations),

and for these purposes, "coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020.]

**F99** Sch. 4 para. 27B inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **13** 

# PART 4

## Other terms of service

## Clinical governance [<sup>F100</sup> and the promotion of healthy living]

**28.**—(1) An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance [<sup>F101</sup> and for the promotion of healthy living].

(2) For these purposes a system of clinical governance [ $^{F102}$  and for the promotion of healthy living] is "acceptable" if it is considered acceptable by the NHSCB and comprises the following components—

(a) a patient and public involvement programme, which includes—

- (i) a requirement that P produces in an approved manner, and makes available in an appropriate manner, a practice leaflet containing approved particulars in respect of P's pharmacy premises,
- (ii) a requirement that the pharmacist publicises the essential services and any advanced services[<sup>F103</sup>, other than an advanced service in respect of the supply of drugs in accordance with regulation 225 of the Human Medicines Regulations 2012 (emergency sale etc by pharmacist: at patient's request),] that are available at or from the pharmacist's pharmacy,
- (iii) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist's pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,
- - (v) P's monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
  - (vi) a requirement that P co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, <sup>F105</sup>...
  - (vii) P's monitoring arrangements in respect of P's compliance with the Equality Act 2010; [<sup>F106</sup>and]
- [<sup>F107</sup>(viii) undertaking at least once in each financial year an approved community engagement exercise in relation to the promotion of healthy living.]
- [<sup>F108</sup>(b) an audit programme, which in each financial year includes at least one clinical audit specified by P, and whichever of the following that the NHSCB specifies—
  - (i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or
  - (ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit;]
  - (c) a risk management programme, which includes-
    - (i) arrangements for ensuring that all stock is procured and 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,
    - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State <sup>M10</sup> and the NHSCB,
    - (v) appropriate standard operating procedures, including standard operating procedures in respect of [<sup>F109</sup>the discharge medicines service] dispensing drugs and appliances, 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 Part 2) for clinical and confidential waste,

- (vii) a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or who is the 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 safeguarding procedures for service users,
  - (ix) P's monitoring arrangements in respect of P's compliance with the Health and Safety at Work etc. Act 1974 <sup>MII</sup>;
- [<sup>F110</sup>(ca) at the request of the NHSCB, a pandemic response programme, which includes—
  - (i) conducting an infection control risk assessment, in the approved manner,
  - (ii) appropriate infection control measures at P's pharmacy premises, having regard to that infection control risk assessment and to any approved particulars designed to support, in a proportionate manner, the safety of service users and pharmacy staff in particular in circumstances where services users or pharmacy staff may be, or are known or suspected to be, suffering from the pandemic disease,
  - (iii) arrangements, which may be approved arrangements, for communicating with potential service users about service availability and service provision at or from P's pharmacy premises during the pandemic,
  - (iv) arrangements for appropriate updating of the standard operating procedures mentioned in sub-paragraph (c)(v) and any business continuity plan of P, and
  - (v) arrangements for appropriate updating of the premises standards programme mentioned in sub-paragraph (g) (including in response to any new approved particulars under sub-paragraph (g)(ii) that are in response to the pandemic),

but prior to making such a request (or revising the terms of such a request), the NHSCB must consult the body that is, for the time being, the body consulted under section 165(1) (a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists;]

- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by P—
  - (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 P, 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 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 for staff (including locums),
  - (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,
- [<sup>F111</sup>(iiia) a requirement that P undertakes an approved workforce survey annually, in an approved manner,]
  - (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 registered pharmacy technicians, and

any necessary accreditation [<sup>F112</sup>, certification or declarations of competence in respect of any role they are asked to perform],

- (v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate), and
- (vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist—
  - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996<sup>M12</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 the NHSCB 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, 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 NHSCB 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 health care acquired infection is minimised, and
  - (ii) arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care [<sup>F113</sup> and for the promotion of healthy living],

and for the purposes of this sub-paragraph, "approved" means approved by the NHSCB.

- **F100** Words in Sch. 4 para. 28 heading inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), **14(2)**
- **F101** Words in Sch. 4 para. 28(1) inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(3)
- F102 Words in Sch. 4 para. 28(2) inserted (1.1.2021) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(4)(a)
- **F103** Words in Sch. 4 para. 28(2)(a)(ii) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **25**
- F104 Sch. 4 para. 28(2)(a)(iv) omitted (1.10.2022) by virtue of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930), regs. 1(2), 8(3)(a)
- F105 Word in Sch. 4 para. 28(2)(a)(vi) omitted (1.1.2021) by virtue of The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(4)(b)(i)
- **F106** Word in Sch. 4 para. 28(2)(a)(vii) inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), **14(4)(b)(ii)**

- **F107** Sch. 4 para. 28(2)(a)(viii) inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), **14(4)(b)(iii)**
- **F108** Sch. 4 para. 28(2)(b) substituted (1.3.2015) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015 (S.I. 2015/58), regs. 1(1), 8(3) (with reg. 10)
- **F109** Words in Sch. 4 para. 28(2)(c)(v) inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(4)(c)
- F110 Sch. 4 para. 28(2)(ca) inserted (1.1.2022) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(b), 8(2)
- F111 Sch. 4 para. 28(2)(e)(iiia) inserted (1.10.2022) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930), regs. 1(2), 8(3)(b)
- F112 Words in Sch. 4 para. 28(2)(e)(iv) substituted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(4)(d)
- F113 Words in Sch. 4 para. 28(2)(g)(ii) inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 14(4)(e)

## **Marginal Citations**

- M10 The Medicines and Healthcare Products Regulatory Agency, which is an executive agency of the Department of Health, issues safety advice, warnings, alerts and recalls in respect of medical devices on behalf of the Secretary of State, and also safety advice, warnings, alerts and recalls in respect of medicines on behalf of the Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly. The Department of Health also, separately, issues other communications concerning patient safety, on behalf of the Secretary of State.
- M11 1974 c. 37.
- M12 1996 c. 18; section 43A was inserted by the Public Interest Disclosure Act 1998 (c. 23), section 1. See also section 43K(1)(c) (i) of the Employment Rights Act 1996 (inserted by the Public Interest Disclosure Act 1998, section 1, and amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17), Schedule 2, paragraph 63; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 177 and 178(b); and S.I. 2007/961).

## [<sup>F114</sup>Premises requirements in respect of consultation rooms

**28A.**—(1) An NHS pharmacist must ensure that at pharmacy premises, other than distance selling premises, there is a consultation room which is—

- (a) clearly designated as a room for confidential conversations;
- (b) distinct from the general public areas of the pharmacy premises; and
- (c) a room where both a person accessing pharmaceutical services and a person performing pharmaceutical services are able to be seated together and communicate confidentially.

(2) Where, in the opinion of the NHSCB, pharmacy premises other than distance selling premises included on a pharmaceutical list on the relevant day are too small for a consultation room—

- (a) the NHS pharmacist in respect of those premises may, with the agreement of the NHSCB, comply with paragraph 28B instead of sub-paragraph (1); and
- (b) for these purposes, references to distance selling premises in paragraph 28B are to be treated as a reference to the premises about which the NHSCB has formed the opinion that they are too small for a consulting room.

(3) An NHS pharmacist in respect of premises that were on a pharmaceutical list on the relevant day but no advanced services were provided at or from those premises during the year before the relevant day need not comply with sub-paragraphs (1) or (2) in respect of those premises before 1st April 2023.

(4) In this paragraph, "the relevant day" means the day of the coming into force of regulation 15(1) of the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020.

F114 Sch. 4 paras. 28A, 28B inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 15(1)

## Consultations held from distance selling premises and some small pharmacy premises

**28B.** An NHS pharmacist in respect of distance selling premises must ensure that there are arrangements in place at those premises which enable a person performing pharmaceutical services to communicate confidentially with a person accessing pharmaceutical services—

- (a) by telephone or another live audio link; and
- (b) via a live video link.]

F114 Sch. 4 paras. 28A, 28B inserted (1.1.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(3), 15(1)

## [<sup>F115</sup>Distance selling premises requirements in respect of websites and health promotion zones

**28C.** An NHS pharmacist (P) in respect of distance selling premises must ensure that P has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.]

F115 Sch. 4 para. 28C inserted (1.4.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(4), 15(2)

## **Professional Standards**

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

## [<sup>F116</sup>Accessing summary care records

**29A.**— $[^{F117}(1)$  An NHS pharmacist (P) must have access to summary care records at P's pharmacy premises, and must ensure that the access that P has to summary care records at those premises is constant and reliable during core and supplementary opening hours, in so far as that is within the control of P.

(2) P must access the summary information in a patient's summary care record whenever P is providing pharmaceutical services to the patient, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so.]

(3) In this paragraph, a "summary care record" and "summary information" mean a summary care record and summary information within the meanings given in—

- (a) regulation 68 of the GMS Regulations (summary care records); and
- (b) regulation 61 of the PMS Regulations (summary care records).]
- F116 Sch. 4 para. 29A inserted (1.4.2016) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016 (S.I. 2016/296), regs. 1(1)(a), 4(3)
- F117 Sch. 4 para. 29A(1)(2) substituted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 16

## [<sup>F118</sup>Electronic Prescription Service access

**29B.** An NHS pharmacist (P) must have access to the EPS at P's pharmacy premises, and must ensure that the access that P has to the EPS at those premises is constant and reliable during core and supplementary opening hours, in so far as that is within the control of P.]

F118 Sch. 4 paras. 29B, 29C inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 17

## [<sup>F118</sup>Contact via NHSmail, pharmacy profiles and the Central Alerting System

**29C.**—(1) An NHS pharmacist (P) must ensure that pharmacy staff at pharmacy premises (including locums) have access to, and are able to send and receive NHSmail from, a premises specific NHSmail account.

(2) P must ensure that at least two members of the pharmacy staff have live, linked NHSmail accounts to the premises specific NHSmail account (unless fewer than two members of the pharmacy staff are engaged in the provision of NHS services).

(3) P must ensure that there is a comprehensive and accurate pharmacy profile in respect of P's pharmacy premises in the [<sup>F119</sup>NHS England directory of services], and P must verify and where necessary update the information contained in that profile at least once each quarter of the financial year.

(4) P must ensure that there is a comprehensive and accurate pharmacy profile in respect of P's pharmacy premises on the NHS.uk website, and P must verify and where necessary update the information contained in that profile at least once each quarter of the financial year.

(5) As regards the Central Alerting System (CAS) operated by the Medicines and Healthcare products Regulatory Agency (MHRA)—

- (a) P must register P's premises specific NHSmail address with MHRA as an address at which P is content to accept notifications as part of the CAS (unless they are content with the address already in the system);
- (b) if P changes P's premises specific NHSmail address, P must immediately notify MHRA of P's new premises specific NHSmail address, in accordance with paragraph (a); and
- (c) P must monitor P's premises specific NHSmail account with sufficient frequency to ensure the safe and effective supply of medicinal products at or from P's pharmacy premises, and must act on the alerts P receives as part of the CAS, as appropriate.]

F118 Sch. 4 paras. 29B, 29C inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 17

F119 Words in Sch. 4 para. 29C(3) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), Sch. para. 47(3)(b) (with reg. 3)

# [<sup>F120</sup>Business continuity plans to deal with temporary suspensions

**29D.**—(1) An NHS Pharmacist (P) must have at all times an up to date business continuity plan for P's pharmacy premises, which is available at those premises, to deal with the temporary suspension because of illness or another reason beyond the control of P of the provision of pharmaceutical services at or from those premises that—

- (a) is proportionate to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P; and
- (b) includes the components set out in sub-paragraph (2).
- (2) The components are—
  - (a) arrangements for notifying NHS England, in the approved manner-
    - (i) about the prospect of a temporary suspension, whenever such a suspension becomes likely, and
    - (ii) about a temporary suspension and its anticipated duration, wherever possible before the start of the suspension;
  - (b) arrangements for updating the pharmacy profile mentioned in paragraph 29C(3) about the suspension, including in due course about the resumption of the provision of pharmaceutical services at the pharmacy premises;
  - (c) if P provides directed services that provide people with urgent care services, arrangements for ensuring, to the extent practicable, that people are not referred to P's pharmacy premises for those services during the temporary suspension;
  - (d) arrangements, where practicable and to an extent that is reasonable having regard to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P, for notifying other providers of pharmaceutical and local pharmaceutical services and providers of primary medical services about the suspension and its anticipated duration;
  - (e) arrangements for displaying information about the suspension and its anticipated duration—
    - (i) in the case of distance selling pharmacies, on the website for the distance selling pharmacy, clearly promoted to any user of the website when they first access it, or
    - (ii) in any other case, on a notice at P's pharmacy premises visible from outside the premises, which also provides information, where appropriate in the approved manner and to an extent that is reasonable having regard to the needs of the people who are anticipating or are accustomed to receiving pharmaceutical services from P, about the availability of pharmaceutical or local pharmaceutical services at or from other pharmacy premises nearby; and
  - (f) arrangements, where practicable, for the continuity of care for the people who are anticipating or are accustomed to receiving pharmaceutical services from P, including for any people who—
    - (i) have booked appointments, or
    - (ii) attend the pharmacy premises regularly for the supervised administration of medicines.
- (3) For the purposes of sub-paragraph (2), "approved" means approved by NHS England.

(4) In the event of the temporary suspension, or the likely temporary suspension, of pharmaceutical services provision at or from P's pharmacy premises, P must use all reasonable endeavours to implement P's business continuity plan, and in the case of a likely temporary suspension, in a manner proportionate to that likelihood.]

**F120** Sch. 4 para. 29D inserted (31.7.2023) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2023 (S.I. 2023/479), regs. 1(3), **13** 

### Inducements etc.

**30.**—(1) An NHS pharmacist (P) (including P's 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 P's business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

- (a) presenting an order for drugs or appliances on a prescription form or repeatable prescription, non-electronic prescription form or non-electronic repeatable prescription;
- (b) nominating P as X's dispensing contractor (or one of them) in X's PDS patient details; or
- (c) receiving from P any directed services.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) Nothing in sub-paragraph (1) prohibits P from providing to a patient to whom P is providing any directed services any gift which—

- (a) is supplied as part of the provision of any directed service to that patient;
- (b) is directly related to that directed service;
- (c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and
- (d) in the case of a gift which—
  - (i) is not a medicine, has a monetary value not exceeding £10, or
  - (ii) is a medicine, is supplied as part of the provision of a minor ailments service.

(4) P (including P's staff) must not give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of P's business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—

- (a) present to P an order for drugs or appliances on a prescription form or repeatable prescription;
- (b) nominate P as their dispensing contractor (or one of them) in their entry in their PDS patient details; or
- (c) ask P to provide them with any directed service.

(5) For the purpose of sub-paragraph (4), "relevant person" means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

- (a) any NHS body or provider of primary medical services; and
- (b) any person employed or engaged by any of the persons mentioned in paragraph (a).

(6) In the case of the provision of appliances, P (including P's staff) must not 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), 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 10(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

#### Duty to provide information about fitness matters as they arise

**31.**—(1) An NHS pharmacist (P) and, where P is a body corporate, every director and superintendent of P must, within 7 days of its occurrence, inform the NHSCB in writing if they—

- (a) are convicted of any criminal offence in the United Kingdom;
- (b) are bound over following a criminal conviction in the United Kingdom;
- (c) accept a police caution in the United Kingdom;
- (d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);
- (e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995 <sup>M13</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992 <sup>M14</sup> (penalty as alternative to prosecution);
- (f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (h) are 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) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;
- (j) become the subject of any investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;
- (k) become the subject of any investigation by the NHS BSA in relation to fraud;
- (l) become the subject of any investigation by another primary care organisation which might lead to their removal from a relevant list; or
- (m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and 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) If a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director or superintendent of a body corporate, X must in addition inform the NHSCB within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom;
- (b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;
- (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 by the NHS BSA 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 primary care organisation which might lead to its removal from any relevant list; or
- (h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and 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) P or X must consent to a request being made by the NHSCB 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.

#### Marginal Citations

- M13 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1); and the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), section 70(3).
- M14 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and amended by the Social Security Fraud Act 2001 (c. 11) ("the 2001 Act"), section 14. The amendments made by the 2001 Act are to be repealed by, and other amendments to section 115A are to be made by, the Welfare Reform Act 2012 (c. 5), sections 113 to 115, and Schedule 14, Part 1.

## Other information to be supplied

**32.**—(1) An NHS pharmacist (P) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about P in the pharmaceutical list which P has not otherwise notified to the NHSCB in accordance with these Regulations;
- (b) if P is an individual, any change to P's private address;
- (c) if P is a body corporate, any change to the name, registration number, registered office or telephone number relating to that office of the body corporate; and
- (d) any occurrence requiring P's addition to or removal from an EPS list or a change in the information recorded about P in that list.

(2) P must give the NHSCB, if it so requests, the name of any pharmacist employed or engaged by P who is responsible for dispensing a particular prescription.

(3) If P is a body corporate, it must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to—

- (a) the names of its directors; and
- (b) the name or address of its superintendent.

(4) If P is a body corporate and appoints a superintendent or director who was not listed on P's application for inclusion on a pharmaceutical list, P must, within 30 days of the person's appointment, supply to the NHSCB the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

(5) If P or a director or superintendent of P (if P is a body corporate) is on, or is a director or superintendent of a body corporate which is on, a relevant list other than a pharmaceutical list held by the NHSCB, they must supply in writing to the NHSCB—

- (a) in the case of a director or superintendent of a body corporate, the name and registered office of the body corporate on the other relevant list; and
- (b) particulars of the other relevant list.

(6) P or the director or superintendent of P (if P is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director or superintendent, apply to be included in a relevant list of another primary care organisation, and of the outcome of any such application.

# [<sup>F121</sup>Facilitating remote access to pharmaceutical services

32A.—(1) An NHS pharmacist (P) must, to the extent reasonable—

- (a) facilitate remote access to the pharmaceutical services provided at or from P's pharmacy premises, where users wish to access those services under arrangements that make those services available using remote access; and
- (b) establish, maintain and keep under review procedures to facilitate remote access to those services under arrangements that make those services available using remote access.]

F121 Sch. 4 para. 32A inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 18

# **Co-operation with** [<sup>F122</sup>NHS England]

**33.** An NHS pharmacist must co-operate with [ $^{F122}$ NHS England] in the discharge by [ $^{F122}$ NHS England] of the duty under section 1F(1) of the 2006 Act <sup>M15</sup> (duty as to education and training).

F122 Words in Sch. 4 para. 33 substituted (1.4.2023) by The Health Education England (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/368), reg. 1(2), Sch. 2 para. 14(3) (with reg. 7)

### **Marginal Citations**

M15 Section 1F was inserted by the Health and Social Care Act 2012 (c. 7), section 7.

## Complaints

**34.**—(1) An NHS pharmacist must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 <sup>M16</sup>, for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

#### **Marginal Citations**

M16 S.I. 2009/309; amended by S.I. 2009/1768.

#### Inspections and access to information

**35.**—(1) An NHS pharmacist (P) must allow persons authorised in writing by the NHSCB to enter and inspect P's pharmacy premises at any reasonable time, for the purposes of—

- (a) ascertaining whether or not P is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing-
  - (i) the provision made by P, 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 P of the pharmaceutical services P 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 Pharmaceutical Committee for the area where the pharmacy premises are situated have been invited to be present at the inspection, where this is requested by P;
- (c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and
- (d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

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

 $[^{F123}(4)$  P must, at the request of the NHSCB, send to the NHSCB by means of an electronic communication of the type specified in the request any information to which a person authorised in writing by the NHSCB would have access during an inspection of P's pharmacy premises pursuant to sub-paragraph (1), if—

- (a) P has that information in a form which means it may be sent by that form of electronic communication; or
- (b) it is reasonable for the NHSCB to request that P convert that information into a form which means that it may be sent by that form of electronic communication (and the NHSCB does so request).

(5) P must, at the request of NHSCB or a person authorised in writing by the NHSCB to make the request, send to the NHSCB or that person by means of an electronic communication, a duly completed questionnaire, which is—

(a) in a format approved by the NHSCB; and

(b) for the purpose of enabling NHSCB, or a person authorised in writing by the NHSCB, to determine whether or when it is necessary or expedient for a person authorised in writing by the NHSCB to undertake an inspection of P's premises pursuant to sub-paragraph (1).

(6) Before information is requested pursuant to sub-paragraph (5), the NHSCB must consult the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act, in respect of pharmaceutical remuneration of NHS pharmacists on the terms of the request.]

F123 Sch. 4 para. 35(4)-(6) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), 19

## Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations.

View outstanding changes

# Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

- blanket amendment words substituted by S.I. 2023/1071 Sch. para. 1