

## SCHEDULE 5

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

### PART 4

#### Clinical governance and complaints

##### Clinical governance

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

(2) A system of clinical governance is “acceptable” if it provides for—

- (a) compliance with the clinical governance components set out in sub-paragraph (3), and
- (b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.

(3) The clinical governance components comprise of the following—

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

- (i) a requirement that the NHS pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of the NHS pharmacist’s pharmacy,
- (ii) a requirement that the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy,
- (iii) a requirement that where the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy (whether the NHS pharmacist is producing their own publicity material or advertising services in material published by another person), the NHS pharmacist does so in a manner which makes clear that those services are funded as part of the health service,
- (iv) a requirement that the NHS pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS pharmacist intends to take,
- (v) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
- (vi) an approved complaints system (which meets the requirements of this Part),

<sup>F1</sup>(vii) . . . . .

(viii) a requirement that the NHS pharmacist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, <sup>F2</sup>...

(ix) monitoring arrangements for compliance with the Equality Act 2010(1), [<sup>F3</sup>and]

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(1) 2010 c. 15.

- [<sup>F4</sup>(x) a requirement that the NHS pharmacist must have regard to the code of practice on access to premises prepared and published by the Welsh Ministers under section 19(1) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (“the 2020 Act”) (so far as the code is relevant) in exercising any function that relates to the provision of health services or social services (within the meaning of those terms in section 21 of the 2020 Act),]
- (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
- (c) a risk management programme, which includes—
- (i) arrangements for ensuring that all stock is handled in an appropriate way,
  - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
  - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
    - (aa) a patient safety incident log, and
    - (bb) a near-miss log,
  - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and [<sup>F5</sup>NHS England],
  - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
  - (vi) appropriate waste disposal arrangements (in addition to those required under paragraphs 14 and 15) for clinical and confidential waste,
  - (vii) a clinical governance lead person for each pharmacy, appointed as such by the NHS pharmacist (or that is the NHS pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
  - (viii) appropriate child protection procedures, and
  - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(2),
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS pharmacist—
- (i) in respect of the provision of drugs in accordance with a repeatable prescription,
  - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
  - (iii) to people caring for themselves or their families,

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

- (e) a staffing and staff management programme, which includes—
- (i) arrangements for appropriate induction training for staff, including any locum,

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(2) 1974 c. 37.

- (ii) appropriate training for all staff in respect of any role they are asked to perform,
- (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
- (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of pharmaceutical, or other NHS, services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
- (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
- (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum, who, arising out of their employment with the NHS pharmacist—
  - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996<sup>(3)</sup> (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
  - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,
- (f) an information governance programme, which provides for—
  - (i) compliance with approved procedures for information management and security, and
  - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—
  - (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised, and
  - (ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

#### Textual Amendments

- F1** Sch. 5 para. 28(3)(a)(vii) omitted (1.4.2023) by virtue of [The Health and Social Care \(Quality and Engagement\) \(Wales\) Act 2020 \(Consequential, Supplementary and Incidental Amendments and Revocations\) \(Secondary Legislation\) Regulations 2023 \(S.I. 2023/299\)](#), regs. 1(2), **9(5)(d)**
- F2** Word in Sch. 5 para. 28(3)(a)(viii) omitted (1.4.2023) by virtue of [The Health and Social Care \(Quality and Engagement\) \(Wales\) Act 2020 \(Consequential, Supplementary and Incidental Amendments and Revocations\) \(Secondary Legislation\) Regulations 2023 \(S.I. 2023/299\)](#), regs. 1(3)(b), **9(5)(e)**

(3) [1996 c. 18](#); section 43A was inserted by section 1 of the Public Interest Disclosure Act [1998 \(c. 23\)](#). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, PART 4. (See end of Document for details)

- F3** Word in Sch. 5 para. 28(3)(a)(ix) inserted (1.4.2023) by The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Consequential, Supplementary and Incidental Amendments and Revocations) (Secondary Legislation) Regulations 2023 (S.I. 2023/299), regs. 1(3)(b), **9(5)(f)**
- F4** Sch. 5 para. 28(3)(a)(x) inserted (1.4.2023) by The Health and Social Care (Quality and Engagement) (Wales) Act 2020 (Consequential, Supplementary and Incidental Amendments and Revocations) (Secondary Legislation) Regulations 2023 (S.I. 2023/299), regs. 1(3)(b), **9(5)(g)**
- F5** Words in Sch. 5 para. 28(3)(c)(iv) substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), regs. 1(1), **103(4)**

#### Commencement Information

- I1** Sch. 5 para. 28 in force at 1.10.2020, see **reg. 1(2)(b)**

### Professional standards

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

#### Commencement Information

- I2** Sch. 5 para. 29 in force at 1.10.2020, see **reg. 1(2)(b)**

### Inducements

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

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

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

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

#### Commencement Information

- I3** Sch. 5 para. 30 in force at 1.10.2020, see **reg. 1(2)(b)**

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

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

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,

- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(4)</sup> (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992<sup>(5)</sup> (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them,
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness grounds,

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

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

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

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(4) 1995 c. 46.

(5) 1992 c. 5.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, PART 4. (See end of Document for details)

(h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness grounds,

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

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

#### Commencement Information

**I4** Sch. 5 para. 31 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Home Local Health Board of bodies corporate

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

#### Commencement Information

**I5** Sch. 5 para. 32 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

### Complaints

**33.** An NHS pharmacist must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011(6), for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

#### Commencement Information

**I6** Sch. 5 para. 33 in force at 1.10.2020, see [reg. 1\(2\)\(b\)](#)

(6) S.I. 2011/704 (W. 108), amended by S.I. 2011/1706 (W. 192).

**Changes to legislation:**

There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, PART 4.