

SCHEDULE 4

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

PART 4

Clinical Governance and Complaints

Clinical governance

27.—(1) An NHS pharmacist must, in connection with all the 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 the 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),
 - (vii) a requirement that the NHS pharmacist co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
 - (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, and
 - (ix) monitoring arrangements for compliance with the Equality Act 2010(1);

(1) 2010 c. 15.

Status: This is the original version (as it was originally made).

- (b) a clinical audit programme (normally of five 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 the National Health Service Commissioning Board,
 - (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 13 and 14) 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 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;
- (e) a staffing and staff management programme, which includes—
 - (i) arrangements for appropriate induction training for staff, including any locum,
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service including continuing

(2) 1974 c. 37.

- 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⁽³⁾ (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, 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.

Professional standards

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

Inducements

29.—(1) An NHS pharmacist or his or her 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 him or her must accept or receive any gift or reward in respect of only—

(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.

Status: This is the original version (as it was originally made).

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 11(4) or 19(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 19(2)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness to practise matters: NHS pharmacists on pharmaceutical lists on 10 May 2013

30. An NHS pharmacist, and subject to paragraph 32 where it is a body corporate every director and superintendent of the NHS pharmacist, who is included in a pharmaceutical list maintained by a Local Health Board on 10 May 2013 must on or before 9 November 2013 provide in writing to the Local Health Board the information about fitness matters set out in paragraph 31.

Duty to provide information about fitness 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 him or her 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⁽⁴⁾ (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992⁽⁵⁾ (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 his or her professional conduct, and there is a finding against him or her;
- (i) becomes the subject of any investigation into his or her professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his or her professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against him or her;
- (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,

(4) 1995 c. 46.

(5) 1992 c. 5.

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

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

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

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

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 30, 31 and 35(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 46). 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.

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.

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