SCHEDULE 4

Terms of service of NHS pharmacists

PART 4

Other terms of service

Clinical governance

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.

(2) For these purposes a system of clinical governance 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 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,

(iv) a requirement that P undertakes an approved patient satisfaction survey annually, in an approved manner,

(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, and

(vii) P's monitoring arrangements in respect of P's compliance with the Equality Act 2010(**1**);

(b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one other audit agreed by the NHSCB in each financial year;

(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,

(**1**) 2010 c. 15.

(iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State(**2**) and the NHSCB,

(v) appropriate standard operating procedures, including standard operating procedures in respect of 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(**3**);

(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,

(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 in respect of the provision of directed services,

(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—

(**2**) 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.

(**3**) 1974 c. 37.

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**4**) (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,

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

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.

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;

(**4**) 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).

(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(**5**) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(**6**) (penalty as alternative to prosecution);

(**5**) 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).

(**6**) 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.

(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.

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.

Co-operation with Health Education England

33. An NHS pharmacist must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act(**7**) (duty as to education and training).

(**7**) 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(**8**), 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.

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.

(**8**) S.I. 2009/309; amended by S.I. 2009/1768.