

SCHEDULE 1

TERMS OF SERVICE OF PHARMACISTS

PART 4

CLINICAL GOVERNANCE, FITNESS TO PRACTISE AND COMPLAINTS

Clinical governance

26.—(1) A pharmacist shall, in connection with all the pharmaceutical services provided by him, participate, in the manner reasonably required by his Primary Care Trust, 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 Secretary of State and comprises the following components—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of his pharmacy,
 - (ii) a requirement that the pharmacist publicises the NHS services that are available at or from his pharmacy,
 - (iii) a requirement that the pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner,
 - (iv) the pharmacist’s monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
 - (v) an approved complaints system (which meets the requirements of this Part),
 - (vi) a requirement that the pharmacist co-operates appropriately with local Patients’ Forum visits and takes appropriate action following the outcome of such visits,
 - (vii) a requirement that the pharmacist co-operates appropriately with any reasonable inspection or review that the Primary Care Trust or any relevant statutory authority wishes to undertake, and
 - (viii) the pharmacist’s monitoring arrangements in respect of his compliance with the Disability Discrimination Act 1995;
- (b) a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by his Primary Care Trust 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,
 - (iv) 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,

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- (v) appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,
 - (vi) a clinical governance lead person in respect of each pharmacy,
 - (vii) appropriate child protection procedures, and
 - (viii) the pharmacist's monitoring arrangements in respect of his compliance with the Health and Safety at Work etc. Act 1974;
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a pharmacist in respect of repeatable prescriptions or to people caring for themselves or their families;
- (e) a staffing and staff management programme, which includes—
- (i) arrangement for appropriate induction for staff and 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 services as part of the health service, including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services, and
 - (v) arrangements for addressing poor performance (in conjunction with a Primary Care Trust as appropriate); and
- (f) a use of information programme, which includes—
- (i) appropriate arrangements (having regard to issues both of rights of access to information and of confidentiality) to support both health care delivery and clinical governance,
 - (ii) appropriate arrangements in respect of compliance with “Confidentiality: the National Health Service Code of Practice”(1),
 - (iii) the pharmacist's monitoring arrangements in respect of his compliance with the Data Protection Act 1998 and with regard to patient confidentiality, and
 - (iv) appropriate training for staff with regard to compliance with the Data Protection Act 1998 and patient confidentiality,
- and for the purposes of this sub-paragraph, “approved” means approved by the Secretary of State.

Professional Standards

27. A pharmacist shall 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.

28.—(1) A pharmacist or his staff shall 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 his—

(1) This Code of Practice is available at www.dh.gov.uk/publicationsandstatistics.

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- (a) presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription; or
 - (b) nominating the pharmacist as his dispensing contractor (or one of them) in his NHS Care Record.
- (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).

Duty to provide information about fitness to practise matters: pharmacists on pharmaceutical lists on 1st April 2005

29.—(1) In the case of a pharmacist who is on a pharmaceutical list on 1st April 2005, subject to paragraph 31, the pharmacist and where the pharmacist is a body corporate, every director and superintendent of the pharmacist shall, by 3rd October 2005, supply in writing information to the Primary Care Trust as to whether he—

- (a) has any criminal convictions in the United Kingdom;
- (b) has accepted a police caution in the United Kingdom;
- (c) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging him absolutely (without proceeding to conviction);
- (d) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995⁽²⁾ (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992⁽³⁾ (penalty as alternative to prosecution);
- (e) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (f) has been charged with an offence and is currently the subject of any proceedings which might lead to a conviction, which have not yet been notified to the Primary Care Trust;
- (g) has been subject to any investigation into his professional conduct by any licensing, regulatory or other body, where the outcome was adverse;
- (h) is currently subject to any investigation into his professional conduct by any licensing, regulatory or other body;
- (i) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (j) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list;
- (k) is, or has been where the outcome was adverse, subject to an investigation into his professional conduct in respect of any current or previous employment; or
- (l) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practice grounds,

and if so, he shall give details of any investigation or proceedings which were or are to be brought, including the nature of that 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 31, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director or superintendent of a body corporate, he shall in addition and

(2) 1995 c. 46.

(3) 1992 c. 5; section 115A was inserted by section 15 of the Social Security Administration (Fraud) Act 1997 (c. 47).

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at the same time supply in writing information to the Primary Care Trust as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom;
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales;
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Primary Care Trust;
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse;
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body;
- (f) is to his knowledge, or has been where the outcome was adverse, the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (g) is the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any of another Primary Care Trust's lists, or equivalent lists kept by an equivalent body, or is currently suspended from such a list, on fitness to practise grounds,

and if so, he shall 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 shall consent to a request being made by the Primary Care Trust 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.

(4) A person need not supply information under sub-paragraph (1)(a) to (e) or (2)(a) or (b) if that information would not be included in an enhanced criminal record certificate issued to that person by the Secretary of State under section 115(1) of the of the Police Act 1997⁽⁴⁾ (enhanced criminal record certificates) on the day on which that person supplies the information to the Primary Care Trust.

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

30.—(1) Subject to paragraph 31, a pharmacist and where the pharmacist is a body corporate, every director and superintendent of the pharmacist shall, within 7 days of its occurrence, inform the Primary Care Trust in writing if he—

- (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 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 or a penalty under section 115A of the Social Security Administration Act 1992;

(4) 1997 c. 50.

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- (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 professional conduct, and there is a finding against him;
- (i) becomes the subject of any investigation into his professional conduct by any licensing, regulatory or other body;
- (j) becomes subject to an investigation into his 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;
- (k) becomes the subject of any investigation by the National Health Service Counter Fraud and Security Management Service in relation to fraud;
- (l) becomes the subject of any investigation by another Primary Care Trust or equivalent body, which might lead to his removal from any list or equivalent list; or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall 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 31, if a person to whom paragraph (1) applies is, or was at the time of the originating events, a director or superintendent of a body corporate, he shall in addition inform the Primary Care Trust 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 by the National Health Service Counter Fraud and Security Management Service 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 Trust or equivalent body, which might lead to its removal from any list or equivalent list; or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in any list, or equivalent list, on fitness to practise grounds,

and if so, he shall 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 shall consent to a request being made by the Primary Care Trust to any employer or former employer or licensing or regulatory body in the

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United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Primary Care Trust of bodies corporate

31. Where a pharmacist is a body corporate with a registered office in England, the information to be provided under paragraphs 29 and 30 may be provided only to the Primary Care Trust in which that registered office is located, if the pharmacist also provides that Primary Care Trust with details of all the other Primary Care Trusts in whose pharmaceutical lists it is included, and in these circumstances that Primary Care Trust shall pass the information on to any other Primary Care Trust—

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

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

that requests it.

Complaints

32. A pharmacist shall have in place arrangements for the handling and consideration of complaints about any matter connected with his provision of pharmaceutical services which are essentially the same as those set out in Part II of the National Health Service (Complaints) Regulations 2004⁽⁵⁾.

(5) *S.I. 2004/1768; see also* regulation 4 of those Regulations which imposes a requirement on Primary Care Trusts to ensure that pharmacists have such arrangements in place.