SCHEDULE 1 Regulation 3(2)

TERMS OF SERVICE FOR PHARMACISTS AND PHARMACY CONTRACTORS

Interpretation

1. In these terms of service unless the context otherwise requires–

(a) except in relation to a pharmacy contractor who has notified the Board under regulation 3(5) that such pharmacy contractor wishes to be excluded from the arrangements for the supply of contraceptive substances and appliances referred to in regulation 3, "drugs" includes contraceptive substances and "appliances" includes contraceptive appliances;

(b) any reference to a numbered paragraph is a reference to the paragraph bearing that number in these terms of service and any reference to a numbered sub-paragraph is a reference to the sub-paragraph bearing that number in that paragraph.

Division of responsibilities between individuals and corporate bodies

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

(a) if the pharmacy contractor is a pharmacist–

(i) that pharmacy contractor must comply with that requirement; and

(ii) if such pharmacy contractor employs or engages a pharmacist in connection with the provision of pharmaceutical services, that pharmacy contractor must secure compliance with that requirement by such pharmacists, and such pharmacists must also comply with that requirement; and

(b) if the pharmacy contractor is not a natural person, that pharmacy contractor must secure compliance with that requirement by the pharmacists whom it employs or engages, and those pharmacists must comply with that requirement,

and references in this Schedule must be construed accordingly.

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

Incorporation of provisions of regulations, etc.

3. Any provisions of the following affecting the rights and obligations of pharmacists and pharmacy contractors shall be deemed to form part of the terms of service:–

(a) these Regulations;

(b) the Drug Tariff;

(c) any scheme made under regulation 11;

(d) so much of the National Health Service (Discipline Committees) (Scotland) Regulations 2006 as relates to–

(i) the investigation of disciplinary matters relating to pharmacists and pharmacy contractors and other investigations to be made by the pharmaceutical discipline committee and the joint discipline committee and the action which may be taken by the Board as a result of such investigations, including the withholding of remuneration from pharmacists and pharmacy contractors where there has been a breach of the terms of service;

(ii) appeals to the Scottish Ministers from decisions of the Board; and

(e) the National Health Service (Tribunal) (Scotland) Regulations 2004.

Provision of pharmaceutical services

4.—(1) Subject to the other provisions of these Regulations where–

(a) any person presents 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; or

(ii) an order for a drug specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug which can only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract signed by and endorsed on its face with the reference "SLS" by a prescriber; or

(iii) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a prescriber; or

(iv) an order for listed drugs signed by a dentist; or

(b) subject to sub-paragraphs (4) and (9), the pharmacist receives from the ePharmacy service an electronic prescription form which contains an order of a kind specified in sub sub-paragraph (a)(i) to (iv) and the patient named on the form, or a person on the patient's behalf, requests the provision of drugs or appliances in accordance with that prescription and completes and signs a declaration of entitlement to exemption or a statement that a charge has been paid,

a pharmacist shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as the pharmacist supplies in the normal course of business and any drugs so specified shall be in a suitable container.

(2) In this paragraph–

(a) "chronic medication service" means a directed service provided by a pharmacy contractor with whom a Health Board has made arrangements in accordance with directions issued by the Scottish Ministers relating to the provision of a chronic medication service;

(b) "serial prescriber" means a doctor who in the course of the provision of primary medical services in terms of the Act orders drugs, medicines or listed appliances for–

(i) a registered patient within the meaning of regulation 2(1) of the GMS Contracts Regulations where the doctor is providing primary medical services in terms of a general medical services contract under section 17J of the Act;

(ii) a registered patient within the meaning of regulation 2 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004(**1**) where the doctor is providing primary medical services in terms of an agreement under section 17C of the Act; or

(iii) a patient registered to receive primary medical services in terms of the Act, other than as in (i) and (ii), except where that patient is a temporary resident, being a person who is resident in Scotland for more than 24 hours and less than 3 months,

and such patient has registered with a pharmacy contractor for the provision of the chronic medication service;

(**1**) S.S.I. 2004/116, to which there are no relevant amending instruments.

(a) "serial prescription" means an order for drugs, medicines or listed appliances which comprises:

(i) a non-electronic prescription form generated by a computer and signed in ink by a serial prescriber containing the following information:

(aa) the drugs, medicines or listed appliances ordered for a patient;

(bb) the total quantity or period for which the drugs, medicines or listed appliances are ordered, which period shall not exceed 48 weeks from the date of issue of the prescription;

(cc) the quantity of the drugs, medicines or listed appliances which are to be dispensed to the patient at any one time; and

(dd) the instructions for use of the drugs, medicines or listed appliances; and

(ii) an electronic copy of that prescription form transmitted through the ePharmacy service to the pharmacy contractor with whom the patient has registered for the provision of the chronic medication service.

(b) "relevant pharmacist" means:

(i) the pharmacy contractor, where the pharmacy contractor is a pharmacist; or

(ii) any pharmacist employed or engaged by, that pharmacy contractor; and

(iii) where the pharmacy contractor is not a pharmacist, any pharmacist employed or engaged by that pharmacy contractor.

(3) Where a person has registered with a pharmacy contractor for the provision of the chronic medication service, that pharmacy contractor shall ensure that a relevant pharmacist, with reasonable promptness, shall provide the drugs, medicines or listed appliances ordered on a serial prescription in the quantities and at the intervals specified on the serial prescription in accordance with the provisions in sub-paragraph (2)(c)(i)(aa) to (dd).

(4) The patient or a person acting on behalf of the patient shall present the non-electronic copy of the serial prescription to the relevant pharmacist on the first occasion that the patient asks to be supplied with drugs, medicines or listed appliances ordered for the patient on a serial prescription.

(5) When the patient or a person acting on behalf of the patient asks to be supplied with drugs, medicines or listed appliances ordered for the patient on a serial prescription at any subsequent interval specified on the serial prescription, the relevant pharmacist shall supply the drugs, medicines or appliances in accordance with the serial prescription in accordance with the provisions in sub-paragraph (2)(c)(i)(aa) to (dd) only after drawing down the electronic copy of that serial prescription from the ePharmacy service to check that the serial prescriber has not cancelled that serial prescription.

(6) A relevant pharmacist shall not provide under a serial prescription a controlled drug within the meaning of the Misuse of Drugs Act 1971(**2**), other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001(**3**).

(7) A relevant pharmacist shall not supply any drugs, medicines or listed appliances ordered on a serial prescription if–

(a) the serial prescription was presented for dispensing for the first time more than 24 weeks after the date the serial prescription was signed by the serial prescriber;

(b) in the pharmacist's professional judgement the supply is not appropriate for the patient;

(c) the non-electronic prescription form is not signed by the serial prescriber; or

(**2**) 1971 c. 38.
(**3**) S.I.2001/398. Schedule 5 was amended by S.I. 2005/2864.

(d) the pharmacist has been informed by the serial prescriber that the serial prescription has been cancelled.

(8) A relevant pharmacist shall ensure on each occasion that drugs, medicines or appliances are supplied on a serial prescription that such supply is appropriate for the patient.

(9) Where a relevant pharmacist reasonably believes that a form presented as a prescription form under sub-paragraph (1) or a form presented as serial prescription under sub-paragraph (4) is not a genuine order for the person named on the form the pharmacist shall refuse to supply the order for drugs or appliances on the form.

(10) A relevant pharmacist shall 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 Schedules 4 and 5 to the Misuse of Drugs Regulations 2001(**4**).

(11) A relevant pharmacist may refuse to supply drugs or appliances ordered on a prescription form or a serial prescription where–

(a) the pharmacist or other person is subjected to or threatened with violence by the person presenting the prescription form or serial prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or serial prescription, or by any person accompanying that person; or

(b) the person presenting the prescription form or serial prescription, or requesting the provision of drugs or appliances in accordance with an electronic prescription form or serial prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(12) A relevant pharmacist shall not, except for the duration of an emergency requiring the flexible provision of pharmaceutical services, accept for dispensing any prescription form or serial prescription transmitted from or received at a registered pharmacy which is not included in the pharmaceutical list.

(13) A relevant pharmacist shall not, except for the duration of an emergency requiring the flexible provision of pharmaceutical services, supply any drugs or listed appliances ordered on a prescription form or serial prescription other than at a registered pharmacy which is included in the pharmaceutical list.

(a) (14) (a) Subject to sub-paragraphs (b) and (c) a pharmacist shall, before supplying a prescribed item to any person presenting a non electronic prescription form or a supply form or a serial prescription with a declaration claiming either charge exemption under regulation 7 of the National Health Service (Charges and Drugs and Appliances) (Scotland) Regulations 2008(**5**) ("the 2008 Regulations") or charge remission under the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) Regulations 2003(**6**), or a declaration of entitlement to such exemption or remission in relation to an electronic prescription form, request evidence of the patient's entitlement to such exemption or remission.

(b) Sub-paragraph (a) shall not apply in respect of claims for exemption under regulation 7(1)(a) or (c) of the 2008 Regulations where–

(i) the prescription form is an electronic prescription form and the person's date of birth is specified in the electronic prescription form; or

(ii) the prescription form is a non-electronic prescription form and the person's date of birth has been printed by means of a computer on the non-electronic prescription form or serial prescription.

(**4**) Schedule 4 was amended by S.I. 2003/1432, 2005/3372 and 2007/2154.
(**5**) S.S.I. 2008/27. Amended by S.S.I. 2008/105 and 2009/37.
(**6**) S.S.I. 2003/460. Amended by S.S.I. 2004/102 and 166, 2005/3 and 179, 2006/142, 183 and 440, 2007/225, 259 and 391 and 2008/27, 147, 288 and 390. S.S.I. 2006/142 was revoked by S.S.I. 2006/183.

(c) Sub-paragraph (a) shall not apply in respect of claims for exemption under regulation 7(1)(a) to (i) of the 2008 Regulations where the pharmacist has information in the pharmacist's possession at the time of supplying the item which confirms that the patient is entitled to the exemption claimed.

(d) Where the person presenting a non electronic prescription form or a supply form, or declaration of entitlement to exemption in relation to an electronic prescription form or serial prescription does not show valid evidence of entitlement and the pharmacist, in respect of a claim for exemption made under regulation 7(1)(a) to (i) of the 2008 Regulations does not have evidence in the pharmacist's possession to confirm that the patient is entitled to make that claim, the pharmacist shall mark that patient's non electronic prescription form or a supply form or that patient's declaration of entitlement to exemption in relation to an electronic prescription form or serial prescription accordingly before supplying the prescribed item.

(a) (15) (a) A pharmacist independent prescriber shall not supply any item ordered on a prescription form by that pharmacist independent prescriber unless the conditions specified in paragraph (b) are met.

(b) The conditions referred to in paragraph (a) are–

(i) the item has been ordered in accordance with the arrangements which a Health Board has made pursuant to Directions issued by the Scottish Ministers in respect of pharmacist independent prescribers; and

(ii) the pharmacist independent prescriber reasonably considers that either–

(aa) exceptional circumstances exist whereby it is in the best interests of the patient to whom the item is to be supplied that the pharmacist independent prescriber who orders the item should supply it; or

(bb) the patient to whom the item is to be supplied, or the patient's representative, is otherwise unlikely to be able to obtain the item without suffering excessive inconvenience or delay.

(c) A pharmacist independent prescriber who supplies an item which such pharmacist independent prescriber has ordered must endorse the prescription form for that item with the words "self-dispensed".

(16) Where an order, not being an order to which the Poisons Rules 1982(**7**) or the Misuse of Drugs Regulations 2001, except Schedules 4 and 5 to those regulations, apply, issued by a prescriber or a dentist on a prescription form for drugs or listed drugs does not prescribe the quantity, strength or dosage thereof, a pharmacist may supply such strength and dosage of drugs or listed drugs so ordered as the pharmacist shall consider to be appropriate, and, subject to the provisions of sub-paragraph (23), in such quantity as the pharmacist considers to be appropriate for a course of treatment of the patient to whom the order relates, for a period not exceeding five days.

(17) Where an order to which sub-paragraph (16) applies is for–

(a) an oral contraceptive; or

(b) a drug or listed drug which is available for supply as part of pharmaceutical services only together with one or more drugs or listed drugs; or

(c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require supply in an unopened package,

which is not available for supply as part of pharmaceutical services except in such packages that the minimum available package contains a quantity appropriate to a course of treatment for a patient

(**7**) S.I. 1982/218. Amended by S.I. 1985/1077, 1986/10 and 1704, 1989/112 and 1992/2293.

for a period of more than five days, the pharmacist may supply for the patient to whom the order relates, such minimum available package.

(18) Where any drug, not being one to which the Misuse of Drugs Regulations 2001, except Schedule 5 to those regulations, apply, ordered by a prescriber or a dentist on a prescription form, or a by a serial prescriber on a serial prescription, is available for provision by a pharmacist 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 calendar pack or special container,

the pharmacist shall, subject to sub-paragraph (19), provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(19) A pharmacist shall not provide, pursuant to sub-paragraph (18), a drug in a calendar pack where in the pharmacist's professional judgement, it was the intention of the prescriber or dentist who ordered the drug that it should be provided only in the exact quantity ordered.

(20) In this paragraph–

(a) "calendar pack" means a blister or strip pack showing the days of the week or month against each of the several units in the pack; and

(b) "special container" means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(21) All drugs and preparations supplied by pharmacists shall, where a standard or formula is specified in the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary (including any Appendix published as part of that Formulary), or the Drug Tariff, conform to the standard or formula so specified, and in any other case shall be of a grade or quality not lower than the grade or quality ordinarily used for medicinal purposes.

(22) All appliances supplied by pharmacists shall conform to the specifications included in the Drug Tariff.

(23) Subject to any regulations in force under the Weights and Measures Act 1985(**8**), a pharmacist shall provide pharmaceutical services only in response to and, subject to sub-paragraphs (16), (17), (18) and (29), in accordance with an order on a non-electronic prescription form signed as specified in sub-paragraph (1)(a), or in accordance with an electronic prescription form received in accordance with sub-paragraph (1)(b), or in accordance with a serial prescription in accordance with the provisions in sub-paragraph (2)(c) or in accordance with the terms of a Patient Group Direction issued by a Board in accordance with Article 12C of the Prescription Only Medicines (Human Use) Order 1997 (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction), except that in a case of urgency where a prescriber personally known to a pharmacist requests that pharmacist to dispense a drug or appliance the pharmacist may supply that drug or appliance before receiving such a prescription form, only if–

(a) that drug is not a scheduled drug;

(b) that drug is not 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;

(**8**) 1985 c. 72.

(c) that appliance is not a restricted availability appliance; and

(d) in any case the prescriber undertakes to furnish the pharmacist, within 72 hours, with such a prescription form.

(24) Except as provided in sub-paragraph (25), a pharmacist shall not supply, by way of pharmaceutical services under the Act or otherwise, any scheduled drug which is ordered by name, formula or other description on a prescription form or a serial prescription.

(25) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or a serial prescription either by that name or by its formula, a pharmacist may supply a drug which has the same specification notwithstanding that it is a scheduled drug.

(26) Where a drug which is ordered as specified in sub-paragraph (23) combines more than one drug, that sub-paragraph shall apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(27) A pharmacist or pharmacy contractor 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 a person presenting an order for drugs or appliances on a prescription form or serial prescription.

(28) A pharmacist or pharmacy contractor shall not, except with the consent of the Scottish Ministers, provide at a health centre services other than pharmaceutical services in accordance with section 27 of the Act.

(29) A pharmacist may dispense a drug where the conditions for urgent supply specified in paragraph (4) of article 8 of the Prescription Only Medicines (Human Use) Order 1997 are satisfied, before receiving a prescription form, if the pharmacist is satisfied that it is appropriate to do so.

Directed services

5. A pharmacy contractor with whom a Health Board makes an arrangement for the provision of any directed service shall comply with the terms and conditions of the arrangement and any terms contained in the relevant Directions.

Premises and hours of business

6.—(1) Subject to regulation 11(5), pharmaceutical services shall be provided from the premises specified in the application made by the pharmacy contractor for inclusion in the Board's list, and the premises shall be open for the supply of pharmaceutical services during the hours specified in the scheme to be made by the Board for that purpose under the Regulations.

(2) At every premises from which pharmaceutical services are provided there shall be exhibited a notice to be provided by the Board in the form prescribed in Schedule 2. There shall also be exhibited at such premises, at times when those premises are not open, and in such a manner as to be visible at such times, a notice in a form approved by the Board, indicating the facilities available for securing the dispensing of medicines urgently required.

(3) Pharmaceutical services shall not, except with the consent of the Board, or on appeal, of the Scottish Ministers, be provided by a pharmacy contractor in premises occupied by a doctor other than at a health centre.

(4) Subject to regulation 6, no pharmacy contractor shall provide pharmaceutical services from any pharmacy or other premises which are not included in the pharmaceutical list in respect of that pharmacy contractor.

Dispensing of medicines

7.—(1) The dispensing of medicines shall be performed either by or under the direct supervision of a pharmacist.

(2) Where the pharmacist referred to in sub-paragraph (1) is employed, the pharmacist must not be one–

(a) who has been disqualified under sections 29B(2) or 30(2) or (5) of the Act (or under any corresponding provision in force in England and Wales or Northern Ireland) from inclusion in the pharmaceutical list of any Board or any equivalent body while the disqualification remains in force; or

(b) who is suspended by direction of the Tribunal or any corresponding decision in England, Wales or Northern Ireland while the suspension remains in force.

Names of pharmacists

8. A pharmacy contractor shall, if so required by the Board, furnish to the Board the name or names of pharmacists employed by that pharmacy contractor in providing pharmaceutical services and directed services.

Drugs, etc. to be supplied without charge

9.—(1) Subject to the provisions of any Regulations made under section 69 of the Act all drugs, containers and appliances supplied under these terms of service shall be supplied free of charge.

(2) Where a pharmacy contractor supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the pharmacy contractor, the container and equipment shall remain the property of the pharmacy contractor who shall have no claim against the Board in the event of the loss of, or damage to, such container or equipment except as may be provided in the Drug Tariff.

Method of payment

10.—(1) A pharmacy contractor is required to furnish to the Board or Agency or to such other person or body as it may direct, on dates to be appointed by the Scottish Ministers after consultation with an organisation which is in their opinion representative of the general body of pharmacy contractors, the prescription forms, serial prescription forms, supply forms and other forms (including electronic copies and electronic claim messages) upon which the orders for drugs and appliances supplied by or on behalf of such pharmacy contractor were given, arranged in such manner as the Board or Agency may direct, together with a statement of accounts containing such particulars relating to the provision by the pharmacy contractor of pharmaceutical services as the Board, with the approval of the Scottish Ministers, may from time to time require.

(2) A pharmacy contractor whose name is included in the pharmaceutical list shall supply, in response to a request from the Scottish Ministers and within one month of the notification of the request, any information which the Scottish Ministers may require for the purpose of conducting any inquiry into the prices, payments, fees, allowances and remuneration specified in these Regulations or the Drug Tariff.

(3) The Board or Agency shall, if any pharmacy contractor so requires, afford the pharmacy contractor reasonable facilities for examining all or any of the forms on which the drugs or appliances supplied by such pharmacy contractor were ordered, together with particulars of the amounts calculated to be payable in respect of such drugs and appliances and if the pharmacy contractor takes objection thereto, the Board or Agency shall take such objection into consideration.

(4) The Board or Agency shall, if so required by an organisation which is recognised by the Scottish Ministers as representative of the general body of pharmacy contractors, afford the said organisation similar facilities for examining such forms and particulars relating to all or any of the pharmacy contractors and shall take into consideration any objection made thereto by the said organisation.

(5) Payment will be made for drugs and appliances in the Drug Tariff at the prices specified therein and for drugs or appliances not in the Drug Tariff in the manner set forth therein subject in either case to any deduction required to be made by regulations made under section 69 of the Act.

(6) Where the Board or Agency is satisfied that adequate reasons have been given, payment may be made to a pharmacy contractor in respect of forms submitted by such pharmacy contractor outwith any set time-limits.

(7) If the Scottish Ministers, after consultation with such organisation as is mentioned in sub-paragraph (4), is satisfied at any time that the method of payment herein before provided for in this paragraph is such that undue delay in payment may be caused thereby, they may direct that the amounts to be payable to a pharmacy contractor shall be calculated by such other method, whether by averaging the amounts payable to a pharmacy contractor or otherwise, as appears to them designed to secure that–

(a) payment may be made within a reasonable time; and

(b) payments to a pharmacy contractor shall, as nearly as may be, remain the same as if the payments had been calculated in accordance with the first mentioned method of payment,

and payments calculated by any such other method shall be deemed for all purposes to be payments made in accordance with these Regulations.

(8) No pharmacy contractor shall be paid in respect of the supply of drugs or listed appliances indicated on a prescription form or serial prescription, or in respect of the supply of drugs or listed appliances in terms of a Patient Group Direction issued by a Health Board in accordance with Article 12C of the Prescription Only Medicines (Human Use) Order 1997, (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction) unless that supply takes place at a registered pharmacy included in the pharmaceutical list in respect of that pharmacy contractor.

(9) Where a payment had been made to a pharmacy contractor to which such pharmacy contractor was not due, the Agency or Board shall draw that over-payment to the attention of such pharmacy contractor and unless the Scottish Ministers direct otherwise the amount overpaid shall be repaid by the pharmacy contractor to the Board or Agency.

Withdrawal from pharmaceutical list

11.—(1) Subject to sub-paragraph (2) a pharmacy contractor may at any time give notice in writing to the Board that such pharmacy contractor desires to withdraw such pharmacy contractor's name from the pharmaceutical list and such pharmacy contractor's name shall be removed therefrom at the expiration of three months from the date of such notice or of such shorter period as the Board may agree.

(2) Where representations are made to the Tribunal under the provisions of section 29 of the Act (the NHS Tribunal), or a request for a review has been made to the Tribunal or a review is to be made by the Tribunal under section 30 of the Act (review etc. of disqualification), such pharmacy contractor shall not, except with the consent of the Scottish Ministers and subject to such conditions as the Scottish Ministers may impose, be entitled to withdraw such pharmacy contractor's name from the list pending the termination of the proceedings on such representations, request for review or review.

(3) The name of any pharmacy contractor whose business is carried on by representatives in accordance with the provisions of the 1968 Act, shall not be removed from the list so long as the

business is carried on by them in accordance with the provisions of that Act, and the representatives agree to be bound by the terms of service of the pharmacy contractor.

Complaints

12.—(1) Subject to sub-paragraph (2), a pharmacy contractor shall establish, and operate in accordance with this paragraph, a procedure (in this paragraph and in paragraph 13 referred to as a "complaints procedure") to deal with any complaints made by or on behalf of any person to whom the pharmacy contractor or a pharmacist acting on its behalf has provided pharmaceutical services.

(2) The complaints procedure to be established by a pharmacy contractor who provides pharmaceutical services from more than one set of premises may be such that it relates to all those premises together.

(3) A complaints procedure shall apply to complaints made in relation to any matter reasonably connected with the pharmacy contractor's provision of pharmaceutical services and within the responsibility or control of–

(a) the pharmacy contractor;

(b) where the pharmacy contractor is a body corporate, any of its directors or former directors;

(c) a former partner of the pharmacy contractor if that pharmacy contractor is a pharmacist;

(d) any pharmacist employed by the pharmacy contractor;

(e) any employee of the pharmacy contractor, other than one falling within sub-paragraph (d),

and in this paragraph and paragraph 13, references to complaints are to complaints falling within this sub-paragraph.

(4) A complaint may be made on behalf of any person with that person's consent, or–

(a) where that person is under 16 years of age–

(i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child; or

(ii) in the care of an authority under Part II of the Social Work (Scotland) Act 1968(**9**) or in the care of a voluntary organisation, by that authority or voluntary organisation; or

(b) where that person is incapable of making a complaint, by a relative or other adult person who has an interest in that person's welfare.

(5) A complaint may be made by a relative or other adult person who had an interest in the person's welfare as respects a person who has died , or where that person was as described in sub-paragraph (4)(a)(ii), by the authority or voluntary organisation.

(6) A complaints procedure shall comply with the following requirements:–

(a) the pharmacy contractor shall specify a person (who need not be connected with the pharmacy contractor and who, in the case of an individual may be specified by such individual's job title) to be responsible for receiving and investigating all complaints;

(b) all complaints shall be–

(i) recorded in writing;

(ii) acknowledged, either orally or in writing, within the period of three days (excluding Saturdays, Sundays, Christmas Day, New Year's Day and any other public or local holiday agreed with the Board) beginning with the day on which the complaint was received by the person specified in sub-paragraph (6)(a) or, where that is not possible as soon as reasonably practicable; and

(**9**) 1968 c. 49.

(iii) properly investigated;

(c) within the period of 10 days (excluding Saturdays, Sundays, Christmas Day, New Year's Day and any other public or local holiday agreed with the Board) beginning with the day on which the complaint was received by the person specified in sub-paragraph (6)(a) or, where that is not possible as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions;

(d) where the investigation of the complaint requires consideration of any records relating to the person as respects whom the complaint is made, the person specified in sub-paragraph (6)(a) shall inform the person who has made the complaint or the person acting on such person's behalf if the investigation will involve disclosure of information contained in those records to a person other than the pharmacist or a director, partner or employee of the pharmacy contractor; and seek that person's consent to such disclosure; and

(e) the pharmacy contractor shall keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from any records relating to the person as respects whom the complaint was made.

(7) At each of the premises at which a pharmacy contractor provides pharmaceutical services the pharmacy contractor shall provide information about such pharmacy contractor's complaints procedure, and give the name (or title) and address of the person specified in sub-paragraph (6)(a); and where the pharmacy contractor provides hypodermic needle exchange services the pharmacy contractor shall provide the same information to the persons referred to in regulation 3(3)(a).

13.—(1) A pharmacy contractor shall cooperate with any investigation of a complaint by the Board in accordance with the procedures which it operates in accordance with directions given under section 2(5) of the Act whether the investigation follows one under the pharmacy contractor's complaints procedure or not.

(2) The cooperation required by sub-paragraph (1) includes–

(a) answering questions reasonably put to the pharmacy contractor by the Board;

(b) providing any information relating to the complaint reasonably required by the Board; and

(c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given), if the pharmacy contractor's presence at the meeting is reasonably required by the Board.

Records

14.—(1) A pharmacy contractor shall keep proper, complete, accurate and up-to-date records in respect of the pharmaceutical services they provide.

(2) A pharmacy contractor shall retain all such records for a minimum period of seven years.

(3) A pharmacy contractor shall, when requested to do so by any authorised officer of the Scottish Ministers, the Agency or the Board during the period in which the contractor is required to retain such records produce them or make them available to such authorised officer of the Scottish Ministers, the Agency or the Board.

(4) A pharmacy contractor shall not be obliged to make records available to a person referred to in sub-paragraph (3) unless they produce, on request, written evidence that they are authorised by the Scottish Ministers, the Agency or the Board, to act on their behalf.

(5) A pharmacy contractor shall designate a person engaged by that pharmacy contractor to take responsibility for practices and procedures relating to the confidentiality of patient data held by them.

Professional standards

15. Without prejudice to any rule or implication of law to that effect, a pharmacist who provides pharmaceutical services in accordance with arrangements made in these Regulations shall do so in conformity with standards generally accepted in the pharmaceutical profession.