

SCHEDULE 1

Regulation 10

CONTENT OF AGREEMENTS

PART 1

PROVISION OF SERVICES

Premises

1. Subject to any plan which is included in the agreement pursuant to regulation 18(3), the provider shall ensure that the premises used for the provision of services under the agreement are—

- (a) suitable for the delivery of those services; and
- (b) sufficient to meet the reasonable needs of the provider's patients.

Attendance outside practice premises

2.—(1) In the case of a patient whose medical condition is such that in the reasonable opinion of the provider—

- (a) attendance on the patient is required; and
- (b) it would be inappropriate for the patient to attend at the practice premises,

the provider shall provide services to that patient at whichever in the provider's judgement is the most appropriate of the places set out in sub-paragraph (2).

(2) The places referred to in sub-paragraph (1) are—

- (a) the place recorded in the patient's medical records as being the patient's last home address or (where the patient's medical record is not immediately available) the place confirmed by the patient as being the patient's home address;
- (b) such other place as the provider has informed the patient and the Health Board is the place where the provider has agreed to visit and treat the patient;
- (c) where the provider has a list of patients, some other place in the provider's practice area; or
- (d) where the provider has no list of patients, some other place within the area specified in the agreement pursuant to regulation 18(1)(e).

(3) Nothing in this paragraph prevents the provider from—

- (a) arranging for the referral of the patient without first seeing the patient, in a case where the medical condition of that patient makes that course of action appropriate; or
- (b) visiting the patient in circumstances where this paragraph does not place the provider under an obligation to do so.

Clinical reports

3.—(1) Where the provider provides any clinical services other than under a private arrangement, to a patient and either—

- (a) the provider has no list of patients; or
- (b) the patient is not on the provider's list of patients,

the provider shall, as soon as reasonably practicable, provide a clinical report relating to the consultation and any treatment provided, to the Health Board.

(2) The Health Board shall send any report received under sub-paragraph (1)—

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- (a) to the person with whom the patient is registered for the provision of essential services (or their equivalent); or
- (b) if the person referred to in paragraph (a) is not known to it, to the Health Board in whose area the patient is resident.

Storage of vaccines

4. The provider shall ensure that—
- (a) all vaccines are stored in accordance with the manufacturer’s instructions; and
 - (b) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken on all working days.

Infection control

5. The provider shall ensure that the provider has effective arrangements for infection control and decontamination.

Duty of co-operation in relation to primary medical services

- 6.—(1) A provider which does not provide to its patients—
- (a) essential services;
 - (b) a particular additional service;
 - (c) a particular enhanced service; or
 - (d) out of hours services, either at all or in respect of some periods or services,
- shall comply with the requirements specified in paragraph (2).
- (2) The requirements referred to in paragraph (1) are that the provider shall—
- (a) co-operate, insofar as is reasonable, with any person responsible for the provision of that service or those services;
 - (b) comply in core hours with any reasonable request for information from such a person or from the Health Board relating to the provision of that service or those services; and
 - (c) in the case of out of hours services, take reasonable steps to ensure that any patient who contacts the practice premises during the out of hours period is provided with information about how to obtain services during that period.
- (3) Nothing in this paragraph shall require a provider, whose agreement does not include the provision of out of hours services, to make itself available during the out of hours period.

Duty of co-operation in relation to primary medical services

- 7.—(1) Where a provider will cease to be required to provide to its patients—
- (a) essential services;
 - (b) a particular additional service;
 - (c) a particular enhanced service; or
 - (d) out of hours services, either at all or in respect of some periods of services,
- the provider shall comply with any reasonable request for information relating to the provision of that service or those services made by the Health Board or by any person with whom the Board intends to make arrangements for the provision of such services.

PART 2

PATIENTS

Patient preference of practitioner

- 8.—(1) Where the provider has accepted a person as a patient the provider shall—
- (a) subject to sub-paragraph (3), notify the patient of the patient’s rights to express a preference to receive services from a particular performer or class of performer either generally or in relation to any particular condition; and
 - (b) record in writing any such preference expressed by or on behalf of the patient.
- (2) The provider shall endeavour to comply with any preference expressed under sub paragraph (1) but need not do so if the preferred performer—
- (a) has reasonable grounds for refusing to provide services to the patient; or
 - (b) does not routinely perform the service in question within the practice.
- (3) Where the patient is—
- (a) a child, the provider may notify—
 - (i) a parent, guardian, or other adult person who has care of the care of the child;
 - (ii) a person duly authorised by a local authority, where the child is in the care of the local authority under the Children (Scotland) Act 1995(1); or
 - (iii) a person duly authorised by a voluntary organisation, by which the child is being accommodated under the provisions of that Act;
 - (b) an adult person who is incapable of expressing such a preference or authorising such a preference to be made on their behalf, the provider may notify the primary carer of that person or by the person authorised under the Adults with Incapacity (Scotland) Act 2000(2) to act on the patients behalf,

of the right to express a preference for the patient to receive services from a particular performer or class of performer either generally or in relation to any particular condition.

Termination of responsibility for patients not registered with the provider

- 9.—(1) Where the provider—
- (a) has no provider’s list of patients but is required in terms of the agreement to accept a person as a patient for the provision of an additional service, an enhanced service or out of hours services; or
 - (b) has a provider’s list of patients and has received an application for the provision of clinical services other than essential services—
 - (i) from a person who is not included in the provider’s list of patients;
 - (ii) from a person whom the provider has not accepted as a temporary resident; or
 - (iii) on behalf of a person mentioned in (i) or (ii) above, from one of the persons specified in paragraph 9(4) of Schedule 2;
- and has accepted that person as a patient for the provision of the service in question, the provider’s responsibility for that patient may be terminated in one of the circumstances referred to in sub-paragraph (2).

(1) 1995, c. 36.
(2) 2000 asp 4.

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- (2) The circumstances referred to in sub-paragraph (1) are–
- (a) the patient informs the provider that the patient no longer wishes the provider to be responsible for the provision of the service in question;
 - (b) in cases where the provider has reasonable grounds for terminating the provider’s responsibility which do not relate to the person’s race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition, the provider informs the patient that the provider no longer wishes to be responsible for providing the patient with the service in question;
 - (c) the patient has committed an act of violence against–
 - (i) an individual that is a party to the agreement;
 - (ii) a partner in a partnership that is a party to the agreement;
 - (iii) a legal and beneficial owner of shares in a company that is a party to the agreement;
 - (iv) a member of the provider’s staff;
 - (v) a person engaged by the provider to perform or assist in the performance of services under the agreement; or
 - (vi) any other person present–
 - (aa) on the practice premises; or
 - (bb) in the place where services were provided to the patient under the agreement,or behaved in such a way that any such person has feared for that person’s own safety and, in either case, the provider has reported that incident to the police or the Procurator Fiscal;
 - (d) it comes to the notice of the provider that the patient–
 - (i) no longer resides in the area for which the provider has agreed to provide the service; or
 - (ii) is no longer a person to which the provider has agreed to provide the service.
- (3) A provider who wishes to terminate its responsibility for a patient under sub paragraph (2) (b) or (c) shall notify the patient of the termination and the reason for it.
- (4) The provider shall keep a written record of terminations under this paragraph and of the reason for them and shall make this record available to the Health Board on request.
- (5) A termination under–
- (a) sub-paragraph (2)(b) shall take effect 14 days from the date on which notice is given; and
 - (b) sub-paragraph (2)(c) shall take effect from the date on which notice is given.

PART 3

PRESCRIBING AND DISPENSING

Prescribing

10. The provider shall ensure that any prescription form for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 11 to 13.

Prescribing

11.—(1) Subject to paragraphs 13 and 14, a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the agreement by issuing to that patient a prescription form and such a prescription form shall not be used in any other circumstances.

(2) In issuing any such prescription form, the prescriber shall sign the prescription form in ink with the prescriber's initials, or forenames, and surname in the prescriber's own handwriting and not by means of a stamp and shall so sign only after particulars of the order have been inserted in the prescription form, and—

- (a) the prescription form shall not refer to any previous prescription form; and
- (b) a separate prescription form shall be used for each patient.

(3) In a case of urgency a prescriber may request a pharmacist to dispense a drug or medicine before a prescription form is issued, only if—

- (a) that drug or medicine is not a Scheduled drug;
- (b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971⁽³⁾, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001⁽⁴⁾; and
- (c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (2).

(4) In a case of urgency a prescriber may request a pharmacist to dispense an appliance before a prescription form is issued only if—

- (a) that appliance does not contain a Scheduled drug or 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 5 to the Misuse of Drugs Regulations 2001;
- (b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2).

Restrictions on prescribing by medical practitioners

12.—(1) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N⁽⁶⁾ of the Act⁽⁵⁾ as being drugs, medicines or other substances which may not be ordered for patients in the provision of primary medical services under a general medical services contract but may, subject to regulation 22, prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(2) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N⁽⁶⁾ of the Act as being a drug, medicine or other substance which may only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract unless:

- (a) that patient is a person of the specified description;

⁽³⁾ 1971 c. 38.

⁽⁴⁾ S.I.2001/3998. Schedule 4 was amended by S.I. 2003/1432.

⁽⁵⁾ Section 17N was inserted by the [Primary Medical Services \(Scotland\) Act 2004 \(asp 1\)](#), section 4.

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- (b) that drug, medicine or other substance is prescribed for that patient only for the specified purpose; and
- (c) the practitioner endorses the form with the reference “SLS”,

but may, subject to regulation 22, prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner shall not order on a prescription form a restricted availability appliance unless—

- (a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (b) the practitioner endorses the face of the form with the reference “SLS”,

but may, subject to regulation 22, prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

13.—(1) The provider shall have arrangements in place to secure that a supplementary prescriber will—

- (a) give a prescription for a prescription only medicine;
- (b) administer a prescription only medicine for parental administration; or
- (c) give directions for the administration of a prescription only medicine for parental administration,

as a supplementary prescriber under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that—

- (a) the supplementary prescriber satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)⁽⁶⁾, unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;
- (b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
- (c) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract;
- (d) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract unless—
 - (i) the patient is a person of the specified description;
 - (ii) the medicine is prescribed for that patient only for the specified purposes; and
 - (iii) if the supplementary prescriber is giving a prescription, the supplementary prescriber endorses the face of the form with the reference “SLS”.

(3) Where the functions of a supplementary prescriber include prescribing, the provider shall have arrangements in place to secure that that person will only give a prescription for—

- (a) an appliance; or
- (b) a medicine which is not a prescription only medicine,

⁽⁶⁾ Article 3B was inserted into the POM Order by S.I. [2003/696](#).

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

- (4) The conditions referred to in sub-paragraph (3) are that—
- (a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time the supplementary prescriber acts and which contains the following particulars:—
 - (i) the name of the patient to whom the plan relates;
 - (ii) the illness or conditions which may be treated by the supplementary prescriber;
 - (iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan;
 - (iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan;
 - (v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan;
 - (vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances;
 - (vii) the arrangements for notification of—
 - (aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan; and
 - (bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient; and
 - (viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;
 - (b) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any medical practitioner or dentist who is a party to the plan;
 - (c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
 - (d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract;
 - (e) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes in the provision or primary medical services under a general medical services contract unless—
 - (i) the patient is a person of the specified description;
 - (ii) the medicine is prescribed for that patient only for the specified purposes; and
 - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference SLS;
 - (f) if it is a prescription for a medicine—

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- (i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission; or
 - (ii) subject to paragraph (6), the use of the medicine is for the purposes of a clinical trial and—
 - (aa) that trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968(7); or
 - (bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;
 - (g) if it is a prescription for an appliance, the appliance is listed in Parts 2 to 6 or 8 to 10 of the Drug Tariff; and
 - (h) if it is a prescription for a restricted availability appliance—
 - (i) the patient is a person of a description mentioned in the entry in Part 3 of the Drug Tariff in respect of that appliance;
 - (ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry; and
 - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference “SLS”.
- (5) In sub-paragraph (4)(a), “clinical management plan” means a plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—
- (a) the patient to whom the plan relates;
 - (b) the medical practitioner or dentist who is a party to the plan; and
 - (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.
- (6) In relation to any time from the coming into force of any regulations made by the Secretary of State under section 2(2) of the European Communities Act 1972 (general implementation of treaties)(8) to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use(9), sub-paragraph (4)(f)(ii) shall be read as if it referred to a clinical trial which has been authorised, or is treated as having been authorised by the licensing authority for the purposes of those regulations.

Excessive prescribing

14.—(1) The provider shall not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.

(2) In considering whether a provider has breached its obligations under sub-paragraph (1), the Health Board shall seek the views of the area medical committee for its area.

Provision of dispensing services

15.—(1) A provider may secure the provision of dispensing services to its patients under the agreement only if it is authorised or required to do so by the Health Board in accordance with the following provisions of this paragraph.

(7) 1968 c. 67.

(8) 1972 c. 68.

(9) O.J. L 311, 28.11.2001, p.67.

(2) Where the Health Board is satisfied, after consultation with the area pharmaceutical committee that a person, by reason of—

- (a) distance;
- (b) inadequacy of means of communication; or
- (c) other exceptional circumstances,

will have serious difficulty in obtaining from a pharmacist any drugs, medicines or appliances, other than Scheduled drugs, required for that person's treatment, the Health Board shall require or authorise the provider with whom the person is a registered patient to supply such drugs, medicines and appliances to that person until further notice.

(3) Notwithstanding anything in sub-paragraph (2)—

- (a) a provider shall not be required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) if the provider satisfies the Health Board that the provider is not in the habit of dispensing drugs, medicines and appliances for the provider's patients;
- (b) a provider shall be entitled to receive reasonable notice from the Health Board that the provider is required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) or that such supply is to be discontinued.

(4) Subject to sub paragraph (6), a provider, who is required by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) to a patient, in the course of treating that patient under these Regulations—

- (a) shall, subject to sub-paragraph (7), record on a prescription form completed in accordance with paragraph 11, an order for supply of any drugs, medicines or appliances which are needed for the treatment of that patient, but shall not be required to issue that form to that patient;
- (b) shall supply those drugs, medicines or appliances for that patient under sub paragraph (2) but—
 - (i) shall not supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract, except that, where the provider has ordered a drug which has an appropriate non proprietary name either by that name or by its formula, the provider may supply a drug which has the same specification notwithstanding that it is such a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non proprietary name);
 - (ii) shall supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may only be ordered for specific patients and purposes in the provision of primary medical services under a general medical services contract, only where—
 - (aa) that patient is a person of the specified description; and
 - (bb) that drug, medicine or other substance is supplied to that patient only for the specified purpose;
 - (iii) shall supply under sub paragraph (2) for that patient a restricted availability appliance only if it is for a patient in a category of person or a purpose specified in the Drug Tariff;
- (c) may supply for that patient with the provider's consent, in respect of that treatment but otherwise than under sub paragraph (2), any Scheduled drug.

(5) A provider shall comply with any arrangements made by the Scottish Ministers, or made by the Health Board after consultation with the area medical committee and the area pharmaceutical

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committee and approved by the Scottish Ministers, under which the provider may obtain and have available any drugs, medicines or appliances which the provider is required or entitled to supply in terms of this paragraph.

(6) Sub paragraph (4) does not apply to drugs, medicines or appliances ordered on a prescription form by a supplementary prescriber or an independent nurse prescriber.

(7) Where a patient presents an order on a prescription form for listed drugs or medicines, or appliances, signed by a supplementary prescriber or an independent nurse prescriber, to a provider who is required under sub paragraph (2) to provide drugs or appliances to that patient, the provider may provide to the patient such drugs, medicines or appliances so ordered as the provider supplies in the normal course of the provider's practice.

(8) A drug supplied by a provider unless administered in person shall be supplied in a suitable container.

(9) Before supplying the drugs, medicines or appliances recorded on a prescription form in accordance with sub paragraph (4) or providing the drugs or medicines or appliances ordered on a prescription form signed by a supplementary prescriber or an independent nurse prescriber in accordance with sub paragraph (7) a provider who is required by the Health Board under sub paragraph (2) to provide drugs, medicines or appliances to a patient shall request any person who makes a declaration on the prescription form claiming either charge exemption under regulation 7 of the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001⁽¹⁰⁾ ("the 2001 Regulations") or charge remission under the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) (No 2) Regulations 2003⁽¹¹⁾ to provide evidence of the patient's entitlement to such exemption or remission.

(10) Sub paragraph (9) shall not apply in respect of claims for exemption under regulation 7(1) (a) to (f) of the 2001 Regulations where the dispensing provider has information in the provider's possession at the time of supplying the item which confirms that the patient is entitled to the exemption claimed.

(11) Where the person presenting the prescription form does not show valid evidence of entitlement and the dispensing provider, in respect of a claim for exemption made under regulation 7(1)(a) to (f) of the 2001 Regulations does not have evidence in the contractor's possession to confirm that the patient is entitled to make that claim, the dispensing provider shall mark the patient's prescription form accordingly before supplying the prescribed item.

(12) The provisions of regulation 22 apply in respect of the provision of any drugs, medicines or appliances by a provider providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(13) Nothing in this paragraph shall prevent a provider providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

Provision of drugs, medicines and appliances for immediate treatment or personal administration

16.—(1) Subject to sub-paragraph (2), a provider—

- (a) shall provide to a patient any drug, medicine or appliance, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and
- (b) may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which the provider personally administers or applies to that patient,

⁽¹⁰⁾ S.S.I. 2001/430, as amended by S.S.I. 2002/100 and 2003/130 and 295.

⁽¹¹⁾ S.S.I. 2003/460.

but shall, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff.

(2) Nothing in sub-paragraph (1) authorises a person to supply any drug or medicine to a patient otherwise than in accordance with Part 3 of the Medicines Act 1968⁽¹²⁾ or any regulations or orders made thereunder.

PART 4

PERSONS WHO PERFORM SERVICES

Qualifications of performers

17.—(1) Subject to sub-paragraph (2), no medical practitioner shall perform medical services under the agreement unless the practitioner is—

- (a) included in the primary medical services performers list for the Health Board which is under a duty to provide or secure the provision of the service to be performed;
- (b) not suspended from that list or from the Medical Register; and
- (c) not subject to interim suspension under section 41A of the Medical Act 1983 (interim orders)⁽¹³⁾.

(2) Sub-paragraph (1) shall not apply in the case of—

- (a) a medical practitioner employed in Scotland by a Health Board, in England and Wales by a NHS trust, a NHS foundation trust, or in Northern Ireland by a Health and Social Services trust who is providing services other than primary medical services at the practice premises;
- (b) a person who is provisionally registered under section 15 (provisional registration), 15A (provisional registration for EEA nationals) or 21 (provisional registration) of the Medical Act 1983⁽¹⁴⁾ acting in the course of the person's employment in a resident medical capacity in an approved medical practice; or
- (c) a GP Registrar during the first two months of the GP Registrar's training period.

Qualifications of performers

18. No health care professional other than one to whom paragraph 17 applies shall perform clinical services under the agreement unless the health care professional is appropriately registered with the health care professional's relevant professional body and the health care professional's registration is not currently suspended.

Qualifications of performers

19. Where the registration of a health care professional or, in the case of a medical practitioner, the practitioner's inclusion in a list, is subject to conditions, the provider shall ensure compliance with those conditions insofar as they are relevant to the agreement.

⁽¹²⁾ 1968 c. 67.

⁽¹³⁾ 1983 c. 54. Section 41A was inserted by S.I. 2000/1803.

⁽¹⁴⁾ 1983 c. 54. Section 15 was amended by the National Health Service (Primary Care) Act 1997 (c. 46) ("the 1997 Act"), Schedule 2, Part 1, paragraph 61(4); section 15A was inserted by S.I. 2000/3041; section 21 was amended by the 1997 Act, Schedule 2, Part 1, paragraph 61(5) and by S.I. 1996/1591 and 2002/3135.

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Qualifications of performers

20. No health care professional shall perform any clinical services unless the health care professional has such clinical experience and training as are necessary to enable the health care professional properly to perform such services.

Conditions for employment and engagement

21.—(1) Subject to sub-paragraphs (2) and (3), a provider shall not employ or engage a medical practitioner (other than one falling within paragraph 17(2)) unless—

- (a) that practitioner has provided the provider with the name and address of the Health Boards on whose primary medical services performers lists the practitioner appears; and
- (b) the provider has checked that the practitioner meets the requirements in paragraph 17.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible for the provider to check the matters referred to in paragraph 17 in accordance with sub-paragraph (1)(b) before employing or engaging the practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) Where the prospective employee is a GP Registrar, the requirements set out in sub paragraph (1) shall apply with the modifications that—

- (a) the name and address provided under sub-paragraph (1) may be the name and address of the Health Boards on whose primary medical services performers lists the GP Registrar has applied for inclusion; and
- (b) confirmation that the GP Registrar’s name appears on those lists shall not be required until the end of the first two months of the GP Registrar’s training period.

Conditions for employment and engagement

22.—(1) A provider shall not employ or engage—

- (a) a health care professional (other than one to whom paragraph 17 applies) unless the provider has checked that the health care professional meets the requirements in paragraph 18;
- (b) a health care professional to perform clinical services unless the provider has taken reasonable steps to satisfy the provider that the health care professional meets the requirements in paragraph 20.

(2) Where the employment or engagement of a health care professional is urgently needed and it is not possible to check the matters referred to in paragraph 18 in accordance with sub paragraph (1) before employing or engaging the health care professional, the health care professional may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) When considering a health care professional’s experience and training for the purposes of sub-paragraph (1)(b) the provider shall have regard in particular to—

- (a) any post-graduate or post-registration qualification held by the health care professional; and
- (b) any relevant training undertaken by the health care professional and any relevant clinical experience gained by the health care professional.

Conditions for employment and engagement

23.—(1) The provider shall not employ or engage a health care professional to perform medical services under the contract unless—

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- (a) that person has provided two clinical references, relating to two recent posts (which may include any current post) as a health care professional which lasted for three months without a significant break, or where this is not possible, a full explanation and alternative referees; and
- (b) the provider has checked and is satisfied with the references.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible to obtain and check the references in accordance with sub-paragraph (1)(b) before employing or engaging the practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 14 days whilst the practitioner's references are checked and considered, and for an additional single period of a further 7 days if the provider believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the provider employs or engages the same person on more than one occasion within a period of three months, it may rely on the references provided on the first occasion, provided that those references are not more than twelve months old.

Conditions for employment and engagement

24.—(1) Before employing or engaging any person to assist the provider in the provision of services under the agreement, the provider shall take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which the person is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 21 to 23.

(3) When considering the competence and suitability of any person for the purpose of sub paragraph (1), the provider shall have regard, in particular, to—

- (a) that person's academic and vocational qualifications;
- (b) the person's education and training; and
- (c) the person's previous employment or work experience.

Training

25. The provider shall ensure that for any health care professional who is—

- (a) performing clinical services under the agreement; or
- (b) employed or engaged to assist in the performance of such services,

has in place arrangements for the purpose of maintaining and updating the health care professional's skills and knowledge in relation to the services which the health care professional is performing or assisting in performing.

Training

26. The provider shall afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

Arrangements for GP registrars

27.—(1) The provider shall only employ a GP Registrar for the purpose of being trained by a GP Trainer with the agreement of the Scottish Ministers and subject to the conditions in sub paragraph (2).

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(2) The conditions referred to in sub-paragraph (1) are that the provider shall not, by reason only of having employed or engaged a GP Registrar, reduce the total number of hours for which other medical practitioners perform primary medical services under the agreement or for which other staff assist them in the performance of those services.

(3) A provider which employs a GP Registrar shall—

- (a) offer the GP Registrar terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Scottish Ministers to Health Boards under 17E(3A) of the Act concerning the grants, fees travelling and other allowances payable to GP Registrars; and
- (b) take into account any guidance issued by the Scottish Ministers in relation to the GP Registrar Scheme⁽¹⁵⁾.

Independent nurse prescribers and supplementary prescribers

28.—(1) Where—

- (a) a provider employs or engages a person who is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing;
- (b) a party to the agreement is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing;
- (c) a partner in a partnership that is a party to the agreement, is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing; or
- (d) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom it already employs or has already engaged are extended to include prescribing,

it shall notify the Health Board in writing within the period of seven days beginning with the date on which the provider employed or engaged the person, the person became a party to the agreement or a partner in a partnership that is a party to the agreement (unless, immediately before becoming such a party or a partner in a partnership that is such a party, the person fell under paragraph (1)(a)) or the person's functions were extended, as the case may be.

(2) Where—

- (a) the provider ceases to employ or engage a person who is an independent nurse prescriber or a supplementary prescriber whose functions included prescribing in the provider's practice;
- (b) the party to the agreement, who is an independent nurse prescriber or supplementary prescriber, whose functions include prescribing, ceases to be a party to the agreement;
- (c) the partner in a partnership that is a party to the agreement, who is an independent nurse prescriber or supplementary prescriber, whose function include prescribing, ceases to be a partner in that partnership;
- (d) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom the provider employs or engages in its practice are changed so that they no longer include prescribing in its practice; or
- (e) the provider becomes aware that a person who is an independent nurse prescriber or a supplementary prescriber whom the provider employs or engages has been removed or suspended from the relevant register,

(15) The current guidance is the GP Registrar Scheme Vocational Guide for General Medical practice – the UK Guide 2000 published by the Department of Health and available on their website at or by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

it shall notify the Health Board in writing by the end of the second day after the day when the event occurred.

(3) The provider shall provide the following information when it notifies the Health Board in accordance with sub-paragraph (1)–

- (a) the person’s full name;
- (b) the person’s professional qualifications;
- (c) the person’s identifying number which appears in the relevant register;
- (d) the date on which the person’s entry in the relevant register was annotated to the effect that the person was qualified to order drugs, medicines and appliances for patients;
- (e) the date–
 - (i) on which the person was employed or engaged, if applicable;
 - (ii) the person became a party to the agreement, if applicable;
 - (iii) the person became a partner in a partnership that is a party to the agreement, if applicable; or
 - (iv) on which one of the person’s functions became to prescribe in its practice.

(4) The provider shall provide the following information when it notifies the Health Board in accordance with sub-paragraph (2):–

- (a) the person’s full name;
- (b) the person’s professional qualifications;
- (c) the person’s identifying number which appears in the relevant register;
- (d) the date–
 - (i) the person ceased to be employed or engaged in its practice,
 - (ii) the person ceased to be a party to the agreement;
 - (iii) the person ceased to be a partner in a partnership that is a party to the agreement;
 - (iv) the person’s functions changed so as no longer to include prescribing; or
 - (v) on which the person was removed or suspended from the relevant register.

Signing of documents

29.—(1) In addition to any other requirements relating to such documents whether in these regulations or otherwise, the provider shall ensure that the documents specified in sub-paragraph (2) include–

- (a) the clinical profession of the health care professional who signed the document; and
- (b) the name of the provider on whose behalf it is signed.

(2) The documents referred to in sub-paragraph (1) are–

- (a) certificates issued in accordance with regulation 19, unless regulations relating to particular certificates provide otherwise;
- (b) prescription forms; and
- (c) any other clinical documents.

Level of skill

30. The provider shall carry out its obligations under the agreement with reasonable skill and care.

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Appraisal and assessment

31.—(1) The provider shall ensure that any medical practitioner performing services under the agreement—

- (a) participates in the appraisal system provided by the Health Board unless the practitioner participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and
- (b) co-operates with any assessment process which the Health Board operates in relation to poorly performing doctors, as set out in NHS circular PCA(M)(2001)17(16).

(2) The Health Board shall provide an appraisal system for the purposes of sub-paragraph (1) (a) after consultation with the area medical committee and such other persons as appear to it to be appropriate.

(3) In sub-paragraph (1)—

“armed forces GP” means a medical practitioner who is employed on a contract of service by the Ministry of Defence, whether or not as a member of the United Kingdom Armed Forces of Her Majesty; and

“health service body” does not include any provider who is to be treated as a health service body in accordance with regulation 8.

Sub-contracting of clinical matters

32.—(1) Subject to sub-paragraph (2) the provider shall not sub-contract any of its rights or duties under the agreement in relation to clinical matters unless—

- (a) in all cases, including those which fall within paragraph 4 of Schedule 4 (if applicable), it has taken reasonable steps to satisfy itself that—
 - (i) it is reasonable in all the circumstances; and
 - (ii) that person is qualified and competent to provide the service; and
- (b) except in cases which fall within paragraph 4 of Schedule 4 (if applicable), it has notified the Health Board of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into force.

(2) Sub-paragraph (1)(b) shall not apply to a contract for services with a health care professional for the provision by that person of clinical services.

(3) The notification referred to in sub-paragraph (1)(b) shall include—

- (a) the name and address of the proposed sub-contractor;
- (b) the duration of the proposed sub-contract;
- (c) the services to be covered; and
- (d) the address of any premises to be used for the provision of services.

(4) Following receipt of a notice in accordance with sub-paragraph (1)(b), the Health Board may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the provider shall supply such information promptly.

(5) The provider shall not proceed with the sub-contract or, if it has already taken effect, shall take appropriate steps to terminate it, where, within 28 days of receipt of the notice referred to in sub-paragraph (1)(b), the Health Board has served notice of objection to the sub-contract on the grounds that—

(16) Copies of NHS Circular PCA(M)(2001)17 may be obtained in writing from the Scottish Executive Health Department, Primary Care Division, St. Andrew’s House, Regent Road, Edinburgh EH1 3DG.

- (a) the sub-contract would—
 - (i) put at serious risk the safety of the provider’s patients; or
 - (ii) put the Board at risk of material financial loss; or
 - (b) the sub-contractor would be unable to meet the provider’s obligations under the agreement.
- (6) Where the Health Board objects to a proposed sub-contract in accordance with sub paragraph (5), it shall include with the notice of objection a statement in writing of the reasons for its objection.
- (7) Sub-paragraphs (1) and (3) to (6) shall also apply in relation to any renewal or material variation of a sub-contract in relation to clinical matters.
- (8) Where a Health Board does not object to a proposed sub-contract under sub-paragraph (5), the parties to the agreement shall be deemed to have consented to a variation of the agreement which has the effect of adding to the list of practice premises any premises whose address was notified to it under sub-paragraph (3)(d) and paragraph 59 shall not apply.
- (9) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the clinical services it has agreed with the provider to provide.

PART 5

RECORDS, INFORMATION, NOTIFICATIONS AND RIGHTS OF ENTRY

Patient records

- 33.**—(1) In this paragraph, “computerised records” means records created by way of entries on a computer.
- (2) The provider shall keep adequate records of its attendance on and treatment of its patients and shall do so—
- (a) on forms supplied to it for the purpose by the Health Board; or
 - (b) with the written consent of the Health Board, by way of computerised records,
- or in a combination of those two ways.
- (3) The provider shall include in the records referred to in sub-paragraph (2) clinical reports sent in accordance with paragraph 3 or, where the provider has a provider’s list of patients, from any other health care professional who has provided clinical services to a person on the provider’s list of patients.
- (4) The consent of the Health Board required by sub-paragraph (2)(b) shall not be withheld nor withdrawn provided the Health Board is satisfied, and continued to be satisfied, that—
- (a) the computer system upon which the provider proposes to keep the records has been accredited by the Scottish Ministers or another person on their behalf as suitable for that purpose in accordance with “RFA V.1. – Requirements for Accreditation in General Practice Computer Systems in Scotland”(17);
 - (b) the security measures, audit and system management function incorporated into the computer system as accredited in accordance with paragraph (a) have been enabled; and
 - (c) the provider is aware of, and has signed an undertaking that it will have regard to any guidelines issued by the Scottish Ministers and notified to the provider by the Health Board concerning good practice in the keeping of electronic patient records.

(17) RFA V.1 is published on Scottish Health on the Web (SHOW) at the following link: <http://www.show.scot.nhs.uk/publications/me/gpcomputerrecords/rfav1.pdf>.

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(5) Where the provider keeps computerised records, the provider shall, as soon as possible following a request from the Health Board, allow the Board to access the information recorded on the provider's computer system by means of the audit function referred to in sub-paragraph (4)(b) to the extent necessary for the Board to confirm that the audit function is enabled and functioning correctly.

(6) A provider whose patient records are computerised records shall not disable, nor attempt to disable, either the security measures or the audit and system management functions referred to in sub-paragraph (4)(b).

Confidentiality of personal data

34. The provider shall nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it.

Practice leaflet

35. The provider shall—

- (a) compile a document (in this paragraph called a practice leaflet) which shall include the information specified in Schedule 6;
- (b) review its practice leaflet at least once in every period of 12 months and make any amendments necessary to maintain its accuracy; and
- (c) make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

Provision of information

36.—(1) Subject to sub-paragraph (2), the provider shall, at the request of the Health Board, produce to the Board or to a person authorised in writing by the Board or allow the Board, or a person authorised in writing by it, to access—

- (a) any information which is reasonably required by the Board for the purposes of or in connection with the agreement; and
- (b) any other information reasonably required in connection with the Health Board's functions.

(2) The provider shall not be required to comply with any request made in accordance with sub paragraph (1) unless it has been made by the Health Board in accordance with directions relating to the provision of information by providers given to it by the Scottish Ministers under section 2(5) of the Act(18).

Inquiries about prescriptions and referrals

37.—(1) The provider shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the Health Board concerning—

- (a) any prescription form issued by a prescriber;
- (b) the considerations by reference to which prescribers issue such forms;
- (c) the referral, by or on behalf of the provider, of any patient to any other services provided under the Act; or
- (d) the considerations by which the provider makes such referrals or provides for them to be made on its behalf.

(18) 1978 c. 29. Section 2(5) was amended by the National Health Service and Community Care Act 1990 (c. 19), Schedule 9, paragraph 19(1).

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist the Health Board to discharge its functions or of assisting the provider in the discharge of its obligations under the agreement.

(3) The provider shall not be obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made—

- (a) in the case of sub-paragraph (1)(a) or (b), by an appropriately qualified health care professional;
- (b) in the case of sub-paragraph (1)(c) or (d), by an appropriately qualified medical practitioner,

appointed in either case by the Health Board to assist the Board in the exercise of its functions under this paragraph and that person produces, on request, written evidence that the person is authorised by the Health Board to make such an inquiry on its behalf.

Reports to a medical officer

38.—(1) The provider shall, if it is satisfied that the patient consents—

- (a) supply in writing to a medical officer within such reasonable period as that officer, or an officer of the Department for Work and Pensions on that officer’s behalf and at that officer’s direction, may specify, such clinical information as the medical officer considers relevant about a patient to whom the provider or a person acting on the provider’s behalf has issued or has refused to issue a medical certificate; and
- (b) answer any inquiries by a medical officer, or by an officer of the Department for Work and Pensions on that officer’s behalf and at that officer’s direction, about a prescription form or medical certificate issued by the provider or on the provider’s behalf or about any statement which the provider or a person acting on the provider’s behalf has made in a report.

(2) For the purpose of satisfying the provider that the patient has consented as required by paragraph (1), the provider may (unless it has reason to believe the patient does not consent) rely on an assurance in writing from the medical officer, or any officer of the Department for Work and Pensions, that that officer holds the patient’s written consent.

Annual return and review

39.—(1) The provider shall submit an annual return relating to the agreement to the Health Board.

(2) Following receipt of the return referred to in sub-paragraph (1), the Health Board shall arrange with the provider an annual review of its performance in relation to the agreement.

(3) Either the provider or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Health Board to participate in the annual review.

(4) The Health Board shall prepare a draft record of the review referred to in sub-paragraph (2) for comment by the provider and, having regard to such comments, shall produce a final written record of the review.

(5) A copy of the final record referred to in sub-paragraph (4) shall be sent to the provider.

Notifications to the Health Board

40. In addition to any requirements of notification elsewhere in the regulations, the provider shall notify the Health Board in writing, as soon as reasonably practicable, of—

- (a) any serious incident that in the reasonable opinion of the provider affects or is likely to affect the provider’s performance of its obligations under the agreement;

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- (b) any circumstances which give rise to the Health Board's right to terminate the agreement under paragraph 66 or 67;
- (c) any appointments system which it proposes to operate and the proposed discontinuance of any such system;
- (d) where the provider has a provider's list of patients, any change of which it is aware in the address of a registered patient; and
- (e) the death of any patient of which it is aware.

Notifications to the Health Board

41. The provider shall, unless it is impracticable for it to do so, notify the Health Board in writing within 28 days of any occurrence requiring a change in the information about it published by the Health Board in accordance with regulations made under section 2C(3) of the Act (functions of Health Boards: primary medical services)(**19**).

Notice provisions specific to agreements with one or more companies limited by shares

42.—(1) Where a company limited by shares is a party to the agreement, the provider shall give notice to the Health Board forthwith when—

- (a) any share in the company is transmitted or transferred (whether legally or beneficially) to another person on a date after the agreement has come into force;
- (b) the company passes a resolution or a court of competent jurisdiction makes an order that one or more of those companies be wound up;
- (c) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the company;
- (d) circumstances arise which would enable the court to make a winding up order in respect of the company; or
- (e) the company is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986(**20**).

(2) A notice under sub-paragraph (1)(a) shall confirm that the new shareholder, or, as the case may be, the personal representative of a deceased shareholder—

- (a) where the company is a qualifying body, within the meaning of section 17D(2) of that Act, a person falling within section 17D(1)(a) to (d) of the Act (persons with whom agreements may be made); and
- (b) satisfies the condition imposed on shareholders by virtue of regulation 3 (general conditions relating to providers).

Notice provisions specific to an agreement with one or more partnerships

43.—(1) Where a partnership is party to the agreement, the provider shall give notice to the Health Board forthwith—

- (a) when a partner leaves or informs the other members of the partnership of which they are a member, that the partner intends to leave the partnership, and the date upon which the partner left or will leave the partnership;
- (b) when a new partner joins a partnership.

(2) A notice under sub-paragraph (1)(b) shall—

(19) Section 2C was inserted into the Act by the [Primary Medical Services \(Scotland\) Act 2004 \(asp 1\)](#), section 1(2).

(20) 1986, c. 45.

- (a) state the date that the new partner joined the partnership;
- (b) confirm that the new partner satisfies the condition imposed by regulation 3 (general conditions relating to providers); and
- (c) state whether the new partner is a general or a limited partner.

Notification of deaths

44.—(1) The provider shall report, in writing, to the Health Board, the death on the provider's practice premises of any patient no later than the end of the first working day after the date on which the death occurred.

(2) The report shall include—

- (a) the patient's full name;
- (b) the patient's National Health Service number where known;
- (c) the date and place of death;
- (d) a brief description of the circumstances, as known, surrounding the death;
- (e) the name of any medical practitioner or other person treating the patient whilst on the practice premises; and
- (f) the name, where known, of any other person who was present at the time of the death.

(3) The provider shall send a copy of the report referred to in sub-paragraph (1) to any other Health Board in whose area the deceased was resident at the time of the patient's death.

Notifications to patients following variation of the agreement

45. Where the agreement is varied in accordance with Part 8 of this Schedule and, as a result of that variation—

- (a) there is to be a change in the range of services provided to the provider's patients; or
- (b) where the provider has a provider's list of patients, patients who are on that list are to be removed from that list,

the Health Board shall notify those patients in writing of the variation and its effect and inform them of the steps they can take to obtain elsewhere the services in question or, as the case may be, register elsewhere for the provision of essential services (or their equivalent).

Entry and inspection by the Health Board

46.—(1) Subject to the conditions in sub-paragraph (2), the provider shall allow persons authorised in writing by the Health Board to enter and inspect the practice premises at any reasonable time.

(2) The conditions referred to in sub-paragraph (1) are that—

- (a) reasonable notice of the intended entry has been given;
- (b) written evidence of the authority of the person seeking entry is produced to the provider on request; and
- (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) Either the provider or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Board to be present at an inspection of the practice premises which takes place under this paragraph.

PART 6 COMPLAINTS

Complaints procedure

47.—(1) The provider shall establish and operate a complaints procedure to deal with any complaints in relation to any matter reasonably connected with the provision of services under the agreement which shall comply with the requirements in paragraphs 48 to 51 and 53.

(2) The provider shall take reasonable steps to ensure that patients are aware of—

- (a) the complaints procedure; and
- (b) the role of the Health Board and other bodies in relation to complaints about services under the agreement.

(3) The provider shall take reasonable steps to ensure that the complaints procedure is accessible to all patients.

Making a complaint

48. A complaint may be made by or, with the patient’s consent, on behalf of a patient, or former patient, who is receiving or has received services under the agreement or—

- (a) where the patient is a child—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child,
 - (ii) by a person duly authorised by a local authority, where the child is in the care of a local authority under the Children (Scotland) Act 1995(21); or
 - (iii) by a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act;
- (b) where the patient is incapable of making a complaint, by a relative or other adult person who has an interest in the patient’s welfare.

Making a complaint

49. Where a patient has died a complaint may be made by a relative or other adult who had an interest in the patient’s welfare or, where the patient falls within paragraph 48(a)(ii) or (iii), by the authority or voluntary organisation.

Period for making complaints

50.—(1) Subject to sub-paragraph (2), the period for making a complaint is—

- (a) 6 months from the date on which the matter which is the subject of the complaint occurred; or
- (b) 6 months from the date on which the matter which is the subject of the complaint comes to the complainant’s notice provided that the complaint is made no later than 12 months after the date on which the matter which is the subject of the complaint occurred.

(2) Where a complaint is not made during the period specified in sub-paragraph (1), it shall be referred to the person nominated under paragraph 51(2)(a) and if the person is of the opinion that—

(21) 1995 c. 36.

- (a) having regard to all the circumstances of the case, it would have been unreasonable for the complainant to make the complaint within that period; and
- (b) notwithstanding the time that has elapsed since the date on which the matter which is the subject matter of the complaint occurred, it is still possible to investigate the complaint properly,

the complaint shall be treated as if it had been received during the period specified in sub paragraph (1).

Further requirements for complaints procedures

51.—(1) A complaints procedure shall also comply with the requirements set out in sub paragraphs (2) to (6).

(2) The provider must nominate—

- (a) a person (who need not be connected with the provider and who, in the case of an individual, may be specified by the person’s job title) to be responsible for the operation of the complaints procedure and the investigation of complaints; and
- (b) a senior person associated with the provider, to be responsible for the effective management of the complaints procedure and for ensuring that action is taken in the light of the outcome of any investigation.

(3) All complaints must be—

- (a) either made or recorded in writing;
- (b) acknowledged in writing within the period of 3 working days beginning with the day on which the complaint was made or, where that is not possible, as soon as is reasonably practicable; and
- (c) properly investigated.

(4) Within the period of 10 working days beginning with the day on which the complaint was received by the person specified under sub-paragraph (2)(a) or, where that is not possible, as soon as is reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions.

(5) Where the investigation of the complaint requires consideration of the patient’s medical records, the person specified under sub-paragraph (2)(a) must inform the patient or person acting on the patient’s behalf if the investigation will involve disclosure of information contained in those records to a person other than the provider or an employee of the provider.

(6) The provider must keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from patients' medical records.

Co-operation with investigations

52.—(1) The provider shall co-operate with—

- (a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the agreement undertaken by—
 - (i) the Health Board; and
 - (ii) the Scottish Public Services Ombudsman; and
- (b) any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the provider.

(2) In sub-paragraph (1)—

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“NHS body” means in Scotland a Health Board, in England and Wales, a Primary Care trust, a NHS trust, a NHS foundation trust, a Strategic Health Authority, a Local Health Board and in Northern Ireland, a Health and Social Services Board or a Health and Social Services trust; and “local authority” means—

- (a) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 (constitution of councils)⁽²²⁾;
 - (b) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities)⁽²³⁾; or
 - (c) the Council of the Isles of Scilly.
- (3) The co-operation required by sub-paragraph (1) includes—
- (a) answering questions reasonably put to the provider by the Health Board;
 - (b) providing any information relating to the complaint reasonably required by the Health 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 provider’s presence at the meeting is reasonably required by the Health Board.

Provision of information about complaints

53. The provider shall inform the Health Board, at such intervals as required, of the number of complaints it has received under the procedure established in accordance with this Part.

PART 7

DISPUTE RESOLUTION

Local resolution of contract disputes

54.—(1) Subject to sub-paragraph (3), in the case of any dispute arising out of or in connection with the agreement, the provider and the Health Board must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

(2) Either the provider or the Health Board may, if it wishes to do so, invite the area medical committee to participate in discussions which take place pursuant to sub-paragraph (1).

(3) In the case of a dispute which falls to be dealt with under the NHS dispute resolution procedure as modified by paragraph 28 of Schedule 2, sub-paragraph (1) does not apply where it is not practicable for the parties to attempt local resolution before the expiry of the period specified in paragraph 56(4) as so modified.

Dispute resolution: non-NHS contracts

55.—(1) In the case of an agreement which is not an NHS contract, any dispute arising out of or in connection with the agreement, except matters dealt with under the complaints procedure pursuant to

(22) 1994 c.39.

(23) 1970 c. 42; section 1 was amended by the Local Government Act 1972 (c. 70), section 195 and by the Local Government (Wales) Act 1994 (c. 19), Schedule 10, paragraph 7.

Part 6 of this Schedule, may be referred for consideration and determination to the Scottish Ministers, if—

- (a) the Health Board so wishes and the provider has agreed in writing; or
 - (b) the provider so wishes (even if the Health Board does not agree).
- (2) In the case of a dispute referred to the Scottish Ministers under sub-paragraph (1)—
- (a) the procedure to be followed is the NHS dispute resolution procedure; and
 - (b) the parties agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

56.—(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 57 applies in the case of any dispute arising out of or in connection with the agreement, which is referred to the Scottish Ministers—

- (a) (where the agreement is an NHS contract) for the purposes of section 17A(4) of the Act; or
 - (b) (where the agreement is not an NHS contract) in accordance with paragraph 55(1).
- (2) In the case where—
- (a) a dispute is referred to the Scottish Ministers in accordance with regulation 7(1) (pre agreement disputes); or
 - (b) a provider (or providers) refers a matter for determination in accordance with paragraph 28(1) or (2) of Schedule 2,

the procedure specified in the following sub paragraphs and paragraph 57 is modified as mentioned in regulation 7 or, as the case may be, paragraph 28 of Schedule 2.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1), shall send to the Scottish Ministers a written request for dispute resolution which shall include or be accompanied by—

- (a) the names and addresses of the parties to the dispute;
- (b) a copy of the agreement; and
- (c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (3) within a period of three years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(5) The Scottish Ministers may determine the dispute themselves or, if they consider it appropriate, appoint a panel consisting of three persons (referred to as “the panel”) to consider and determine the dispute.

(6) Before reaching a decision as to who should determine the dispute under sub paragraph (5), the Scottish Ministers shall, within the period of 7 days beginning with the date on which the dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(7) The Scottish Ministers shall give, with the notice given under sub-paragraph (6), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(8) The Scottish Ministers shall give a copy of any representations received from a party to the other party and shall in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

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(9) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (6) or (8), the Scottish Ministers shall, if they decide to appoint a panel to hear the dispute—

- (a) inform the parties in writing of the names of the persons whom he has appointed on the panel; and
- (b) pass to the panel any documents received from the parties under or pursuant to paragraph (3), (6) or (8).

(10) For the purpose of assisting it in its consideration of the matter, the adjudicator may—

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which it wishes them to give special consideration; or
- (b) consult other persons whose expertise the adjudicator considers will assist the adjudicator in the adjudicator’s consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), the adjudicator shall notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator shall give to the parties such opportunity as it considers reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the adjudicator shall consider—

- (a) any written representations made in response to a request under sub-paragraph (6), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (10)(a);
- (d) the results of any consultation under sub-paragraph (10)(b); and
- (e) any observations made in accordance with an opportunity given under sub-paragraph (11).

(13) In this paragraph, “specified period” means such period as the Scottish Ministers shall specify in the request under sub-paragraph (6) or (8), being not less than 2, nor more than 4, weeks beginning with the date on which the request is sent, but the adjudicator may, if the adjudicator considers that there is good reason for doing so, extend any such period (even after it has expired) and, where it does so, a reference in this paragraph to the specified period is to the period as so extended.

(14) Subject to the other provisions of this paragraph and paragraph 57 and to any agreement by the parties, the adjudicator shall have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(15) Where the adjudicator is a panel, any decision or determination by the panel for the purposes of this paragraph and paragraph 57 may be by a majority.

Determination of dispute

57.—(1) The adjudicator shall record the its determination, and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties and, in the case where the adjudicator is a panel, to the Scottish Ministers.

(2) A determination of a reference to the Scottish Ministers for the purposes of section 17A(4) of the Act or in accordance with paragraph 55(1) may contain such directions (including directions as to payment) as the adjudicator considers appropriate to resolve the matter in the dispute, and it shall be the duty of the provider and the Health Board to comply with such directions.

(3) Without prejudice to the generality of the adjudicators powers on a reference to the Scottish Ministers for the purposes of section 17A(4) or referred in accordance with paragraph 55(1), the adjudicator may, by the adjudicators determination, in relation to an agreement vary the terms of the agreement or bring it to an end; and where the agreement is so varied or brought to an end—

- (a) subject to paragraph (b), the variation or termination shall be treated as being effected by agreement between the Health Board and the provider; and
- (b) directions included in the determination by virtue of sub-paragraph (2) may contain such provisions as the adjudicator considers appropriate in order satisfactorily to give effect to the variation or to bring the agreement to an end.

Interpretation of Part 7

58.—(1) In this Part, “any dispute arising out of or in connection with the agreement” includes any dispute arising out of or in connection with the termination of the agreement.

(2) Any term of the agreement that makes provision in respect of the requirements in this Part shall survive even where the agreement has terminated.

PART 8

VARIATION AND TERMINATION OF AGREEMENTS

Variation of an agreement: general

59.—(1) Subject to paragraphs 32(8), 60, 61 and 71 of this Schedule and paragraphs 4(8) and 9 of Schedule 4 no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the Health Board and the provider.

(2) In addition to the specific provision made in paragraph 71 the Health Board may vary the agreement without the provider’s consent where it—

- (a) is reasonably satisfied that it is necessary to vary the agreement so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Scottish Ministers pursuant to that Act; and
- (b) notifies the provider in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect shall not be less than 14 days after the date on which the notice under paragraph (b) is served on the provider.

(3) In sub-paragraph (1) “writing” does not include transmission by electronic means.

Termination by agreement

60. The Health Board and the provider may agree in writing to terminate the agreement, and if the parties so agree, they shall agree the date upon which that termination should take effect and any further terms upon which the agreement should be terminated.

Termination by the provider

61.—(1) A provider may terminate the agreement by serving notice in writing on the Health Board at any time.

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(2) Where a provider serves notice pursuant to sub-paragraph (1), the agreement shall, subject to sub-paragraph (3), terminate 6 months after the date on which the notice is served (“the termination date”), save that if the termination date is not the last calendar day of a month, the agreement shall instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the provider is an individual, sub-paragraph (2) shall apply to the provider, save that the reference to “6 months” shall instead be to “3 months”.

(4) This paragraph and paragraph 63 are without prejudice to any other rights to terminate the agreement that the provider may have.

Withdrawal by parties to an agreement other than Health Boards

62.—(1) Where the provider comprises more than one party to the agreement, a party to the agreement may withdraw from the agreement by serving notice in writing on the Health Board and the other parties to the agreement at any time.

(2) Where a party serves notice pursuant to sub-paragraph (1), the agreement shall, subject to sub-paragraph (3), be varied to the extent that that party is no longer a party to the agreement 6 months after the date on which the notice is served (“the variation date”), save that if the variation date is not the last calendar day of a month, the agreement shall instead vary on the last calendar day of the month in which the variation date falls.

(3) Where a party to the agreement is an individual, sub-paragraph (2) shall apply to that party, save that the reference to “6 months” shall instead be to “3 months”.

(4) This paragraph is without prejudice to the right of the Health Board to terminate an agreement in accordance with paragraph 70.

Late payment notices

63.—(1) The provider may give notice in writing (a “late payment notice”) to the Health Board if the Board has failed to make any payments due to the provider in accordance with a term of the agreement that has the effect specified in regulation 20 and the provider shall specify in the late payment notice the payments that the Board has failed to make in accordance with that regulation.

(2) Subject to sub-paragraph (3), the provider may, at least 28 days after having served a late payment notice, terminate the agreement by a further written notice if the Health Board has still failed to make the payments due to the provider, and that were specified in the late payment notice served on the Health Board pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Health Board refers the matter to the NHS dispute resolution procedure within 28 days of the date upon which it is served with the late payment notice, and it notifies the provider in writing that it has done so within that period of time, the provider may not terminate the agreement pursuant to sub-paragraph (2) until—

- (a) there has been a determination of the dispute pursuant to paragraph 57 and that determination permits the provider to terminate the agreement; or
- (b) the Health Board ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

Termination by the Health Board: general

64. The Health Board may only terminate the agreement with the provider or a party to the agreement in accordance with the provisions in this Part.

Termination by the Health Board for the provision of untrue etc information

65.—(1) The Health Board may serve notice in writing on a party to the agreement terminating the agreement with that party to the agreement forthwith, or from such date as may be specified in the notice if, after the agreement has been made, it comes to the attention of the Health Board that written information provided to the Health Board by that party to the agreement before the agreement was entered into in relation to the condition set out in regulation 3 (and compliance with that condition) was, when given, untrue or inaccurate in a material respect.

(2) Where the provider comprises more than one party to the agreement, the Health Board shall send a copy of the notice served under sub-paragraph (1) to any other party to the agreement with which the agreement is not being terminated.

Other grounds for termination by the Health Board

66.—(1) The Health Board may serve notice in writing on a party to the agreement terminating the agreement with that party forthwith, or from such date as may be specified in the notice if—

- (a) where an individual is a party to the agreement, that individual;
- (b) where a partnership is a party to the agreement, any partner or the partnership; and
- (c) where a company limited by shares is a party to the agreement—
 - (i) the company;
 - (ii) any person legally or beneficially owning a share in the company; or
 - (iii) any director or secretary of the company,

falls within sub-paragraph (3) during the existence of the agreement.

(2) Where the provider comprises more than one party to the agreement, a Health Board that serves notice pursuant to sub-paragraph (1) shall send a copy of that notice to any other party to the agreement whose agreement is not being terminated.

(3) A person falls within this sub-paragraph if—

- (a) the person has been or is the subject of a national disqualification;
- (b) subject to sub-paragraph (4), the person is disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill-health) from practising by any licensing body anywhere in the world;
- (c) subject to sub-paragraph (5), the person has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Health Board has served a notice terminating the agreement pursuant to this paragraph, the person is employed by the health service body that dismissed the person or by another health service body;
- (d) the person is disqualified from a list unless the person's name has subsequently been included in such a list;
- (e) the person has been convicted in the United Kingdom of murder;
- (f) the person has been convicted in the United Kingdom of a criminal offence other than murder, and has been sentenced to a term of imprisonment of over 6 months;
- (g) subject to sub-paragraph (5), the person has been convicted elsewhere of an offence which would, if committed in Scotland, constitute—
 - (i) murder; or
 - (ii) a criminal offence other than murder, and been sentenced to a term of imprisonment of over 6 months;

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- (h) the person has been convicted of an offence referred to in Schedule 1 to the Criminal Procedure (Scotland) Act 1995⁽²⁴⁾ (offences against children under the age of 17 to which special provisions apply) or Schedule 1 to the Children and Young Persons Act 1933⁽²⁵⁾ (offences against children and young persons with respect to which special provisions apply);
- (i) the person has—
 - (i) had sequestration of the person’s estate awarded or been adjudged bankrupt unless (in either case) the person has been discharged or the bankruptcy order has been annulled;
 - (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986⁽²⁶⁾, unless that order has ceased to have effect or has been annulled;
 - (iii) made a composition or arrangement with, or granted a trust deed for, the person’s creditors unless the person has been discharged in respect of it; or
 - (iv) been wound up under Part IV of the Insolvency Act 1986.
- (j) there is—
 - (i) an administrator, administrative receiver or receiver appointed in respect of it; or
 - (ii) an administration order made in respect of it under Schedule B1 to the Insolvency Act 1986⁽²⁷⁾;
- (k) that person is a partnership and—
 - (i) a dissolution of the partnership is ordered by any competent court, tribunal or arbitrator; or
 - (ii) an event happens that makes it unlawful for the business of the partnership to continue, or for members of the partnership to carry on in partnership;
- (l) the person has been—
 - (i) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990⁽²⁸⁾ (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body; or
 - (ii) removed from the office of charity trustee or a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person by the person’s conduct contributed to or facilitated; or
- (m) the person is subject to a disqualification order under the Company Directors Disqualification Act 1986⁽²⁹⁾, the Companies (Northern Ireland) Order 1986⁽³⁰⁾ or to an order made under section 429(2)(b) of the Insolvency Act 1986⁽³¹⁾ (failure to pay under county court administration order);
- (n) that person has refused to comply with a request by the Health Board for that person to be medically examined on the grounds that the Health Board is concerned that the person is

⁽²⁴⁾ 1995 c. 46.

⁽²⁵⁾ 1933 c. 12 as amended by the Criminal Justice Act 1988 (c. 33), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; the Sexual Offences Act 1956 (c. 69), sections 48 and 51 and Schedules 3 and 4 as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

⁽²⁶⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of and Schedule 2 to the Enterprise Act 2002 (c. 40).

⁽²⁷⁾ Schedule B1 was inserted by section 248 of and Schedule 16 to the Enterprise Act 2002.

⁽²⁸⁾ 1990 c. 40.

⁽²⁹⁾ 1986 c. 45.

⁽³⁰⁾ S.I. 1986/1032 (N.I.6).

⁽³¹⁾ 1986 c. 46 as amended by the Insolvency Act (2000 c. 39).

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incapable of adequately providing services under the agreement and, in a case where that person is a partner in a partnership, or a legal and beneficial owner of shares in a company, that is a party to the agreement, the Health Board is not satisfied that the partnership or company is taking adequate steps to deal with the matter; or

- (o) that person would otherwise fall within paragraph 101(2)(p) of Schedule 5 to the GMS Contracts Regulations.

(4) A Health Board shall not terminate the agreement pursuant to sub-paragraph (2)(c) where the Health Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—

- (a) a party to the agreement;
- (b) in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership; or
- (c) in the case where the person is—
 - (i) a person legally or beneficially holding a share in a company limited by shares that is a party to the agreement; or
 - (ii) a director or secretary of a company limited by shares that is a party to the agreement, a person legally or beneficially holding share in that company or a director or secretary of that company, as the case may be.

(5) A Health Board shall not terminate the agreement pursuant to sub-paragraph (2)(d)—

- (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or
- (b) if, during the period of time specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

and the Health Board may only terminate the agreement at the end of the period specified in paragraph (b) if there is no finding of unfair dismissal at the end of those proceedings.

(6) A Health Board shall not terminate the agreement pursuant to sub-paragraph (2)(h) where the Health Board is satisfied that the conviction does not make the person unsuitable to be—

- (a) a party to the agreement;
- (b) in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership;
- (c) in the case where the person is—
 - (i) a person legally and beneficially holding a share in a company limited by shares that is a party to the agreement; or
 - (ii) a director or secretary of a company limited by shares that is a party to the agreement, a person legally and beneficially holding share in that company or a director or secretary of that company, as the case may be.

(7) In this paragraph “health service body” does not include any provider who is to be treated as a health service body in accordance with regulation 8.

Other grounds for termination by the Health Board

67. The Health Board may serve notice in writing on the provider terminating the agreement with the provider forthwith or with effect from such date as may be specified in the notice if—

- (a) the provider has breached the agreement and, as a result of that breach, the safety of the provider's patients is at serious risk if the agreement is not terminated; or

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- (b) the provider’s financial situation is such that the Health Board considers that the Health Board is at risk of material financial loss.

Termination by the Health Board: remedial notices and breach notices

68.—(1) Where a provider has breached the agreement other than as specified in paragraphs 65 to 67 and the breach is capable of remedy, the Health Board shall, before taking any action it is otherwise entitled to take by virtue of the agreement, serve a notice on the provider requiring it to remedy the breach (“remedial notice”).

(2) A remedial notice shall specify—

- (a) details of the breach;
- (b) the steps the provider must take to the satisfaction of the Health Board in order to remedy the breach; and
- (c) the period during which the steps must be taken (“the notice period”).

(3) The notice period shall, unless the Health Board is satisfied that a shorter period is necessary to—

- (a) protect the safety of the provider’s patients; or
- (b) protect itself from material financial loss,

be no less than 28 days from the date that notice is given.

(4) Where a Health Board is satisfied that the provider has not taken the required steps to remedy the breach by the end of the notice period, the Health Board may terminate the agreement with the provider with effect from such date as the Health Board may specify in a further notice to the provider.

(5) Where a provider has breached the agreement other than as specified in paragraphs 65 to 67 and the breach is not capable of remedy, the Health Board may serve notice on the provider requiring the provider not to repeat the breach (“breach notice”).

(6) If, following a breach notice or a remedial notice, the provider—

- (a) repeats the breach that was the subject of the breach notice or the remedial notice; or
- (b) otherwise breaches the agreement resulting in either a remedial notice or a further breach notice,

the Health Board may serve notice on the provider terminating the agreement with effect from such date as may be specified in that notice.

(7) The Health Board shall not exercise its right to terminate the agreement under sub paragraph (6) unless it is satisfied that the cumulative effect of the breaches is such that the Health Board considers that to allow the agreement to continue would be prejudicial to the efficiency of the services to be provided under the agreement.

(8) If the provider is in breach of any obligation and a breach notice or a remedial notice in respect of that default has been given to the provider, the Health Board may withhold or deduct monies which would otherwise be payable under the agreement in respect of that obligation which is the subject of the default.

Termination by the Health Board: additional provisions specific to agreements with one or more companies limited by shares

69.—(1) Where a company limited by shares is a party to the agreement, if the Health Board becomes aware that a company is carrying on any business which the Health Board considers to be detrimental to the provider’s performance of its obligations under the agreement—

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- (a) the Health Board shall be entitled to give notice to the company requiring that the company ceases carrying on that business before the end of a period of not less than 28 days beginning on the day on which the notice is given (“the notice period”); and
- (b) if the company has not satisfied the Health Board that the company has ceased carrying on that business by the end of the notice period, the Health Board may, by a further written notice, terminate the agreement with that company forthwith or from such date as may be specified in the notice.

(2) Where the provider comprises more than one party to the agreement, a Health Board that serves notice pursuant to sub-paragraph (1)(a) or (b) shall send a copy of that notice to any other party to the agreement.

Termination by the Health Board: changes in the provider

70.—(1) The Health Board shall be entitled to terminate the agreement with the provider by notice in writing on such date as may be specified in that notice where, during the existence of the agreement—

- (a) one or more parties to the agreement have withdrawn from or ceased to be parties to the agreement; or
- (b) where one or more partnerships are parties to the agreement, one or more partners have left that partnership or those partnerships,

if in its reasonable opinion, the Health Board considers that the change in the parties to the agreement or membership of the partnership (as the case may be) is likely to have a serious adverse impact on the ability of the provider or the Health Board to perform its obligations under the agreement.

(2) A notice given to the provider pursuant to sub-paragraph (1) shall specify—

- (a) the date upon which the agreement is to be terminated; and
- (b) the Health Board’s reasons for considering that the change in the parties to the agreement or the membership of the partnership (as the case may be) is likely to have a serious adverse impact on the ability of the provider or the Health Board to perform its obligations under the agreement.

Agreement sanctions

71.—(1) In this paragraph and paragraph 72, “agreement sanction” means—

- (a) the termination of specified obligations under the agreement;
- (b) the suspension of specified obligations under the agreement for a period of up to six months; or
- (c) the withholding or deducting of monies otherwise payable under the agreement.

(2) Where the Health Board is entitled to terminate the agreement with the provider or with a party to the agreement pursuant to paragraph 65, 66, 67, 68(4) or (6), 69 or 70 it may instead impose any of the agreement sanctions if the Health Board is reasonably satisfied that the agreement sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Health Board’s entitlement to terminate the agreement.

(3) Where the agreement includes the provision of essential services, the Health Board shall not, under sub-paragraph (2), be entitled to impose any agreement sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

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(4) If the Health Board decides to impose an agreement sanction, it must notify the provider of the agreement sanction that it proposes to impose, the date upon which that sanction will be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(5) Subject to paragraph 72 the Health Board shall not impose the agreement sanction until at least 28 days after it has served notice on the provider pursuant to sub-paragraph (4) unless the Health Board is satisfied that it is necessary to do so in order to—

- (a) protect the safety of the provider’s patients; or
- (b) protect itself from material financial loss.

(6) Where the Health Board imposes an agreement sanction, the Health Board shall be entitled to charge the provider the reasonable costs of additional administration that the Health Board has incurred in order to impose, or as a result of imposing, the agreement sanction.

Agreement sanctions and the dispute resolution procedure

72.—(1) If there is a dispute between the Health Board and the provider in relation to an agreement sanction that the Health Board is proposing to impose, the Health Board shall not, subject to sub-paragraph (4), impose the proposed agreement sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the provider refers the dispute relating to the agreement sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the Health Board served notice on the provider in accordance with paragraph 71(4) (or such longer period as may be agreed in writing with the Health Board), and notifies the Health Board in writing that it has done so, the Health Board shall not impose the agreement sanctions unless—

- (a) there has been a determination of the dispute pursuant to paragraph 57 and that determination permits the Health Board to impose the agreement sanction; or
- (b) the provider ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(3) If the provider does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Health Board shall be entitled to impose the agreement sanction forthwith.

(4) If the Health Board is satisfied that it is necessary to impose the agreement sanction before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the provider’s patients; or
- (b) protect itself from material financial loss,

the Health Board shall be entitled to impose the agreement sanction forthwith, pending the outcome of that procedure.

Termination and the NHS dispute resolution procedure

73.—(1) Where the Health Board is entitled to serve written notice on the provider or a party to the agreement terminating the agreement with the provider or a party to the agreement pursuant to paragraph 65, 66, 67 or 68(4) or (6) the Health Board shall, in the notice served on the provider or the party to the agreement pursuant to those provisions, specify a date on which the agreement with the provider or a party to the agreement terminates that is not less than 28 days after the date on which the Health Board has served that notice on the provider or the party to the agreement unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Health Board is satisfied that a period less than 28 days is necessary in order to—

- (a) protect the safety of the provider’s patients; or

(b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1), where the exceptions in sub-paragraph (2) do not apply, where the provider invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Health Board in writing that it has done so, the agreement shall not terminate at the end of the notice period but instead shall only terminate in the circumstances specified in sub-paragraph (4).

(4) The agreement shall only terminate if and when—

(a) there has been a determination of the dispute pursuant to paragraph 57 and that determination permits the Health Board to terminate the agreement with the provider or the party to the agreement; or

(b) the provider ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Health Board is satisfied that it is necessary to impose the agreement sanction before the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the provider's patients; or

(b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the Health Board shall be entitled to confirm, by written notice to be served on the provider, that the agreement with the provider or a party to the agreement will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 65, 66(1), 67, 68(4) or (6), 69 or 70.

Consultation with the area medical committee

74.—(1) Whenever the Health Board is considering—

(a) terminating the agreement with the provider or with a party to the agreement pursuant to paragraph 66, 67(1), 68, 69(4) or (6), 70 or 71; or

(b) imposing an agreement sanction,

it shall, whenever it is reasonably practicable to do so, consult the area medical committee for its area before it terminates the agreement with the provider or with a party to the agreement or imposes a agreement sanction.

(2) Whether or not the area medical committee has been consulted pursuant to sub paragraph (1), whenever the Health Board imposes a agreement sanction on the provider or terminates a agreement with the provider or a party to the agreement pursuant to this Part, it shall, as soon as reasonably practicable, notify the area medical committee in writing of the agreement sanction imposed or of the termination of the agreement (as the case may be).

PART 9

MISCELLANEOUS

Clinical governance

75.—(1) The provider shall have an effective system of clinical governance.

(2) The provider shall nominate a person who will have responsibility for ensuring the effective operation of a system of clinical governance.

(3) The person nominated under sub-paragraph (2) shall be a person who performs or manages services under the agreement.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(4) In this paragraph “system of clinical governance” means a framework through which the provider endeavours continuously to improve the quality of its services and safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Insurance

76.—(1) The provider shall at all times hold adequate insurance against liability arising from negligent performance of clinical services under the agreement.

(2) The provider shall not sub-contract its obligations to provide clinical services under the agreement unless it has satisfied itself that the sub-contractor holds adequate insurance against liability arising from negligent performance of such services.

(3) In this paragraph—

- (a) “insurance” means a contract of insurance or other arrangement made for the purpose of indemnifying the provider; and
- (b) a provider shall be regarded as holding insurance if the insurance is held by an employee of that provider in connection with clinical services which that employee provides under the agreement or, as the case may be, sub-contract.

Insurance

77. The provider shall at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the agreement which are not covered by the insurance referred to in paragraph 76(1).

Gifts

78.—(1) The provider shall keep a register of gifts which—

- (a) are given to any of the persons specified in sub-paragraph (2) by or on behalf of—
 - (i) a patient;
 - (ii) a relative of a patient; or
 - (iii) any person who provides or wishes to provide services to the provider or its patients in connection with the agreement; and
- (b) have, in its reasonable opinion, an individual value of more than £100.00.

(2) The persons referred to in sub-paragraph (1) are—

- (a) the provider;
- (b) where a partnership is a party to the agreement, any partner in the partnership;
- (c) where a company is a party to the agreement—
 - (i) any person legally and beneficially holding a share in the company, or
 - (ii) a director or secretary of the company;
- (d) any person employed by the provider for the purposes of the agreement;
- (e) any general medical practitioner engaged by the provider for the purposes of the agreement;
- (f) any spouse of an individual (where an individual is a party to the agreement) or of a person specified in paragraphs (b) to (e); or
- (g) any person (whether or not of the opposite sex) whose relationship with any individual (where an individual is a party to the agreement) or with a person specified in paragraphs (b) to (e) has the characteristics of the relationship between husband and wife.

- (3) Sub-paragraph (1) does not apply where–
 - (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the provider;
 - (b) the provider is not aware of the gift; or
 - (c) the provider is not aware that the donor wishes to provide services to the provider.
- (4) The provider shall take reasonable steps to ensure that it is informed of gifts which fall within sub-paragraph (1) and which are given to the persons specified in sub-paragraph (2)(b) to (g).
- (5) The register referred to in sub-paragraph (1) shall include the following information–
 - (a) the name of the donor;
 - (b) in a case where the donor is a patient, the patient’s National Health Service number or, if the number is not known, his address;
 - (c) in any other case , the address of the donor;
 - (d) the nature of the gift;
 - (e) the estimated value of the gift; and
 - (f) the name of the person or persons who received the gift.
- (6) The provider shall make the register available to the Health Board on request.

Compliance with legislation and guidance

- 79.** The provider shall–
 - (a) comply with all relevant legislation; and
 - (b) have regard to all relevant guidance issued by the Health Board and the Scottish Ministers.

Third party rights

- 80.** The agreement shall not create any right enforceable by any person not a party to it.