SCOTTISH STATUTORY INSTRUMENTS

2004 No. 116

The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004

PART 1

GENERAL

Citation and commencement

1. These Regulations may be cited as the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 and shall come into force on 1st April 2004.

Interpretation

2. In these Regulations-

"the Act" means the National Health Service (Scotland) Act 1978;

"the 2004 Act" means the Primary Medical Services (Scotland) Act 2004(1);

"the 2003 Order" means the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003(2);

"additional services" means one or more of-

- (a) cervical screening services;
- (b) contraceptive services;
- (c) vaccinations and immunisations;
- (d) childhood vaccinations and immunisations;
- (e) child health surveillance services;
- (f) maternity medical services; and
- (g) minor surgery;

"agreement" means, unless the context otherwise requires, an agreement pursuant to section 17C of the Act(3) (personal medical or dental services) under which primary medical services are provided;

[&]quot;adjudicator" means the Scottish Ministers or a panel of 3 persons appointed by the Scottish Ministers under paragraph 56 of Schedule 1;

^{(1) 2004} asp 1.

⁽²⁾ S.I.2003/1250.

⁽³⁾ Section 17C was inserted by the National Health Service (Primary Care) Act 1997 (c. 46), section 21(2) and was amended by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 2(2).

"appliance" means an appliance which is included in a list for the time being approved by the Scottish Ministers for the purposes of section 27(1)(4) of the Act;

"approved medical practice" shall be construed in accordance with section 11(4) of the Medical Act 1983(5);

"area medical committee" means the committee of that name recognised under section 9 of the Act (local consultative committees) in the area of the Health Board;

"area pharmaceutical committee" means the committee of that name recognised under section 9 of the Act (local consultative committees) in the area of the Health Board;

"assessment panel" means a committee or sub-committee of a Health Board ("the first Health Board") (other than the Health Board ("the second Health Board") which is a party to the agreement in question) appointed by the first Health Board at the request of the second Health Board to exercise functions under paragraph 23 or paragraph 27 of Schedule 2 and which shall consist of—

- (a) the Chief Executive of the first Health Board or an Executive Director of that Health Board nominated by that Chief Executive;
- (b) a person representative of patients in an area other than that of the second Health Board; and
- (c) a person representative of the area medical committee which does not represent practitioners in the area of the second Health Board;

"CCT" means a Certificate of Completion of Training awarded under article 8 of the 2003 Order, including any such certificate awarded in pursuance of the competent authority functions of the Postgraduate Medical Education and Training Board specified in article 20(3) (a) of that Order;

"cervical screening services" means the services described in paragraph 2(2) of Schedule 3;

"charity trustee" means one of the persons having the general control and management of the administration of a charity;

"child" means a person who has not attained the age of 16 years;

"child health surveillance services" means the services described in paragraph 6(2) of Schedule 3;

"childhood vaccinations and immunisations" means the services described in paragraph 5(2) of Schedule 3;

"closed", in relation to a provider's list of patients, means closed to applications for inclusion in the list of patients other than from immediate family members of registered patients;

"contraceptive services" means the services described in paragraph 3(2) of Schedule 3;

"core hours" means the period beginning at 8 a.m. and ending at 6.30 p.m. on any working day;

"dispensing services" means the provision of drugs, medicines and appliances;

"disqualified" means, unless the context otherwise requires, local or national disqualification by the Tribunal (or a decision under provisions in force in England, Wales or Northern Ireland corresponding to local or national disqualification), but does not include conditional disqualification;

"Drug Tariff" means the statement published under regulation 9 (payments to pharmacists and standards of drugs and appliances) of the Pharmaceutical Regulations;

⁽⁴⁾ Section 27 was amended by the National Health Service and Community Care Act 1990 (c. 19), Schedule 9, the Medicine Products: Prescription by Nurses etc. Act 1992 (c. 28), section 3, the National Health Service (Primary Care) Act1997 (c. 46), Schedule 2, paragraph 44, the Health and Social Care Act 2001 (c. 15), section 44 and S.I. 2003/1590.

^{(5) 1983} c. 54; section 11(4) was amended by the National Health Service (Primary Care) Act 1997 (c. 46), section 35(4) and Schedule 2, paragraph 61(2).

"enhanced services" are-

- (a) services other than essential services, additional services or out of hours services; or
- (b) essential services or additional services or out of hours services or an element of such a service that a provider agrees in the agreement to provide in accordance with specifications set out in a plan, which requires of the provider an enhanced level of service provision compared to that which the provider needs generally to provide in relation to that service or element of service;

"essential services" means the services described in paragraph 1(2),(4), (5) and (7) of Schedule 2;

"general medical practitioner" means-

- (a) from the coming into force of article 10 of the 2003 Order, a medical practitioner whose name is included in the General Practitioner Register otherwise than by virtue of paragraph 1(d) of Schedule 6 to that Order; and
- (b) until the coming into force of that article, a medical practitioner who is either-
 - (i) until the coming into force of paragraph 22 of Schedule 8 to the 2003 Order, suitably experienced within the meaning of section 21(2) of the Act, section 31(2) of the National Health Service Act 1977(6) or Article 8(2) of the Health and Personal Social Services (Northern Ireland) Order 1978(7); or
 - upon the coming into force of paragraph 22 of Schedule 8 to the 2003 Order, an eligible general practitioner pursuant to that paragraph other than by virtue of having an acquired right under paragraph 1(d) of Schedule 6 to the 2003 Order;

"general medical services contract" means a general medical services contract under section 17J of the Act(8) (Health Boards power to enter into general medical services contracts);

"general medical services contractor" means a person who is providing primary medical services in accordance with a general medical services contract;

"General Practitioner Register" means the register kept by the General Medical Council under article 10 of the 2003 Order;

"GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(9);

"GP Registrar"-

- (a) until the coming into force of article 5 of the 2003 Order, means a medical practitioner who is being trained in general practice by a medical practitioner who—
 - (i) has been approved for that purpose by the Joint Committee on Postgraduate Training for General Practice under regulation 7 of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998(10); and
 - (ii) performs primary medical services; and
- (b) from the coming into force of that article, means a medical practitioner who is being trained in general practice by a GP Trainer whether as part of training leading to the award of a CCT or otherwise;

"GP Trainer" means a general medical practitioner who is-

^{(6) 1977} c. 49.

⁽⁷⁾ S.I. 1978/1907 (N.I. 26).

⁽⁸⁾ Section 17J was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4.

⁽⁹⁾ S.S.I. 2004/115.

⁽¹⁰⁾ S.I. 1998/5 as amended by S.I. 1998/669 and S.S.I. 2000/23.

- (a) until the coming into force of article 4(5)(d) of the 2003 Order, approved as a GP Trainer by the Joint Committee on Postgraduate Training for General Practice under regulation 7 of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998; or
- (b) from the coming into force of that article, approved by the Postgraduate Medical Education and Training Board under article 4(5)(d) of the 2003 Order for the purposes of providing training to a GP Registrar under article 5(1)(c)(i) of that Order;

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(11);

"Health and Social Services trust" means a Health and Social Services trust established under Article 10(1) of the Health and Personal Social Services (Northern Ireland) Order 1991(12);

"Health Authority" means a Health Authority established under section 8 of the National Health Service Act 1977;

"Health Board" means, unless the context otherwise requires, the Health Board which is a party, or prospective party, to an agreement;

"health care professional" has the same meaning as in section 17D(2) of the Act(13) and "health care profession" shall be construed accordingly;

"health service body" means any person or body referred to in section 17A(2)(14) of the Act (NHS contracts) and includes, except where otherwise expressly provided, any provider who is to be treated as a health service body in accordance with regulation 8;

"immediate family member" means-

- (a) a spouse;
- (b) a person (whether or not of the opposite sex) whose relationship with the registered patient has the characteristics of the relationship between husband and wife;
- (c) a parent or step-parent;
- (d) a son;
- (e) a daughter;
- (f) a child of whom the registered patient is-
 - (i) the guardian; or
 - (ii) the carer duly authorised by the local authority to whose care the child has been committed under the Children (Scotland) Act 1995(15); or
- (g) a grandparent;

"independent nurse prescriber" means a person-

- (a) who is either engaged or employed by the provider, is a party to the agreement or is a partner in a partnership that is a party to the agreement;
- (b) who is registered in the Nursing and Midwifery Register; and
- (c) in respect of whom an annotation is also recorded in that register signifying that the person is qualified to order drugs, medicines and appliances from—

⁽¹¹⁾ S.I. 1972/1265 (N.I. 14).

⁽¹²⁾ S.I. 1991/194 (N.I. 1).

⁽¹³⁾ Section 17D(2) was inserted by the National Health Service (Primary Care) Act 1997 (c. 46), section 21(2) and was amended by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 23(d) and schedule, paragraph 1(3).

⁽¹⁴⁾ Section 17A(2) was inserted by the National Health Service and Community Care Act 1990 (c. 19), section 30 and amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 102(2), the National Health Service (Primary Care) Act 1997 (c. 46), Schedule 2, paragraph 36, the Health Act 1999 (c. 8), Schedule 4, paragraph 46 and S.I. 1991/195.

^{(15) 1995} c. 36.

- (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part 8B of the Drug Tariff; or
- (ii) the Nurse Prescribers' Extended Formulary in Part 8C of the Drug Tariff;
- "licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(16);
- "licensing body" means any body that licenses or regulates any profession;
- "limited partnership" means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907(17);
- "list" has, unless the context otherwise requires, the meaning assigned to it in section 29(8) of the Act(18) and includes a list corresponding to such a list in England, Wales or Northern Ireland;
- "Local Health Board" means a Local Health Board established under section 16BA of the National Health Service Act 1977(19) (local health boards);
- "local or national disqualification" has the meaning indicated in section 29B(2) of the Act(20)
- "maternity medical services" means the services described in paragraph 7 of Schedule 3;
- "medical card" means a card issued by a Health Board, Primary Care trust, Local Health Board, Health Authority or Health and Social Services Board to a person for the purpose of enabling that person to obtain, or establishing that person's title to receive, primary medical services;
- "medical officer" means a medical practitioner who is-
- (a) employed or engaged by the Department for Work and Pensions; or
- (b) provided by an organisation in pursuance of a contract entered into with the Secretary of State for Work and Pensions:
- "Medical Register" means the registers kept under section 2 of the Medical Act 1983(21);
- "minor surgery" means the services described in paragraph 8(2) of Schedule 3;
- "national disqualification" means-
- (a) a national disqualification by the Tribunal; or
- (b) a decision under provisions in force in England, Wales or Northern Ireland corresponding to a national disqualification by the Tribunal;
- "NHS contract" means an agreement which is an NHS contract within the meaning of section 17A(3) of the Act as a result of the provider being treated as a health service body pursuant to regulation 8(1) or (5);
- "NHS dispute resolution procedure" means the procedure for resolution of disputes specified in paragraphs 56 and 57 of Schedule 1;
- "NHS foundation trust" has the same meaning as in section 1 of the Health and Social Care (Community Health and Standards) Act 2003(22);

^{(16) 1968} c. 67.

^{(17) 1907} c. 24.

⁽¹⁸⁾ Section 29(8) was substituted by the Health Act 1999 (c. 8), section 58(1) and amended by the Community Care and Health (Scotland) Act 2002 (asp 5), Schedule 2, paragraph 2(4)(b) and the Primary Medical Services (Scotland) Act 2004 (asp 1), section 5(3).

^{(19) 1977} c. 49. Section 16BA was inserted by the National Health Service Reform and Health Care Professions Act 2002 (c. 17), section 6.

⁽²⁰⁾ Section 29B(2) was inserted by the Health Act 1999 (c. 8), section 58 and amended by the Community Care and Health (Scotland) Act 2002 (asp 5), schedule 2, paragraph 2 and the Primary Medical Services (Scotland) Act 2004 (asp 1), schedule, paragraph 1(13).

^{(21) 1983} c. 54; section 2 was amended by S.I. 1996/1591 and 2002/3135.

^{(22) 2003} c. 43.

"NHS trust" means a National Health Service trust established under section 5 of the National Health Service and Community Care Act 1990(23);

"normal hours" means those days and hours on which and the times at which services under the agreement are normally made available and may be different for different services;

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(24);

"open" in relation to a provider's list of patients, means open to applications from patients in accordance with paragraph 9 of Schedule 2;

"out of hours period" means-

- (a) the period beginning at 6.30 p.m. on any day from Monday to Thursday and ending 8 a.m. on the following day;
- (b) the period between 6.30 p.m. on Friday and 8 a.m. on the following Monday; and
- (c) Christmas Day, New Year's Day and other public or local holiday,

and "part" of an out of hours period means any part of any one or more of the periods described in sub-paragraphs (a) to (c);

"out of hours services" means services agreed to be provided in all or part of the out of hours period which would be essential services or additional services if provided in core hours, and in the case of a provider who does not provide essential services or additional services in core hours, would be such services if the provider provided them;

"parent" includes, in relation to any child, any adult who, in the opinion of the provider, is for the time being discharging in respect of that child the obligations normally attaching to a parent in respect of a child;

"party to the agreement" means where a Health Board makes an agreement with-

- (a) one person, the provider; and
- (b) more than one person, one of those persons;

"patient" means-

- (a) where the provider has a provider's list of patients—
 - (i) a registered patient;
 - (ii) a temporary resident; and
 - (iii) person to whom the provider is required to provide immediately necessary treatment under paragraph 1(5) or (7) of Schedule 2 respectively; and
- (b) in all cases any person (or, where the provider has a provider's list of patients, any other person) to whom the provider has agreed to provide services under the agreement;

"Pharmaceutical Regulations" means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995(25);

"pharmacist" means-

(a) a registered pharmacist within the meaning of the Medicines Act 1968(26) who provides pharmaceutical services; or

^{(23) 1990} c. 19.

⁽²⁴⁾ S.I. 2002/253.

⁽²⁵⁾ S.I. 1995/414 as amended by S.I. 1996/840 and 1504, 1997/696, 1998/2224 and 3031 and S.S.I. 1999/57, 2001/70, 2002/111 and 153, 2003/296.

^{(26) 1968} c. 67.

- (b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(27) who provides such services; or
- (c) a supplier of appliances,

who is included in the list of a Health Board under section 27 of the Act (arrangements for provision of pharmaceutical services);

"the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(28);

"practice" means the business operated by the provider for the purpose of delivering services under the agreement;

"practice area" means the area referred to in regulation 11(1)(a);

"practice premises" means an address specified in the agreement as one at which services are to be provided under the agreement;

"prescriber" means-

- (a) a medical practitioner;
- (b) an independent nurse prescriber; and
- (c) a supplementary prescriber,

who is either engaged or employed by the provider or is a party to the agreement or is a partner in a partnership that is a party to the agreement;

"prescription form" means a form provided by a Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services;

"prescription only medicine" means a medicine referred to in article 3 of the POM Order (medicinal products on prescription only);

"Primary Care trust" means a Primary Care trust established under section 16A of the National Health Service Act 1977(29) (primary care trusts);

"primary medical services performers list" means the list of primary medical services performers prepared in accordance with regulations made under section 17P of the Act(30) (persons performing primary medical services);

"provider", means, unless the context otherwise requires, where the Health Board makes an agreement with-

- (a) one person, that person; and
- (b) more than one person, all those persons, but references to employment, engagement or sub-contracting by those persons shall be deemed to include employment, or engagement or sub-contracting by any one of them;

"provider's list of patients" means the list prepared and maintained by the Health Board under paragraph 8 of Schedule 2;

"public or local holiday" means any public or local holiday which is agreed in writing between the Health Board and the provider and which shall, in aggregate, be no less than those available to NHS staff employed by the Health Board;

"registered patient" means-

(a) a person who is recorded by the Health Board as being on a provider's list of patients; or

⁽²⁷⁾ Section 69 was amended by the Statute Law (Repeals) Act 1993 (c. 50) and the Pharmacists (Fitness to Practise) Act1997 (c. 19), Schedule 4, paragraph 5.

⁽²⁸⁾ S.I. 1997/1830 as amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/1044 and 3463, 2000/1917, 2889 and 3231, 2001/2777, 2889 and 3942, 2002/549 and 2469 and 2003/696.

^{(29) 1977} c. 49. Section 16A was inserted by the Health Act 1999 (c. 8), section 2(1).

⁽³⁰⁾ Section 17P was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 5(2).

(b) a person whom a provider has accepted for inclusion on the provider's list of patients, whether or not notification of that acceptance has been received by the Health Board and who has not been notified by the Health Board as having ceased to be on that list;

"relevant register" means-

- (a) in relation to a nurse, the Nursing and Midwifery Register; and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(31) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(32);

"restricted availability appliance" means an appliance which is approved for particular categories of persons or particular purposes only;

"Scheduled drug" means-

- (a) a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act(33) 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; or
- (b) a drug, medicine or other substance which is 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;

"supplementary prescriber" means a person-

- (a) who is either engaged or employed by the provider or is a party to the agreement or a partner in a partnership that is a party to the agreement; and
- (b) whose name is registered in-
 - (i) the Nursing and Midwifery Register;
 - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954; or
 - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, and

against whose name is recorded in the relevant register an annotation signifying that that person is qualified to order drugs medicines and appliances as a supplementary prescriber;

"temporary resident" means a person accepted by a provider as a temporary resident under paragraph 10 of Schedule 2 and for whom the provider's responsibility has not been terminated in accordance with that paragraph;

"working day" means any day apart from Saturday, Sunday, Christmas Day, New Year's Day and any other public or local holiday;

"writing" includes, unless otherwise expressly provided, transmission by electronic means and "written" should be construed accordingly.

- (2) In these Regulations, the use of the term "it" in relation to-
 - (a) a provider, shall be deemed to include a reference to a provider who is
 - (i) comprised of more than one party to the agreement; or
 - (ii) an individual; and

^{(31) 1954,} c. 61.

⁽³²⁾ S.I. 1976/1213.

⁽³³⁾ Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4.

(b) the adjudicator, shall be deemed to refer either to the Scottish Ministers or the panel of 3 persons appointed by them as the case may be,

and related expressions shall be construed accordingly.

(3) Any reference in these Regulations to a numbered regulation or Schedule or to a numbered paragraph of such a Schedule is, unless otherwise expressly provided, a reference to a regulation or Schedule bearing that number in these Regulations or, as the case may be, to a paragraph bearing that number in such a regulation or Schedule.

PART 2

PROVIDERS

General conditions relating to providers

- 3.—(1) Subject to the provisions of any order made by the Scottish Ministers under section 7 (ancillary provision) of the 2004 Act a Health Board may only make an agreement with one or more of the persons falling within section 17D(1)(b), (d) or (e) of the Act(34), where—
 - (a) if a person is an individual, the individual;
 - (b) if a person is a partnership, any member of the partnership and the partnership; and
 - (c) if a person is a company limited by shares-
 - (i) the company;
 - (ii) any person legally and beneficially owning a share in the company; and
 - (iii) any director or secretary of the company,

satisfies the condition set out in paragraph (2).

- (2) It is a condition that the person must not—
 - (a) be the subject of a national disqualification;
 - (b) subject to paragraph (3), be disqualified or suspended (otherwise than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
 - (c) within the period of 5 years prior to the signing of the agreement or commencement of the agreement, whichever is the earlier, have been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless the person has subsequently been employed by that health service body or another health service body and paragraph (4) applies to that person, or that dismissal was the subject of a finding of unfair dismissal by any competently established tribunal or court;
 - (d) within the period of 5 years prior to signing the agreement or commencement of the agreement, whichever is the earlier, have been disqualified from a list unless the person's name has subsequently been included in such a list;
 - (e) have been convicted in the United Kingdom of murder;
 - (f) have been convicted in the United Kingdom of a criminal offence, other than murder, and been sentenced to a term of imprisonment of over 6 months;
 - (g) subject to paragraph (5), have been convicted elsewhere of an offence which would if committed in Scotland, constitute—

^{(34) 1978,} c. 29. Section 17D(1) was inserted by the National Health Service (Primary Care) Act 1997 (c. 46), section 21(2) and amended by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 2(3).

- (i) murder; or
- (ii) a criminal offence other than murder, and been sentenced to a term of imprisonment of over 6 months:
- (h) have been convicted of an offence referred to in Schedule 1 to the Criminal Procedure (Scotland) Act 1995 (offences against children under the age of 17 years to which special provisions apply)(35) or Schedule 1 to the Children and Young Persons Act 1933 (offences against children and young persons with respect to which special provisions apply)(36);
- (i) have-
 - (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(37) unless that order has ceased to have effect or has been annulled; or
 - (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;
- (j) have an administrator, administrative receiver or receiver appointed in respect of the person;
- (k) have been-
 - (i) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(38) (powers of the Court of Session to deal with the management of charities), from being concerned in the management or control of any body; or
 - (ii) removed from the office of charity trustee or trustee for 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 that person's conduct contributed to or facilitated;
- (l) be subject to a disqualification order under the Company Directors Disqualification Act 1986(39), the Companies (Northern Ireland) Order 1986(40) or to an order made under section 429(2)(b) of the Insolvency Act 1986(41) (failure to pay under county court administration order); or
- (m) fall within regulation 5(2)(m) of the GMS Contracts Regulations.
- (3) A person shall not fall within paragraph (2)(b) where the Health Board is satisfied that the disqualification or suspension from practising is imposed by a licensing body outside the United Kingdom and it 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 proposed party to the agreement, a partner in that partnership;
 - (c) in the case where the person is-

^{(35) 1995} c. 46.

^{(36) 1933} c. 12 as amended by the Sexual Offences Act 1956 (c. 69), sections 48 and 51 and Schedules 3 and 4 and the Criminal Justice Act 1988 (c. 33) ("the 1988 Act"), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; and as modified by the 1988 Act, section 170(1) Schedule 15, paragraph 9.

^{(37) 1986} c. 45. Schedule 4A was inserted by section 257 of and Schedule 20 to the Enterprise Act 2002 (c. 40).

^{(38) 1990} c. 40.

^{(39) 1986} c. 46.

⁽⁴⁰⁾ S.I. 1986/1032 (N.I. 6).

^{(41) 1986} c. 45 as amended by the Insolvency Act 2000 (c. 39).

- (i) a person legally and beneficially holding a share in a company limited by shares that is a proposed party to the agreement; or
- (ii) a director or secretary of a company limited by shares that is a proposed party to the agreement,
- a person legally and beneficially holding a share in that company, or a director or secretary of that company (as the case may be).
- (4) Where a person has been employed as a member of a health care profession any subsequent employment must also be as a member of that profession.
- (5) A person shall not fall within paragraph (2)(g) 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 proposed 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 proposed party to the agreement; or
 - (ii) a director or secretary of a company limited by shares that is a proposed party to the agreement,
 - a person legally and beneficially holding a share in that company, or a director or secretary of that company (as the case may be).
- (6) In this regulation, "health service body" does not include any provider who is to be treated as a health service body in accordance with regulation 8.

Reasons

- **4.**—(1) Where a Health Board is of a view that a person does not satisfy the condition in regulation 3(2), it shall notify in writing the person intending to make an agreement of the Health Board's view and its reasons for that view, and of that person's right of appeal under regulation 5.
 - (2) The Health Board shall also notify in writing of its view and its reasons for that view-
 - (a) any other persons intending to make the agreement;
 - (b) any partner in a partnership that is notified under paragraph (1); and
 - (c) any person legally and beneficially owning a share in, or a director or secretary of, a company that is notified under paragraph (1) where its reasons for that view relate to that person or persons.

Appeal

5. A person who has been served with a notice under regulation 4(1) may appeal to the Scottish Ministers against the decision of the Health Board by giving notice in writing to the Scottish Ministers within the period of 28 days beginning on the day that the Health Board served its notice.

Prescribed period under section 17D(3) of the Act

6. The period prescribed for the purposes of section 17D(3) of the Act (persons with whom agreements may be made)(42) is 6 months.

PRE-AGREEMENT DISPUTE RESOLUTION

Pre-agreement dispute resolution

- 7.—(1) Except where the proposed provider is a health service body (in which case section 17A(5)(43) of the Act applies), if, in the course of negotiations intending to lead to any agreement, the proposed parties to that agreement are unable to agree on a particular term of the agreement, either the Health Board or the proposed provider may refer the terms of the proposed agreement to the Scottish Ministers to consider and determine the matter.
- (2) Disputes as to the terms of any proposed agreement referred to the Scottish Ministers in accordance with paragraph (1) shall be determined in accordance with—
 - (a) the NHS dispute resolution procedure, as if, in Schedule 1–
 - (i) in paragraph 56(3)(b) "agreement" read "terms of the proposed agreement"; and
 - (ii) paragraph 57(2) and (3) were omitted; and
 - (b) paragraph (3) of this regulation.
- (3) In a dispute referred to the Scottish Ministers under paragraph (1), the determination of the adjudicator—
 - (a) may specify terms to be included in the proposed agreement;
 - (b) may require the Health Board to proceed with the proposed agreement, but may not require the proposed provider to proceed with the proposed agreement; and
 - (c) shall be binding on the proposed parties to the agreement.
- (4) In this regulation "health service body" does not include any provider who is to be treated as a health service body in accordance with regulation 8.

PART 4

HEALTH SERVICE BODY STATUS

Health service body status

- **8.**—(1) Where a proposed provider elects in a written notice served on the Health Board at any time prior to the agreement being entered into to be treated as a health service body for the purposes of section 17A of the Act (NHS contracts), the proposed provider shall be so treated from the date on which the agreement is made.
- (2) If, pursuant to paragraph (1) or (5), a provider is to be treated as a health service body, it shall not be treated as a health service body to the extent that—
 - (a) the nature of, or any rights or liabilities arising under, any other arrangement or proposed arrangement with a health service body entered into or to be entered into by a provider is affected; and
 - (b) a matter referred to the Scottish Ministers for the purposes of section 17A(4) of the Act shall be determined under the provisions of section 17A.

^{(43) 1978,} c. 29. Section 17A was inserted by the National Health Service and Community Care Act 1990 (c. 19), section 30 and amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 102(2), the National Health Service (Primary Care) Act 1997 (c. 46), Schedule 2, paragraph 36, the Health Act 1999 (c. 8), Schedule 4, paragraph 46 and S.I. 1991/195.

- (3) Where an agreement is made with a provider, and that provider is to be treated as a health service body in accordance with paragraph (1) or (5), the provider shall, subject to paragraph (4) continue to be treated as a health service body for the purposes of section 17A of the Act, for as long as that agreement continues irrespective of any change in—
 - (a) where a partnership is a party to the agreement, the membership of the partnership; and
 - (b) the parties to the agreement comprising the provider.
- (4) A provider may at any time request in writing to be treated or cease to be treated as a health service body for the purposes of section 17A of the Act, and if the provider does so—
 - (a) the procedure in paragraph 59(1) of Schedule 1 shall have effect; and
 - (b) the Health Board shall agree to the variation.
 - (5) If the provider makes a request under paragraph (4), the provider shall
 - (a) be treated; or
 - (b) subject to paragraph (7) cease to be treated,

as a health service body for the purposes of section 17A of the Act from the date that variation is to take effect pursuant to paragraph 59(1) of Schedule 1.

- (6) Subject to paragraph (7) a provider shall cease to be treated as a health service body for the purposes of section 17A of the Act if the agreement terminates.
 - (7) Where a provider ceases to be treated as a health service body pursuant to—
 - (a) paragraph (5), the provider shall, if the provider or the Health Board has referred any matter to the Scottish Ministers for the purposes of section 17A(4) of the Act before the provider ceases to be a health service body, be bound by the determination of the adjudicator;
 - (b) paragraph (6), the provider shall continue to be treated as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced—
 - (i) before the termination of the agreement; or
 - (ii) after the termination of the agreement, whether in connection with or arising out of the termination of the agreement or otherwise,

for which purpose the provider shall cease to be treated as such a body on the conclusion of that procedure.

PART 5

PROVISION OF PRIMARY MEDICAL SERVICES

Provision of primary medical services

- **9.**—(1) Whether or not the agreement includes arrangements for the provision of services which are not primary medical services, an agreement must include arrangements for the provision of one or more of the following primary medical services:–
 - (a) essential services;
 - (b) additional services;
 - (c) enhanced services;
 - (d) out of hours services, in respect of, subject to regulation 26 and paragraph 3 of Schedule 4, part or all of the out of hours period and some or all services.

Primary medical services and content of agreements

- **10.**—(1) An agreement shall contain terms which have the same effect as those specified in Schedule 1 (content of agreements), unless it is of a type or nature to which a particular provision does not apply, except paragraphs 56(5) to (15), and 57.
- (2) The paragraphs specified in paragraph (1) shall have effect in relation to matters set out in those paragraphs.

Essential services and content of agreements

- 11.—(1) An agreement which includes the provision of essential services shall specify—
 - (a) the area as respects which persons resident in it will, subject to any other terms of the agreement relating to patient registration, be entitled to—
 - (i) register with the provider; or
 - (ii) seek acceptance by the provider as a temporary resident; and
 - (b) whether, at the date on which the agreement comes into force, the provider's list of patients is open or closed.
- (2) Where, in accordance with sub-paragraph (1), the agreement specifies that the provider's list of patients is closed it must also specify in relation to that closure each of the items listed in paragraph 22(8)(a) to (d) of Schedule 2 (agreements to provide essential services).
- (3) An agreement which includes the provision of essential services shall, in addition to any other terms required by these Regulations, unless it is of a type or nature to which a particular provision does not apply contain terms with the same effect as those specified in Schedule 2, except paragraphs 23(6) to (8) and 28(3).
- (4) The paragraphs specified in paragraph (3) shall have effect in relation to matters set out in those paragraphs.
- (5) An agreement which does not include the provision of essential services shall not specify the matters referred to in paragraph (1) nor contain terms with the same effect as those specified in Schedule 2.

Additional services and content of agreements

- **12.** An agreement which includes the provision of additional services must, in addition to any other terms required by these Regulation—
 - (a) in relation to all such services included in the agreement, contain a provision which has the same effect as that specified in paragraph 1 of Schedule 3;
 - (b) in relation to each such service included in the agreement, contain provisions which have the same effect as those specified in Schedule 3, which are relevant to that service.

Out of hours services and content of agreements

13. An agreement which includes the provision of out of hours services by virtue of this regulation or regulation 26 must, in addition to any other terms required by these Regulations, unless it is of a type or nature to which a particular provision does not apply, contain terms with the same effect as those specified in Schedule 4.

CONTENT OF AGREEMENTS

Parties to the agreement

- 14. An agreement must specify-
 - (a) the names of the parties;
 - (b) where a party to the agreement is a partnership-
 - (i) whether or not that partnership is a limited partnership; and
 - (ii) the names of the partners and, in the case of a limited partnership, their status as general or limited partner; and
 - (c) in the case of the Health Board and the provider and each party to the agreement comprising the provider, the address to which official correspondence and notices should be sent.

NHS contracts

15. If the provider is to be treated as a health service body the agreement must state that it is an NHS contract.

Agreements with one or more partnerships

- **16.**—(1) Where a partnership is a party to the agreement, the agreement shall be treated as made with that partnership as it is from time to time constituted, and the agreement shall make specific provision to this effect.
- (2) Where a partnership is a party to the agreement, the provider must be required by the terms of the agreement to ensure that any person who becomes a member of the partnership after the agreement has been made is bound automatically by the agreement, whether by virtue of the partnership deed or otherwise.

Arrangements on termination

17. An agreement shall make suitable provision for arrangements on termination of an agreement, including the consequences (whether financial or otherwise) of the agreement ending.

Services generally

- 18.—(1) An agreement must specify-
 - (a) the services to be provided;
 - (b) subject to paragraph (2), the address of each of the premises to be used by the provider or any sub-contractor for the provision of such services;
 - (c) to whom such services are to be provided;
 - (d) the period (if any) for which the services are to be provided; and
 - (e) where the agreement does not include the provision of essential services, the area (if any) in which the provider agrees to attend on patients outside the practice premises.
- (2) The premises referred to in paragraph (1)(b) do not include—
 - (a) the homes of patients;
 - (b) any other premises where services are provided on an emergency basis.

- (3) Where on the date on which the agreement is to be made, the Health Board is not satisfied that all or any of the premises specified in accordance with sub-paragraph (1)(b) meet the requirements set out in paragraph 1 of Schedule 1, the agreement may not be made unless it includes a plan, drawn up jointly by the Health Board and the provider, which specifies—
 - (a) the steps to be taken by the provider to bring the premises up to the relevant standard;
 - (b) any financial support that may be made available from the Health Board; and
 - (c) the timescale on which the steps referred to in sub-paragraph (a) will be taken.

Certificates

- 19.—(1) An agreement must contain a term which has the effect of requiring the provider to issue free of charge to a patient or a patient's personal representatives any medical certificate of a description prescribed in column 1 of Schedule 3 (list of prescribed medical certificates) to the GMS Contracts Regulations, which is reasonably required under or for the purposes of the enactments specified in relation to the certificate in column 2 of that Schedule, except where, for the condition to which the certificate relates, the patient—
 - (a) is being attended by a medical practitioner who is not-
 - (i) employed or engaged by the provider;
 - (ii) a party to the agreement;
 - (iii) in the case where a partnership is a party to the agreement, a partner in such a partnership; or
 - (iv) in the case where a company limited by shares is a party to the agreement, a person legally or beneficially owning shares in such a company; or
 - (b) is not being treated by or under the supervision of a health care professional.
- (2) The exception in paragraph (1)(a) shall not apply where the certificate is issued pursuant to regulation 2(1)(b) of the Social Security (Medical Evidence) Regulations 1976(44) (which provides for the issue of a certificate in the form of a special statement by a doctor on the basis of a written report made by another doctor).

Finance

- **20.**—(1) Subject to paragraph (2), the agreement must contain a term which has the effect of requiring the Health Board to make payments to the provider under the agreement promptly and in accordance with both the terms of the agreement and, as respects the provision or performance of primary medical services, any other conditions relating to the payment contained in directions by the Scottish Ministers under section 17E(3A) of the Act(45).
- (2) The obligation referred to in paragraph (1) is subject to any right the Health Board may have to set off, against any amount payable to the provider under the agreement, any amount—
 - (a) that is owed by the provider to the Health Board under the agreement; or
 - (b) that the Health Board may withhold from the provider in accordance with the terms of the agreement or any other applicable provisions contained in directions given by the Scottish Ministers under section 17E(3A) of the Act.

⁽⁴⁴⁾ S.I. 1976/615. Relevant amending instruments are S.I. 1982/699, 1992/247, 1994/2975, 1995/987 and 2000/590.

^{(45) 1978} c. 29. Section 17E(3A) was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 2(4)(c).

Finance

21. An agreement must contain a term to the effect that where, pursuant to directions of the Scottish Ministers under sections 2(5)(46) or section 17E(3A) of the Act, a Health Board is required to make a payment to a provider under an agreement but subject to conditions, those conditions shall be a term of the agreement.

Fees and charges

- 22.—(1) An agreement must contain terms relating to fees and charges to the effect that, subject to provisions of paragraph 7 of Schedule 2, the provider shall not, directly or indirectly, demand or accept a fee or other remuneration from any patient of the provider for—
 - (a) the provision of any treatment whether under the agreement or otherwise; or
 - (b) any prescription for any drug, medicine or appliance,
- except in the circumstances set out in sub-paragraphs (a) to (d) and (f) to (l) of Schedule 4 (Fees and Charges) to the GMS Contracts Regulations, subject to the modifications specified in paragraph (2).
- (2) The modifications to referred to in paragraph (1) of sub-paragraphs (a) to (d) and (f) to (l) of Schedule 4 are—
 - (a) for "contractor" read "provider" in each place where it occurs;
 - (b) for "contract" read "agreement" in each place where it occurs; and
 - (c) in sub-paragraph (k) for "paragraph 44 of Schedule 5" read "paragraph 15 of Schedule 1".

PART 7

FUNCTIONS OF AREA MEDICAL COMMITTEE

Functions of area medical committee

- **23.**—(1) The functions of an area medical committee which are prescribed for the purposes of section 9(6) of the Act (local consultative committees) are—
 - (a) the functions which are conferred upon it by these Regulations or by any order made under section 7 of the 2004 Act;
 - (b) the making of arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the provider or the Health Board is concerned that the medical practitioner is incapable of adequately providing services under the agreement and the provider so requests with the agreement of the medical practitioner concerned; and
 - (c) the consideration of the report of any medical examination arranged in accordance with sub-paragraph (b) and the making of a written report as to the capability of the medical practitioner of adequately providing services under the agreement to the medical practitioner concerned, the provider and the Health Board with whom the provider has made the agreement.
 - (2) The medical practitioner referred to in paragraph (1)(b) is a medical practitioner who is—
 - (a) a party to the agreement;
 - (b) a partner in a partnership that is a party to the agreement;
 - (c) a legal and beneficial shareholder in a company that is a party to the agreement.

RIGHT TO A GENERAL MEDICAL SERVICES CONTRACT

Right to a general medical services contract

- **24.**—(1) A provider which is providing essential services under an agreement and which wishes a general medical services contract to be entered into pursuant to this regulation shall notify the Health Board in writing at least three months before the date on which it wishes the general medical services contract to be entered into.
 - (2) A notice under paragraph (1) shall-
 - (a) state that the provider wishes to terminate the agreement and the date on which the provider wishes the agreement to terminate, which must be at least three months after the date of service of the notice;
 - (b) subject to paragraph (3), give the name of the person with whom the provider wishes the Health Board to enter into a general medical services contract; and
 - (c) confirm that the person so named meet the conditions set out in section 17L of the Act (eligibility to be contractor under general medical services contract)(47) and regulations 4 (conditions relating solely to medical practitioners) and 5 (general conditions relating to all contracts) of the GMS Contracts Regulations or, where the provider is not able so to confirm, the reason why it is not able to do so and confirmation that the person immediately prior to entering into the general medical services contract will meet those conditions.
- (3) A person's name may only be given in a notice referred to in paragraph (1) if that person is a party to the agreement.
- (4) The Health Board shall acknowledge receipt of the notice served under paragraph (1) within the period of 7 days beginning on the day that it received the notice.
- (5) Provided that the conditions set out in section 17L of the Act and regulations 4 and 5 of the GMS Contracts Regulations are met, the Health Board shall enter into a general medical services contract with the person named in the notice served under paragraph (1).
- (6) In addition to the terms required by the Act and the GMS Contracts Regulations, a general medical services contract entered into pursuant to this regulation shall provide for—
 - (a) the general medical services contract to commence immediately after the termination of the agreement;
 - (b) the names of the patients included in the provider's list of patients immediately before the termination of the agreement to be included in the first list of patients to be prepared and maintained by the Health Board pursuant to paragraph 14 of Schedule 5 to the GMS Contracts Regulations; and
 - (c) the same services to be provided under the general medical services contract as were provided under the agreement immediately before it was terminated unless the parties otherwise agree.
- (7) An agreement shall terminate on the date stated in the notice given by the provider under paragraph (1) unless a different date is agreed by the provider and the Health Board or no general medical services contract is entered into by the Health Board pursuant to this regulation.
- (8) Where the Health Board is of the view that the conditions in section 17L of the Act or regulation 4 or 5 of the GMS Contracts Regulations are not met it shall notify in writing the provider of its view and its reasons for that view and of the provider's right of appeal under sub-paragraph (9).

- (9) The provider may appeal to the Scottish Ministers against the decision of the Health Board by giving notice in writing to the Scottish Ministers within the period of 28 days beginning on the day that the Health Board served its notice.
- (10) Any other dispute relating to this regulation may be referred by the prospective party to the general medical services contract or the Health Board to the Scottish Ministers to consider and determine the matter in accordance with regulation 9(2) and (3) of the GMS Contracts Regulations.

TRANSITIONAL PROVISIONS

Commencement

25. An agreement shall provide for services to be provided under it from any date on or after 1st April 2004.

Out of hours services

- **26.** Subject to paragraph 1 of Schedule 4, where a party to the agreement to provide essential services is a person who, on 31st March 2004, was providing personal medical services under section 17C of the Act, the agreement under which services are to be provided before 1st January 2005 (whether or not such services will be provided after that date) must provide for services which would be essential services, if provided in core hours, to be provided throughout the out of hours period unless—
 - (a) the Health Board has accepted in writing, prior to the signing of the agreement, a written request from the provider that the agreement should not require the provider to make such provision; or
 - (b) the agreement has been otherwise varied to exclude a requirement to make such provision.

Revocation

27. Subject to the provisions of any order made by the Scottish Ministers section 7 of the 2004 Act (ancillary provisions), the National Health Service (Personal Medical Services) (Scotland) Regulations 2001(**48**) are hereby revoked.

St Andrew's House, Edinburgh 10th March 2004

MALCOLM CHISHOLM
A member of the Scottish Executive