

SI 2004 No 291

NATIONAL HEALTH SERVICE, ENGLAND

National Health Service (General Medical Services Contracts) Regulations 2004

UPDATED TO 1 APRIL 2010

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 28D(1)(bc), 28R, 28S, 28V, 28W, 45A(9) and 126(4) of the National Health Service Act 1977, section 4(5) of the National Health Service and Community Care Act 1990 and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Text in black is the original text – in force on 1 March 2004

Text in light pink inserted/substituted by SI 2004/433 – in force on 17 March 2004

Text in dark brown inserted/substituted by SI 2004/906 – in force on 1 April 2004

Text in red inserted/substituted by SI 2004/2694 – in force on 15 November 2004

Text in dark pink inserted/substituted by SI 2005/893 – in force on 14 April 2005

Text in light green inserted/substituted by SI 2005/3315 – in force on 6 January 2006

Text in dark grey inserted/substituted by SI 2005/3491 – in force on 1 April 2006

Text in dark blue inserted/substituted by SI 2006/1501 – in force on 24 July 2006

Text in light brown inserted/substituted by SI 2007/289 – in force on 30 March 2007

Text in light blue inserted/substituted by SI 2007/3491 – in force on 28 January 2008

Text in orange inserted/substituted by SI 2008/528 – in force on 1 April 2008

Text in dark purple inserted/substituted by SI 2008/1514 – in force on 14 July 2008

Text in lavender inserted/substituted by SI 2008/1700 – in force on 1 August 2008

Text in light grey inserted/substituted by SI 2009/309 – in force on 1 April 2009

Text in mauve inserted/substituted by SI 2009/2230 – in force on 21 August 2009

Text in dark green inserted/substituted by SI 2009/2205 – in force on 17 September 2009

Text in indigo inserted/substituted by SI 2010/578 – in force on 1 April 2010

Part 1

General

Citation, commencement and application

1 - (1) These Regulations may be cited as the National Health Service (General Medical Services Contracts) Regulations 2004 and shall come into force on 1st March 2004.

(2) These Regulations apply in relation to England only.

Interpretation

2 - (1) In these Regulations-

"the Act" means the National Health Service Act 1977;

"the 1990 Act" means the National Health Service and Community Care Act 1990;

"The 2010 Order" means the Postgraduate Education and Training Order of Council 2010;

"Abolition of the Tribunal Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001;

"Abolition of the Tribunal (Wales) Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002;

"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;

"adjudicator" means the Secretary of State or a person or persons appointed by the Secretary of State under section 4(5) of the 1990 Act or paragraph 101(5) of Schedule 6;

["advanced electronic signature" means an electronic signature which is-

- (a) uniquely linked to the signatory,
- (b) capable of identifying the signatory,
- (c) created using means that the signatory can maintain under his sole control, and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;]

"appliance" means an appliance which is included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

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

"assessment panel" means a committee or sub-committee of a Primary Care Trust (other than the Primary Care Trust which is a party to the contract in question) appointed to exercise functions under paragraphs 31 and 35 of Schedule 6;

"bank holiday" means any day that is specified or proclaimed as a bank holiday [in England and Wales] pursuant to section 1 of the Banking and Financial Dealings Act 1971;

"batch issue" means a form provided by a Primary Care Trust and issued by a [repeatable] prescriber at the same time as a [non-electronic repeatable prescription] to enable a chemist to receive payment for the provision of repeat dispensing services which is in the format [set out in respect of form FP10SS batch issue in the document issued by the [Prescription Pricing Division of the NHS Business Services Authority] entitled "Prescription Form Overprint Specifications-GP System Prescription Overprint Specification", [version 2 dated August 2006]], and which-

- (a) is generated by a computer and not signed by a [repeatable] prescriber,
- (b) relates to a particular [non-electronic repeatable prescription] and contains the same dates as that prescription,
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs, medicines or appliances ordered on the [non-electronic repeatable prescription] may be provided, and
- (d) specifies a number denoting its place in the sequence referred to in paragraph (c);

"CCT" means Certificate of Completion of Training awarded under article 8 of the 2003 Order. [NB: Additional words deleted by SI 2007/3491];

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

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

"chemist" means-

- (a) a registered pharmacist,
- (b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968, or
- (c) a supplier of appliances,

who is included in the list of a Primary Care Trust or a Local Health Board under section 42 of the Act, or who provides local pharmaceutical services in accordance with LPS arrangements;

"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 2;

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

"closed", in relation to the contractor'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 2;

"contract" means, except where the context otherwise requires, a general medical services contract under section 28Q of the Act;

"contractor's list of patients" means the list prepared and maintained by the Primary Care Trust under paragraph 14 of Schedule 6;

"core hours" means the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday except Good Friday, Christmas Day or bank holidays;

["dispenser" means a chemist, medical practitioner or contractor whom a patient wishes to dispense his electronic prescriptions;]

"dispensing services" means the provision of drugs, medicines or appliances that may be provided as pharmaceutical services by a medical practitioner in accordance with arrangements made under [regulation 60] of the Pharmaceutical Regulations;

"Drug Tariff" has the same meaning as in [regulation 56] of the Pharmaceutical Regulations;

["electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000;

"electronic prescription" means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" means a prescription form which falls within paragraph (b) of the definition of "prescription form";

"electronic repeatable prescription" means a prescription which falls within paragraph (a)(ii) of the definition of "repeatable prescription";]

"enhanced services" are-

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

"essential services" means the services required to be provided in accordance with regulation 15;

["ETP service" means the electronic prescription service which forms part of the NHS Care Record Service;]

... [NB: Definition of FHSAA deleted by SI 2010/578];

"general medical practitioner" means[, unless the context otherwise requires]-

- (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 [NB: Words deleted by SI 2004/2694]. . ., 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 31(2) of the Act, section 21 of the National Health Service (Scotland) Act 1978 or Article 8(2) of the Health and Personal Social Services (Northern Ireland) Order 1978, [or a person who has an acquired right to practise as a general medical practitioner pursuant to regulation 5(1)(d) of the Vocational Training for General Medical Practice (European Requirements) Regulations 1994] or
 - (ii) upon the coming into force of paragraph 22 of Schedule 8 to the 2003 Order, an eligible general practitioner pursuant to that paragraph ... [NB: Words deleted by SI 2004/2694] ;

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

"global sum" has the same meaning as in the GMS Statement of Financial Entitlements;

"GMS Statement of Financial Entitlements" means the directions given by the Secretary of State under section 28T of the Act;

["GP Registrar" means a medical practitioner who is being trained in general practice by-

- (a) until the coming into force for all purposes of article 4(5)(d) of the 2003 Order, a general 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) Regulations 1997, and
 - (ii) performs primary medical services; and
- (b) from the coming into force for all purposes of that article, a general medical practitioner who is approved under that article for the purpose of providing training under article 5(1)(c)(i) of the 2003 Order, whether as part of training leading to the award of a CCT or otherwise;]

....[NB: Definition of GP trainer deleted by SI 2004/2694]

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

"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;

"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978;

"health care professional" has the same meaning as in section 28M of the Act and "health care profession" shall be construed accordingly;

"health service body" has, unless the context otherwise requires, the meaning given to it in section 4(2) of the 1990 Act;

["home oxygen order form" means a form provided by the Primary Care Trust and issued by a health care professional to authorise a person to supply home oxygen services to a patient requiring oxygen therapy at home;

"home oxygen services" means any of the following forms of oxygen therapy or supply-

- (a) ambulatory oxygen supply,
- (b) urgent supply,
- (c) hospital discharge supply,
- (d) long term oxygen therapy, and
- (e) short burst oxygen therapy;]

"immediate family member" means-

- (a) a spouse [or civil partner],
- (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 Act 1989, or
- (g) a grandparent;

"independent nurse prescriber" means a person-

- (a) who is either engaged or employed by the contractor or is party to the contract,
- (b) who is registered in the Nursing and Midwifery Register, and
- [(c) against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or as a nurse independent/supplementary prescriber;]

"licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968;

"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;

["listed medicine" means a medicine mentioned in regulation 7C(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2000;

"listed medicines voucher" means a form provided by a Primary Care Trust for use for the purpose of ordering a listed medicine;]

"Local Medical Committee" means a committee recognised under section 45A of the Act;

"local pharmaceutical services" has the same meaning as in regulation 2 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002;

"maternity medical services" means the services described in paragraph 7(1) of Schedule 2;

"medical card" means a card issued by a Primary Care Trust, Local Health Board, Health Authority, Health Board or Health and Social Services Board to a person for the purpose of enabling him to obtain, or establishing his title to receive, primary medical services;

... [NB: Definition of medical officer deleted by SI 2010/578];

"medical performers list" means a list of medical practitioners prepared in accordance with regulations made under section 28X of the Act;

"Medical Register" means the registers kept under section 2 of the Medical Act 1983;

"minor surgery" means the services described in paragraph 8(2) of Schedule 2;

... [NB: Definition of NCAA deleted by SI 2005/893]

"national disqualification" means-

(a) a decision made by the FHSAA under section 49N of the Act [or under regulations corresponding to that section made under section 28X(4) of the Act (persons performing primary medical and dental services)],

(b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act, or

(c) a decision by the NHS Tribunal which was treated as a national disqualification by the FHSAA by virtue of regulation 6(4)(b) of the Abolition of the Tribunal Regulations or regulation 6(4)(b) of the Abolition of the Tribunal (Wales) Regulations;

["NHS Care Record" means the records relating to an individual patient held by the NHS Care Record Service;

"NHS Care Record Service" means the information technology systems procured by the Department of Health and used by the health service to hold medical records relating to patients;]

"NHS contract" has the meaning assigned to it in section 4 of the 1990 Act;

"the NHS dispute resolution procedure" means the procedure for resolution of disputes specified-

(a) in paragraphs 101 and 102 of Schedule 6; or

(b) in a case to which paragraph 36 of Schedule 6 applies, in that paragraph;

"the NHS Tribunal" means the Tribunal constituted under section 46 of the Act for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001 and in relation to Wales only until 26th August 2002;

["nominated dispenser" means a chemist, medical practitioner or contractor whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

"non-electronic prescription form" means a prescription form which falls within paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" means a prescription which falls within paragraph (a)(i) of the definition of "repeatable prescription";]

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

["NPSA" means the National Patient Safety Agency established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001;]

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

"open", in relation to a contractor's list of patients, means open to applications from patients in accordance with paragraph 15 of Schedule 6;

["optometrist independent prescriber" means a person-

- (a) who is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989; and
- (b) against whose name is recorded in that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;]

"out of hours period" means-

- (a) the period beginning at 6.30pm on any day from Monday to Thursday and ending at 8am on the following day,
- (b) the period between 6.30pm on Friday and 8am on the following Monday, and
- (c) Good Friday, Christmas Day and bank holidays,

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

"out of hours services" means services required to be provided in all or part of the out of hours period which-

- (a) would be essential services if provided [by a contractor to its registered patients] in core hours, or
- (b) are included in the contract as additional services funded under the global sum;

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

"patient" means-

- (a) a registered patient,
- (b) a temporary resident,
- (c) persons to whom the contractor is required to provide immediately necessary treatment under regulation 15(6) or (8) respectively,
- (d) any other person to whom the contractor has agreed to provide services under the contract,
- (e) any person for whom the contractor is responsible under regulation 31, and
- (f) any person for whom the contractor is responsible under arrangements made with another contractor in accordance with Schedule 7;

. . . [NB: Definition of PCT Patients' Forum deleted by SI 2008/528]

"Pharmaceutical Regulations" means the [National Health Service (Pharmaceutical Services) Regulations 2005];

["pharmacist independent prescriber" means a person-

- (a) who is either engaged or employed by the contractor or is party to the contract,
- (b) who is registered in [Part 1 of the register maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007] or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, and
- (c) against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;]

"pilot scheme" means an agreement made under Part 1 of the National Health Service (Primary Care) Act 1997;"the POM Order" means the Prescription Only Medicines (Human Use) Order 1997;"practice" means the business operated by the contractor for the purpose of delivering services under the contract;

"practice area" means the area referred to in regulation 18(1)(d);

"practice leaflet" means a leaflet drawn up in accordance with paragraph 76 of Schedule 6;

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

"prescriber" means-

- (a) a medical practitioner,
- [(aa) a pharmacist independent prescriber,]
- [(ab) an optometrist independent prescriber;]
- (b) an independent nurse prescriber, and
- (c) a supplementary prescriber,

who is either engaged or employed by the contractor or is a party to the contract;

["prescription form" means-

- (a) a form provided by the Primary Care Trust and issued by a prescriber, or
- (b) where paragraph 39A(1) of Schedule 6 applies, data that are created in an electronic form, signed with a prescriber's advanced electronic signature and transmitted as an electronic communication to the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services and does not include a repeatable prescription;]

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

"primary care list" means-

- (a) a list of persons performing [primary medical services, primary dental services or primary ophthalmic services] prepared in accordance with regulations made under section 28X of the Act,
- (b) a list of persons undertaking to provide general medical services, general dental services, general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under sections 29, 36, 39, 42 or 43 of the Act,
- (c) a list of persons approved for the purposes of assisting in the provision of any services mentioned in paragraph (b) prepared in accordance with regulations made under section 43D of the Act,
- (d) a services list referred to in section 8ZA of the National Health Service (Primary Care) Act 1997,
- (e) a list corresponding to a services list prepared by virtue of regulations made under section 41 of the Health and Social Care Act 2001, or
- (f) a list corresponding to any of the above lists in Scotland or Northern Ireland;

"Primary Care Trust" means, unless the context otherwise requires, the Primary Care Trust which is a party, or prospective party, to the contract;

"primary carer" means, in relation to an adult, the adult or organisation primarily caring for him;

"registered patient" means-

- (a) a person who is recorded by the Primary Care Trust as being on the contractor's list of patients, or
- (b) a person whom the contractor has accepted for inclusion on its list of patients, whether or not notification of that acceptance has been received by the Primary Care Trust and who has not been notified by the Primary Care Trust 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, [Part 1 of the register maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007] or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

"relevant Strategic Health Authority" means the Strategic Health Authority established for an area which includes the area for which the Primary Care Trust is established;

"repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs, medicines or appliances by a chemist in accordance with a repeatable prescription;

["repeatable prescriber" means a prescriber who is-

- (a) engaged or employed by a contractor which provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 of Schedule 6, or
- (b) a party to a contract under which such services are provided;]

"repeatable prescribing services" means services which involve the prescribing of drugs, medicines or appliances on a repeatable prescription;

["repeatable prescription" means a prescription which-

- (a) either-
 - (i) is contained in a form provided by the Primary Care Trust and issued by a repeatable prescriber which is in the format [set out in respect of form FP10SS repeatable prescription (authorising form) in the document issued by the [Prescription Pricing Division of the NHS Business Services Authority] entitled "Prescription Form Overprint Specifications-GP System Prescription Overprint Specification", [version 2 dated August 2006]] and which is generated by a computer and signed in ink by a repeatable prescriber; or
 - (ii) where paragraph 39A(1) of Schedule 6 applies, consists of data that are created in an electronic form, signed with a repeatable prescriber's advanced electronic signature and transmitted as an electronic communication to the ETP service,
- (b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services, and
- (c) indicates that the drugs, medicines or appliances ordered on that prescription may be provided more than once and specifies the number of occasions on which they may be provided;]

"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 Secretary of State under section 28U of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract, or

(b) except where the conditions in paragraph 42(2) of Schedule 6 are satisfied, a drug, medicine or other substance which is specified in any directions given by the Secretary of State under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes;

"section 28C provider" means a person who is providing services under a pilot scheme or in accordance with section 28C arrangements;

"supplementary prescriber" means a person-

(a) who is either engaged or employed by the contractor or is a party to the contract,

(b) whose name is registered in-

(i) the Nursing and Midwifery Register,

[(ii) Part 1 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007,]

(iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, . . . [NB: Text deleted by SI 2005/3315]

[(iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to-

(aa) chiropodists and podiatrists;

(bb) physiotherapists; or

(cc) radiographers: diagnostic or therapeutic.] [or]

[(v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989, and]

(c) against whose name is recorded in the relevant register an annotation [or entry] signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber [or, in the case of the Nursing and Midwifery Register, a nurse independent/supplementary prescriber];

"temporary resident" means a person accepted by the contractor as a temporary resident under paragraph 16 of Schedule 6 and for whom the contractor's responsibility has not been terminated in accordance with that paragraph;

"walk-in centre" means a centre at which information and treatment for minor conditions is provided to the public under arrangements made by or on behalf of the Secretary of State;

"working day" means any day apart from Saturday, Sunday, Christmas Day, Good Friday or a bank holiday;

"writing", except in paragraph 104(1) of Schedule 6 and unless the context otherwise requires, includes electronic mail and "written" shall be construed accordingly.

(2) In these Regulations, the use of the term "it" in relation to the contractor shall be deemed to include a reference to a contractor that is an individual medical practitioner or two or more individuals practising in partnership and related expressions shall be construed accordingly.

Part 2

Contractors

Conditions: general

3 - Subject to the provisions of any order made by the Secretary of State under section 176 of the Health and Social Care (Community Health and Standards) Act 2003 (general medical services: transitional), a Primary Care Trust may only enter into a contract if the conditions set out in regulations 4 and 5 are met.

Conditions relating solely to medical practitioners

4 - (1) In the case of a contract to be entered into with a medical practitioner, that practitioner must be a general medical practitioner.

(2) In the case of a contract to be entered into with two or more individuals practising in partnership-

(a) at least one partner (who must not be a limited partner) must be a general medical practitioner; and

(b) any other partner who is a medical practitioner must-

(i) be a general medical practitioner, or

(ii) be employed by a Primary Care Trust, a Local Health Board, (in England and Wales and Scotland) an NHS Trust, an NHS foundation trust, (in Scotland) a Health Board or (in Northern Ireland) a Health and Social Services Trust.

(3) In the case of a contract to be entered into with a company limited by shares-

(a) at least one share in the company must be legally and beneficially owned by a general medical practitioner; and

(b) any other share or shares in the company that are legally and beneficially owned by a medical practitioner must be so owned by-

(i) a general medical practitioner, or

(ii) a medical practitioner who is employed by a Primary Care Trust, a Local Health Board, (in England and Wales and Scotland) an NHS Trust, an NHS foundation trust, (in Scotland) a Health Board or (in Northern Ireland) a Health and Social Services Trust.

[(4) In paragraphs (1), (2)(a) and (3)(a), "general medical practitioner" does not include a medical practitioner whose name is included in the General Practitioner Register by virtue of -

(a) article 4(3) of the 2010 Order (general practitioners eligible for entry in the General Practitioner Register) because of an exemption from regulation 5(1)(d) of one or more of the sets of Regulations specified in paragraph (5);

(b) article 6(2) of the 2010 Order (persons with acquired rights) by virtue of being a restricted services principal (within the meaning of one or more of the sets of Regulations specified in paragraph (6)) included in a list specified in that article; or

(c) article 6(6) or the 2010 Order.

(5) The regulations referred to in paragraph 4(a) are the National Health Service (Vocational Training for General Medical Practice) Regulations 1997, the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998 and the Medical Practitioners (Vocational Training) Regulations (Northern Ireland) 1998.

(6) The Regulations referred to in paragraph (4)(b) are the National Health Service (General Medical Services) Regulations 1992, the National Health Service (General Medical Services) (Scotland) Regulations 1995 and the General Medical Services Regulations (Northern Ireland) 1997.]

General condition relating to all contracts

5 - (1) It is a condition in the case of a contract to be entered into-

- (a) with a medical practitioner, that the medical practitioner;
- (b) with two or more individuals practising in partnership, that any individual or the partnership; and
- (c) with a company limited by shares, that-
 - (i) the company,
 - (ii) any person legally and beneficially owning a share in the company, and
 - (iii) any director or secretary of the company,

must not fall within paragraph (2).

(2) A person falls within this paragraph if-

- (a) he or it is the subject of a national disqualification;
- (b) subject to paragraph (3), he or it is disqualified or suspended (other 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 five years prior to the signing of the contract or commencement of the contract, whichever is the earlier, he has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body, unless he has subsequently been employed by that health service body or another health service body and paragraph (4) applies to him or that dismissal was the subject of a finding of unfair dismissal by any competent tribunal or court;
- (d) within the period of five years prior to signing the contract or commencement of the contract, whichever is the earlier, he or it has been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act respectively) unless his name has subsequently been included in such a list;
- (e) he has been convicted in the United Kingdom of murder;
- (f) he has been convicted in the United Kingdom of a criminal offence other than murder, committed on or after 14th December 2001, and has been sentenced to a term of imprisonment of over six months;
- (g) subject to paragraph (5) he has been convicted elsewhere of an offence-
 - (i) which would, if committed in England and Wales, constitute murder, or
 - (ii) committed on or after 14th December 2001, which would if committed in England and Wales, constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
- (h) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933 (offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1995 (offences against children under the age of 17 years to which special provisions apply) committed on or after 1st March 2004;
- (i) he or it has-
 - (i) been adjudged bankrupt or had sequestration of his estate awarded unless (in either case) he 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 [\[or Schedule 2A to the Insolvency \(Northern Ireland\) Order 1989\]](#) 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, his or its creditors unless he or it has been discharged in respect of it;
- (j) an administrator, administrative receiver or receiver is appointed in respect of it;

(k) [within the period of five years prior to signing the contract or commencement of the contract, whichever is the earlier,] he has been-

(i) 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 he was responsible or to which he was privy, or which he by his conduct contributed to or facilitated, or

(ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990 (powers of the Court of Session to deal with management of charities) or under section 34 of the Charities and Trustee Investment (Scotland) Act 2005 (powers of Court of Session), from being concerned in the management or control of any body; or

(l) he is subject to a disqualification order under the Company Directors Disqualification Act 1986, the Companies (Northern Ireland) Order 1986 or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order).

(3) A person shall not fall within paragraph (2)(b) where the Primary Care Trust 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 contractor;

(b) a partner, in the case of a contract with two or more individuals practising in partnership;

(c) in the case of a contract with a company limited by shares-

(i) a person legally and beneficially holding a share in the company, or

(ii) a director or secretary of the 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 Primary Care Trust is satisfied that the conviction does not make the person unsuitable to be-

(a) a contractor;

(b) a partner, in the case of a contract with two or more individuals practising in partnership;

(c) in the case of a contract with a company limited by shares-

(i) a person legally and beneficially holding a share in the company, or

(ii) a director or secretary of the company,

as the case may be.

Reasons

6 - (1) Where a Primary Care Trust is of the view that the conditions in regulation 4 or 5 for entering into a contract are not met it shall notify in writing the person or persons intending to enter into the contract of its view and its reasons for that view and of his, its or their right of appeal under regulation 7.

(2) The Primary Care Trust shall also notify in writing of its view and its reasons for that view, 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 reason for the decision relates to that person or those persons.

Appeal

7 - A person who has been served with a notice under regulation 6(1) may appeal to the FHSAA against the decision of the Primary Care Trust that the conditions in regulation 4 or 5 are not met by giving notice in writing to the FHSAA within the period of 28 days beginning on the day that the Primary Care Trust served its notice.

Prescribed period under section 28D(1)(bc) of the Act

8 - The period prescribed for the purposes of section 28D(1)(bc) of the Act (persons with whom agreements may be made) is six months.

Part 3

Pre-contract Dispute Resolution

Pre-contract disputes

9 - (1) Except where both parties to the prospective contract are health service bodies (in which case section 4(4) of the 1990 Act (NHS contracts) applies), if, in the course of negotiations intending to lead to a contract, the prospective parties to that contract are unable to agree on a particular term of the contract, either party may refer the dispute to the Secretary of State to consider and determine the matter.

(2) Disputes referred to the Secretary of State in accordance with paragraph (1), or section 4(4) of the 1990 Act, shall be considered and determined in accordance with the provisions of paragraphs 101(3) to 102(1) of Schedule 6, and paragraph (3) (where it applies) of this regulation.

(3) In the case of a dispute referred to the Secretary of State under paragraph (1), the determination-

- (a) may specify terms to be included in the proposed contract;
- (b) may require the Primary Care Trust to proceed with the proposed contract, but may not require the proposed contractor to proceed with the proposed contract; and
- (c) shall be binding upon the prospective parties to the contract.

Part 4

Health Service Body Status

Health service body status

10 - (1) Where a proposed contractor elects in a written notice served on the Primary Care Trust at any time prior to the contract being entered into to be regarded as a health service body for the purposes of section 4 of the 1990 Act, it shall be so regarded from the date on which the contract is entered into.

(2) If, pursuant to paragraph (1) or (5), a contractor is to be regarded as a health service body, that fact shall not affect the nature of, or any rights or liabilities arising under, any other contract with a health service body entered into by a contractor before the date on which the contractor is to be so regarded.

(3) Where a contract is made with an individual medical practitioner or two or more persons practising in partnership, and that individual, or that partnership is to be regarded as a health service body in accordance with paragraph (1) or (5), the contractor shall, subject to paragraph (4), continue to be regarded as a health service body for the purposes of section 4 of the 1990 Act for as long as that contract continues irrespective of any change in-

- (a) the partners comprising the partnership;

- (b) the status of the contractor from that of an individual medical practitioner to that of a partnership;
or
 - (c) the status of the contractor from that of a partnership to that of an individual medical practitioner.
- (4) A contractor may at any time request in writing a variation of the contract to include provision in or remove provision from the contract that the contract is an NHS contract, and if it does so-
- (a) the Primary Care Trust shall agree to the variation; and
 - (b) the procedure in paragraph 104(1) of Schedule 6 shall apply.
- (5) If, pursuant to paragraph (4), the Primary Care Trust agrees to the variation to the contract, the contractor shall-
- (a) be regarded; or
 - (b) subject to paragraph (7), cease to be regarded,

as a health service body for the purposes of section 4 of the 1990 Act from the date that variation is to take effect pursuant to paragraph 104(1) of Schedule 6.

- (6) Subject to paragraph (7), a contractor shall cease to be a health service body for the purposes of section 4 of the 1990 Act if the contract terminates.
- (7) Where a contractor ceases to be a health service body pursuant to-
- (a) paragraph (5) or (6), it shall continue to be regarded as a health service body for the purposes of being a party to any other NHS contract entered into after it became a health service body but before the date on which the contractor ceased to be a health service body (for which purpose it ceases to be such a body on the termination of that NHS contract);
 - (b) paragraph (5), it shall, if it or the Primary Care Trust has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, be bound by the determination of the adjudicator as if the dispute had been referred pursuant to paragraph 100 of Schedule 6;
 - (c) paragraph (6), it shall continue to be regarded 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 contract, or
 - (ii) after the termination of the contract, whether in connection with or arising out of the termination of the contract or otherwise,
- for which purposes it ceases to be such a body on the conclusion of that procedure.

Part 5

Contracts: Required Terms

Parties to the contract

11 - A contract must specify-

- (a) the names of the parties;
- (b) in the case of a partnership-
 - (i) whether or not it is a limited partnership, and
 - (ii) the names of the partners and, in the case of a limited partnership, their status as a general or limited partner; and

- (c) in the case of each party, the address to which official correspondence and notices should be sent.

Health service contract

12 - If the contractor is to be regarded as a health service body pursuant to regulation 10, the contract must state that it is an NHS contract.

Contracts with individuals practising in partnership

13 - (1) Where the contract is with two or more individuals practising in partnership, the contract shall be treated as made with the partnership as it is from time to time constituted, and the contract shall make specific provision to this effect.

(2) Where the contract is with two or more individuals practising in partnership, the contractor must be required by the terms of the contract to ensure that any person who becomes a member of the partnership after the contract has come into force is bound automatically by the contract whether by virtue of a partnership deed or otherwise.

Duration

14 - (1) Except in the circumstances specified in paragraph (2), a contract must provide for it to subsist until it is terminated in accordance with the terms of the contract or the general law.

(2) The circumstances referred to in paragraph (1) are that the Primary Care Trust wishes to enter into a temporary contract for a period not exceeding twelve months for the provision of services to the former patients of a contractor, following the termination of that contractor's contract.

(3) Either party to a prospective contract to which paragraph (2) applies may, if it wishes to do so, invite the Local Medical Committee for the area of the Primary Care Trust to participate in the negotiations intending to lead to such a contract.

Essential services

15 - (1) For the purposes of section 28R(1) of the Act (requirement to provide certain primary medical services), the services which must be provided under a general medical services contract ("essential services") are the services described in paragraphs (3), (5), (6) and (8).

(2) Subject to regulation 20, a contractor must provide the services described in paragraphs (3) and (5) throughout the core hours.

(3) The services described in this paragraph are services required for the management of its registered patients and temporary residents who are, or believe themselves to be-

- (a) ill, with conditions from which recovery is generally expected;
- (b) terminally ill; or
- (c) suffering from chronic disease,

delivered in the manner determined by the practice in discussion with the patient.

(4) For the purposes of paragraph (3)-

"disease" means a disease included in the list of three-character categories contained in the tenth revision of the International Statistical Classification of Diseases and Related Health Problems; and

"management" includes-

- (a) offering consultation and, where appropriate, physical examination for the purpose of identifying the need, if any, for treatment or further investigation; and

- (b) the making available of such treatment or further investigation as is necessary and appropriate, including the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care.
- (5) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all registered patients and temporary residents taking account of their specific needs including-
- (a) the provision of advice in connection with the patient's health, including relevant health promotion advice; and
 - (b) the referral of the patient for other services under the Act.
- (6) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person to whom the contractor has been requested to provide treatment owing to an accident or emergency at any place in its practice area.
- (7) In paragraph (6), "emergency" includes any medical emergency whether or not related to services provided under the contract.
- (8) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person falling within paragraph (9) who requests such treatment, for the period specified in paragraph (10).
- (9) A person falls within paragraph (8) if he is a person-
- (a) whose application for inclusion in the contractor's list of patients has been refused in accordance with paragraph 17 of Schedule 6 and who is not registered with another provider of essential services (or their equivalent) in the area of the Primary Care Trust;
 - (b) whose application for acceptance as a temporary resident has been rejected under paragraph 17 of Schedule 6; or
 - (c) who is present in the contractor's practice area for less than 24 hours.
- (10) The period referred to in paragraph (8) is-
- (a) in the case of paragraph (9)(a), 14 days beginning with the date on which that person's application was refused or until that person has been subsequently registered elsewhere for the provision of essential services (or their equivalent), whichever occurs first;
 - (b) in the case of paragraph (9)(b), 14 days beginning with the date on which that person's application was rejected or until that person has been subsequently accepted elsewhere as a temporary resident, whichever occurs first; and
 - (c) in the case of paragraph (9)(c), 24 hours or such shorter period as the person is present in the contractor's practice area.

Additional services

16 - A contract which includes the provision of any additional services must-

- (a) in relation to all such services as are included in the contract, contain a term which has the same effect as that specified in paragraph 1 of Schedule 2; and
- (b) in relation to each such service as is included in the contract, contain terms which have the same effect as those specified in Schedule 2 which are relevant to that service.

Opt outs of additional and out of hours services

17 - (1) Where a contract provides for the contractor to provide an additional service that is to be funded through the global sum the contract must contain terms relating to the procedure for opting out of additional services which have the same effect as those specified in paragraphs 1, 2, 3 and 6 of Schedule 3, except paragraph 3(12) to (14).

(2) Where a contract which is entered into before 1st October 2004 provides for the contractor to provide out of hours services pursuant to regulation 30 or 31, the contract must contain terms relating to the procedure for opting out of those services which have the same effect as those specified in paragraphs 4, 5 and 6 of Schedule 3, except paragraphs 4(9) and 5(17) in so far as those paragraphs relate to paragraph 3(12) to (14).

(3) Where a contract which is entered into on or after 1st October 2004 provides for the contractor to provide out of hours services pursuant to regulation 30 or 31, the contract must contain terms relating to the procedure for opting out of those services which have the same effect as those specified in paragraphs 4 and 6 of Schedule 3, except paragraph 4(8) in so far as that paragraph relates to paragraph 3(12) to (14).

(4) Paragraph 3(12) to (14) and paragraphs 4(9) and 5(17), in so far as those paragraphs relate to paragraph 3(12) to (14) of Schedule 3, shall have effect in relation to the matters set out in those paragraphs.

Services generally

18 - (1) A contract 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 contractor or any sub-contractor for the provision of such services;
- (c) to whom such services are to be provided;
- (d) the area as respects which persons resident in it will, subject to any other terms of the contract relating to patient registration, be entitled to-
 - (i) register with the contractor, or
 - (ii) seek acceptance by the contractor as a temporary resident; and
- (e) whether, at the date on which the contract comes into force, the contractor's list of patients is open or closed.

(2) The premises referred to in paragraph (1)(b) do not include-

- (a) the homes of patients; or
- (b) any other premises where services are provided on an emergency basis.

(3) Where, on the date on which the contract is signed, the Primary Care Trust is not satisfied that all or any of the premises specified in accordance with paragraph (1)(b) meet the requirements set out in paragraph 1 of Schedule 6, the contract must include a plan, drawn up jointly by the Primary Care Trust and the contractor, which specifies-

- (a) the steps to be taken by the contractor to bring the premises up to the relevant standard;
- (b) any financial support that may be available from the Primary Care Trust; and
- (c) the timescale on which the steps referred to in sub-paragraph (a) will be taken.

(4) Where, in accordance with paragraph (1)(e), the contract specifies that the contractor's list of patients is closed, it must also specify in relation to that closure each of the items listed in paragraph 29(8)(a) to (d) of Schedule 6.

19 - (1) Except in the case of the services referred to in paragraph (2), the contract must state the period (if any) for which the services are to be provided.

(2) The services referred to in paragraph (1) are-

- (a) essential services;
- (b) additional services funded under the global sum; and
- (c) out of hours services provided pursuant to regulations 30 and 31.

20 - A contract must contain a term which requires the contractor in core hours-

(a) to provide-

- (i) essential services, and
- (ii) additional services funded under the global sum,

at such times, within core hours, as are appropriate to meet the reasonable needs of its patients; and

(b) to have in place arrangements for its patients to access such services throughout the core hours in case of emergency.

Certificates

21 - (1) A contract must contain a term which has the effect of requiring the contractor to issue free of charge to a patient or his personal representatives any medical certificate of a description prescribed in column 1 of Schedule 4, 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 contractor,
- (ii) in the case of a contract with two or more individuals practising in partnership, one of those individuals; or
- (iii) in the case of a contract with a company limited by shares, one of the persons legally or beneficially owning shares in that company; or

(b) is not being treated by or under the supervision of a health care professional.

[(2) The exception in paragraph (1)(a) does not apply where the certificate is issued in accordance with regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976 (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985 (medical information).]

Finance

22 - (1) Subject to paragraph (2), the contract must contain a term which has the effect of requiring [payments to be made] under the contract promptly and in accordance with both the terms of the contract and any other conditions relating to the payment contained in directions given by the Secretary of State under section 28T of the Act (GMS contracts: payments).

(2) The obligation referred to in paragraph (1) is subject to any right the Primary Care Trust may have to set off against any amount payable to the contractor under the contract any amount-

- (a) that is owed by the contractor to the Primary Care Trust under the contract; or
- (b) that the Primary Care Trust may withhold from the contractor in accordance with the terms of the contract or any other applicable provisions contained in directions given by the Secretary of State under section 28T of the Act.

23 - The contract must contain a term to the effect that where, pursuant to directions under section 17 (Secretary of State's directions: exercise of functions) or 28T of the Act, a Primary Care Trust is required to make a payment to a contractor under a contract but subject to conditions, those conditions are to be a term of the contract.

Fees and charges

24 - (1) The contract must contain terms relating to fees and charges which have the same effect as those set out in paragraphs (2) to (4).

(2) The contractor shall not, either itself or through any other person, demand or accept from any patient of its a fee or other remuneration, for its own or another's benefit, for-

- (a) the provision of any treatment whether under the contract or otherwise; or
- (b) any prescription or repeatable prescription for any drug, medicine or appliance,

except in the circumstances set out in Schedule 5.

(3) Where a person applies to a contractor for the provision of essential services and claims to be on that contractor's list of patients, but fails to produce his medical card on request and the contractor has reasonable doubts about that person's claim, the contractor shall give any necessary treatment and shall be entitled to demand and accept a reasonable fee in accordance with paragraph 1(e) of Schedule 5, subject to the provision for repayment contained in paragraph (4).

(4) Where a person from whom a contractor received a fee under paragraph 1(e) of Schedule 5 applies to the Primary Care Trust for a refund within 14 days of payment of the fee (or such longer period not exceeding a month as the Primary Care Trust may allow if it is satisfied that the failure to apply within 14 days was reasonable) and the Primary Care Trust is satisfied that the person was on the contractor's list of patients when the treatment was given, the Primary Care Trust may recover the amount of the fee from the contractor, by deduction from its remuneration or otherwise, and shall pay that amount to the person who paid the fee.

Arrangements on termination

25 - A contract shall make suitable provision for arrangements on termination of a contract, including the consequences (whether financial or otherwise) of the contract ending.

Other contractual terms

26 - (1) A contract must, unless it is of a type or nature to which a particular provision does not apply, contain other terms which have the same effect as those specified in Schedule 6 except paragraphs 31(6) to (8), 35(5) to (9), 36(5) to (17), [48(2) and (4), 48A(6) (in so far as it relates to a determination by the Secretary of State of an appeal) and (15) (in so far as it relates to an appeal to the Secretary of State), 48C(4), 48D (in so far as this paragraph relates to a Primary Care Trust which is not a party to the contract or an appeal to the Secretary of State), 49A(8),] 101(5) to (14) and 102.

(2) The paragraphs specified in paragraph (1) shall have effect in relation to the matters set out in those paragraphs.

Part 6

Functions of Local Medical Committees

27 - (1) The functions of a Local Medical Committee which are prescribed for the purposes of section 45A(9) (Local Medical Committees) of the Act are-

- (a) the consideration of any complaint made to it by any medical practitioner against a medical practitioner specified in paragraph (2) providing services under a contract in the relevant area involving any question of the efficiency of those services;
 - (b) the reporting of the outcome of the consideration of any such complaint to the Primary Care Trust with whom the contract is held in cases where that consideration gives rise to any concerns relating to the efficiency of services provided under a contract;
 - (c) the making of arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the contractor or the Primary Care Trust is concerned that the medical practitioner is incapable of adequately providing services under the contract and it so requests with the agreement of the medical practitioner concerned; and
 - (d) the consideration of the report of any medical examination arranged in accordance with subparagraph (c) and the making of a written report as to the capability of the medical practitioner of adequately providing services under the contract to the medical practitioner concerned, the contractor and the Primary Care Trust with whom the contractor holds a contract.
- (2) The medical practitioner referred to in paragraph (1)(a) and (c) is a medical practitioner who is-
- (a) a contractor;
 - (b) one of two or more individuals practising in partnership who hold a contract; or
 - (c) a legal and beneficial shareholder in a company which holds a contract.
- (3) In this regulation, "the relevant area" means the area for which the Local Medical Committee is formed.

Part 7

Transitional Provisions

Commencement

28 - The contract shall provide for services to be provided under it from any date after 31st March 2004.

Additional services

29 - (1) Where the contract is with one of the persons specified in paragraph (2), the contract must, subject to regulation 17, provide for the contractor to provide in core hours to the contractor's registered patients and persons accepted by it as temporary residents, such of the additional services as are equivalent to services which that medical practitioner or practitioners was or were providing to his or their patients on the date that the contract is entered into except to the extent that-

- (a) the provision of any of those services by that medical practitioner or practitioners is due to come to an end on or before the date on which services are required to start being provided under the contract; or
 - (b) prior to the signing of the contract, the Primary Care Trust has accepted in writing a written request from the contractor that the contract should not require it to provide all or any of those additional services.
- (2) The persons referred to in paragraph (1) are-
- (a) an individual medical practitioner who, on 31st March 2004, was providing services under section 29 of the Act (general medical services);
 - (b) two or more individuals practising in partnership at least one of whom was, on 31st March 2004, a medical practitioner providing services under that section; or

(c) a company in which one or more of the shareholders was, on 31st March 2004, a medical practitioner providing services under that section.

(3) This regulation applies only to contracts under which services which are to be provided from 1st April 2004.

Out of hours services

30 - (1) Subject to paragraph 10 of Schedule 6, a contract 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 the services specified in paragraph (2) to be provided throughout the out of hours period unless-

(a) the Primary Care Trust has accepted in writing, prior to the signing of the contract, a written request from the contractor that the contract should not require the contractor to make such provision;

(b) the contract is, at the date on which it is signed, with-

(i) a medical practitioner who is, or was on 31st March 2004, relieved of responsibility for providing services to his patients under paragraph 18(2) of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992,

(ii) a partnership in which all of the partners who are general medical practitioners are a or were on 31st March 2004, relieved of responsibility for providing services to their patients under that paragraph, or

(iii) a company in which all of the general medical practitioners who own shares in that company are, or were on 31st March 2004, relieved of responsibility for providing services to their patients under that paragraph;

(c) the contractor has opted out in accordance with paragraph 4 or 5 of Schedule 3; or

(d) the contract has been otherwise varied to exclude a requirement to make such provision.

(2) The services referred to in paragraph (1) are-

(a) the services which must be provided in core hours under regulation 15; and

(b) such additional services as are included in the contract pursuant to regulation 29.

31 - (1) Where the contract is with-

(a) an individual medical practitioner who is, or was on 31st March 2004, responsible for providing services during all or part of the out of hours period to the patients of a medical practitioner who meets the requirements in paragraph (2);

(b) two or more individuals practising in partnership at least one of whom is, or was on 31st March 2004, a medical practitioner responsible for providing such services; or

(c) a company in which one or more of the shareholders is, or was on 31st March 2004, a medical practitioner responsible for providing such services,

the contract with that contractor must require the contractor to continue to provide such services to the patients of the exempt contractor until the happening of one of the events in paragraph (3).

(2) The requirements referred to in paragraph (1)(a) are that-

(a) the medical practitioner was relieved of responsibility for providing services to his patients under paragraph 18(2) of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992; and

(b) he-

- (i) has entered or intends to enter into a contract which does not include out of hours services pursuant to regulation 30(1)(b)(i),
 - (ii) is one of two or more individuals practising in partnership who have entered or intends to enter into a contract which does not include out of hours services pursuant to regulation 30(1)(b)(ii), or
 - (iii) is the owner of shares in a company which has entered or intends to enter into a contract which does not include out of hours services pursuant to regulation 30(1)(b)(iii).
- (3) The events referred to in paragraph (1) are-
- (a) the contractor has opted out of the provision of out of hours services in accordance with paragraph 4 or 5 of Schedule 3; or
 - (b) the Primary Care Trust (and, if it is different, the Primary Care Trust with whom the exempt contractor holds its contract) has or have agreed in writing that the contractor need no longer provide some or all of those services to some or all of those patients.
- (4) In this regulation "exempt contractor" means a contractor who is exempt from providing out of hours services pursuant to regulation 30(1)(b).

32 - A contract which includes the provision of out of hours services pursuant to regulation 30 or 31 must contain terms which have the same effect as those set out in Schedule 7.

Signed by authority of the Secretary of State

John Hutton

Minister of State,

Department of Health

8th February 2004

SCHEDULE 1

...

[NB: Schedule 1 on repeat dispensing forms was deleted by SI 2005/3315]

SCHEDULE 2

ADDITIONAL SERVICES

Regulation 16

Additional services generally

1 - The contractor shall provide, in relation to each additional service, such facilities and equipment as are necessary to enable it properly to perform that service.

Cervical screening

2 - (1) A contractor whose contract includes the provision of cervical screening services shall-

- (a) provide all the services described in sub-paragraph (2); and

(b) make such records as are referred to in sub-paragraph (3).

(2) The services referred to in sub-paragraph (1)(a) are-

- (a) the provision of any necessary information and advice to assist women identified by the Primary Care Trust as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Cervical Screening Programme;
- (b) the performance of cervical screening tests on women who have agreed to participate in that Programme;
- (c) arranging for women to be informed of the results of the test; and
- (d) ensuring that test results are followed up appropriately.

(3) The records referred to in sub-paragraph (1)(b) are an accurate record of the carrying out of a cervical screening test, the result of the test and any clinical follow up requirements.

Contraceptive services

3 - (1) A contractor whose contract includes the provision of contraceptive services shall make available to all its patients who request such services the services described in sub-paragraph (2).

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

- (a) the giving of advice about the full range of contraceptive methods;
- (b) where appropriate, the medical examination of patients seeking such advice;
- (c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);
- (d) the giving of advice about emergency contraception and where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the contractor has a conscientious objection to emergency contraception, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (e) the provision of advice and referral in cases of unplanned or unwanted pregnancy, including advice about the availability of free pregnancy testing in the practice area and, where appropriate, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and
- (g) the referral as necessary for specialist sexual health services, including tests for sexually transmitted infections.

Vaccinations and immunisations

4 - (1) A contractor whose contract includes the provision of vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall-

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee was provided for under the 2003-04 Statement of Fees and Allowances made under regulation 34 of the National Health Service (General Medical Services) Regulations 1992 other than **[influenza and pneumococcal vaccinations]**;

- (b) provide appropriate information and advice to patients about such vaccinations and immunisations;
 - (c) record in the patient's record kept in accordance with paragraph 73 of Schedule 6 any refusal of the offer referred to in paragraph (a);
 - (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 73 of Schedule 6-
 - (i) the patient's consent to the vaccination or immunisation or the name of the person who gave consent to the vaccination or immunisation and his relationship to the patient,
 - (ii) the batch numbers, expiry date and title of the vaccine,
 - (iii) the date of administration,
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine,
 - (v) any contraindications to the vaccination or immunisation, and
 - (vi) any adverse reactions to the vaccination or immunisation.
- (3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Childhood vaccinations and immunisations

5 - (1) A contractor whose contract includes the provision of childhood vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall-

- (a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee was provided for under the 2003-04 Statement of Fees and Allowances made under regulation 34 of the National Health Service (General Medical Services) Regulations 1992;
- (b) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;
- (c) record in the patient's record kept in accordance with paragraph 73 of Schedule 6 any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 73 of Schedule 6-
 - (i) the name of the person who gave consent to the vaccination or immunisation and his relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Child health surveillance

- 6 - (1)** A contractor whose contract includes the provision of child health surveillance services shall, in respect of any child under the age of five for whom it has responsibility under the contract-
- (a) provide all the services described in sub-paragraph (2), other than any examination so described which the parent refuses to allow the child to undergo, until the date upon which the child attains the age of five years; and
 - (b) maintain such records as are specified in sub-paragraph (3).
- (2) The services referred to in sub-paragraph (1)(a) are-
- (a) the monitoring-
 - (i) by the consideration of any information concerning the child received by or on behalf of the contractor, and
 - (ii) on any occasion when the child is examined or observed by or on behalf of the contractor (whether pursuant to paragraph (b) or otherwise),

of the health, well-being and physical, mental and social development (all of which characteristics are referred to in this paragraph as "development") of the child while under the age of 5 years with a view to detecting any deviations from normal development;

- (b) the examination of the child at a frequency that has been agreed with the Primary Care Trust in accordance with the nationally agreed evidence based programme set out in the fourth edition of "Health for all Children".
- (3) The records mentioned in sub-paragraph (1)(b) are an accurate record of-
- (a) the development of the child while under the age of 5 years, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination; and
 - (b) the responses (if any) to offers made to the child's parent for the child to undergo any examination referred to in sub-paragraph (2)(b).

Maternity medical services

- 7 - (1)** A contractor whose contract includes the provision of maternity medical services shall-
- (a) provide to female patients who have been diagnosed as pregnant all necessary maternity medical services throughout the antenatal period;
 - (b) provide to female patients and their babies all necessary maternity medical services throughout the postnatal period other than neonatal checks;
 - (c) provide all necessary maternity medical services to female patients whose pregnancy has terminated as a result of miscarriage or abortion or, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections.
- (2) In this paragraph-
- "antenatal period" means the period from the start of the pregnancy to the onset of labour;
- "maternity medical services" means-
- (a) in relation to female patients (other than babies) all primary medical services relating to pregnancy, excluding intra partum care, and
 - (b) in relation to babies, any primary medical services necessary in their first 14 days of life;

"postnatal period" means the period starting from the conclusion of delivery of the baby or the patient's discharge from secondary care services, whichever is the later, and ending on the fourteenth day after the birth.

Minor surgery

8 - (1) A contractor whose contract includes the provision of minor surgery shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall make available to patients where appropriate-

- (a) curettage;
- (b) cautery; and
- (c) cryocautery of warts, verrucae and other skin lesions.

(3) The contractor shall ensure that its record of any treatment provided under this paragraph includes the consent of the patient to that treatment.

SCHEDULE 3

OPT OUTS OF ADDITIONAL AND OUT OF HOURS SERVICES

Regulation 17

Opt outs of additional services: general

1 - (1) In this Schedule-

"opt out notice" means a notice given under sub-paragraph (5) to permanently opt out or temporarily opt out of the provision of the additional service;

"permanent opt out" in relation to the provision of an additional service that is funded through the global sum, means the termination of the obligation under the contract for the contractor to provide that service; and "permanently opt out" shall be construed accordingly;

"permanent opt out notice" means an opt out notice to permanently opt out;

"preliminary opt out notice" means a notice given under sub-paragraph (2) that a contractor wishes to temporarily opt out or permanently opt out of the provision of an additional service;

"temporary opt out" in relation to the provision of an additional service that is funded through the global sum, means the suspension of the obligation under the contract for the contractor to provide that service for a period of more than six months and less than twelve months and includes an extension of a temporary opt out and "temporarily opt out" and "temporarily opted out" shall be construed accordingly; and

"temporary opt out notice" means an opt out notice to temporarily opt out.

(2) A contractor who wishes to permanently or temporarily opt out shall give to the relevant Primary Care Trust in writing a preliminary opt out notice which shall state the reasons for wishing to opt out.

(3) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the receipt of the preliminary opt out notice by the Primary Care Trust, the Primary Care Trust shall enter into discussions with the contractor concerning the support which the Primary Care Trust may give the contractor, or concerning other changes which the Primary Care Trust or the contractor may make, which would enable the contractor to continue to provide the additional service and the Primary Care Trust and the contractor shall use reasonable endeavours to achieve this aim.

- (4) The discussions mentioned in sub-paragraph (3) shall be completed within the period of 10 days beginning with the date of the receipt of the preliminary opt out notice by the Primary Care Trust or as soon as reasonably practicable thereafter.
- (5) Subject to sub-paragraph (9), if following the discussions mentioned in sub-paragraph (3), the contractor still wishes to opt out of the provision of the additional service, it shall send an opt out notice to the Primary Care Trust.
- (6) An opt out notice shall specify-
- (a) the additional service concerned;
 - (b) whether the contractor wishes to-
 - (i) permanently opt out, or
 - (ii) temporarily opt out;
 - (c) the reasons for wishing to opt out;
 - (d) the date from which the contractor would like the opt out to commence, which must-
 - (i) in the case of a temporary opt out be at least 14 days after the date of service of the opt out notice, and
 - (ii) in the case of a permanent opt out must be the day either three or six months after the date of service of the opt out notice, and
 - (e) in the case of a temporary opt out, the desired duration of the opt out.
- (7) Where a contractor has given two previous temporary opt out notices within the period of three years ending with the date of the service of the latest opt out notice (whether or not the same additional service is concerned), the latest opt out notice shall be treated as a permanent opt out notice (even if the opt out notice says that it wishes to temporarily opt out).
- (8) Paragraph 2 applies following the giving of a temporary opt out notice and paragraph 3 applies following the giving of a permanent opt out notice or a temporary opt out notice which pursuant to sub-paragraph (7) is treated as a permanent opt out notice.
- (9) No temporary opt out notice may be served by a contractor prior to 1st April 2004.

Temporary opt outs and permanent opt outs following temporary opt outs

- 2 - (1) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the date of receipt of a temporary opt out notice under paragraph 1(5), the Primary Care Trust shall-
- (a) approve the opt out notice and specify in accordance with sub-paragraphs (3) and (4) the date on which the temporary opt out is to commence and the date that it is to come to an end ("the end date"); or
 - (b) reject the opt out notice in accordance with sub-paragraph (2),
- and shall notify the contractor of its decision as soon as possible, including reasons for its decision.
- (2) A Primary Care Trust may reject the opt out notice on the ground that the contractor-
- (a) is providing additional services to patients other than its own registered patients or enhanced services; or
 - (b) has no reasonable need temporarily to opt out having regard to its ability to deliver the additional service.
- (3) The date specified by the Primary Care Trust for the commencement of the temporary opt out shall wherever reasonably practicable be the date requested by the contractor in its opt out notice.

- (4) Before determining the end date, the Primary Care Trust shall make reasonable efforts to reach agreement with the contractor.
- (5) Where the Primary Care Trust approves an opt out notice, the contractor's obligation to provide the additional service specified in the notice shall be suspended from the date specified by the Primary Care Trust in its decision under sub-paragraph (1), and shall remain suspended until the end date unless-
- (a) the contractor and the Primary Care Trust agree in writing an earlier date, in which case the suspension shall come to an end on the earlier date agreed;
 - (b) the Primary Care Trust specifies a later date under sub-paragraph (6), in which case the suspension shall end on the later date specified;
 - (c) sub-paragraph (7) applies and the contractor refers the matter to the NHS dispute resolution procedure or the court, in which case the suspension shall end-
 - (i) where the outcome of the dispute is to uphold the decision of the Primary Care Trust, on the day after the date of the decision of the Secretary of State or the court,
 - (ii) where the outcome of the dispute is to overturn the decision of the Primary Care Trust, 28 days after the decision of the Secretary of State or the court, or
 - (iii) where the contractor ceases to pursue the NHS dispute resolution procedure or court proceedings, on the day after the date that the contractor withdraws its claim or the procedure is or proceedings are otherwise terminated by the Secretary of State or the court;
 - (d) sub-paragraph (9) applies and-
 - (i) the Primary Care Trust refuses the contractor's request for a permanent opt out within the period of 28 days ending with the end date, in which case the suspension shall come to an end 28 days after the end date,
 - (ii) the Primary Care Trust refuses the contractor's request for a permanent opt out after the end date, in which case the suspension shall come to an end 28 days after the date of service of the notice, or
 - (iii) the Primary Care Trust notifies the contractor after the end date that the relevant Strategic Health Authority has not approved its proposed decision to refuse the contractor's request to permanently opt out under sub-paragraph (14), in which case the suspension shall come to an end 28 days after the date of service of the notice under this paragraph.
- (6) Before the end date, a Primary Care Trust may, in exceptional circumstances and with the agreement of the contractor, notify the contractor in writing of a later date on which the temporary opt out is to come to an end, being a date no more than six months later than the end date.
- (7) Where the Primary Care Trust considers that-
- (a) the contractor will be unable to satisfactorily provide the additional service at the end of the temporary opt out; and
 - (b) it would not be appropriate to exercise its discretion under sub-paragraph (6) to specify a later date on which the temporary opt out is to come to an end or the contractor does not agree to a later date,
- the Primary Care Trust may notify the contractor in writing at least 28 days before the end date that a permanent opt out shall follow a temporary opt out.
- (8) Where a Primary Care Trust notifies the contractor under sub-paragraph (7) that a permanent opt out shall follow a temporary opt out, the permanent opt out shall take effect immediately after the end of the temporary opt out.

(9) A contractor who has temporarily opted out may, at least three months prior to the end date, notify the relevant Primary Care Trust in writing that it wishes to permanently opt out of the additional service in question.

(10) Where the contractor has notified the Primary Care Trust under sub-paragraph (9) that it wishes to permanently opt out, the temporary opt out shall be followed by a permanent opt out beginning on the day after the end date unless the Primary Care Trust refuses the contractor's request to permanently opt out by giving a notice in writing to the contractor to this effect.

(11) A Primary Care Trust may only give a notice under sub-paragraph (10) with the approval of the relevant Strategic Health Authority.

(12) Where a Primary Care Trust seeks the approval of a Strategic Health Authority to a proposed decision to refuse a permanent opt out, it shall notify the contractor of having done so.

(13) If the relevant Strategic Health Authority has not reached a decision as to whether or not to approve the Primary Care Trust's proposed decision to refuse a permanent opt out before the end date, the contractor's obligation to provide the additional service shall remain suspended until the date specified in sub-paragraph (5)(d)(ii) or (iii) (whichever is applicable).

(14) Where after the end date the relevant Strategic Health Authority notifies the Primary Care Trust that it does not approve the Primary Care Trust's proposed decision to refuse a permanent opt out, the Primary Care Trust shall notify the contractor in writing of this fact as soon as is reasonably practicable.

(15) A temporary opt out or permanent opt out commences, and a temporary opt out ends, at 08.00 on the relevant day unless-

(a) the day is a Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday, in which case the opt out shall take effect on the next working day at 08.00; or

(b) the Primary Care Trust and the contractor agree a different day or time.

Permanent opt outs

3 - (1) In this paragraph-

"A day" is the day specified by the contractor in its permanent opt out notice to a Primary Care Trust for the commencement of the permanent opt out;

"B day" is the day six months after the date of service of the permanent opt out notice; and

"C day" is the day nine months after the date of service of the permanent opt out notice.

(2) As soon as is reasonably practicable and in any event within the period of 28 days beginning with the date of receipt of a permanent opt out notice under paragraph 1(5) (or temporary opt out notice which is treated as a permanent opt out notice under paragraph 1(7)), the Primary Care Trust shall-

(a) approve the opt out notice; or

(b) reject the opt out notice in accordance with sub-paragraph (3),

and shall notify the contractor of its decision as soon as possible, including reasons for its decision where its decision is to reject the opt out notice.

(3) A Primary Care Trust may reject the opt out notice on the ground that the contractor is providing an additional service to patients other than its registered patients or enhanced services.

(4) A contractor may not withdraw an opt out notice once it has been approved by the Primary Care Trust in accordance with sub-paragraph (2)(a) without the Primary Care Trust's agreement.

(5) If the Primary Care Trust approves the opt out notice under sub-paragraph (2)(a), it shall use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the additional service from an alternative provider from A day.

- (6) The contractor's duty to provide the additional service shall terminate on A day unless the Primary Care Trust serves a notice under sub-paragraph (7) (extending A day to B day or C day).
- (7) If the Primary Care Trust is not successful in finding an alternative provider to take on the provision of the additional service from A day, then it shall notify the contractor in writing of this fact no later than one month before A day, and-
- (a) in a case where A day is three months after service of the opt out notice, the contractor shall continue to provide the additional service until B day unless at least one month before B day it receives a notice in writing from the Primary Care Trust under sub-paragraph (8) that despite using its reasonable endeavours, it has failed to find an alternative provider to take on the provision of the additional service from B day;
 - (b) in a case where A day is six months after the service of the opt out notice, the contractor shall continue to provide the additional service until C day unless at least one month before C day it receives a notice from the Primary Care Trust under sub-paragraph (11) that it has made an application to the relevant Strategic Health Authority under sub-paragraph (10) seeking its approval of a decision to refuse a permanent opt out or to delay the commencement of a permanent opt out until after C day.
- (8) Where in accordance with sub-paragraph (7)(a) the permanent opt out is to commence on B day and the Primary Care Trust, despite using its reasonable endeavours has failed to find an alternative provider to take on the provision of the additional service from that day, it shall notify the contractor in writing of this fact at least one month before B day, in which case the contractor shall continue to provide the additional service until C Day unless at least one month before C day it receives a notice from the Primary Care Trust under sub-paragraph (11) that it has applied to the relevant Strategic Health Authority under sub-paragraph (10) seeking the approval of the relevant Strategic Health Authority to a decision to refuse a permanent opt out or to postpone the commencement of a permanent opt out until after C day.
- (9) As soon as is reasonably practicable and in any event within 7 days of the Primary Care Trust serving a notice under sub-paragraph (8), the Primary Care Trust shall enter into discussions with the contractor concerning the support that the Primary Care Trust may give to the contractor or other changes which the Primary Care Trust or the contractor may make in relation to the provision of the additional service until C day.
- (10) The Primary Care Trust may, if it considers that there are exceptional circumstances, make an application to the relevant Strategic Health Authority for approval of a decision to-
- (a) refuse a permanent opt out; or
 - (b) postpone the commencement of a permanent opt out until after C day.
- (11) As soon as practicable after making an application under sub-paragraph (10) to the Strategic Health Authority, the Primary Care Trust shall notify the contractor in writing that it has made such an application.
- (12) On receiving an application under sub-paragraph (10) for approval of a decision to refuse a permanent opt out, the Strategic Health Authority shall-
- (a) approve the Primary Care Trust's application;
 - (b) reject the Primary Care Trust's application, but nonetheless recommend a different date for the commencement of the permanent opt out which shall be later than C day; or
 - (c) reject the Primary Care Trust's application.
- (13) On receiving an application under sub-paragraph (10) for approval of a decision to postpone the commencement of a permanent opt out until after C day, the Strategic Health Authority shall-
- (a) approve the Primary Care Trust's application;
 - (b) reject the Primary Care Trust's application, but nonetheless recommend-

(i) that the permanent opt out commence on an earlier date to that proposed by the Primary Care Trust in its application, or

(ii) that the permanent opt out be refused; or

(c) reject the Primary Care Trust's application.

(14) The relevant Strategic Health Authority shall notify the Primary Care Trust and the contractor in writing of its decision under sub-paragraph (12) or (13) as soon as is practicable, including reasons for its decision.

(15) Where the Strategic Health Authority-

(a) approves a decision to refuse an opt out under sub-paragraph (12)(a); or

(b) recommends that a permanent opt out be refused under sub-paragraph (13)(b)(ii),

the Primary Care Trust shall notify the contractor in writing that it may not opt out of the additional service.

(16) Where a Primary Care Trust notifies a contractor under sub-paragraph (15), the contractor may not serve a preliminary opt out notice in respect of that additional service for a period of 12 months beginning with the date of service of the Primary Care Trust's notice under sub-paragraph (15) unless there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

(17) Where the Strategic Health Authority-

(a) recommends a different date for the commencement of the permanent opt out under sub-paragraph (12)(b);

(b) approves a Primary Care Trust's application to postpone a permanent opt out under sub-paragraph (13)(a); or

(c) recommends an earlier date to that proposed by the Primary Care Trust in its application under sub-paragraph (13)(b)(i),

the Primary Care Trust shall in accordance with the decision of the Strategic Health Authority notify the contractor in writing of its decision and the notice shall specify the date from which the permanent opt out shall commence.

(18) Where the Strategic Health Authority rejects the Primary Care Trust's application under sub-paragraph (12)(c) or (13)(c), the Primary Care Trust shall notify the contractor in writing that there shall be a permanent opt out and the permanent opt out shall commence on C day or 28 days after the date of service of the Primary Care Trust's notice, whichever is the later.

(19) If the relevant Strategic Health Authority has not reached a decision on the Primary Care Trust's application under sub-paragraph (10) before C day, the contractor's obligation to provide the additional service shall continue until a notice is served on it by the Primary Care Trust under sub-paragraph (17) or (18).

(20) Nothing in sub-paragraphs (1) to (19) above shall prevent the contractor and the Primary Care Trust from agreeing a different date for the termination of the contractor's duty under the contract to provide the additional service and accordingly, varying the contract in accordance with paragraph 104(1) of Schedule 6.

(21) The permanent opt out takes effect at 08.00 on the relevant day unless-

(a) the day is a Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday, in which case the opt out shall take effect on the next working day at 08.00; or

(b) the Primary Care Trust and the contractor agree a different day or time.

Out of hours opt outs where the opt out notice is served after 30th September 2004

4 - (1) This paragraph applies where a contractor wishes to serve or serves an out of hours opt out notice after 30th September 2004.

(2) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the relevant Primary Care Trust in writing to that effect ("an out of hours opt out notice").

(3) An out of hours opt out notice shall specify the date from which the contractor would like the opt out to take effect, which must be either three or six months after the date of service of the out of hours opt out notice.

(4) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Primary Care Trust shall approve the notice and specify in accordance with sub-paragraph (6) the date on which the out of hours opt out is to commence ("OOH day").

(5) The Primary Care Trust shall notify the contractor of its decision as soon as possible.

(6) The date specified in sub-paragraph (4) shall be the date specified in the out of hours opt out notice.

(7) A contractor may not withdraw an out of hours opt out notice once it has been approved by the Primary Care Trust under sub-paragraph (4) without the Primary Care Trust's agreement.

(8) Following receipt of the out of hours opt out notice, the Primary Care Trust must use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the out of hours services from an alternative provider from OOH day.

(9) Sub-paragraphs (6) to (21) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "A day" was a reference to "OOH day" and the reference in paragraph 3(16) to a "preliminary opt out notice" was a reference to "an out of hours opt out notice".

Out of hours opt outs where the opt out notice is served before 1st October 2004

5 - (1) This paragraph shall apply where a contractor wishes to serve or serves an out of hours opt out notice before 1st October 2004.

(2) In this paragraph-

"OOH day" is the day specified by the Primary Care Trust for the commencement of the out of hours opt out in its decision under sub-paragraph (5);

"OOHB day" is the day six months after the date of service of the out of hours opt out notice; and

"OOHC day" is the day specified by the Primary Care Trust in its decision under sub-paragraph (11) or (13) (which must be nine months after the date of service of the out of hours opt out notice or before 2nd January 2005).

(3) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the relevant Primary Care Trust in writing to that effect ("an out of hours opt out notice").

(4) An out of hours opt out notice shall state the date on which the contractor would like the opt out to take effect, which must be either three or six months after the date of service of the out of hours opt out notice.

(5) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Primary Care Trust shall approve the notice and specify in accordance with sub-paragraphs (6) and (7) the date on which the out of hours opt out is to commence (OOH day) and the Primary Care Trust shall notify the contractor in writing of its decision as soon as possible, including reasons for its decision.

(6) Subject to sub-paragraph (7), OOH day shall be-

- (a) the date specified in the out of hours opt out notice; or
 - (b) any other date before 2nd January 2005.
- (7) A Primary Care Trust may not specify under sub-paragraph (5) a date earlier than the date specified in the out of hours opt out notice.
- (8) A contractor may not withdraw an out of hours opt out notice once it has been approved by a Primary Care Trust under sub-paragraph (5) without the Primary Care Trust's agreement.
- (9) Following receipt of the out of hours opt out notice, the Primary Care Trust must use its reasonable endeavours to make arrangements for the contractor's registered patients to receive out of hours services from an alternative provider from OOH day.
- (10) The contractor's duty to provide the out of hours services shall terminate on OOH day unless the Primary Care Trust-
- (a) serves a notice under sub-paragraph (11) (extending OOH day to OOHB day or OOHC day); or
 - (b) makes an application under sub-paragraph (14) (seeking the approval of the relevant Strategic Health Authority to a decision to refuse an opt out or to delay the taking of effect of an opt out until after OOH day).
- (11) If the Primary Care Trust is not successful in finding an alternative provider to take on the provision of the out hours services from OOH day, then it shall notify the contractor in writing of this fact no later than one month before OOH day, and-
- (a) in a case where OOH day is three months after service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHB day unless at least one month before OOHB day it receives a notice in writing from the Primary Care Trust under sub-paragraph (13) that despite using its reasonable endeavours, it has failed to find an alternative provider to take on the provision of the out of hours services from OOHB day;
 - (b) in a case where OOH day is after the day three months after the service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHC day (which shall be specified by the Primary Care Trust in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day it receives a notice from the Primary Care Trust under sub-paragraph (16) that it has made an application to the relevant Strategic Health Authority under sub-paragraph (14) seeking its approval to a decision to refuse an opt out or to delay the commencement of the opt out until after OOHC day.
- (12) OOHC day shall be any day before 2nd January 2005 or the day nine months after the service of the out of hours opt out notice.
- (13) Where in accordance with sub-paragraph (11)(a) the out of hours opt out is to commence on OOHB day and the Primary Care Trust, despite using its reasonable endeavours has failed to find an alternative provider to take on the provision of the out of hours services from that day, it shall notify the contractor in writing of this fact at least one month before OOHB day, in which case the contractor shall continue to provide the out of hours services until OOHC day (which shall be specified by the Primary Care Trust in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day it receives a notice from the Primary Care Trust under sub-paragraph (16) that it has applied to the relevant Strategic Health Authority under sub-paragraph (14) seeking the approval of the relevant Strategic Health Authority to a decision to refuse an opt out or to postpone the commencement of an opt out until after OOHC day.
- (14) The Primary Care Trust may, if it considers there are exceptional circumstances, make an application to the relevant Strategic Health Authority for approval of a decision to-
- (a) refuse an opt out; or
 - (b) postpone the commencement of an opt out until after-

- (i) OOHC day, or
 - (ii) OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.
- (15) Where OOH day is 1st January 2005, and 1st January 2005 is nine months or more after the date of the out of hours opt out notice, an application under sub-paragraph (14) shall be made at least one month before OOH day.
- (16) As soon as practicable after making an application under sub-paragraph (14) to the Strategic Health Authority, the Primary Care Trust shall notify the contractor in writing that it has made such an application.
- (17) Sub-paragraphs (12) to (21) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "C day" was a reference to OOHC day or OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.

Informing patients of opt outs

- 6 - (1) Prior to any opt out taking effect, the Primary Care Trust and the contractor shall discuss how to inform the contractor's patients of the proposed opt out.
- (2) The contractor shall, if requested by the Primary Care Trust inform its registered patients of an opt out and the arrangements made for them to receive the additional service or out of hours services by-
- (a) placing a notice in the practice's waiting rooms; or
 - (b) including the information in the practice leaflet.
- (3) In this paragraph "opt out" means an out of hours opt out, a permanent opt out or a temporary opt out.

SCHEDULE 4

LIST OF PRESCRIBED MEDICAL CERTIFICATES

Regulation 21

<i>Description of medical certificate</i>	<i>Enactment under or for the purpose of which certificate required</i>
1 To support a claim or to obtain payment either personally or by proxy; to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc	Naval and Marine Pay and Pensions Act 1865 Air Force (Constitution) Act 1917 Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939 Personal Injuries (Emergency Provisions) Act 1939 Pensions (Mercantile Marine) Act 1942 Polish Resettlement Act 1947 Social Security Administration Act 1992 Social Security Contributions and Benefits Act 1992 Social Security Act 1998
2 To establish pregnancy for the purpose of obtaining welfare foods	Section 13 of the Social Security Act 1988 (schemes for distribution etc of welfare foods)
3 To secure registration of still-birth	Section 11 of the Births and Deaths Registration Act 1953 (special provision as to registration of still-birth)
4 To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment from	Section 142 of the Mental Health Act 1983 (pay, pensions etc of mentally disordered persons)

public funds

5 To establish unfitness for jury service	Juries Act 1974
6 To support late application for reinstatement in civil employment or notification of non-availability to take up employment owing to sickness	Reserve Forces (Safeguarding of Employment) Act 1985
7 To enable a person to be registered as an absent voter on grounds of physical incapacity	Representation of the People Act 1983
8 To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances	National Health Service Act 1977
9 To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable	Local Government Finance Act 1992

SCHEDULE 5

FEES AND CHARGES

Regulation 24

1 - The contractor may demand or accept a fee or other remuneration-

- (a) from any statutory body for services rendered for the purposes of that body's statutory functions;
- (b) from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take;
- (c) for treatment which is not primary medical services or otherwise required to be provided under the contract and which is given-
 - (i) pursuant to the provisions of section 65 of the Act (accommodation and services for private patients), or
 - (ii) in a registered nursing home which is not providing services under that Act,
 if, in either case, the person administering the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving the treatment, the contractor or the person providing the treatment supplies the Primary Care Trust, on a form provided by it for the purpose, with such information about the treatment as it may require;
- (d) under section 158 of the Road Traffic Act 1988 (payment for emergency treatment of traffic casualties);
- (e) when it treats a patient under regulation 24(3), in which case it shall be entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if it gives the patient a receipt;
- (f) for attending and examining (but not otherwise treating) a patient-
 - (i) at his request at a police station in connection with possible criminal proceedings against him,
 - (ii) at the request of a commercial, educational or not-for-profit organisation for the purpose of creating a medical report or certificate,

- (iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;
- (g) for treatment consisting of an immunisation for which no remuneration is payable by the Primary Care Trust and which is requested in connection with travel abroad;
- (h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed;
- (i) for a medical examination-
 - (i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or
 - (ii) for the purpose of creating a report-
 - (aa) relating to a road traffic accident or criminal assault, or
 - (bb) that offers an opinion as to whether a patient is fit to travel;
- (j) for testing the sight of a person to whom none of paragraphs (a), (b) or (c) of section 38(1) of the Act (arrangements for general ophthalmic services) applies (including by reason of regulations under section 38(6) of that Act);
- (k) where it is a contractor which is authorised or required by a Primary Care Trust under [regulation 60] of the Pharmaceutical Regulations or paragraphs 47 or 49 of Schedule 6 to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of pharmaceutical services or dispensing services, any Scheduled drug;
- (l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

SCHEDULE 6

OTHER CONTRACTUAL TERMS

Regulation 26

Part 1

Provision of Services

Premises

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

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

[Telephone services

1A - (1) The contractor shall not be a party to any contract or other arrangement under which the number for telephone services to be used by-

- (a) patients to contact the practice for any purpose related to the contract; or

- (b) any other person to contact the practice in relation to services provided as part of the health service,

starts with the digits 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller.

- (2) In this paragraph, "personal number" means a telephone number which starts with the number 070 followed by a further 8 digits.]

[Cost of relevant calls

1B – (1) The contractor must not enter into, renew or extend a contract or other arrangement for telephone services unless it is satisfied that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number.

(2) Where a contractor is party to an existing contract or other arrangements for telephone services under which persons making relevant calls to the practice call a number which is not a geographical number, the contractor must comply with sub-paragraph (3).

(3) The contractor must –

(a) before 1st April 2011, review the arrangements and consider whether, having regard to the arrangement as a whole, persons pay more to make relevant calls than they would to make equivalent calls to a geographical number; and

(b) if the contractor so considers, take all reasonable steps, including in particular considering the matters specified in sub-paragraph (4), to ensure that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls than they would to make equivalent calls to a geographical number.

(4) The matters referred to in sub-paragraph (3)(b) are –

(a) varying the terms of the contract or arrangement;

(b) renegotiating the terms of the contract or arrangement; and

(c) terminating the contract or arrangement.

(5) If, despite taking all reasonable steps referred to in sub-paragraph (3)(b), it has not been possible to ensure that, having regard to the arrangements as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number, the contractor must consider introducing a system under which if a caller asks to be called back, the contractor will do so at the contractor's expense.

(6) In this paragraph –

(a) "existing contract or other arrangement" means a contract or arrangement that was entered into prior to 1st April 2010 and which remains in force on 1st April 2010;

(b) "geographical number" means a number which has a geographical area code as its prefix; and

(c) "relevant calls" means calls –

(i) made by patients to the practice for any reason related to services provided under the contract, and

(ii) made by persons, other than patients, to the practice in relation to services provided as part of the health service.

Attendance at practice premises

2 - (1) The contractor shall take steps to ensure that any patient who-

- (a) has not previously made an appointment; and

(b) attends at the practice premises during the normal hours for essential services, is provided with such services by an appropriate health care professional during that surgery period except in the circumstances specified in sub-paragraph (2).

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

- (a) it is more appropriate for the patient to be referred elsewhere for services under the Act; or
- (b) he is then offered an appointment to attend again within a time which is appropriate and reasonable having regard to all the circumstances and his health would not thereby be jeopardised.

Attendance outside practice premises

3 - (1) In the case of a patient whose medical condition is such that in the reasonable opinion of the contractor-

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

the contractor shall provide services to that patient at whichever in its 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 his last home address;
- (b) such other place as the contractor has informed the patient and the Primary Care Trust is the place where it has agreed to visit and treat the patient; or
- (c) some other place in the contractor's practice area.

(3) Nothing in this paragraph prevents the contractor from-

- (a) arranging for the referral of a 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 it under an obligation to do so.

Newly registered patients

4 - (1) Where a patient has been-

- (a) accepted on a contractor's list of patients under paragraph 15; or
- (b) assigned to that list by the Primary Care Trust,

the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, invite the patient to participate in a consultation either at its practice premises or, if the medical condition of the patient so warrants, at one of the places referred to in paragraph 3(2).

(2) An invitation under sub-paragraph (1) shall be issued within six months of the date of the acceptance of the patient on, or their assignment to, the contractor's list.

(3) Where a patient (or, where appropriate, in the case of a patient who is a child, his parent) agrees to participate in a consultation mentioned in sub-paragraph (1) the contractor shall, in the course of that consultation make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

Patients not seen within three years

5 - Where a registered patient who-

- (a) has attained the age of 16 years but has not attained the age of 75 years; and

- (b) has attended neither a consultation with, nor a clinic provided by, the contractor within the period of three years prior to the date of his request,

requests a consultation the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, provide such a consultation in the course of which it shall make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

Patients aged 75 years and over

- 6 - (1) Where a registered patient who-

- (a) has attained the age of 75 years; and
(b) has not participated in a consultation under this paragraph within the period of twelve months prior to the date of his request,

requests a consultation, the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, provide such a consultation in the course of which it shall make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

- (2) A consultation under sub-paragraph (1) shall take place in the home of the patient where, in the reasonable opinion of the contractor, it would be inappropriate, as a result of the patient's medical condition, for him to attend at the practice premises.

Clinical reports

- 7 - (1) Where the contractor provides any clinical services, other than under a private arrangement, to a patient who is not on its list of patients, it shall, as soon as reasonably practicable, provide a clinical report relating to the consultation, and any treatment provided, to the Primary Care Trust.

- (2) The Primary Care Trust shall send any report received under sub-paragraph (1)-
(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 Primary Care Trust in whose area the patient is resident.

[(3) This paragraph does not apply in relation to out of hours services provided by a contractor on or after 1st January 2005.]

Storage of vaccines

- 8 - The contractor 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

- 9 - The contractor shall ensure that it has appropriate arrangements for infection control and decontamination.

Criteria for out of hours services

- 10 - A contractor whose contract includes the provision of out of hours services shall only be required to provide such services if, in the reasonable opinion of the contractor in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait for the services required until the next time at which he could obtain such services during core hours.

Standards for out of hours services

11 – [... NB: Words deleted by SI 2010/578] A contractor which provides out of hours services must, in the provision of such services, meet the [quality requirements] set out in the document entitled ["National Quality Requirements in the Delivery of Out of Hours Services" published on 20th July 2006].

[Supply of medicines etc by contractors providing out of hours services

11A - (1) In this paragraph-

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000;

"complete course" means the course of treatment appropriate to the patient's condition, being the same as the amount that would have been prescribed if the patient had been seen during core hours;

"necessary drugs, medicines and appliances" means those drugs, medicines and appliances which the patient requires and for which, in the reasonable opinion of the contractor, and in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait until such time as he could obtain them during core hours;

"out of hours performer" means a prescriber, a person acting in accordance with a Patient Group Direction or any other health care professional employed or engaged by the contractor who can lawfully supply a drug, medicine or appliance, who is performing out of hours services under the contract;

"Patient Group Direction" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997; and

"supply form" means a form provided by a Primary Care Trust and completed by or on behalf of the contractor for the purpose of recording the provision of drugs, medicines or appliances to a patient during the out of hours period.

(2) Where a contractor whose contract includes the provision of out of hours services has agreed with the Primary Care Trust that its contract should also include the supply of necessary drugs, medicines and appliances to patients at the time that it is providing them with out of hours services, the contractor shall comply with the requirements in sub-paragraphs (3) to (5).

(3) The contractor shall ensure that an out of hours performer-

- (a) only supplies necessary drugs, medicines and appliances;
- (b) supplies the complete course of the necessary medicine or drug required to treat the patient; and
- (c) does not supply-
 - (i) drugs, medicines or appliances which he could not lawfully supply,
 - (ii) appliances which are not listed in Part IX of the Drug Tariff,
 - (iii) restricted availability appliances, except where the patient is a person, or it is for a purpose, specified in the Drug Tariff, or
 - (iv) a drug, medicine or other substance listed in Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004, or a drug, medicine or other substance listed in Schedule 2 to those Regulations other than in the circumstances specified in that Schedule.

(4) The out of hours performer shall record on a separate supply form for each patient any drugs, medicines or appliances supplied to the patient provided that a single supply form may be completed where the out of hours performer supplies necessary drugs, medicines or appliances to two or more persons in a school or other institution in which at least 20 persons normally reside, when the out of hours performer may write on the supply form the name of the school or institution rather than the name of the individual patient.

(5) The out of hours performer shall-

(a) ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations by virtue of either-

- (i) entitlement to exemption under regulation 7(1) of the Charges Regulations, or
- (ii) entitlement to remission of charges under regulation 5 of the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations, and at the time of the declaration the out of hours performer already has such evidence available to him; and

(b) if no satisfactory evidence is produced to him (and, where it is relevant, none is already available to him as mentioned in paragraph (a)), endorse the supply form to that effect.

(6) Subject to sub-paragraph (7), nothing in this paragraph shall prevent an out of hours performer supplying a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(7) The provisions of regulation 24 (fees and charges) apply in respect of the supply of necessary drugs, medicines and appliances under this paragraph as they apply in respect of prescriptions for drugs, medicines and appliances.]

Duty of co-operation in relation to additional, enhanced and out of hours services

12 - (1) A contractor which does not provide to its registered patients or to persons whom it has accepted as temporary residents-

- (a) a particular additional service;
- (b) a particular enhanced service; or
- (c) out of hours services, either at all or in respect of some periods or some services,

shall comply with the requirements specified in sub-paragraph (2).

(2) The requirements referred to in sub-paragraph (1) are that the contractor 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 Primary Care Trust 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 contractor whose contract does not include the provision of out of hours services to make itself available during the out of hours period.

13 - Where a contractor is to cease to be required to provide to its patients-

- (a) a particular additional service;
- (b) a particular enhanced service; or
- (c) out of hours services, either at all or in respect of some periods or some services,

it shall comply with any reasonable request for information relating to the provision of that service or those services made by the Primary Care Trust or by any person with whom the Trust intends to enter into a contract for the provision of such services.

Part 2

Patients

List of patients

14 - The Primary Care Trust shall prepare and keep up to date a list of the patients-

- (a) who have been accepted by the contractor for inclusion in its list of patients under paragraph 15 and who have not subsequently been removed from that list under paragraphs 19 to 27; and
- (b) who have been assigned to the contractor under paragraph 32 or 33 and whose assignment has not subsequently been rescinded.

Application for inclusion in a list of patients

15 - (1) The contractor may, if its list of patients is open, accept an application for inclusion in its list of patients made by or on behalf of any person whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(2) The contractor may, if its list of patients is closed, only accept an application for inclusion in its list of patients from a person who is an immediate family member of a registered patient whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(3) Subject to sub-paragraph (4), an application for inclusion in a contractor's list of patients shall be made by delivering to the practice premises a medical card or an application signed (in either case) by the applicant or a person authorised by the applicant to sign on his behalf.

(4) An application may be made-

- (a) on behalf of any child-
 - (i) by either parent, or in the absence of both parents, the guardian or other adult who has care of the child,
 - (ii) by a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989, or
 - (iii) by a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act; or

[(b) on behalf of any adult who lacks the capacity to make such an application, or to authorise such an application to be made on their behalf, by a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005].

(5) A contractor which accepts an application for inclusion in its list of patients shall notify the Primary Care Trust in writing as soon as possible.

(6) On receipt of a notice under sub-paragraph (5), the Primary Care Trust shall-

- (a) include that person in the contractor's list of patients from the date on which the notice is received; and
- (b) notify the applicant (or, in the case of a child or [an adult who lacks capacity], the person making the application on their behalf) of the acceptance.

Temporary residents

16 - (1) The contractor may, if its list of patients is open, accept a person as a temporary resident provided it is satisfied that the person is-

- (a) temporarily resident away from his normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where he is temporarily residing; or

(b) moving from place to place and not for the time being resident in any place.

(2) For the purposes of sub-paragraph (1), a person shall be regarded as temporarily resident in a place if, when he arrives in that place, he intends to stay there for more than 24 hours but not more than three months.

(3) A contractor which wishes to terminate its responsibility for a person accepted as a temporary resident before the end of-

(a) three months; or

(b) such shorter period for which it agreed to accept him as a patient,

shall notify him either orally or in writing and its responsibility for that patient shall cease 7 days after the date on which the notification was given.

(4) At the end of three months, or on such earlier date as its responsibility for the temporary resident has come to an end, the contractor shall notify the Primary Care Trust in writing of any person whom it accepted as a temporary resident.

Refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident

17 – (1) The contractor shall only refuse an application made under paragraph 15 or 16 if it has reasonable grounds for doing so which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition.

(2) The reasonable grounds referred to in paragraph (1) shall, in the case of applications made under paragraph 15, include the ground that the applicant does not live in the contractor's practice area.

(3) A contractor which refuses an application made under paragraph 15 or 16 shall, within 14 days of its decision, notify the applicant (or, in the case of a child [an adult who lacks capacity], the person making the application on their behalf) in writing of the refusal and the reason for it.

(4) The contractor shall keep a written record of refusals of applications made under paragraph 15 and of the reasons for them and shall make this record available to the Primary Care Trust on request.

Patient preference of practitioner

18 - (1) Where the contractor has accepted an application for inclusion in its list of patients, it shall-

(a) notify the patient (or, in the case of a child or [an adult who lacks capacity], the person who made the application on their behalf) of the patient's right 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 contractor shall endeavour to comply with any reasonable 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.

Removal from the list at the request of the patient

19 - (1) The contractor shall notify the Primary Care Trust in writing of any request for removal from its list of patients received from a registered patient.

(2) Where the Primary Care Trust-

(a) receives notification from the contractor under sub-paragraph (1); or

(b) receives a request from the patient to be removed from the contractor's list of patients,

it shall remove that person from the contractor's list of patients.

- (3) A removal in accordance with sub-paragraph (2) shall take effect-
- (a) on the date on which the Primary Care Trust receives notification of the registration of the person with another provider of essential services (or their equivalent); or
 - (b) 14 days after the date on which the notification or request made under sub-paragraph (1) or (2) respectively is received by the Primary Care Trust,

whichever is the sooner.

- (4) The Primary Care Trust shall, as soon as practicable, notify in writing-
- (a) the patient; and
 - (b) the contractor,

that the patient's name will be or has been removed from the contractor's list of patients on the date referred to in sub-paragraph (3).

- (5) In this paragraph and in paragraphs 20(1)(b) and (10), 21(6) and (7), 23 and 26, a reference to a request received from or advice, information or notification required to be given to a patient shall include a request received from or advice, information or notification required to be given to-

- (a) in the case of a patient who is a child, a parent or other person referred to in paragraph 15(4)(a); or

[(b) in the case of an adult patient who lacks the capacity to make the relevant request or receive the relevant advice, information or notification, a relative of that person, the primary carer of that person, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005].

Removal from the list at the request of the contractor

20 - (1) Subject to paragraph 21, a contractor which has reasonable grounds for wishing a patient to be removed from its list of patients which do not relate to the [patient's] race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition shall-

- (a) notify the Primary Care Trust in writing that it wishes to have the patient removed; and
- (b) subject to sub-paragraph (2), notify the patient of its specific reasons for requesting removal.

(2) Where, in the reasonable opinion of the contractor-

- (a) the circumstances of the removal are such that it is not appropriate for a more specific reason to be given; and
- (b) there has been an irrevocable breakdown in the relationship between the patient and the contractor,

the reason given under sub-paragraph (1) may consist of a statement that there has been such a breakdown.

(3) Except in the circumstances specified in sub-paragraph (4), a contractor may only request a removal under sub-paragraph (1), if, within the period of 12 months prior to the date of its request to the Primary Care Trust, it has warned the patient that he is at risk of removal and explained to him the reasons for this.

(4) The circumstances referred to in sub-paragraph (3) are that-

- (a) the reason for removal relates to a change of address;
- (b) the contractor has reasonable grounds for believing that the issue of such a warning would-
 - (i) be harmful to the physical or mental health of the patient, or
 - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (5); or

(c) it is, in the opinion of the contractor, not otherwise reasonable or practical for a warning to be given.

(5) The persons referred to in sub-paragraph (4) are-

- (a) the contractor, where it is an individual medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, a partner in that partnership;
- (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;
- (d) a member of the contractor's staff;
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
- (f) any other person present-
 - (i) on the practice premises, or
 - (ii) in the place where services are being provided to the patient under the contract.

(6) The contractor shall record in writing-

- (a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the patient; or
- (b) the reason why no such warning was given.

(7) The contractor shall keep a written record of removals under this paragraph which shall include-

- (a) the reason for removal given to the patient;
- (b) the circumstances of the removal; and
- (c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate,

and shall make this record available to the Primary Care Trust on request.

(8) A removal requested in accordance with sub-paragraph (1) shall, subject to sub-paragraph (9), take effect from-

- (a) the date on which the Primary Care Trust receives notification of the registration of the person with another provider of essential services (or their equivalent); or
- (b) the eighth day after the Primary Care Trust receives the notice referred to in sub-paragraph (1)(a),

whichever is the sooner.

(9) Where, on the date on which the removal would take effect under sub-paragraph (8), the contractor is treating the patient at intervals of less than seven days, the contractor shall notify the Primary Care Trust in writing of the fact and the removal shall take effect-

- (a) on the eighth day after the Trust receives notification from the contractor that the person no longer needs such treatment; or
- (b) on the date on which the Primary Care Trust receives notification of the registration of the person with another provider of essential services (or their equivalent),

whichever is the sooner.

(10) The Primary Care Trust shall notify in writing-

- (a) the patient; and
- (b) the contractor,

that the patient's name has been or will be removed from the contractor's list of patients on the date referred to in sub-paragraph (8) or (9).

Removals from the list of patients who are violent

21 - (1) A contractor which wishes a patient to be removed from its list of patients with immediate effect on the grounds that-

- (a) the patient has committed an act of violence against any of the persons specified in sub-paragraph (2) or behaved in such a way that any such person has feared for his safety; and
- (b) it has reported the incident to the police,

shall notify the Primary Care Trust in accordance with sub-paragraph (3).

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

- (a) the contractor where it is an individual medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, a partner in that partnership;
- (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;
- (d) a member of the contractor's staff;
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
- (f) any other person present-
 - (i) on the practice premises, or
 - (ii) in the place where services were provided to the patient under the contract.

(3) Notification under sub-paragraph (1) may be given by any means including telephone or fax but if not given in writing shall subsequently be confirmed in writing within seven days (and for this purpose a faxed notification is not a written one).

(4) The Primary Care Trust shall acknowledge in writing receipt of a request from the contractor under sub-paragraph (1).

(5) A removal requested in accordance with sub-paragraph (1) shall take effect at the time that the contractor-

- (a) makes the telephone call to the Primary Care Trust; or
- (b) sends or delivers the notification to the Primary Care Trust.

(6) Where, pursuant to this paragraph, the contractor has notified the Primary Care Trust that it wishes to have a patient removed from its list of patients, it shall inform the patient concerned unless-

- (a) it is not reasonably practicable for it to do so; or
- (b) it has reasonable grounds for believing that to do so would-
 - (i) be harmful to the physical or mental health of the patient, or
 - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (2) .

(7) Where the Primary Care Trust has removed a patient from the contractor's list of patients in accordance with sub-paragraph (5) it shall give written notice of the removal to that patient.

(8) Where a patient is removed from the contractor's list of patients in accordance with this paragraph, the contractor shall record in the patient's medical records that the patient has been removed under this paragraph and the circumstances leading to his removal.

Removals from the list of patients registered elsewhere

- 22** - (1) The Primary Care Trust shall remove a patient from the contractor's list of patients if-
- (a) he has subsequently been registered with another provider of essential services (or their equivalent) in the area of the Primary Care Trust; or
 - (b) it has received notice from another Primary Care Trust, a Local Health Board, a Health Board or a Health and Social Services Board that he has subsequently been registered with a provider of essential services (or their equivalent) outside the area of the Primary Care Trust.
- (2) A removal in accordance with sub-paragraph (1) shall take effect-
- (a) on the date on which the Primary Care Trust receives notification of the registration of the person with the new provider; or
 - (b) with the consent of the Primary Care Trust, on such other date as has been agreed between the contractor and the new provider.
- (3) The Primary Care Trust shall notify the contractor in writing of persons removed from its list of patients under sub-paragraph (1).

Removals from the list of patients who have moved

- 23** - (1) Subject to sub-paragraph (2), where the Primary Care Trust is satisfied that a person on the contractor's list of patients has moved and no longer resides in that contractor's practice area, the Primary Care Trust shall-
- (a) inform that patient and the contractor that the contractor is no longer obliged to visit and treat the person;
 - (b) advise the patient in writing either to obtain the contractor's agreement to the continued inclusion of the person on its list of patients or to apply for registration with another provider of essential services (or their equivalent); and
 - (c) inform the patient that if, after the expiration of 30 days from the date of the advice mentioned in paragraph (b), he has not acted in accordance with the advice and informed it accordingly, the Primary Care Trust will remove him from the contractor's list of patients.
- (2) If, at the expiration of the period of 30 days referred to in sub-paragraph (1)(c), the Primary Care Trust has not been notified of the action taken, it shall remove the patient from the contractor's list of patients and inform him and the contractor accordingly.

24 - Where the address of a patient who is on the contractor's list of patients is no longer known to the Primary Care Trust, the Primary Care Trust shall-

- (a) give to the contractor notice in writing that it intends, at the end of the period of six months commencing with the date of the notice, to remove the patient from the contractor's list of patients; and
- (b) at the end of that period, remove the patient from the contractor's list of patients unless, within that period, the contractor satisfies the Primary Care Trust that it is still responsible for providing essential services to that patient.

Removals from the list of patients absent from the United Kingdom etc

- 25** - (1) The Primary Care Trust shall remove a patient from the contractor's list of patients where it receives notification that that patient-
- (a) intends to be away from the United Kingdom for a period of at least three months;
 - (b) is in Her Majesty's Forces;
 - (c) is serving a prison sentence of more than two years or sentences totalling in the aggregate more than that period;
 - (d) has been absent from the United Kingdom for a period of more than three months; or

- (e) has died.
- (2) A removal in accordance with sub-paragraph (1) shall take effect-
 - (a) in the cases referred to in sub-paragraph (1)(a) to (c) from the date of the departure, enlistment or imprisonment or the date on which the Primary Care Trust first receives notification of the departure, enlistment or imprisonment whichever is the later; or
 - (b) in the cases referred to in sub-paragraph (1)(d) and (e) from the date on which the Primary Care Trust first receives notification of the absence or death.
- (3) The Primary Care Trust shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

Removals from the list of patients accepted elsewhere as temporary residents

- 26 - (1)** The Primary Care Trust shall remove from the contractor's list of patients a patient who has been accepted as a temporary resident by another contractor or other provider of essential services (or their equivalent) where it is satisfied, after due inquiry-
- (a) that the patient's stay in the place of temporary residence has exceeded three months; and
 - (b) that he has not returned to his normal place of residence or any other place within the contractor's practice area.
- (2) The Primary Care Trust shall notify in writing of a removal under sub-paragraph (1)-
- (a) the contractor; and
 - (b) where practicable, the patient.
- (3) A notification to the patient under sub-paragraph (2)(b) shall inform him of-
- (a) his entitlement to make arrangements for the provision to him of essential services (or their equivalent), including by the contractor by which he has been treated as a temporary resident; and
 - (b) the name and address of the Primary Care Trust in whose area he is resident.

Removals from the list of pupils etc of a school

- 27 - (1)** Where the contractor provides essential services under the contract to persons on the grounds that they are pupils at or staff or residents of a school, the Primary Care Trust shall remove from the contractor's list of patients any such persons who do not appear on particulars of persons who are pupils at or staff or residents of that school provided by that school.
- (2) Where the Primary Care Trust has made a request to a school to provide the particulars mentioned in sub-paragraph (1) and has not received them, it shall consult the contractor as to whether it should remove from its list of patients any persons appearing on that list as pupils at, or staff or residents of, that school.
- (3) The Primary Care Trust shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

Termination of responsibility for patients not registered with the contractor

- 28 - (1)** Where a contractor-
- (a) has received an application for the provision of medical services other than essential services-
 - (i) from a person who is not included in its list of patients,
 - (ii) from a person whom it has not accepted as a temporary resident, or
 - (iii) on behalf of a person mentioned in sub-paragraph (i) or (ii), from one of the persons specified in paragraph 15(4); and

(b) has accepted that person as a patient for the provision of the service in question, its responsibility for that patient shall be terminated in the circumstances referred to in sub-paragraph (2).

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

(a) the patient informs the contractor that he no longer wishes it to be responsible for provision of the service in question;

(b) in cases where the contractor has reasonable grounds for terminating its responsibility which do not relate to the person's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition, the contractor informs the patient that it no longer wishes to be responsible for providing him with the service in question; or

(c) it comes to the notice of the contractor that the patient-

(i) no longer resides in the area for which the contractor has agreed to provide the service in question, or

(ii) is no longer included in the list of patients of another contractor to whose registered patients the contractor has agreed to provide that service.

(3) A contractor which wishes to terminate its responsibility for a patient under sub-paragraph (2)(b) shall notify the patient of the termination and the reason for it.

(4) The contractor shall keep a written record of terminations under this paragraph and of the reasons for them and shall make this record available to the Primary Care Trust on request.

(5) A termination under sub-paragraph (2)(b) shall take effect-

(a) from the date on which the notice is given where the grounds for termination are those specified in paragraph 21(1); or

(b) in all other cases, 14 days from the date on which the notice is given.

Closure of lists of patients

29 - (1) A contractor which wishes to close its list of patients shall notify the Primary Care Trust in writing to that effect.

(2) Within a period of 7 days beginning with the date of receipt of the notification referred to in sub-paragraph (1), or, if that is not reasonably practicable, as soon as is practicable thereafter, the Primary Care Trust shall enter into discussions with the contractor concerning the support which the Primary Care Trust may give the contractor, or other changes which the Primary Care Trust or the contractor may make, which would enable the contractor to keep its list of patients open.

(3) In the discussions referred to in sub-paragraph (2), both parties shall use reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.

(4) The discussions mentioned in sub-paragraph (2) shall be completed within a period of 28 days beginning with the date of the Primary Care Trust's receipt of the notification referred to in sub-paragraph (1), or within such longer period as the parties may agree.

(5) If, following the discussions mentioned in sub-paragraph (2), the Primary Care Trust and the contractor reach agreement that the contractor's list of patients should remain open, the Primary Care Trust shall send full details of the agreement in writing to the contractor.

(6) The Primary Care Trust and the contractor shall comply with the terms of an agreement reached as mentioned in sub-paragraph (5).

(7) If, following the discussions mentioned in sub-paragraph (2)-

(a) the Primary Care Trust and the contractor reach agreement that the contractor's list of patients should close; or

(b) the Primary Care Trust and the contractor fail to reach agreement and the contractor still wishes to close its list of patients,

the contractor shall send a closure notice to the Primary Care Trust.

(8) A closure notice shall be submitted in the form specified in Schedule 8, and shall include the following details which (in a case falling within sub-paragraph (7)(a)) have been agreed between the parties or (in a case falling within sub-paragraph (7)(b)) are proposed by the contractor-

- (a) the period of time (which may not exceed 12 months) for which the contractor's list of patients will be closed;
- (b) the current number of the contractor's registered patients;
- (c) the number of registered patients (lower than the current number of such patients, and expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-opening of the contractor's list of patients;
- (d) the number of registered patients (expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-closure of the contractor's list of patients; and
- (e) any withdrawal from or reduction in provision of any additional or enhanced services which had previously been provided under the contract.

(9) The Primary Care Trust shall forthwith acknowledge receipt of the closure notice in writing to the contractor.

(10) Before the Primary Care Trust reaches a decision as to whether to approve or reject the closure notice under sub-paragraph (12), the Primary Care Trust and the contractor may enter into further discussions concerning the details of the closure notice referred to in sub-paragraph (8), with a view to reaching agreement; and, in particular, if the parties are unable to reach agreement regarding the period of time for which the contractor's list of patients will be closed, that period shall be 12 months.

(11) A contractor may not withdraw a closure notice for a period of three months beginning with the date on which the Primary Care Trust has received the notice, unless the Primary Care Trust has agreed otherwise in writing.

(12) Within a period of 14 days beginning with the date of receipt of the closure notice, the Primary Care Trust shall-

- (a) approve the closure notice; or
- (b) reject the closure notice,

and shall notify the contractor of its decision in writing as soon as possible.

(13) Approval of the closure notice under sub-paragraph (12)(a) includes approval of the details specified in accordance with sub-paragraph (8) (or, where those details are revised following discussions under sub-paragraph (10), approval of those details as so revised).

Approval of closure notice by the Primary Care Trust

30 - (1) If the Primary Care Trust approves the closure notice in accordance with paragraph 29(12)(a), the contractor shall close its list of patients-

- (a) with effect from a date agreed between the Primary Care Trust and the contractor; or
- (b) if no such agreement has been reached, with effect from the date on which the contractor receives notification of the Primary Care Trust's decision to approve the closure notice.

(2) Subject to sub-paragraph (3), the contractor's list of patients shall remain closed for the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where the period of 12 months specified in paragraph 29(10) applies, for that period).

(3) The contractor's list of patients shall re-open before the expiry of the period mentioned in sub-paragraph (2) if-

- (a) the number of the contractor's registered patients falls to the number specified in the closure notice in accordance with paragraph 29(8)(c); or
- (b) the Primary Care Trust and the contractor agree that the list of patients should re-open.

(4) If the contractor's list of patients has re-opened pursuant to sub-paragraph (3)(a), it shall nevertheless close again if, during the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where the period of 12 months specified in paragraph 29(10) applies, during that period) the number of the contractor's registered patients rises to the number specified in the closure notice in accordance with paragraph 29(8)(d).

(5) Except in cases where the contractor's list of patients is already open pursuant to sub-paragraph (3), the Primary Care Trust shall notify the contractor in writing between seven and fourteen days before the expiry of the period of closure specified in sub-paragraph (2), confirming the date on which the contractor's list of patients will re-open.

(6) Where the details specified in the closure notice in accordance with paragraph 29(8) have been revised following discussions under paragraph 29(10), references in this paragraph to details specified in the closure notice are references to those details as so revised.

Rejection of closure notice by the Primary Care Trust

31 - (1) This regulation applies where the Primary Care Trust rejects the closure notice in accordance with paragraph 29(12)(b).

(2) The contractor and the Primary Care Trust may not refer the matter for determination in accordance with the NHS dispute resolution procedure (or, where applicable, commence court proceedings) until the assessment panel has given its determination in accordance with the following sub-paragraphs.

(3) The Primary Care Trust must ensure that the assessment panel is appointed as soon as is practicable to consider and determine whether the contractor should be permitted to close its list of patients, and if so, the terms on which it should be permitted to do so.

(4) The Primary Care Trust shall provide the assessment panel with such information as the assessment panel may reasonably require to enable it to reach a determination and shall include in such information any written observations received from the contractor.

(5) The members of the assessment panel shall be-

- (a) the Chief Executive of the Primary Care Trust of which the assessment panel is a committee or sub-committee;
- (b) a person representative of patients in an area other than that of the Primary Care Trust which is a party to the contract; and
- (c) a person representative of a Local Medical Committee which does not represent practitioners in the area of the Primary Care Trust which is a party to the contract.

(6) At least one member of the assessment panel shall visit the contractor before reaching a determination under sub-paragraph (7).

(7) Within the period of 28 days beginning with the date on which the Primary Care Trust rejected the closure notice, the assessment panel shall-

- (a) approve the list closure; or
- (b) reject the list closure,

and shall notify the Primary Care Trust and the contractor of its determination in writing as soon as possible.

(8) Where the assessment panel determines in accordance with sub-paragraph (7)(a) that the contractor's list of patients should close, it shall specify-

- (a) a date from which the closure shall take effect, which must be within a period of 7 days beginning with the date of the assessment panel's determination; and
- (b) those details specified in paragraph 29(8).

[(8A) Subject to sub-paragraph (8B), the contractor's list of patients shall remain closed for the period specified by the assessment panel in accordance with sub-paragraph (8)(b).

(8B) The contractor's list of patients shall re-open before the expiry of the period mentioned in sub-paragraph (8A) if-

- (a) the number of the contractor's registered patients falls to the number specified by the assessment panel in accordance with sub-paragraph (8)(b) as the number of registered patients which, if that number were reached, would trigger the re-opening of the contractor's list of patients; or
- (b) the Primary Care Trust and the contractor agree that the list of patients should re-open.

(8C) If the contractor's list of patients has re-opened pursuant to sub-paragraph (8B)(a), it shall nevertheless close again if, during the period specified by the assessment panel as the period for which the list should remain closed, the number of the contractor's registered patients rises to the number specified by the assessment panel in accordance with sub-paragraph (8)(b) as the number of registered patients which, if that number were reached, would trigger the re-closure of the contractor's list of patients.

(8D) Except in cases where the contractor's list of patients is already open pursuant to paragraph (8B), the Primary Care Trust shall notify the contractor in writing between seven and fourteen days before the expiry of the closure period specified in paragraph (8A), confirming the date on which the contractor's list of patients will re-open.]

(9) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, that list shall remain open, and the Primary Care Trust and the contractor shall enter into discussions with a view to ensuring that the contractor receives support from the Primary Care Trust which will enable it to continue to provide services safely and effectively.

(10) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, the contractor may not submit a further closure notice as described in paragraph 29 until-

- (a) the expiry of a period of three months beginning with the date of the assessment panel's determination; or
- (b) (if applicable) the final determination of the NHS dispute resolution procedure (or any court proceedings),

whichever is the later, unless there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

Assignment of patients to lists: open lists

32 - (1) A Primary Care Trust may, subject to paragraph 34, assign a new patient to a contractor whose list of patients is open.

- (2) In this paragraph and in paragraphs 33 and 35 to 37, a "new" patient means a person who-
 - (a) is resident (whether or not temporarily) within the area of the Primary Care Trust;
 - (b) has been refused inclusion in a list of patients of, or has not been accepted as a temporary resident by, a contractor whose premises are within such an area; and
 - (c) wishes to be included in the list of patients of a contractor whose practice premises are within that area.

Assignment of patients to lists: closed lists

33 - (1) A Primary Care Trust may not assign a new patient to a contractor which has closed its list of patients except in the circumstances specified in sub-paragraph (2).

(2) A Primary Care Trust may, subject to paragraph 34, assign a new patient to a contractor whose practice premises are within the Primary Care Trust's area and which has closed its list of patients, if-

- (a) most or all of the providers of essential services (or their equivalent) whose practice premises are within the Primary Care Trust's area have closed their lists of patients;
- (b) the assessment panel has determined under paragraph 35(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Secretary of State under paragraph 36(13) or (where applicable) by a court; and
- (c) the Primary Care Trust has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 37.

Factors relevant to assignments

34 - In making an assignment to a contractor under paragraph 32 or 33, the Primary Care Trust shall have regard to-

- (a) the wishes and circumstances of the patient to be assigned;
- (b) the distance between the patient's place of residence and the contractor's practice premises;
- (c) whether, during the six months ending on the date on which the application for assignment is received by the Primary Care Trust, the patient's name has been removed from the list of patients of any contractor in the area of the Primary Care Trust under paragraph 20 or its equivalent provision in relation to a section 28C provider in the area of the Primary Care Trust;
- (d) whether the patient's name has been removed from the list of patients of any contractor in the area of the Primary Care Trust under paragraph 21 or its equivalent provision in relation to a section 28C provider in the area of the Primary Care Trust and, if so, whether the contractor has appropriate facilities to deal with such a patient;
- (e) such other matters as the Primary Care Trust considers to be relevant.

Assignments to closed lists: determinations of the assessment panel

35 - (1) This paragraph applies where most or all of the providers of essential services (or their equivalent) whose practice premises are within the area of a Primary Care Trust have closed their lists of patients.

(2) If the Primary Care Trust wishes to assign new patients to contractors which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel which must include details of those contractors to which the Primary Care Trust wishes to assign patients.

(3) The Primary Care Trust must ensure that the assessment panel is appointed to consider and determine its proposal made under sub-paragraph (2), and the composition of the assessment panel shall be as described in paragraph 31(5).

(4) The Primary Care Trust shall notify in writing-

- (a) the relevant Strategic Health Authority;
- (b) contractors or section 28C providers whose practice premises are within the Primary Care Trust's area which-
 - (i) have closed their list of patients, and
 - (ii) may, in the opinion of the Primary Care Trust, be affected by the determination of the assessment panel; and
- (c) the Local Medical Committee (if any) for the area of the Primary Care Trust,

that it has referred the matter to the assessment panel.

- (5) In reaching its determination, the assessment panel shall have regard to relevant factors including-
 - (a) whether the Primary Care Trust has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of their assignment to contractors with closed lists of patients; and
 - (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.
- (6) The assessment panel shall reach a determination within the period of 28 days beginning with the date on which the panel was appointed.
- (7) The assessment panel shall determine whether the Primary Care Trust may assign patients to contractors which have closed their lists of patients; and if it determines that the Primary Care Trust may make such assignments, it shall also determine those contractors to which patients may be assigned.
- (8) The assessment panel may determine that the Primary Care Trust may assign patients to contractors other than those contractors specified by the Primary Care Trust in its proposal under sub-paragraph (2), as long as the contractors were notified under sub-paragraph (4)(b).
- (9) The assessment panel's determination shall include its comments on the matters specified in sub-paragraph (5), and shall be notified in writing to-
 - (a) the relevant Strategic Health Authority; and
 - (b) those contractors which were notified under sub-paragraph (4)(b).

Assignments to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel

- 36 - (1)** Where an assessment panel makes a determination under paragraph 35(7) that the Primary Care Trust may assign new patients to contractors which have closed their lists of patients, any contractor specified in that determination may refer the matter to the Secretary of State to review the determination of the assessment panel.
- (2) Where a matter is referred to the Secretary of State in accordance with sub-paragraph (1), it shall be reviewed in accordance with the procedure specified in the following sub-paragraphs.
 - (3) Where more than one contractor specified in the determination in accordance with paragraph 35(7) wishes to refer the matter for dispute resolution, those contractors may, if they all agree, refer the matter jointly, and in that case the Secretary of State shall review the matter in relation to those contractors together.
 - (4) Within the period of 7 days beginning with the date of the determination by the assessment panel in accordance with paragraph 35(7), the contractor (or contractors) shall send to the Secretary of State 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 contract (or contracts); and
 - (c) a brief statement describing the nature and circumstances of the dispute.
 - (5) Within the period of 7 days beginning with the date on which the matter was referred to him, the Secretary of State shall-
 - (a) give to the parties notice in writing that he is dealing with the matter; and
 - (b) include with the notice a written request to the parties to make in writing within a specified period any representations which they may wish to make about the dispute.

(6) The Secretary of State shall give, with the notice given under sub-paragraph (5), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the dispute was referred to dispute resolution.

(7) The Secretary of State shall, upon receiving any representations from a party, give a copy of them to the other party, and shall in each case request (in writing) a party to which a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(8) For the purpose of assisting it in its consideration of the matter, the Secretary of State may-

(a) invite representatives of the parties to appear before him 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 he wishes them to give special consideration; or

(b) consult other persons whose expertise he considers will assist him in his consideration of the dispute.

(9) Where the Secretary of State consults another person under sub-paragraph (8)(b), he shall notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he shall give to the parties such opportunity as he considers reasonable in the circumstances to make observations on those results.

(10) In considering the dispute, the Secretary of State shall consider-

(a) any written representations made in response to a request under sub-paragraph (5)(b), but only if they are made within the specified period;

(b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within the specified period;

(c) any oral representations made in response to an invitation under sub-paragraph (8)(a);

(d) the results of any consultation under sub-paragraph (8)(b); and

(e) any observations made in accordance with an opportunity given under sub-paragraph (9).

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

(12) In this paragraph, "specified period" means such period as the Secretary of State shall specify in the request, being not less than one, nor more than two, weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if the period for determination of the dispute has been extended in accordance with sub-paragraph (16), extend any such period (even after it has expired) and, where he does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to sub-paragraph (16), within the period of 21 days beginning with the date on which the matter was referred to him, the Secretary of State shall determine whether the Primary Care Trust may assign patients to contractors which have closed their lists of patients; and if he determines that the Primary Care Trust may make such assignments, he shall also determine those contractors to which patients may be assigned.

(14) The Secretary of State may not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 35(7).

(15) In the case of a matter referred jointly by contractors in accordance with sub-paragraph (3), the Secretary of State may determine that patients may be assigned to one, some or all of the contractors which referred the matter.

(16) The period of 21 days referred to in sub-paragraph (13) may be extended (even after it has expired) by a further specified number of days if an agreement to that effect is reached by-

- (a) the Secretary of State;
- (b) the Primary Care Trust; and
- (c) the contractor (or contractors) which referred the matter to dispute resolution.

(17) The Secretary of State shall record his determination, and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties.

Assignments to closed lists: assignments of patients by a Primary Care Trust

37 - (1) Before the Primary Care Trust may assign a new patient to a contractor, it shall, subject to sub-paragraph (3), enter into discussions with that contractor regarding additional support that the Primary Care Trust can offer the contractor, and the Primary Care Trust shall use its best endeavours to provide appropriate support.

(2) In the discussions referred to in sub-paragraph (1), both parties shall use reasonable endeavours to reach agreement.

(3) The requirement in sub-paragraph (1) to enter into discussions applies-

- (a) to the first assignment of a patient to a particular contractor; and
- (b) to any subsequent assignment to that contractor to the extent that it is reasonable and appropriate having regard to the numbers of patients who have been or may be assigned to it and the period of time since the last discussions under sub-paragraph (1) took place.

Part 3

Prescribing and Dispensing

Prescribing

[38 - The contractor shall ensure that-

- (a) any prescription form or repeatable prescription for drugs, medicines or appliances issued or created by a prescriber; [NB: Word deleted by SI 2009/2230] . . .
- (b) any home oxygen order form issued by a health care [professional, and]
- [(c) any listed medicines voucher issued by a prescriber or any other person acting under the contract,]

complies as appropriate with the requirements in paragraphs 39, 39A and 41 to 44.]

39 - (1) Subject to [sub-paragraph (1A) [and (1B)] and to] paragraphs 42 and 43, a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract [by-

(a) issuing to that patient a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3); or

(b) where paragraph 39A(1) applies, creating and transmitting an electronic prescription,

and such a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription shall not be used in any other circumstances].

[(1A) A health care professional shall order any home oxygen services which are needed for the treatment of any patient who is receiving treatment under the contract by issuing a home oxygen order form.]

[(1B) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if-

- (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge; and
- (b) that listed medicine is needed for treatment or prophylaxis of any patient who is receiving treatment under the contract,

a prescriber may, or if the patient has not attained the age of 13 years must, order that listed medicine by using a listed medicines voucher, which the prescriber must sign.

(1C) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if-

- (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge;
- (b) those arrangements contain criteria set out in a protocol which enable persons who are not prescribers to identify the symptoms of, and whether there is a need for treatment or prophylaxis of, that disease;
- (c) a person acting on behalf of the contractor, who is not a prescriber but who is authorised to order listed medicines by the Primary Care Trust, has applied the criteria referred to in paragraph (b) to any patient who is receiving treatment under the contract; and
- (d) having applied the criteria, the person acting on behalf of the contractor has concluded that the listed medicine is needed for treatment or prophylaxis of that patient,

the person acting on behalf of the contractor must order that listed medicine by using a listed medicines voucher, which the person ordering the listed medicine must sign.]

(2) A prescriber may order drugs, medicines or appliances on a repeatable prescription only where the drugs, medicines or appliances are to be provided more than once.

(3) In issuing any [non-electronic] prescription form or [non-electronic] repeatable prescription the prescriber shall himself sign the prescription form or repeatable prescription in ink with his initials, or forenames, and surname in his 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 or repeatable prescription, [NB: Words deleted by SI 2005/893] . . .

[(3A) A prescription form or repeatable prescription shall not refer to any previous prescription form or repeatable prescription.

(3B) A separate prescription form or repeatable prescription shall be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 44.]

[(3C) A home oxygen order form shall be signed by a health care professional.]

(4) Where a prescriber orders the drug buprenorphine [or diazepam] or a drug specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, he shall-

- (a) use only the [non-electronic] prescription form provided specially for the purposes of supply by instalments;
- (a) specify the number of instalments to be dispensed and the interval between each instalment; and
- (c) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.

(5) The [non-electronic] prescription form provided specially for the purpose of supply by instalments shall not be used for any purpose other than ordering drugs in accordance with sub-paragraph (4).

(6) In a case of urgency a prescriber may request a chemist to dispense a drug or medicine before a prescription form or repeatable prescription is issued [or created], 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, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001; and

[(c) he undertakes to-

- (i) furnish the chemist within 72 hours with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3), or
- (ii) transmit to the ETP service within 72 hours an electronic prescription].

(7) In a case of urgency a prescriber may request a chemist to dispense an appliance before a prescription form or repeatable prescription is issued [or created] 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) he undertakes to-

- (i) furnish the chemist within 72 hours with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (3), or
- (ii) transmit to the ETP service within 72 hours an electronic prescription].

[Electronic prescriptions

39A - (1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if-

(a) the contractor holds a contract with a Primary Care Trust which is specified in directions issued by the Secretary of State under section 17 of the Act as being a Primary Care Trust which can authorise its contractors to use the ETP service;

(b) the patient to whom the prescription relates has-

- (i) nominated one or more dispensers in his NHS Care Record,
- (ii) confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription in question, and
- (iii) consents to the use of an electronic prescription on the particular occasion; and

(c) the prescription is not-

- (i) for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,
- (ii) for supply by instalments under paragraph 39(4), or
- (iii) a bulk prescription issued for a school or institution under paragraph 44.

[(1A) A health care professional may not order home oxygen services by means of an electronic prescription.]

(2) In relation to a patient who is a child or [an adult who lacks the capacity to nominate a dispenser], sub-paragraph (1)(b) shall apply as if the reference to the patient to whom the prescription relates included a reference to-

- (a) in the case of a child, that patient's parent or other person referred to in paragraph 15(4)(a); or
- [(b) in the case of an adult, that patient's relative, primary carer, a donee of a lasting power of attorney granted by that person or a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005].

(3) A prescriber who orders drugs, medicines or appliances by means of an electronic prescription shall-

- (a) in the case of an electronic repeatable prescription, issue the patient with a form provided by the Primary Care Trust for the purpose of recording details of that electronic repeatable prescription and linked to that electronic repeatable prescription by a number contained on the form; and
- (b) in the case of an electronic prescription form, issue the patient, if he so requests, with a written record of the prescription which has been created.

Nomination of dispensers for the purpose of electronic prescriptions

39B - (1) A contractor which operates the ETP service for its patients shall, if requested to do so by a patient, enter in that patient's NHS Care Record-

- (a) where he does not have a nominated dispenser, the dispenser chosen by that patient; and
- (b) where he does have a nominated dispenser-
 - (i) a replacement dispenser, or
 - (ii) a further dispenser,chosen by that patient.

(2) Sub-paragraph (1)(b)(ii) shall not apply if the number of nominated dispensers would thereby exceed the maximum number permitted by the ETP service.

(3) Paragraph 15(4) shall apply in relation to requests under sub-paragraph (1) as it applies to applications for inclusion in a list of patients.

(4) A contractor-

- (a) shall not seek to persuade a patient to nominate a dispenser recommended by the prescriber or the contractor; and
- (b) shall, if asked by the patient to recommend a chemist whom he might nominate as his dispenser, provide the patient with the list of all the chemists in the area who provide an ETP service as given to the contractor by the Primary Care Trust.]

Repeatable prescribing services

40 - (1) The contractor may only provide repeatable prescribing services to any person on its list of patients if it-

- (a) satisfies the conditions in sub-paragraph (2); and
 - (b) has notified the Primary Care Trust of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).
- (2) The conditions referred to in sub-paragraph (1)(a) are-
- (a) . . . [NB: Words deleted by SI 2005/893]
 - (b) the contractor has access to computer systems and software which enable it to issue [non-electronic] repeatable prescriptions and batch issues; and
 - (c) the practice premises at which the repeatable prescribing services are to be provided are located in an area of the Primary Care Trust in which there is also located the premises of at least one chemist

who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

- (3) The notification referred to in sub-paragraph (1)(b) is a notification, in writing, by the contractor to the Primary Care Trust that it-
- (a) wishes to provide repeatable prescribing services; and
 - (b) intends to begin to provide those services from a specified date; and
 - (c) satisfies the conditions in paragraph (2).
- (4) The date specified by the contractor pursuant to sub-paragraph (3)(b) must be at least ten days after the date on which the notification specified in sub-paragraph (1) is given.
- (5) Nothing in this paragraph requires a contractor or prescriber to provide repeatable prescribing services to any person.
- (6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if-
- (a) that person has agreed to receive such services on that occasion; and
 - (b) the prescriber considers that it is clinically appropriate to provide such services to that person on that occasion.
- (7) The contractor may not provide repeatable prescribing services to any patient of its to whom-
- (a) it is authorised or required by the Primary Care Trust to provide dispensing services under paragraph 47 or 49; or
 - (b) any of the persons specified in sub-paragraph (8) is authorised or required by the Primary Care Trust under [regulation 60] of the Pharmaceutical Regulations to provide pharmaceutical services.
- (8) The persons referred to in sub-paragraph (7) are-
- (a) in the case of a contract with an individual medical practitioner, that medical practitioner;
 - (b) in the case of a contract with two or more individuals practising in partnership, any medical practitioner who is a partner;
 - (c) in the case of a contract with a company, any medical practitioner who is a legal and beneficial shareholder in that company; or
 - (d) any medical practitioner employed by the contractor.

Repeatable prescriptions

41 - (1) A prescriber who issues a [non-electronic] repeatable prescription must at the same time issue the appropriate number of batch issues.

[(2) Where a prescriber wishes to make any change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription he must-

- (a) in the case of a non-electronic repeatable prescription-
 - (i) notify the person, and
 - (ii) make reasonable efforts to notify the chemist providing repeat dispensing services to that person,

that the original repeatable prescription should no longer be used to obtain or provide repeat dispensing services and make arrangements for a replacement repeatable prescription to be issued to that person; or

- (b) in the case of an electronic repeatable prescription-

- (i) arrange with the ETP service for the cancellation of the original repeatable prescription in the person's NHS Care Record, and
 - (ii) create a replacement electronic repeatable prescription relating to that person and notify him that he has done so.
- (3) A prescriber who has created an electronic repeatable prescription for a person must as soon as practicable arrange with the ETP service for its cancellation in that person's NHS Care Record if, before the expiry of that prescription-
 - (a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his electronic repeatable prescription or no longer appropriate or safe for him to continue to receive repeatable prescribing services;
 - (b) he has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription; or
 - (c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.
- (4) Where a prescriber has cancelled a person's electronic repeatable prescription in accordance with sub-paragraph (3) he must, as soon as is practicable, notify that person.
- (5) A prescriber who has issued a non-electronic repeatable prescription in respect of a person must, as soon as practicable, make reasonable efforts to notify the chemist that that repeatable prescription should no longer be used to provide repeat dispensing services to that person, if, before the expiry of that repeatable prescription-
 - (a) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his repeatable prescription or no longer appropriate or safe for him to continue to receive repeatable prescribing services;
 - (b) he issues or creates a further repeatable prescription in respect of the person to replace the original repeatable prescription other than in the circumstances referred to in sub-paragraph (2)(a) (for example, because the person wishes to obtain the drugs, medicines or appliances from a different chemist); or
 - (c) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.
- (6) Where the circumstances in sub-paragraph (5)(a) to (c) apply, the prescriber must as soon as practicable notify the person on whose behalf the non-electronic repeatable prescription was issued that that repeatable prescription should no longer be used to obtain repeat dispensing services.]

Restrictions on prescribing by medical practitioners

42 - (1) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on [a listed medicines voucher,] a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Secretary of State under section 28U of the Act (GMS contracts: prescription of drugs etc) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract but may, subject to regulation 24(2)(b), 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 he is providing treatment under the contract, a medical practitioner shall not order on [a listed medicines voucher,] a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Secretary of State under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless-

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

(b) that drug, medicine or other substance is prescribed for that patient only for the specified purpose; and

[(c) if the order is on a prescription form, the practitioner includes-

(i) the reference "SLS", or

(ii) if the order is under arrangements made by the Secretary of State or the Primary Care Trust for the distribution of a listed medicine free of charge, the reference "ACP";]

but may, subject to regulation 24(2)(b), 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 he is providing treatment under the contract, a medical practitioner shall not order on a prescription form or repeatable prescription 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 [includes on the prescription form] the reference "SLS",

but may, subject to regulation 24(2)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

(4) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a repeatable prescription a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, but may, subject to regulation 24(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

43 - (1) The contractor shall have arrangements in place to secure that a supplementary prescriber will-

(a) [issue or create] a prescription for a prescription only medicine;

(b) administer a prescription only medicine for parenteral administration; or

(c) give directions for the administration of a prescription only medicine for parenteral administration,

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

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

(a) the person satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;

(b) . . . [NB: Words deleted by SI 2005/893]

(c) the drug, medicine or other substance is not specified in any directions given by the Secretary of State under section 28U of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(d) the drug, medicine or other substance is not specified in any directions given by the Secretary of State under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes 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 [issuing or creating a] [prescription on a prescription form, the prescriber includes on the form the reference "SLS" or, in the case of a listed medicine ordered under arrangements made by the Secretary of State or the Primary Care Trust for the medicine's distribution free of charge, the reference "ACP"].

(3) Where the functions of supplementary prescriber include prescribing, the contractor shall have arrangements in place to secure that that person will only [issue or create] a prescription for-

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

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 he 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,
 - (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) he 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) . . . [NB: Words deleted by SI 2005/893]

(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 Secretary of State under section 28U of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the 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 Secretary of State under section 28U of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes 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 [issuing or creating the prescription, he includes on the prescription form] the reference "SLS";

(f) . . .

- (g) if it is a prescription for an appliance, the appliance is listed in Part IX 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 IX 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 [issuing or creating the prescription, he includes on the prescription form] the reference "SLS".
- (5) In sub-paragraph (4)(a), "clinical management plan" means a written 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) . . . [NB: Words deleted by SI 2005/893]

Bulk prescribing

44 - (1) Where-

- (a) a contractor is responsible under the contract for the treatment of 10 or more persons in a school or other institution in which at least 20 persons normally reside; and
- (b) a prescriber orders, for any two or more of those persons for whose treatment the contractor is responsible, drugs, medicines or appliances to which this paragraph applies,

the prescriber may use a single [non-electronic] prescription form for the purpose.

(2) Where a prescriber uses a single [non-electronic] prescription form for the purpose mentioned in sub-paragraph (1)(b), he shall (instead of entering on the form the names of the persons for whom the drugs, medicines or appliances are ordered) enter on the form-

- (a) the name of the school or institution in which those persons reside; and
- (b) the number of persons residing there for whose treatment the contractor is responsible.

(3) This paragraph applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which-

- (a) in the case of a drug or medicine, is not a product of a description or class which is for the time being specified in an order made under section 58(1) of the Medicines Act 1968 (medicinal products on prescription only); or
- (b) in the case of an appliance, does not contain such a product.

Interpretation of paragraphs 38, 39 and 41 to 44

45 - For the purposes of paragraphs 38, 39 and 41 to 44 in their application to a contractor whose contract includes the provision of contraceptive services, drugs includes contraceptive substances and appliances includes contraceptive appliances.

Excessive prescribing

46 - (1) The contractor 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 contractor has breached its obligations under sub-paragraph (1) the Primary Care Trust shall seek the views of the Local Medical Committee (if any) for its area.

[Provision of dispensing services

47 - (1) Without prejudice to any separate right one or more medical practitioners may have under regulation 60 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors), a contractor may provide dispensing services to its registered patients under the contract only if it is authorised or required to do so by the Primary Care Trust in accordance with the following provisions of this paragraph or paragraph 49.

(2) A Primary Care Trust may authorise or require a contractor to provide dispensing services to a registered patient only if that patient-

- (a) satisfies one of the conditions in sub-paragraph (3); and
- (b) has requested the contractor in writing to provide him with dispensing services.

(3) The conditions referred to in sub-paragraph (2)(a) are that the patient-

- (a) satisfies the Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication;
- (b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy (other than a distance selling chemist), and all of the conditions in sub-paragraph (4) are satisfied in his case;
- (c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives-
 - (i) has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination, or
 - (ii) is a distance selling chemist,

and all of the conditions in sub-paragraph (4) are satisfied in his case; or

(d) is one to whom paragraph (a) or (b) applies and at the time of the request the patient is living as a member of the household, other than as a temporary resident, of another person in respect of whom a contractor has residual premises approval.

(4) The conditions referred to in sub-paragraphs (3)(b) and (c) are that-

- (a) the contractor has been granted consent to dispense under paragraph 48 in respect of-
 - (i) the area in which the patient resides, and
 - (ii) the contract under which the patient receives primary medical services;
- (b) there is in effect premises approval in relation to the premises from which the contractor will dispense to the patient; and
- (c) any conditions imposed in connection with that grant under regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(4) are such as to permit dispensing services to be provided under this paragraph by that contractor to the patient.

(5) If a contractor which has been requested to provide dispensing services by a patient who satisfies one of the conditions in sub-paragraph (3)-

(a) applies to the Primary Care Trust for (a) the right to provide dispensing services to that patient, and sends with its application the patient's request to the contractor, the Primary Care Trust shall grant its application; or

(b) does not so apply, within the period of 30 days beginning with the date on which the patient made that request, the Primary Care Trust may, subject to sub-paragraph (7), require the contractor to

provide dispensing services to that patient at listed premises in the case of a patient falling within sub-paragraph (3)(b) or (c), or practice premises in the case of a patient falling within sub-paragraph (3)(a), and shall give the contractor notice in writing to that effect.

(6) An application granted by the Primary Care Trust under sub-paragraph (5)(a) shall, with effect from the date of the patient's request to the contractor, enable that contractor to provide dispensing services at listed premises in the case of a patient falling within sub-paragraph (3)(b) or (c) or practice premises in the case of a patient falling within sub-paragraph (3)(a) to that patient, so long as the contract remains in effect.

(7) A Primary Care Trust shall not, under sub-paragraph (5)(b), require a contractor to provide dispensing services at listed premises or practice premises to a patient if the contractor satisfies the Primary Care Trust that-

- (a) it does not normally provide dispensing services under the contract; or
- (b) in the case of a patient to whom sub-paragraph (3)(b), (c) or (d) applies, the patient would not have serious difficulty by reason of distance or inadequacy of means of communication in obtaining drugs, medicines or appliances from a pharmacy.

(8) A Primary Care Trust shall give the contractor reasonable notice-

- (a) that it requires it to provide dispensing services to a registered patient in accordance with the contract; or
- (b) that, subject to sub-paragraph (9), where a patient no longer satisfies the requirements of sub-paragraph (3), the contractor shall discontinue the provision of dispensing services to that patient.

(9) A notice under sub-paragraph (8)(b)-

(a) shall be subject to any postponement or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions imposed under regulation 20(2) or 38(14)(b) of the Pharmaceutical Regulations as they apply pursuant to paragraph 48(4); and

(b) shall not be given-

- (i) pending the outcome of the resolution of any dispute concerning the decision by a Primary Care Trust to postpone the making or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions referred to in paragraph (a); or
- (ii) during the period for bringing an appeal, or pending the determination of any appeal, referred to in regulation 31(9) of the Pharmaceutical Regulations (determination of whether an area is a controlled locality).

(10) A contractor which has been granted the right under this paragraph to provide dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom that contractor has accepted as a temporary resident.

(11) In this paragraph and in paragraphs 48 to 51 "controlled locality", "distance selling chemist", "pharmacy", "premises approval", "reserved location" and "residual premises approval" have the same meanings as in the Pharmaceutical Regulations, and "listed premises" means the premises specified in relation to the contractor in the dispensing contractor list.

Consent to dispense and premises approval

48 - (1) A contractor which wishes to be granted the right under paragraph 47 to secure the provision of dispensing services to some or all of its registered patients may apply to the Primary Care Trust in writing for-

- (a) consent to dispense, specifying-
 - (i) the area, and
 - (ii) the contract,

in relation to which it wishes the consent to dispense to be granted; and

(b) premises approval, specifying-

(i) the premises for which it wishes to be granted premises approval and whether those premises are listed premises in relation to a different area, and

(ii) whether the application arises because there has been a practice amalgamation and, if so, the names of the contractors participating in the amalgamation.

(2) An application under sub-paragraph (1) shall be determined in accordance with paragraph 48A and regulations 18, 20(2), 33, 34 and 36 to 38 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraph (4)), as though it were an application for outline consent or premises approval under regulation 61 of those Regulations.

(3) The Primary Care Trust may refuse an application in respect of some of the premises for which approval is sought (notwithstanding that it would, if determining the application for those premises in isolation, grant it) where the number of applications for premises approval are such, or the circumstances in which they are made are such, that to grant all or some of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.

(4) Regulations 18, 20(2), 33, 34 and 36 to 38 of the Pharmaceutical Regulations shall apply as if-

(a) in regulations 18(1), 34(1) and 38(2)(e), for the references to "outline consent" there were substituted references to "consent to dispense";

(b) in regulation 18(2), for the reference to provisions being "subject to regulations 25, 26 and 65(4)" there were substituted a reference to the provisions being, "subject to paragraph 48D(4)";

(c) in regulations 18(2)(b) and (c), 33(2)(j), and 34(1)(a), for the references to "regulation 61" there were substituted references to this paragraph;

(d) in regulations 33(2) and 36(1) and (9), the references to provisions being "subject to regulations 25 and 26" were omitted;

(e) for regulation 33(3) there were substituted-

"(3) Where the Primary Care Trust has sent a copy of an application under paragraph (2)(f) to another Primary Care Trust or Local Health Board it shall also, as soon as practicable, send a copy to-

(a) the Local Pharmaceutical Committee for the locality of that other Primary Care Trust or Local Health Board (if any);

(b) the Local Medical Committee for the locality of that other Primary Care Trust or Local Health Board (if any);

(c) any person whose name is included in the pharmaceutical list of that other Primary Care Trust or Local Health Board, and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(d) any LPS chemist in the locality of that other Primary Care Trust or Local Health Board whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(e) any person (except that other Primary Care Trust or Local Health Board) who is a provider of primary medical services or whose name is included in the dispensing contractor list, or dispensing doctor list maintained in accordance with regulation 68 of the Pharmaceutical Regulations, of that other Primary Care Trust or Local Health Board who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

(f) any . . . Community Health Council serving the area of that other Primary Care Trust or Local Health Board; [NB: Words deleted by SI 2008/528]. . .

[(ff) any relevant local involvement network; and]

(g) any other patient, consumer or community group in the area of that other Primary Care Trust or Local Health Board that the Primary Care Trust considers has an interest in the provision of dispensing services in the neighbourhood.

[(3A) In this regulation-

(a) "relevant local authority" means a local authority whose area falls, wholly or partly, with the area of the Primary Care Trust;

(b) "relevant local involvement network" means a person who in pursuance of arrangements made by a relevant local authority under section 221(1) of the Local Government and Public Involvement in Health Act 2007 is to carry on activities specified in section 221(2) of that Act.];

(f) in regulation 38(2)(c), for the references to "regulation 60" there were substituted a reference to paragraph 47;

(g) in regulation 38(2)(e)(i), for the reference to "regulation 62(8)" there were substituted a reference to paragraph 48A(8);

(h) in regulation 38(2)(e)(ii), for "paragraph (13)(a) of that regulation" there were substituted "paragraph 48A(13)(a)."; and

(i) in regulation 38(2)(e)(iii), for "paragraph (13)(b) of that regulation" there were substituted "paragraph 48A(13)(b)."]

(5) Any reference in paragraphs 48A, 48C, 48D or 49A to regulations 18, 20(2), 33, 34 and 36 to 38 shall apply as modified by sub-paragraph (4).

Taking effect of consent to dispense and premises approval

48A - (1) When granting consent to dispense, the Primary Care Trust shall determine in accordance with sub-paragraph (2) when the consent to dispense is to take effect.

(2) The consent to dispense shall take effect-

(a) in relation to premises to which sub-paragraph (3) applies, on the date on which consent to dispense is finally granted; and

(b) in relation to premises to which sub-paragraph (4) applies, in accordance with sub-paragraphs (11) to (13).

(3) This sub-paragraph applies to premises for which consent to dispense is sought and-

(a) which were, on the date of receipt of the application by the Primary Care Trust-

(i) practice premises, or

(ii) in a reserved location; or

(b) in relation to which, on the day before the date on which the application for consent to dispense is granted, there are no outstanding applications.

(4) This sub-paragraph applies where, on the day before the date on which the application for outline consent is granted, there are outstanding applications.

(5) For the purposes of sub-paragraphs (3), (4), (6), (9) and (10) and paragraphs 48C and 48D, an "outstanding application" means an application by a pharmacist under regulation 5 or 40 of the Pharmaceutical Regulations which-

(a) is in relation to premises which are within 1.6 kilometres of the premises for which premises approval has been sought; and

(b) which-

- (i) has been made, but not determined (including on appeal), or
 - (ii) has been granted but the provision of pharmaceutical services from those premises has not commenced.
- (6) Where sub-paragraph (2)(b) applies, notification of the determination of the application for consent to dispense by the Primary Care Trust or, on appeal, by the Secretary of State, shall give details of-
 - (a) the outstanding applications; and
 - (b) the earliest date on which an application can be made under sub-paragraph (11) to the Primary Care Trust for a determination that the consent to dispense should come into effect ("provisional date").
- (7) The provisional date is the day after the end of a period of one year beginning with the date of-
 - (a) the determination of the application for consent to dispense; or
 - (b) where that determination is the subject of an appeal, the determination of that appeal.
- (8) The Primary Care Trust may, at any time before the provisional date, for good cause determine that the provisional date shall be extended for a period not exceeding three months beginning with the date specified in sub-paragraph (7)(a) or (b), and any reference in this paragraph or in paragraph 48C to the provisional date shall include a reference to the provisional date as extended under this sub-paragraph.
- (9) The Primary Care Trust shall-
 - (a) ensure that any notifications required to be given by the Primary Care Trust or the Secretary of State in relation to any outstanding applications are also given to the contractor who made the application under paragraph 48;
 - (b) notify that contractor if any outstanding application is withdrawn; and
 - (c) where it extends the provisional date under sub-paragraph (8), notify that contractor of the new provisional date.
- (10) The consent to dispense shall lapse if, before the provisional date, pharmaceutical services are provided from premises which were the subject of an outstanding application which has been granted.
- (11) On, or as soon as reasonably practicable after, the provisional date, the Primary Care Trust shall notify the contractor who made the application under paragraph 48 and-
 - (a) it may within three months of the provisional date require the Primary Care Trust in writing to determine whether the consent to dispense should come into effect; and
 - (b) the Primary Care Trust shall determine the request as soon as practicable and in accordance with sub-paragraphs (12) and (13).
- (12) Where, on the date of the determination under sub-paragraph (11), the premises are practice premises, the Primary Care Trust shall determine that the consent to dispense and premises approval in respect of those premises shall come into effect on that date.
- (13) Where, on the date of the determination under sub-paragraph (11), the premises are not practice premises-
 - (a) the application for consent to dispense shall be refused as regards premises approval for those premises; or
 - (b) where none of the premises for which premises approval has been granted are practice premises, the consent to dispense shall lapse.
- (14) The Primary Care Trust shall notify its determination under sub-paragraph (11) to the contractor and those persons to whom notice of the application under paragraph 48 was required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations.
- (15) Where the Primary Care Trust has determined that-

- (a) the provisional date shall be extended under sub-paragraph (8);
- (b) the application for consent to dispense shall be refused under sub-paragraph (13)(a); or
- (c) consent to dispense shall lapse under sub-paragraph (13)(b),

the contractor may appeal to the Secretary of State against any such determination by giving notice of appeal in accordance with regulation 38(5) of the Pharmaceutical Regulations, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations.

(16) Premises approval shall take effect when the related consent to dispense takes effect.

Lapse of consent to dispense and premises approval

48B - (1) A consent to dispense shall cease to have effect-

- (a) where no arrangement under paragraph 47 has been made pursuant to it within 12 months from its taking effect;
- (b) where more than 12 months have elapsed since the last provision of drugs and appliances under an arrangement made pursuant to paragraph 47;
- (c) in accordance with paragraph 48A(10) or (13);
- (d) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval; or
- (e) where the contract has terminated.

(2) Premises approval shall cease to have effect in relation to-

- (a) listed premises which have permanently ceased to be practice premises;
- (b) listed premises which have not been used for dispensing by the contractor for six months or such longer period as the Primary Care Trust may for good cause allow;
- (c) listed premises which were granted premises approval under paragraph 48E(3), where no practice amalgamation takes place within the period specified in paragraph 48E(7).

(3) Premises approval shall cease to have effect where the related consent to dispense ceases to have effect.

Premises approval: change of premises before consent to dispense takes effect

48C - (1) Where-

- (a) consent to dispense has been granted but has not yet taken effect under paragraph 48A; and
- (b) before the provisional date, the contractor intends to change the premises from which he wishes to dispense,

the contractor may apply to the Primary Care Trust in writing for the Primary Care Trust to determine whether premises approval should be given in relation to the new premises, and the Primary Care Trust shall make the determination in accordance with sub-paragraph (2).

(2) If the Primary Care Trust is satisfied that the change of premises is a minor relocation it may grant premises approval for those premises, but if it is not so satisfied the application for the premises approval to be given in relation to the new premises shall be refused.

(3) The Primary Care Trust shall notify those persons to whom notice of the application under paragraph 48 was required to be given and applicants in relation to the outstanding applications, of its determination under sub-paragraph (2).

(4) The determination by the Primary Care Trust under sub-paragraph (2) may be appealed to the Secretary of State by the contractor, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations.

Premises approval: additional and new premises after consent to dispense has taken effect

48D - (1) A contractor who has been granted consent to dispense which has taken effect and who wishes to be granted premises approval in relation to premises in addition to those in respect of which premises approval has been given ("additional premises") may apply to all the appropriate Primary Care Trusts and-

- (a) the application shall be determined by the relevant Primary Care Trust, and
- (b) this paragraph and paragraph 48 and regulations 18, 20(2), 34, 36(1) and (3) to (9), 37 and 38 of the Pharmaceutical Regulations shall apply to such an application as they apply to an application for consent to dispense under paragraph 48.

(2) For the purposes of this paragraph-

- (a) the "appropriate Primary Care Trusts" are those who hold dispensing contractor lists on which the contractor making the application is included; and
- (b) the "relevant Primary Care Trust" is the Primary Care Trust in whose area the additional premises are situated.

(3) A contractor wishing to be granted premises approval in relation to premises ("new premises") where it wishes to dispense instead of listed premises may apply to all the appropriate Primary Care Trusts and the application shall be determined by the relevant Primary Care Trust in accordance with sub-paragraph (4).

(4) The relevant Primary Care Trust shall-

- (a) grant the application made in accordance with sub-paragraph (3) where-
 - (i) the new premises are less than 500 metres by the most practicable route on foot from the listed premises which they are to replace, or
 - (ii) the Primary Care Trust is otherwise satisfied that granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services in any part of a controlled locality,

provided that no further applications shall be granted under this sub-paragraph for a period of 12 months beginning with the date on which the contractor commenced providing services from the new premises unless the Primary Care Trust shall for good cause allow; and

- (b) in any other case determine the application in accordance with sub-paragraph (1) as if the references to additional premises were to new premises.

(5) The relevant Primary Care Trust shall notify its determination under sub-paragraph (4)(a) to the persons to whom the notice is required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations and to the appropriate Primary Care Trusts.

(6) A determination by the relevant Primary Care Trust may be appealed to the Secretary of State by the contractor and any of the persons notified under sub-paragraph (5) apart from any Local Pharmaceutical Committee or any Local Medical Committee, and such appeal shall be determined in accordance with regulation 38 of the Pharmaceutical Regulations.

(7) Subject to sub-paragraph (8), when granted in relation to new or additional premises, the premises approval shall take effect from the date of notification of the grant and for this purpose the date of the notification of a grant of any application shall be-

- (a) where no appeal is made under sub-paragraph (6) against the decision of the relevant Primary Care Trust, the date after the expiry of the period of 30 days beginning with the date on which notice of that decision is given under sub-paragraph (5); or
- (b) where such an appeal is made, the date on which the Secretary of State gives notice of his decision under regulation 38 of the Pharmaceutical Regulations.

(8) Where-

- (a) the premises approval is granted in relation to additional premises; and
- (b) in relation to the premises for which the approval is granted there was, at the date of the grant, an outstanding application,

the premises approval shall provisionally take effect on the date which is the day after the end of a period of one year, or such longer period (not exceeding three months) as the relevant Primary Care Trust may for good cause allow before the expiration of that year, from the final resolution of any outstanding application.

(9) The relevant Primary Care Trust may grant temporary premises approval to a contractor who has consent to dispense and premises approval in relation to additional or new premises where it considers it desirable to do so to secure the adequate provision of dispensing services in the area served by the premises, and renew any such temporary approval granted, to secure such adequate provision, and where it does so it shall-

- (a) notify those persons to whom notice of the application under paragraph 48 was required to be given under regulation 33(2) and (3) of the Pharmaceutical Regulations and applicants in relation to outstanding applications;
- (b) state the period during which the temporary premises approval is to apply; and
- (c) include those premises in the dispensing contractors list in relation to that contractor.

(10) Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding three months.

Premises approval: practice amalgamations

48E - (1) "A practice amalgamation" occurs where two or more providers of primary medical services merge as a result of which two or more patient lists are combined and the contract is varied.

(2) If, following a practice amalgamation, all the practice premises of the new practice are premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, then consent to dispense and premises approval shall continue to have effect.

(3) Where there is, or will be, a practice amalgamation and none or not all of the practice premises of the contractor are, or will be, premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, the contractor if it has been granted consent to dispense and premises approval which is in effect either immediately before the practice amalgamation or the date of the application under this sub-paragraph, may make an application for premises approval, and it shall be determined as provided in paragraph 48D as if it were an application from a contractor with premises approval to have the right to dispense from-

- (a) additional premises where the premises approval is required for additional premises as defined in paragraph 48D(1); or
- (b) new premises where the premises approval is required for new premises as defined in paragraph 48D(3),

and the Primary Care Trust may grant temporary premises approval under paragraph 48D(9).

(4) An application mentioned in sub-paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined-

- (a) any premises approval in effect at the date of the practice amalgamation shall have effect from the date of the amalgamation as if it were a temporary approval under paragraph 48D(9) for a period stated by the Primary Care Trust not exceeding one year; and

(b) the contractor shall have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Primary Care Trust not exceeding one year.

(5) When the practice amalgamation takes effect the contractor shall notify all Primary Care Trusts in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to sub-paragraph (7), where an application made under sub-paragraph (3) was granted before the practice amalgamation takes place, premises approval shall take effect from the date of the practice amalgamation.

(7) Where an application was made under sub-paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted under that sub-paragraph, that grant shall lapse.

(8) Where an application under sub-paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the contractor, if it had premises approval prior to making the application, shall have residual premises approval.

(9) For the purposes of this paragraph "residual premises approval" means approval to dispense-

(a) from premises in respect of which the contractor had premises approval at the time of the application in relation to the practice amalgamation; and

(b) to-

(i) a patient for whom the contractor making the application is authorised to provide dispensing services on the date the application was refused, but excluding any such patient who ceases to be a patient mentioned in paragraph 47(3)(b) or (c); or

(ii) a patient who is not mentioned in sub-paragraph (i) but who is mentioned in paragraph 47(3)(a) or (d) and for whom the contractor making the application is authorised to provide dispensing services on the date the application was refused.

(10) For the purposes of sub-paragraph (9), paragraph 47(3)(b) or (c) shall be read as if the words "and all of the conditions in sub-paragraph (4) are satisfied in his case" were omitted.

Contractors who previously provided dispensing services under section 28C arrangements

49 - (1) This paragraph applies where the contractor was, immediately before the commencement of the contract, providing primary medical services in the area of the Primary Care Trust in accordance with section 28C arrangements and-

(a) the contractor was, immediately before the commencement of the contract, providing dispensing services to some or all of its patients in accordance with the section 28C arrangements; and

(b) the contractor has notified the Primary Care Trust before entering into the contract that it intends to provide dispensing services under it.

(2) In a case to which this paragraph applies the contractor shall be regarded as-

(a) being authorised or required under paragraph 47 to provide dispensing services under the contract to any patient-

(i) to whom, immediately before commencement of the contract, it provided dispensing services under section 28C arrangements, and

(ii) who wishes the contractor to continue to provide him with such services;

(b) having been granted consent to dispense in relation to the contract under paragraph 48 in relation to the area for which it had such consent under the section 28C arrangements; and

- (c) having been granted premises approval in relation to the contract under paragraph 48 for those premises from which it had, immediately before the commencement of the contract, authority to provide dispensing services in accordance with the section 28C arrangements.

Transitional provisions

49A - (1) This paragraph applies where the contractor has been granted, prior to 6th January 2006 consent to dispense in accordance with paragraph 48 and that consent is in effect on 6th January 2006.

(2) For the purposes of this paragraph, "relevant premises" means-

(a) premises from which, at the date of notification under sub-paragraph (5), the contractor is providing primary medical services; or

(b) premises in addition to or in place of the premises specified in paragraph (a) where, immediately before 6th January 2006, the contractor intended to dispense.

(3) The Primary Care Trust shall determine whether or not to grant premises approval to relevant premises in accordance with sub-paragraphs (4) to (6).

(4) Before 5th February 2006 the Primary Care Trust shall notify the contractor that-

(a) the Primary Care Trust is required to make a determination under sub-paragraph (3) as to whether or not to grant premises approval in respect of the relevant premises; and

(b) it may make written representations to the Primary Care Trust in relation to such a determination within the period of 30 days beginning with the date of the Primary Care Trust's notification or such longer period as the Primary Care Trust may for good cause allow.

(5) The Primary Care Trust shall-

(a) also notify the Local Medical Committee (if any) and the Local Pharmaceutical Committee (if any) which were required to be sent a copy of the application under regulations 33(2) and (3) of the Pharmaceutical Regulations and inform them that they may make written representations within the period of 30 days beginning with the Primary Care Trust's notification;

(b) consider any representations received from the Committees mentioned in paragraph (a) and the contractor;

(c) determine that the contractor has premises approval for premises which are, or are part of, relevant premises; and

(d) notify its decision to the contractor, the Committees mentioned in paragraph (a), any person providing pharmaceutical services or dispensing services in the Primary Care Trust's area whose interests might, in the opinion of the Primary Care Trust, be affected and all Patients' Forums in that area.

(6) The Primary Care Trust shall grant premises approval under sub-paragraph (3) where it is satisfied that the relevant premises were, prior to 6th January 2006, being routinely used to provide dispensing services.

(7) The Primary Care Trust shall not refuse to grant premises approval under sub-paragraph (3) by reason of the relevant premises being within 1.6 kilometres of any pharmacy.

(8) The Primary Care Trust's determination under sub-paragraph (5)(c) may be appealed to the Secretary of State by a person notified of the determination under sub-paragraph (5)(d) except the Committees mentioned in sub-paragraph (5)(a), and regulations 38(5) to (15) of the Pharmaceutical Regulations shall apply to such appeals except that, for this purpose, regulation 38 shall be read as if-

(a) in paragraph (7), for "those persons mentioned in paragraph (3)(a)" to the end, there were substituted "those persons notified under sub-paragraph (5)(d)";

(b) in paragraph (12), the list of persons to whom notice of the hearing should be sent were a reference to the persons notified under sub-paragraph (5)(d); and

(c) in paragraph (14), sub-paragraphs (b), (c) and (d) were omitted.

(9) Until-

(a) the date of the determination of the Primary Care Trust under sub-paragraph (3); or

(b) the date that any appeal under sub-paragraph (8) is decided,

whichever is the later, a contractor shall be deemed to have been granted premises approval for the relevant premises, but it may not make any application to which paragraph 48C or 48D applies.]

Terms relating to the provision of dispensing services

50 - (1) A contractor which has been granted the right to provide dispensing services under paragraph 47 or 49 shall ensure that dispensing services are provided in accordance with the following sub-paragraphs.

(2) Subject to sub-paragraphs (3) and (4), a contractor providing dispensing services shall-

(a) record an order for the provision of any drugs, medicines or appliances which are needed for the treatment of the patient [on-

(i) a non-electronic prescription form completed in accordance with paragraph 39(3), or

(ii) if the contractor is the patient's nominated dispenser (or one of them), an electronic prescription form];

(b) provide those drugs, medicines or appliances in a suitable container;

(c) provide for the patient a drug or medicine specified in any directions given by the Secretary of State under section 28U of the Act (GMS contracts: prescription of drugs etc) as being a drug or medicine which can only be ordered for specified patients and specified purposes only if-

(i) that patient is a person of the specified description, and

(ii) the drug or medicine is supplied for that patient only for the specified purpose; and

(d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

(3) Sub-paragraph (2) does not apply to drugs, medicines or appliances ordered on a prescription form by an independent nurse prescriber [or a pharmacist independent prescriber].

[(4) Where a patient-

(a) presents to a contractor who may provide dispensing services an order on a non-electronic prescription form for drugs, medicines or appliances signed by an independent nurse prescriber [or a pharmacist independent prescriber], or an order for a restricted availability appliance signed by and endorsed with the reference "SLS" by an independent nurse prescriber [or a pharmacist independent prescriber]; or

(b) informs a contractor who may provide dispensing services and who is his nominated dispenser (or one of them) that an independent nurse prescriber [or a pharmacist independent prescriber] has ordered drugs, medicines or appliances for him by means of an electronic prescription form,

the contractor may, provided, in a case to which paragraph (b) applies, it has received the electronic prescription form from the ETP service, provide to the patient such of the drugs, medicines or appliances so ordered as it supplies in the normal course of its practice.]

(5) Drugs, medicines or appliances provided under sub-paragraph (4) shall be provided in a suitable container.

(6) A contractor providing dispensing services shall not provide for a patient a drug or medicine specified in any directions given by the Secretary of State under section 28U of the Act as being drugs or medicines which may not be ordered for patients in the provision of medical services under the contract, except that, where it has ordered a drug or medicine which has an appropriate non-proprietary name either by the name or by its formula, it may provide a drug or medicine which has the same specification notwithstanding that it is a drug or medicine specified in such directions (but, in the case of a drug or medicine which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(7) Subject to sub-paragraph (9), nothing in this paragraph shall prevent a contractor providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

[(8) A contractor providing dispensing services shall comply with paragraph 5 of Schedule 2 (terms of service of dispensing doctors) to the Pharmaceutical Regulations, as if modified as follows-

(a) for "paragraph 3, or in the circumstances set out in paragraph 4" there were substituted "paragraph 50(2) or (4) of Schedule 6 to the GMS Regulations"; and

(b) for "the dispensing doctor", in each place where it occurs, there were substituted "the contractor providing dispensing services".]

[(8A) A contractor providing dispensing services shall comply with paragraphs 7(1), (3) and (4) of Schedule 2 (terms of service of dispensing doctors) to the Pharmaceutical Regulations, with all references to "a dispensing doctor" or "the dispensing doctor" being read as references to the contractor providing dispensing services.]

(9) The provisions of regulation 24 (fees and charges) apply in respect of the provision of any drugs, medicines or appliances by a contractor providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(10) A contractor who is entitled to provide dispensing services may, with the consent of the patient, order a drug, medicine or appliance for a patient on a prescription form or a repeatable prescription, rather than providing it itself.

Dispensing contractor list

51 - [(1) Where the contractor is authorised or required by the Primary Care Trust under paragraph 47 or 49 to provide dispensing services to its patients and is actually doing so the Primary Care Trust shall-

(a) include the contractor's name;

(b) include the address of the practice premises from which it is authorised or required to dispense;

(c) include the premises in relation to which the contractor has premises approval;

(d) state in relation to each premises included-

(i) if premises approval is deemed, temporary or residual, that this is the case, and

(ii) the date on which premises approval took effect or where it has not taken effect, the date that it was finally granted;

(e) state the area in relation to which there is consent to dispense and premises approval; and

(f) include and identify separately, any premises in relation to which the contractor has undetermined applications for premises approval,

on a list of such contractors (to be called the dispensing contractors list) which it shall prepare, maintain and publish.]

(2) The Primary Care Trust shall remove the name of the contractor from the list referred to in sub-paragraph (1) where-

- (a) the contractor's consent to dispense ceases to have effect [in accordance with paragraph 48B(1)];
or
- (b) the contractor ceases to provide dispensing services to its patients for any other reason.

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

52 - (1) Subject to sub-paragraph (2), a contractor-

- (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 he personally administers or applies to that patient,

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 or any regulations or orders made thereunder.

Part 4

Persons Who Perform Services

Qualifications of performers

53 - (1) Subject to sub-paragraph (2), no medical practitioner shall perform medical services under the contract unless he is-

- (a) included in a medical performers list for a Primary Care Trust in England;
- (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).

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

- (a) a medical practitioner employed by an NHS trust, an NHS foundation trust, (in Scotland) a Health Board, or (in Northern Ireland) 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 acting in the course of his employment in a resident medical capacity in an approved medical practice; . . . [NB word omitted revoked by SI 2006/1501]

[(c) a GP Registrar who has applied to a Primary Care Trust to have his name included in its medical performers list until the first of the following events arises-

- (i) the Primary Care Trust notifies him of its decision on that application; or
- (ii) the end of a period of two months, starting with the date on which his vocational training scheme [began; or]

[(d) a medical practitioner, who-

- (i) is not a GP Registrar;

- (ii) is undertaking a programme of post-registration supervised clinical practice supervised by the Postgraduate Medical Education and Training Board ("a post-registration programme");
- (iii) has notified the Primary Care Trust that he will be undertaking part or all of a post-registration programme in its area at least 24 hours before commencing any part of that programme taking place in the Primary Care Trust's area; and
- (iv) has, with that notification, provided the Primary Care Trust with evidence sufficient for it to satisfy itself that he is undergoing a post-registration programme,

but only in so far as any medical services that the medical practitioner performs constitute part of a post-registration programme].

[(3) In this paragraph, "vocational training scheme" has the meaning given in regulation 21(2) of the National Health Service (Performers Lists) Regulations 2004.]

54 - No health care professional other than one to whom paragraph 53 applies shall perform clinical services under the contract unless he is appropriately registered with his relevant professional body and his registration is not currently suspended.

55 - Where the registration of a health care professional or, in the case of a medical practitioner, his inclusion in a primary care list is subject to conditions, the contractor shall ensure compliance with those conditions insofar as they are relevant to the contract.

56 - No health care professional shall perform any clinical services unless he has such clinical experience and training as are necessary to enable him properly to perform such services.

Conditions for employment and engagement

57 - (1) Subject to sub-paragraphs (2) and (3), a contractor shall not employ or engage a medical practitioner (other than one falling within paragraph 53(2)) unless-

- (a) that practitioner has provided it with the name and address of the Primary Care Trust on whose medical performers list he appears; and
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 53.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible for the contractor to check the matters referred to in paragraph 53 in accordance with sub-paragraph (1)(b) before employing or engaging him he 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 Primary Care Trust on whose list he has applied for inclusion; and
- (b) confirmation that his name appears on that list shall not be required until the end of the first two months of the Registrar's training period.

58 - (1) A contractor shall not employ or engage-

- (a) a health care professional other than one to whom paragraph 53 applies unless the contractor has checked that he meets the requirements in paragraph 54; or

(b) a health care professional to perform clinical services unless he has taken reasonable steps to satisfy himself that he meets the requirements in paragraph 56.

(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 54 in accordance with sub-paragraph (1) before employing or engaging him, he 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 contractor 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 him and any relevant clinical experience gained by him.

59 - (1) The contractor shall not employ or engage a health care professional to perform medical services under the contract [other than a medical practitioner falling within paragraph 53(2)(d),] unless-

- (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 contractor has checked and is satisfied with the references.

(2) Where the employment or engagement of a health care professional 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 him, he may be employed or engaged on a temporary basis for a single period of up to 14 days whilst his references are checked and considered, and for an additional single period of a further 7 days if the contractor believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the contractor 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.

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

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 57 to 59.

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

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

Training

61 - The contractor shall ensure that for any health care professional who is-

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

there are in place arrangements for the purpose of maintaining and updating his skills and knowledge in relation to the services which he is performing or assisting in performing.

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

Terms and conditions

63 - The contractor shall only offer employment to a general medical practitioner on terms and conditions which are no less favourable than those contained in the "Model terms and conditions of service for a salaried general practitioner employed by a GMS practice" published by the British Medical Association and the NHS Confederation as item 1.2 of the supplementary documents to the new GMS contract 2003.

Arrangements for GP Registrars

64 - (1) The contractor shall only employ a GP Registrar . . . [NB words omitted revoked by SI 2004/2694] subject to the conditions in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that the contractor 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 contract or for which other staff assist them in the performance of those services.

(3) A contractor which employs a GP Registrar shall-

(a) offer him terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Secretary of State to Strategic Health Authorities under section 17 of the Act (Secretary of State's directions: exercise of functions) concerning the grants, fees, travelling and other allowances payable to GP Registrars; and

(b) take into account any guidance issued by the Secretary of State in relation to the GP Registrar Scheme.

Independent nurse prescribers[, pharmacist independent prescribers] and supplementary prescribers

65 - (1) Where-

(a) a contractor employs or engages a person who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whose functions will include prescribing;

(b) a party to the contract is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whose functions will include prescribing; or

(c) the functions of a person who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whom the contractor already employs or has already engaged are extended to include prescribing,

it shall notify the Primary Care Trust in writing within the period of seven days beginning with the date on which the contractor employed or engaged the person, the party became a party to the contract (unless immediately before becoming such a party, he fell under paragraph (a)), or the person's functions were extended, as the case may be.

(2) Where-

(a) the contractor ceases to employ or engage a person who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whose functions included prescribing in its practice;

- (b) the party to the contract who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whose functions include prescribing, ceases to be a party to the contract;
- (c) the functions of a person who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whom the contractor employs or engages in its practice are changed so that they no longer include prescribing in its practice; or
- (d) the contractor becomes aware that a person who is an independent nurse prescriber [, a pharmacist independent prescriber] or a supplementary prescriber whom it employs or engages has been removed or suspended from the relevant register,

it shall notify the Primary Care Trust in writing by the end of the second working day after the day when the event occurred.

(3) The contractor shall provide the following information when it notifies the Primary Care Trust in accordance with sub-paragraph (1)-

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

(4) The contractor shall provide the following information when it notifies the Primary Care Trust in accordance with sub-paragraph (2)-

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

[Signing of documents

66 - (1) In addition to any other requirements relating to such documents whether in these regulations or otherwise, the contractor shall ensure-

- (a) that the documents specified in sub-paragraph (2) include-
 - (i) the clinical profession of the health care professional who signed the document; and
 - (ii) the name of the contractor on whose behalf it is signed; and

(b) that the documents specified in sub-paragraph (3) include the clinical profession of the health care professional who signed the document.

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

(a) certificates issued in accordance with regulation 21, unless regulations relating to particular certificates provide otherwise; and

[(b) any other clinical documents, apart from-

(i) home oxygen order forms, and

(ii) those documents specified in sub-paragraph (3)].

(3) The documents referred to in sub-paragraph (1)(b) are batch issues, prescription forms and repeatable prescriptions.]

Level of skill

67 - The contractor shall carry out its obligations under the contract with reasonable care and skill.

Appraisal and assessment

68 - (1) The contractor shall ensure that any medical practitioner performing services under the contract-

(a) participates in the appraisal system provided by the Primary Care Trust unless he participates in an [appropriate] appraisal system provided by another health service body or is an armed forces GP; and

(b) co-operates with an assessment by the [NPSA] when requested to do so by the Primary Care Trust.

(2) The Primary Care Trust shall provide an appraisal system for the purposes of sub-paragraph (1)(a) after consultation with the Local Medical Committee (if any) for the area of the Primary Care Trust 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.

Sub-contracting of clinical matters

69 - (1) Subject to sub-paragraph (2), the contractor shall not sub-contract any of its rights or duties under the contract in relation to clinical matters unless-

(a) in all cases, including those which fall within paragraph 70, 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 70, it has notified the Primary Care Trust in writing 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 professional personally 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 Primary Care Trust may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the contractor shall supply such information promptly.

(5) The contractor 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 Primary Care Trust has served notice of objection to the sub-contract on the grounds that-

- (a) the sub-contract would-
 - (i) put at serious risk the safety of the contractor's patients, or
 - (ii) put the Trust at risk of material financial loss; or
- (b) the sub-contractor would be unable to meet the contractor's obligations under the contract.

(6) Where the Primary Care Trust 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 Primary Care Trust does not object to a proposed sub-contract under paragraph (5), the parties to the contract shall be deemed to have agreed a variation of the contract 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 104(1) 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 contractor to provide.

[(10) The contractor shall not sub-contract any of its rights or duties under the contract in relation to the provision of essential services to a company or firm-

- (a) owned wholly or partly by the contractor, or by any former or current employee of, or partner or shareholder in, the contractor;
- (b) formed by or on behalf of the contractor, or from which it derives or may derive a pecuniary benefit; or
- (c) formed by or on behalf of a former or current employee of, or partner or shareholder in, the contractor, or from which such a person derives or may derive a pecuniary benefit,

where that company or firm is or was formed wholly or partly for the purpose of avoiding the restrictions on the sale of the goodwill of a medical practice in section 54 of the Act or any Regulations made wholly or partly under that section.]

Sub-contracting of out of hours services

70 - (1) A contractor shall not, otherwise than in accordance with the written approval of the Primary Care Trust, sub-contract all or part of its duty to provide out of hours services to any person other than those listed in sub-paragraph (2) other than on a short-term occasional basis.

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

- (a) a person who holds a general medical services contract with a Primary Care Trust which includes out of hours services;

(b) a section 28C provider who is required to provide the equivalent of essential services to his patients during all or part of the out of hours period;

(c) a health care professional, not falling within paragraph (a) or (b), who is to provide the out of hours services personally under a contract for services; or

(d) a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota arrangements.

(3) An application for approval under sub-paragraph (1) shall be made by the contractor in writing to the Primary Care Trust and shall state-

(a) the name and address of the proposed sub-contractor;

(b) the address of any premises to be used for the provision of services;

(c) the duration of the proposed sub-contract;

(d) the services to be covered by the arrangement; and

(e) how it is proposed that the sub-contractor will meet the contractor's obligations under the contract in respect of the services covered by the arrangement.

(4) Within 7 days of receipt of an application under sub-paragraph (3), a Primary Care Trust may request such further information relating to the proposed arrangements as seem to it to be reasonable.

(5) Within 28 days of receipt of an application which meets the requirements specified in sub-paragraph (3) or the further information requested under sub-paragraph (4) (whichever is the later), the Primary Care Trust shall-

(a) approve the application;

(b) approve the application with conditions; or

(c) refuse the application.

(6) The Primary Care Trust shall not refuse the application if it is satisfied that the proposed arrangement will, in respect of the services to be covered, enable the contractor to meet satisfactorily its obligations under the contract and will not-

(a) put at serious risk the safety of the contractor's patients; or

(b) put the Trust at risk of material financial loss.

(7) The Primary Care Trust shall inform the contractor by notice in writing of its decision on the application and, where it refuses an application, it shall include in the notice a statement of the reasons for its refusal.

(8) Where a Primary Care Trust approves an application under this paragraph the parties to the contract shall be deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises, for the purposes of the provision of services in accordance with that application, any premises whose address was notified to it under sub-paragraph (3)(b) and paragraph 104(1) shall not apply.

(9) Sub-paragraphs (1) to (8) shall also apply in relation to any renewal or material variation of a sub-contract in relation to out of hours services.

(10) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the out of hours services it has agreed with the contractor to provide.

Withdrawal and variation of approval under paragraph 70

71 - (1) Without prejudice to any other remedies which it may have under the contract, where a Primary Care Trust has approved an application made under paragraph 70(3) it shall, subject to paragraph 72, be entitled to serve notice on the contractor withdrawing or varying that approval, from a date specified in the notice, if it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract.

(2) The date specified in the notice shall be such as appears reasonable in all the circumstances to the Primary Care Trust.

(3) The notice referred to in sub-paragraph (1) shall take effect on whichever is the later of-

(a) the date specified in the notice; or

(b) (if applicable) the date of the final determination of the NHS dispute resolution procedure (or any court proceedings) relating to the notice in favour of the Primary Care Trust.

72 - (1) Without prejudice to any other remedies which it may have under the contract, where a Primary Care Trust has approved an application made under paragraph 70(3) it shall be entitled to serve notice on the contractor withdrawing or varying that approval with immediate effect if-

(a) it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract; and

(b) it is satisfied that immediate withdrawal or variation is necessary to protect the safety of the contractor's patients.

[(2) A notice served under sub-paragraph (1) shall take effect on the date on which it is received by the contractor.]

Part 5

Records, Information, Notifications and Rights of Entry

Patient records

73 - (1) In this paragraph, "computerised records" means records created by way of entries on a computer.

(2) The contractor 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 Primary Care Trust; or

(b) with the written consent of the Primary Care Trust, by way of computerised records,

or in a combination of those two ways.

(3) The contractor shall include in the records referred to in sub-paragraph (2) clinical reports sent in accordance with paragraph 7 of this Schedule or from any other health care professional who has provided clinical services to a person on its list of patients.

(4) The consent of the Primary Care Trust required by sub-paragraph (2)(b) shall not be withheld or withdrawn provided the Primary Care Trust is satisfied, and continues to be satisfied, that-

(a) the computer system upon which the contractor proposes to keep the records has been accredited by the Secretary of State or another person on his behalf in accordance with ["[General Practice Systems of Choice Level 2](#)"];

(b) the security measures, audit and system management functions incorporated into the computer system as accredited in accordance with paragraph (a) have been enabled; and

(c) the contractor is aware of, and has signed an undertaking that it will have regard to the guidelines contained in ["Good Practice Guidelines for General Practice Electronic Patient Records (Version 3.1)" published on 29th July 2005].

(5) Where a patient's records are computerised records, the contractor shall, as soon as possible following a request from the Primary Care Trust, allow the Trust to access the information recorded on the computer system on which those records are held by means of the audit function referred to in sub-paragraph (4)(b) to the extent necessary for the Trust to confirm that the audit function is enabled and functioning correctly.

(6) The contractor shall send the complete records relating to a patient to the Primary Care Trust-

(a) where a person on its list dies, before the end of the period of 14 days beginning with the date on which it was informed by the Primary Care Trust of the death, or (in any other case) before the end of the period of one month beginning with the date on which it learned of the death; or

(b) in any other case where the person is no longer registered with the contractor, as soon as possible at the request of the Primary Care Trust.

(7) To the extent that a patient's records are computerised records, the contractor complies with sub-paragraph (6) if it sends to the Primary Care Trust a copy of those records-

(a) in written form; or

(b) with the written consent of the Primary Care Trust in any other form.

(8) The consent of the Primary Care Trust to the transmission of information other than in written form for the purposes of sub-paragraph (7)(b) shall not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with the following matters-

(a) the contractor's proposals as to how the record will be transmitted;

(b) the contractor's proposals as to the format of the transmitted record;

(c) how the contractor will ensure that the record received by the Primary Care Trust is identical to that transmitted; and

(d) how a written copy of the record can be produced by the Primary Care Trust.

(9) A contractor whose patient records are computerised records shall not disable, or attempt to disable, either the security measures or the audit and system management functions referred to in sub-paragraph (4)(b).

74 - ... [NB: revoked by SI 2005/893]

Confidentiality of personal data

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

Practice leaflet

76 - The contractor shall-

(a) compile a document (in this paragraph called a practice leaflet) which shall include the information specified in Schedule 10;

(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

77 - (1) Subject to sub-paragraph (2), the contractor shall, at the request of the Primary Care Trust, produce to the Primary Care Trust or to a person authorised in writing by the Primary Care Trust or allow it, or a person authorised in writing by it, to access-

(a) any information which is reasonably required by the Primary Care Trust for the purposes of or in connection with the contract; and

(b) any other information which is reasonably required in connection with the Primary Care Trust's functions.

(2) The contractor shall not be required to comply with any request made in accordance with sub-paragraph (1) unless it has been made by the Primary Care Trust in accordance with directions relating to the provision of information by contractors given to it by the Secretary of State under section 17 of the Act (Secretary of State's directions: exercise of functions).

[(3) The contractor shall produce the information requested, or, as the case may be, allow access to it-

(a) by such date as has been agreed as reasonable between the contractor and the Primary Care Trust; or

(b) in the absence of such agreement, within 28 days of the request being made.]

78 - . . . [NB revoked by SI 2008/528]

Inquiries about prescriptions and referrals

79 - (1) The contractor shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the Primary Care Trust concerning-

(a) any prescription form or repeatable prescription issued [or created] by a prescriber;

(b) the considerations by reference to which prescribers issue such forms;

(c) the referral by or on behalf of the contractor of any patient to any other services provided under the Act; or

(d) the considerations by which the contractor makes such referrals or provides for them to be made on its behalf.

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist the Primary Care Trust to discharge its functions or of assisting the contractor in the discharge of its obligations under the contract.

(3) The contractor 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; or

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

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

[Provision of information to a medical officer etc

80 - (1) The contractor shall, if it is satisfied that the patient consents-

(a) supply in writing to any person specified in sub-paragraph (3), within such reasonable period as that person may specify, such clinical information as any of the persons mentioned in sub-paragraph (3)(a) to (d) considers relevant about a patient to whom the contractor or a person acting on behalf of the contractor has issued or has refused to issue a medical certificate; and

- (b) answer any inquiries by any person mentioned in sub-paragraph (3) about –
 - (i) a prescription form or medical certificate issued or created by, or on behalf of, the contractor, or
 - (ii) any statement which the contractor or a person acting on behalf of the contractor has made in a report.
- (2) For the purpose of being satisfied that a patient consents, a contractor may rely on an assurance in writing from any person mentioned in sub-paragraph (3) that the consent of the patient has been obtained, unless the contractor has reason to believe that the patient does not consent.
- (3) For the purposes of sub-paragraph (1) and (2), the persons are –
 - (a) a medical officer;
 - (b) a nursing officer;
 - (c) an occupational therapist;
 - (d) a physiotherapist; or
 - (e) an officer of the Department for Work and Pensions who is acting on behalf of, and at the direction of, any person specified in paragraphs (a) to (d).
- (4) In this paragraph –
 - (a) “medical officer” means a medical practitioner who is –
 - (i) employed or engaged by the Department for Work and Pensions, or
 - (ii) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions;
 - (b) “nursing officer” means a health care professional who is registered on the Nursing and Midwifery Register and –
 - (i) employed or engaged by the Department for Work and Pensions, or
 - (ii) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions;
 - (c) “occupational therapist” means a health care professional who is registered in the part of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001 relating to occupational therapists and –
 - (i) employed or engaged by the Department for Work and Pensions, or
 - (ii) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions; and
 - (d) “physiotherapist” means a health care professional who is registered in the part of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001 relating to physiotherapists and –
 - (i) employed or engaged by the Department for Work and Pensions, or
 - (ii) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions.]

Annual return and review

81 - (1) The contractor shall submit an annual return relating to the contract to the Primary Care Trust which shall require the same categories of information from all persons who hold contracts with that Trust.

[(1A) Subject to article 53 (annual returns and reviews) of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004, one such return may be

requested by the Primary Care Trust at any time during each financial year in relation to such period (not including any period covered by a previous annual return) as may be specified in the request.

(1B) The contractor shall submit the completed return to the Primary Care Trust-

(a) by such date as has been agreed as reasonable between the contractor and the Primary Care Trust; or

(b) in the absence of such agreement, within 28 days of the request being made.]

(2) Following receipt of the return referred to in sub-paragraph (1), the Primary Care Trust shall arrange with the contractor an annual review of its performance in relation to the contract.

(3) Either the contractor or the Primary Care Trust may, if it wishes to do so, invite the Local Medical Committee for the area of the Primary Care Trust to participate in the annual review.

(4) The Primary Care Trust shall prepare a draft record of the review referred to in sub-paragraph (2) for comment by the contractor 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 contractor.

[(6) In this paragraph, "financial year" means the twelve months ending with 31st March.]

Notifications to the Primary Care Trust

82 - In addition to any requirements of notification elsewhere in the regulations, the contractor shall notify the Primary Care Trust in writing, as soon as reasonably practicable, of-

(a) any serious incident that, in the reasonable opinion of the contractor, affects or is likely to affect the contractor's performance of its obligations under the contract;

(b) any circumstances which give rise to the Primary Care Trust's right to terminate the contract under paragraph 111, 112 or 113(1);

(c) any appointments system which it proposes to operate and the proposed discontinuance of any such system;

(d) 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.

83 - The contractor shall, unless it is impracticable for it to do so, notify the Primary Care Trust in writing within 28 days of any occurrence requiring a change in the information about it published by the Primary Care Trust in accordance with regulations made under section 16CC(3) of the Act (primary medical services).

84 - The contractor shall notify the Primary Care Trust in writing of any person other than a registered patient or a person whom it has accepted as a temporary resident to whom it has provided the essential services described in regulation 15(6) or (8) within the period of 28 days beginning on the day that the services were provided.

Notice provisions specific to a contract with a company limited by shares

85 - (1) A contractor which is a company limited by shares shall give notice in writing to the Primary Care Trust forthwith when-

(a) any share in the contractor is transmitted or transferred (whether legally or beneficially) to another person on a date after the contract has been entered into;

[(aa) a new director or secretary is appointed;]

(b) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;

- (c) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
 - (d) circumstances arise which would enable the court to make a winding up order in respect of the contractor; or
 - (e) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts) .
- (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) is a medical practitioner, or that he satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act (persons eligible to enter into GMS contracts); and
 - (b) meets the further conditions imposed on shareholders by virtue of regulations 4 and 5.

[(3) A notice under sub-paragraph (1)(aa) shall confirm that the new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 5.]

Notice provisions specific to a contract with two or more individuals practising in partnership

86 - (1) A contractor which is a partnership shall give notice in writing to the Primary Care Trust forthwith when-

- (a) a partner leaves or informs his partners that he intends to leave the partnership, and the date upon which he left or will leave the partnership;
 - (b) a new partner joins the partnership.
- (2) A notice under sub-paragraph (1)(b) shall-
- (a) state the date that the new partner joined the partnership;
 - (b) confirm that the new partner is a medical practitioner, or that he satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act;
 - (c) confirm that the new partner meets the conditions imposed by regulations 4 and 5; and
 - (d) state whether the new partner is a general or a limited partner.

Notification of deaths

87 - (1) The contractor shall report in writing to the Primary Care Trust the death on its 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 contractor shall send a copy of the report referred to in sub-paragraph (1) to any other Primary Care Trust in whose area the deceased was resident at the time of his death.

Notifications to patients following variation of the contract

88 - Where the contract 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 contractor's registered patients; or

- (b) patients who are on the contractor's list of patients are to be removed from that list,

the Primary Care Trust 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 Primary Care Trust

89 - (1) Subject to the conditions in sub-paragraph (2), the contractor shall allow persons authorised in writing by the Primary Care Trust 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 contractor 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 contractor or the Primary Care Trust may, if it wishes to do so, invite the Local Medical Committee for the area of the Primary Care Trust to be present at an inspection of the practice premises which takes place under this paragraph.

90 - . . . [NB revoked by SI 2008/528]

Entry and inspection by the [Care Quality Commission]

91 - The contractor shall allow persons authorised by the [Care Quality Commission] to enter and inspect the premises in accordance with section 66 of the Health and Social Care (Community Health and Standards) Act 2008 (right of entry)[, as modified by paragraph 15 of Schedule 3 to the Health and Social Care Act 2008 (Commencement No.9, Consequential Amendments and Transitory, Transitional and Saving Provisions) Order 2009 and section 62 of the Health and Social Care Act 2008 (entry and inspection).]

[Entry and viewing by local involvement network representatives]

91A - The contractor must comply with regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008 in so far as it applies to the contractor.]

Part 6

Complaints

[Complaints procedure]

92 - (1) The contractor 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 contract.

(2) In respect of complaints made on or after 1st April 2009, the complaints procedure required by sub-paragraph (1) shall comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

(3) In respect of complaints received by the contractor prior to 1st April 2009 which have not been resolved by that date, the contractor shall continue to deal with such complaints in accordance with the complaints procedure that it was required to establish and operate prior to 1st April 2009.]

93 - . . . [NB revoked by SI 2009/309]

94 - . . . [NB revoked by SI 2009/309]

95 - . . . [NB revoked by SI 2009/309]

96 - . . . [NB revoked by SI 2009/309]

Co-operation with investigations

97 - (1) The contractor shall co-operate with-

(a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the contract undertaken by-

- (i) the Primary Care Trust, and
- (ii) [the Health Service Commissioner]; and

(b) any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the contractor.

(2) In sub-paragraph (1)-

"NHS body" means a Primary Care Trust, (in England and Wales and Scotland) an NHS trust, an NHS foundation trust, a Strategic Health Authority, a Local Health Board, a Health Board, a Health and Social Services Board or a Health and Social Services Trust;

"local authority" means-

- (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities),
- (b) the Council of the Isles of Scilly, or
- (c) a council constituted under section 2 of the Local Government etc, (Scotland) Act 1994 (constitution of councils);

["Health Service Commissioner" means the person appointed Health Service Commissioner for England in accordance with section 1 of, and Schedule 1 to, the Health Service Commissioners Act 1993].

(3) The co-operation required by sub-paragraph (1) includes-

- (a) answering questions reasonably put to the contractor by the Primary Care Trust;
- (b) providing any information relating to the complaint reasonably required by the Primary Care Trust; 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 contractor's presence at the meeting is reasonably required by the Primary Care Trust.

98 - . . . [NB revoked by SI 2009/309]

Part 7

Dispute Resolution

Local resolution of contract disputes

99 - (1) Subject to sub-paragraph (3), in the case of any dispute arising out of or in connection with the contract, the contractor and the Primary Care Trust must make every reasonable effort to communicate and cooperate 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 contractor or the Primary Care Trust may, if it wishes to do so, invite the Local Medical Committee for the area of the Primary Care Trust 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 procedure specified in paragraph 36, 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 36(4).

Dispute resolution: non-NHS contracts

100 - (1) In the case of a contract which is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the complaints procedure pursuant to Part 6 of this Schedule, may be referred for consideration and determination to the Secretary of State, if-

- (a) the Primary Care Trust so wishes and the contractor has agreed in writing; or
- (b) the contractor so wishes (even if the Primary Care Trust does not agree).

(2) In the case of a dispute referred to the Secretary of State 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

101 - (1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 102 applies in the case of any dispute arising out of or in connection with the contract which is referred to the Secretary of State-

- (a) in accordance with section 4(3) of the 1990 Act (where the contract is an NHS contract); or
- (b) in accordance with paragraph 100(1) (where the contract is not an NHS contract).

(2) The procedure specified in this paragraph and paragraph 102 does not apply where a contractor refers a matter for determination in accordance with paragraph 36(1) of this Schedule, and in such a case the procedure specified in that paragraph shall apply instead.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) shall send to the Secretary of State 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 contract; 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) Where the dispute relates to a contract which is not an NHS contract, the Secretary of State may determine the matter himself or, if he considers it appropriate, appoint a person or persons to consider and determine it.

(6) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (5) or under section 4(5) of the 1990 Act, the Secretary of State shall, within the period of 7 days beginning with the date on which a matter was referred to him, 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 **[under dispute]**.

(7) The Secretary of State 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 Secretary of State 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.

(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 Secretary of State shall, if he decides to appoint a person or persons to hear the dispute-

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

(10) For the purpose of assisting him in his consideration of the matter, the adjudicator may-

- (a) invite representatives of the parties to appear before him 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 he wishes them to give special consideration; or
- (b) consult other persons whose expertise he considers will assist him in his consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), he shall notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he shall give to the parties such opportunity as he 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 Secretary of State shall specify in the request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if he considers that there is good reason for doing so, extend any such period (even after it has expired) and, where he 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 102 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.

Determination of dispute

102 - (1) The adjudicator shall record his determination and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties.

(2) In the case of a contract referred for determination in accordance with paragraph 100(1), subsection (8) of section 4 of the 1990 Act shall apply as that subsection applies in the case of a contract referred for determination in accordance with subsection (3) of section 4 of that Act.

(3) In the case of a contract referred for determination in accordance with paragraph 100(1), subsection (5) of section 28W of the Act shall apply as that subsection applies in the case of a contract referred for determination in accordance with subsection (3) of section 4 of the 1990 Act.

Interpretation of Part 7

103 - (1) In this Part, "any dispute arising out of or in connection with the contract" includes any dispute arising out of or in connection with the termination of the contract.

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

Part 8

Variation and Termination of Contracts

Variation of a contract: general

104 - (1) Subject to Schedule 3, paragraphs 69(8), 70(8), 105, 106 and 117 and paragraph 3 of Schedule 7, no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the Primary Care Trust and the contractor.

(2) In addition to the specific provision made in paragraphs 105(6), 106(6) and 117, the Primary Care Trust may vary the contract without the contractor's consent where it-

(a) is reasonably satisfied that it is necessary to vary the contract so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Secretary of State pursuant to that Act; and

(b) notifies the contractor 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 be not less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

Variation provisions specific to a contract with an individual medical practitioner

105 - (1) If a contractor which is an individual medical practitioner proposes to practise in partnership with one or more persons during the existence of the contract, the contractor shall notify the Primary Care Trust in writing of-

(a) the name of the person or persons with whom it proposes to practise in partnership; and

(b) the date on which the contractor wishes to change its status as a contractor from that of an individual medical practitioner to that of a partnership, which shall be not less than 28 days after the date upon which it has served the notice on the Primary Care Trust pursuant to this sub-paragraph.

(2) A notice under sub-paragraph (1) shall in respect of the person or each of the persons with whom the contractor is proposing to practise in partnership, and also in respect of itself as regards the matters specified in paragraph (c)-

(a) confirm that he is either-

(i) a medical practitioner, or

(ii) a person who satisfies the conditions specified in section 28S(2)(b)(i) to (iv) of the Act;

- (b) confirm that he is a person who satisfies the conditions imposed by regulations 4 and 5; and
- (c) state whether or not it is to be a limited partnership, and if so, who is to be a limited and who a general partner,

and the notice shall be signed by the individual medical practitioner and by the person, or each of the persons (as the case may be), with whom he is proposing to practise in partnership.

(3) The contractor shall ensure that any person who will practise in partnership with it is bound by the contract, whether by virtue of a partnership deed or otherwise.

(4) If the Primary Care Trust is satisfied as to the accuracy of the matters specified in sub-paragraph (2) that are included in the notice, the Primary Care Trust shall give notice in writing to the contractor confirming that the contract shall continue with the partnership entered into by the contractor and its partners, from a date that the Primary Care Trust specifies in that notice.

(5) Where it is reasonably practicable, the date specified by the Primary Care Trust pursuant to sub-paragraph (4) shall be the date requested in the notice served by the contractor pursuant to sub-paragraph (1), or, where that date is not reasonably practicable, the date specified shall be a date after the requested date that is as close to the requested date as is reasonably practicable.

(6) Where a contractor has given notice to the Primary Care Trust pursuant to sub-paragraph (1), the Primary Care Trust-

- (a) may vary the contract but only to the extent that it is satisfied is necessary to reflect the change in status of the contractor from an individual medical practitioner to a partnership; and
- (b) if it does propose to so vary the contract, it shall include in the notice served on the contractor pursuant to sub-paragraph (4) the wording of the proposed variation and the date upon which that variation is to take effect.

Variation provisions specific to a contract with two or more individuals practising in partnership

106 - (1) Subject to sub-paragraph (4), where a contractor consists of two or more individuals practising in partnership in the event that the partnership is terminated or dissolved, the contract shall only continue with one of the former partners if that partner is-

- (a) nominated in accordance with sub-paragraph (3); and
- (b) a medical practitioner who meets the condition in regulation 4(2)(a),

and provided that the requirements in sub-paragraphs (2) and (3) are met.

(2) A contractor shall notify the Primary Care Trust in writing at least 28 days in advance of the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner pursuant to sub-paragraph (1).

(3) A notice under sub-paragraph (2) shall-

- (a) specify the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner;
- (b) specify the name of the medical practitioner with whom the contract will continue, which must be one of the partners; and
- (c) be signed by all of the persons who are practising in partnership.

(4) If a partnership is terminated or dissolved because, in a partnership consisting of two individuals practising in partnership, one of the partners has died, [the remaining individual shall notify the Primary Care Trust in writing as soon as is reasonably practicable of the death of his partner and sub-paragraph (4A) or (4B) shall apply].

[(4A) If the remaining individual is a general medical practitioner, the contract shall continue with that individual.

(4B) If sub-paragraph (4A) does not apply, the Primary Care Trust may, if it thinks fit, serve notice in writing on the remaining individual confirming that the Primary Care Trust will allow the contract to continue with that individual, for a period specified by the Primary Care Trust of up to six months (the "interim period") provided that he consents to the Primary Care Trust employing or supplying a general medical practitioner to him for the interim period to assist in the provision of clinical services under the contract.

(4C) Before deciding whether to serve a notice pursuant to paragraph (4B), the Primary Care Trust shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area.

(4D) If, during the interim period, the contractor withdraws his consent to the Primary Care Trust employing or supplying a general medical practitioner, the Primary Care Trust shall serve notice in writing on the contractor terminating the contract forthwith.

(4E) If, at the end of the interim period, the contractor has not entered into partnership with a general medical practitioner who is not a limited partner, the Primary Care Trust shall serve notice on the contractor terminating the contract forthwith.]

(5) When the Primary Care Trust receives a notice pursuant to sub-paragraph (2) or [(4)], it shall acknowledge in writing receipt of the notice, and in relation to a notice served pursuant to sub-paragraph (2), the Trust shall do so before the date specified pursuant to sub-paragraph (3)(a).

(6) Where a contractor gives notice to the Primary Care Trust pursuant to sub-paragraph (2) or [(4)], the Primary Care Trust may vary the contract but only to the extent that it is satisfied is necessary to reflect the change in status of the contractor from a partnership to an individual medical practitioner.

(7) If the Primary Care Trust varies the contract pursuant to sub-paragraph (6), it shall notify the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect.

[(8) In this paragraph, "general medical practitioner" has the same meaning as in regulation 4(1).]

Termination by agreement

107 - The Primary Care Trust and the contractor may agree in writing to terminate the contract, 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 contract should be terminated.

[Termination on the death of an individual medical practitioner

107A - (1) Where the contract is with an individual medical practitioner and that practitioner dies, the contract shall terminate at the end of the period of seven days after the date of his death unless, before the end of that period-

(a) the Primary Care Trust has agreed in writing with the contractor's personal representatives that the contract should continue for a further period, not exceeding 28 days after the end of the period of seven days; and

(b) the contractor's personal representatives have consented in writing to the Primary Care Trust employing or supplying one or more general medical practitioners to assist in the provision of clinical services under the contract throughout the period for which it continues.

(2) In sub-paragraph (1), "general medical practitioner" has the same meaning as in regulation 4(1).

(3) Sub-paragraph (1) does not affect any other rights to terminate the contract which the Primary Care Trust may have under paragraphs 112 to 115.]

Termination by the contractor

108 - (1) A contractor may terminate the contract by serving notice in writing on the Primary Care Trust at any time.

(2) Where a contractor serves notice pursuant to sub-paragraph (1), the contract shall, subject to sub-paragraph (3), terminate six 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 contract shall instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the contractor is an individual medical practitioner, sub-paragraph (2) shall apply to the contractor, save that the reference to "six months" shall instead be to "three months".

(4) This paragraph and paragraph 109 are without prejudice to any other rights to terminate the contract that the contractor may have.

Late payment notices

109 - (1) The contractor may give notice in writing (a "late payment notice") to the Primary Care Trust if the Trust has failed to make any payments due to the contractor in accordance with a term of the contract that has the effect specified in regulation 22, and the contractor shall specify in the late payment notice the payments that the Trust has failed to make in accordance with that regulation.

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

(3) If, following receipt of a late payment notice, the Primary Care Trust 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 contractor in writing that it has done so within that period of time, the contractor may not terminate the contract pursuant to sub-paragraph (2) until-

(a) there has been a determination of the dispute pursuant to paragraph 102 and that determination permits the contractor to terminate the contract; or

(b) the Primary Care Trust ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

Termination by the Primary Care Trust: general

110 - The Primary Care Trust may only terminate the contract in accordance with the provisions in this Part.

Termination by the Primary Care Trust for breach of conditions in regulation 4

111 - (1) [Subject to sub-paragraph (1A),] the Primary Care Trust shall serve notice in writing on the contractor terminating the contract forthwith if the contractor is an individual medical practitioner and the medical practitioner no longer satisfies the condition specified in regulation 4(1).

[(1A) Where the failure of an individual medical practitioner to continue to satisfy the condition specified in regulation 4(1) is the result of a suspension specified in sub-paragraph (3B), sub-paragraph (1) shall not apply unless-

(a) the contractor is unable to satisfy the Primary Care Trust that it has in place adequate arrangements for the provision of clinical services under the contract for so long as the suspension continues; or

(b) the Primary Care Trust is satisfied that the circumstances of the suspension are such that if the contract is not terminated forthwith-

(i) the safety of the contractor's patients is at serious risk, or

(ii) the Primary Care Trust is at risk of material financial loss.]

(2) [Except in a case to which paragraph 106(4) applies,] where the contractor is-

(a) two or more persons practising in partnership, and the condition specified in regulation 4(2)(a) is no longer satisfied; or

(b) a company limited by shares, and the condition specified in regulation 4(3)(a) is no longer satisfied,

sub-paragraph (3) shall apply.

(3) Where sub-paragraph (2)(a) or (b) applies, the Primary Care Trust shall-

(a) serve notice in writing on the contractor terminating the contract forthwith; or

(b) serve notice in writing on the contractor confirming that the Primary Care Trust will allow the contract to continue, for a period specified by the Primary Care Trust [in accordance with paragraph (3A)] (the "interim period"), during which time the Primary Care Trust shall, with the consent of the contractor, employ or supply one or more general medical practitioners to the contractor for the interim period to assist the contractor in the provision of clinical services under the contract.

[(3A) The period specified by the Primary Care Trust under sub-paragraph (3)(b) shall not exceed-

(a) six months; or

(b) in a case where the failure of the contractor to continue to satisfy the condition in regulation 4(2)(a) or, as the case may be, 4(3)(a), is the result of a suspension referred to in sub-paragraph (3B), the period for which that suspension continues.

(3B) The suspensions referred to in sub-paragraphs (1A) and (3A)(b) are suspension-

(a) by a Fitness to Practise Panel under-

(i) section 35D (functions of a fitness to practise panel) of the Medical Act 1983 in a health case, other than an indefinite suspension under section 35D(6) of that Act, or

(ii) section 38(1) (power to order immediate suspension etc after a finding of impairment of fitness to practise) of that Act; or

(b) by a Fitness to Practise Panel or an Interim Orders Panel under section 41A (interim orders) of that Act.

(3C) In paragraph (3B), "health case" has the meaning given in section 35E(4) of the Medical Act 1983.]

(4) Before deciding which of the options in sub-paragraph (3) to pursue, the Primary Care Trust shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area.

(5) If the contractor does not, pursuant to sub-paragraph (3)(b), consent to the Primary Care Trust employing or supplying a general medical practitioner during the interim period, the Primary Care Trust shall serve notice in writing on the contractor terminating the contract forthwith.

(6) If, at the end of the interim period, the contractor still falls within sub-paragraph (2)(a) or (b), the Primary Care Trust shall serve notice in writing on the contractor terminating the contract forthwith.

[(7) In sub-paragraphs (3) and (5), "general medical practitioner" has the same meaning as in regulation 4(1).]

Termination by the Primary Care Trust for the provision of untrue etc information

112 - The Primary Care Trust may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if, after the contract has been entered into, it comes to the attention of the Primary Care Trust that written information provided to the Primary Care Trust [by the contractor-

(a) before the contract was entered into; or

(b) pursuant to paragraph 85(2) or (3) or 86(2),

in relation to the conditions set out in regulations 4 and 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect].

Other grounds for termination by the Primary Care Trust

113 - (1) The Primary Care Trust may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if-

- (a) in the case of a contract with a medical practitioner, that medical practitioner;
- (b) in the case of a contract with two or more individuals practising in partnership, any individual or the partnership; and
- (c) in the case of a contract with a company limited by shares-
 - (i) the company,
 - (ii) any person legally and beneficially owning a share in the company, or
 - (iii) any director or secretary of the company,

falls within sub-paragraph (2) during the existence of the contract [or, if later, on or after the date on which a notice in respect of his compliance with the conditions in regulation 5 was given under paragraph 85(2) or (3) or 86(2)].

(2) A person falls within this sub-paragraph if-

- (a) it does not satisfy the conditions prescribed in section 28S(2)(b) or (3)(b) of the Act;
- (b) he or it is the subject of a national disqualification;
- (c) subject to sub-paragraph (3), he or it 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;
- (d) subject to sub-paragraph (4), he has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Primary Care Trust has served a notice terminating the contract pursuant to this paragraph, he is employed by the health service body that dismissed him or by another health service body;
- (e) he or it is removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act respectively) unless his name has subsequently been included in such a list;
- (f) he has been convicted in the United Kingdom of murder;
- (g) he 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 six months;
- (h) subject to sub-paragraph (5), he has been convicted elsewhere of an offence which would if committed in England and Wales-
 - (i) constitute murder, or
 - (ii) constitute a criminal offence other than murder and been sentenced to a term of imprisonment of over six months;
- (i) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933 (offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1995 (offences against children under the age of 17 years to which special provisions apply);
- (j) he or it has-
 - (i) been adjudged bankrupt or had sequestration of his estate awarded unless (in either case) he 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 [\[or Schedule 2A to the Insolvency \(Northern Ireland\) Order 1989\]](#), 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, his or its creditors unless he or it has been discharged in respect of it, or
 - (iv) been wound up under Part IV of the Insolvency Act 1986;
- (k) 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;
- (l) 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;
- (m) he has been-
- (i) 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 he was responsible or to which he was privy, or which he by his conduct contributed to or facilitated, or
 - (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990 (powers of the Court of Session to deal with management of charities)[\[or under section 34 of the Charities and Trustee Investment \(Scotland\) Act 2005 \(powers of Court of Session\)\]](#), from being concerned in the management or control of any body;
- (n) he is subject to a disqualification order under the Company Directors Disqualification Act 1986, the Companies (Northern Ireland) Order 1986 or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or
- (o) he has refused to comply with a request by the Primary Care Trust for him to be medically examined on the grounds that it is concerned that he is incapable of adequately providing services under the contract and, in a case where the contract is with two or more individuals practising in partnership or with a company, the Primary Care Trust is not satisfied that the contractor is taking adequate steps to deal with the matter.
- (3) A Primary Care Trust shall not terminate the contract pursuant to sub-paragraph (2)(c) where the Primary Care Trust 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 contractor;
 - (b) a partner, in the case of a contract with two or more individuals practising in partnership; or
 - (c) in the case of a contract with a company limited by shares-
 - (i) a person legally and beneficially holding a share in the company, or
 - (ii) a director or secretary of the company,
- as the case may be.

- (4) A Primary Care Trust shall not terminate the contract 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 his dismissal, until proceedings before that tribunal or court are concluded,

and the Primary Care Trust may only terminate the contract at the end of the period specified in paragraph (b) if there is no finding of unfair dismissal at the end of those proceedings.

(5) A Primary Care Trust shall not terminate the contract pursuant to sub-paragraph (2)(h) where the Primary Care Trust is satisfied that the conviction does not make the person unsuitable to be-

- (a) a contractor;
- (b) a partner, in the case of a contract with two or more individuals practising in partnership; or
- (c) in the case of a contract with a company limited by shares-
 - (i) a person legally and beneficially holding a share in the company, or
 - (ii) a director or secretary of the company,

as the case may be.

114 - The Primary Care Trust may serve notice in writing on the contractor terminating the contract forthwith or with effect from such date as may be specified in the notice if-

- (a) the contractor has breached the contract and as a result of that breach, the safety of the contractor's patients is at serious risk if the contract is not terminated; or
- (b) the contractor's financial situation is such that the Primary Care Trust considers that the Primary Care Trust is at risk of material financial loss.

[Termination by the Primary Care Trust for unlawful sub-contracting

114A - If the contractor breaches the condition specified in paragraph 69(10) and it comes to the Primary Care Trust's attention that the contractor has done so, the Primary Care Trust shall serve a notice in writing on the contractor-

- (a) terminating the contract forthwith; or
- (b) instructing it to terminate the sub-contracting arrangements that give rise to the breach forthwith, and if it fails to comply with the instruction, the Primary Care Trust shall serve a notice in writing on the contractor terminating the contract forthwith.]

Termination by the Primary Care Trust: remedial notices and breach notices

115 - (1) Where a contractor has breached the contract other than as [specified in paragraphs 111 to 114A] and the breach is capable of remedy, the Primary Care Trust shall, before taking any action it is otherwise entitled to take by virtue of the contract, serve a notice on the contractor requiring it to remedy the breach ("remedial notice").

- (2) A remedial notice shall specify-
- (a) details of the breach;
 - (b) the steps the contractor must take to the satisfaction of the Primary Care Trust 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 Primary Care Trust is satisfied that a shorter period is necessary to-

- (a) protect the safety of the contractor'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 Primary Care Trust is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Primary Care Trust may terminate the contract with effect from such date as the Primary Care Trust may specify in a further notice to the contractor.

(5) Where a contractor has breached the contract other than as [specified in paragraphs 111 to 114A] and the breach is not capable of remedy, the Primary Care Trust may serve notice on the contractor requiring the contractor not to repeat the breach ("breach notice").

(6) If, following a breach notice or a remedial notice, the contractor-

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

the Primary Care Trust may serve notice on the contractor terminating the contract with effect from such date as may be specified in that notice.

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

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

Termination by the Primary Care Trust: additional provisions specific to contracts with two or more individuals practising in partnership and companies limited by shares

116 - (1) Where the contractor is a company limited by shares, if the Primary Care Trust becomes aware that the contractor is carrying on any business which the Primary Care Trust considers to be detrimental to the contractor's performance of its obligations under the contract-

- (a) the Primary Care Trust shall be entitled to give notice to the contractor requiring that it 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 contractor has not satisfied the Primary Care Trust that it has ceased carrying on that business by the end of the notice period, the Primary Care Trust may, by a further written notice, terminate the contract forthwith or from such date as may be specified in the notice.

(2) Where the contractor is two or more persons practising in partnership, the Primary Care Trust shall be entitled to terminate the contract by notice in writing on such date as may be specified in that notice where one or more partners have left the practice during the existence of the contract if in its reasonable opinion, the Primary Care Trust considers that the change in membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Primary Care Trust to perform its obligations under the contract.

(3) A notice given to the contractor pursuant to sub-paragraph (2) shall specify-

- (a) the date upon which the contract is to be terminated; and
- (b) the Primary Care Trust's reasons for considering that the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Primary Care Trust to perform its obligations under the contract.

Contract sanctions

117 - (1) In this paragraph and paragraph 118, "contract sanction" means-

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

(2) Where the Primary Care Trust is entitled to terminate the contract pursuant to paragraph 112, 113, 114 or 115(4) or (6) or paragraph 116, it may instead impose any of the contract sanctions if the Primary Care Trust is reasonably satisfied that the contract sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Primary Care Trust's entitlement to terminate the contract.

(3) The Primary Care Trust shall not, under sub-paragraph (2), be entitled to impose any contract sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

(4) If the Primary Care Trust decides to impose a contract sanction, it must notify the contractor of the contract 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 118, the Primary Care Trust shall not impose the contract sanction until at least 28 days after it has served notice on the contractor pursuant to sub-paragraph (4) unless the Primary Care Trust is satisfied that it is necessary to do so in order to-

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

(6) Where the Primary Care Trust imposes a contract sanction, the Primary Care Trust shall be entitled to charge the contractor the reasonable costs of additional administration that the Primary Care Trust has incurred in order to impose, or as a result of imposing, the contract sanction.

Contract sanctions and the NHS dispute resolution procedure

118 - (1) If there is a dispute between the Primary Care Trust and the contractor in relation to a contract sanction that the Primary Care Trust is proposing to impose, the Primary Care Trust shall not, subject to sub-paragraph (4), impose the proposed contract sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the contractor refers the dispute relating to the contract sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the Primary Care Trust served notice on the contractor in accordance with paragraph 117(4) (or such longer period as may be agreed in writing with the Primary Care Trust), and notifies the Primary Care Trust in writing that it has done so, the Primary Care Trust shall not impose the contract sanction unless-

- (a) there has been a determination of the dispute pursuant to paragraph 102 and that determination permits the Primary Care Trust to impose the contract sanction; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(3) If the contractor does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Primary Care Trust shall be entitled to impose the contract sanction forthwith.

(4) If the Primary Care Trust is satisfied that it is necessary to impose the contract sanction before the NHS dispute resolution procedure is concluded in order to-

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

the Primary Care Trust shall be entitled to impose the contract sanction forthwith, pending the outcome of that procedure.

Termination and the NHS dispute resolution procedure

119 - (1) Where the Primary Care Trust is entitled to serve written notice on the contractor terminating the contract pursuant to paragraph 112, 113, 114, [115(4) or (6) or 116(2)], the Primary Care Trust shall, in the notice served on the contractor pursuant to those provisions, specify a date on which the contract terminates that is not less than 28 days after the date on which the Primary Care Trust has served that notice on the contractor unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Primary Care Trust is satisfied that a period less than 28 days is necessary in order to-

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

(3) In a case falling with sub-paragraph (1), where the exceptions in sub-paragraph (2) do not apply, where the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Primary Care Trust in writing that it has done so, the contract 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 contract shall only terminate if and when-

- (a) there has been a determination of the dispute pursuant to paragraph 102 and that determination permits the Primary Care Trust to terminate the contract; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Primary Care Trust is satisfied that it is necessary to terminate the contract before the NHS dispute resolution procedure is concluded in order to-

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

sub-paragraphs (3) and (4) shall not apply and the Primary Care Trust shall be entitled to confirm, by written notice to be served on the contractor, that the contract will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 112, 113(1), 114, 115(4) or (6) or 116.

Consultation with the Local Medical Committee

120 - (1) Whenever the Primary Care Trust is considering-

- [(a) terminating the contract pursuant to paragraph 112, 113, 114, 115(4) or (6) or 116;

(b) which of the alternative notices in writing available under the provisions of paragraph 114A it will serve; or

(c) imposing a contract sanction],

it shall, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area before it terminates the contract or imposes a contract sanction.

(2) Whether or not the Local Medical Committee has been consulted pursuant to sub-paragraph (1), whenever the Primary Care Trust imposes a contract sanction on a contractor or terminates a contract pursuant to this Part, it shall, as soon as reasonably practicable, notify the Local Medical Committee in writing of the contract sanction imposed or of the termination of the contract (as the case may be).

Part 9

Miscellaneous

Clinical governance

121 - (1) The contractor shall have an effective system of clinical governance [which shall include appropriate standard operating procedures in relation to the management and use of controlled drugs].

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

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

(4) In this paragraph "system of clinical governance" means a framework through which the contractor 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.

[121A - The contractor shall co-operate with the Primary Care Trust in the discharge of any obligations of the Primary Care Trust or its accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006.]

Insurance

122 - (1) The contractor shall at all times hold adequate insurance against liability arising from negligent performance of clinical services under the contract.

(2) The contractor shall not sub-contract its obligations to provide clinical services under the contract 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 contractor; and

(b) a contractor shall be regarded as holding insurance if it is held by [a person employed or engaged by it in connection with clinical services which that person] provides under the contract or, as the case may be, sub-contract.

123 - The contractor shall at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the contract which are not covered by the insurance referred to in paragraph 122(1).

Gifts

- 124 - (1) The contractor 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 contractor or its patients in connection with the contract; 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 contractor;
 - (b) where the contract is with two or more individuals practising in partnership, any partner;
 - (c) where the contract is with a company-
 - (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 contractor for the purposes of the contract;
 - (e) any general medical practitioner engaged by the contractor for the purposes of the contract;
 - (f) any spouse [or civil partner] of a contractor (where the contractor is an individual medical practitioner) or of a person specified in paragraphs (b) to (e); or
 - (g) any person (whether or not of the opposite sex) whose relationship with a contractor (where the contractor is an individual medical practitioner) 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 only apply where-
- (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the contractor;
 - (b) the contractor is not aware of the gift; or
 - (c) the contractor is not aware that the donor wishes to provide services to the contractor.
- (4) The contractor 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 contractor shall make the register available to the Primary Care Trust on request.

Compliance with legislation and guidance

125 - The contractor shall-

- (a) comply with all relevant legislation; and
- (b) have regard to all relevant guidance issued by the Primary Care Trust, the relevant Strategic Health Authority or the Secretary of State.

Third party rights

126 - The contract shall not create any right enforceable by any person not a party to it.

SCHEDULE 7

OUT OF HOURS SERVICES

Regulation 32

Temporary arrangements for transfer of obligations and liabilities in relation to certain out of hours services

1 - (1) In this Schedule-

"accredited service provider" has the meaning given to it by regulation 2 of the Out of Hours Regulations;

"Out of Hours Regulations" means the National Health Service (Out of Hours Medical Services) and National Health Service (General Medical Services) Amendment Regulations 2002;

"out of hours arrangement" means an arrangement under sub-paragraph (2); and

"transferee doctor" means a person referred to in sub-paragraph (5)(b) who has undertaken to carry out the obligations of a contractor during all or part of the out of hours period in accordance with an out of hours arrangement referred to in sub-paragraph (2).

(2) Subject to the provisions of this Schedule, where a contractor is required to provide out of hours services pursuant to regulation 30 or 31, it may, with the approval of the Primary Care Trust, make an arrangement with one of the persons specified in sub-paragraph (5) as if regulations 1 to 11 of the Out of Hours Regulations, subject to the modifications specified in sub-paragraph (6), were still in force.

(3) Any arrangement made pursuant to sub-paragraph (2) shall cease to have effect on 1st January 2005.

(4) An arrangement made in accordance with sub-paragraph (2) shall, for so long as it continues, or is not suspended under paragraph 7(1), relieve the contractor of-

- (a) its obligations to provide out of hours services pursuant to regulation 30 or 31; and
- (b) all liabilities under the contract in respect of those services.

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

- (a) an accredited service provider; or
- (b) a person who holds a general medical services contract with the Primary Care Trust which includes the provision of out of hours services.

- (6) The modifications referred to in sub-paragraph (2) are-
- (a) as if out of hours period had the meaning given in regulation 2 of these Regulations;
 - (b) as if the requirements relating to an assessing authority in regulation 4(5) to (8) did not apply in cases where, in the opinion of the accrediting authority, it was appropriate and safe to dispense with them;
 - (c) as if the reference to a medical practitioner in regulation 11(2)(c) was a reference to a contractor;
 - (d) as if the reference to section 44 in regulation 11(2)(d) was to section 45A of the Act; and
 - (e) as if the reference to a medical list or supplementary list in paragraph 7 of the Schedule was to a medical performers list and the words "or he is named in an agreement under section 2 of the 1997 Act as a performer of personal medical services" were omitted.

(7) A contractor may make more than one out of hours arrangement and may do so (for example) with different transferee doctors or accredited service providers and in respect of different patients, different times and different parts of its practice area.

(8) A contractor may retain responsibility for, or make separate out of hours arrangements in respect of, the provision to any patients of maternity medical services during the out of hours period which the contractor is required to provide pursuant to regulation 30 or 31 and any separate out of hours arrangements it makes may encompass all or any part of the maternity medical services it provides.

(9) Nothing in this paragraph prevents a contractor from retaining or resuming its obligations in relation to named patients.

Application for approval of an out of hours arrangement

2 - (1) An application to the Primary Care Trust for approval of an out of hours arrangement shall be made in writing and shall state-

- (a) the name and address of the accredited service provider or the proposed transferee doctor;
- (b) the periods during which the contractor's obligations under the contract are to be transferred;
- (c) how the accredited service provider or proposed transferee doctor intends to meet the contractor's obligations during the periods specified under paragraph (b);
- (d) the arrangements for the transfer of the contractor's obligations under the contract to and from the accredited service provider or transferee doctor at the beginning and end of the periods specified under paragraph (b);
- (e) whether the proposed arrangement includes the contractor's obligations in respect of maternity medical services; and
- (f) how long the proposed arrangements are intended to last and the circumstances in which the contractor's obligations under the contract during the periods specified under paragraph (b) would revert to it.

(2) The Primary Care Trust shall determine the application before the end of the period of 28 days beginning with the day on which the Primary Care Trust received it.

(3) The Primary Care Trust shall grant approval to a proposed out of hours arrangement if it is satisfied-

- (a) having regard to the overall provision of primary medical services provided in the out of hours period in its area, that the arrangement is reasonable and will contribute to the efficient provision of such services in the area;
- (b) having regard, in particular, to the interests of the contractor's patients, that the arrangement is reasonable;

- (c) having regard, in particular, to all reasonably foreseeable circumstances, that the arrangement is practicable and will work satisfactorily;
- (d) that any arrangement with a person referred to in paragraph 1(5)(b) will be of an equivalent standard to an arrangement with a person referred to in paragraph 1(5)(a);
- (e) that in the case of an arrangement with a person referred to in paragraph 1(5)(a), the practice premises are within the geographical area in respect of which approval is given under regulation 5 of the Out of Hours Regulations;
- (f) that it will be clear to the contractor's patients how to seek primary medical services during the out of hours period;
- (g) where maternity medical services are to be provided under the out of hours arrangement, that they will be performed by a medical practitioner who has such medical experience and training as are necessary to enable him properly to perform such services; and
- (h) that if the arrangement comes to an end, the contractor has in place proper arrangements for the immediate resumption of its responsibilities,

and shall not refuse to grant approval without first consulting the Local Medical Committee (if any) for its area.

(4) The Primary Care Trust shall give notice to the contractor of its determination and, where it refuses an application, it shall send the contractor a statement in writing of the reasons for its determination.

(5) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Primary Care Trust's notification under sub-paragraph (4) was sent.

Effect of approval of an arrangement with a transferee doctor

3 - Where the Primary Care Trust has approved an out of hours arrangement with a transferee doctor the Primary Care Trust and the transferee doctor shall be deemed to have agreed a variation of their contract which has the effect of including in it, from the date on which the out of hours arrangement commences and for so long as that arrangement is not suspended or terminated, the services covered by that arrangement and paragraph 104(1) of Schedule 6 shall not apply.

Review of approval

4 - (1) Where it appears to the Primary Care Trust that it may no longer be satisfied of any of the matters referred to in paragraphs (a) to (h) of paragraph 2(3), it may give notice to the contractor that it proposes to review its approval of the out of hours arrangement.

(2) On any review under sub-paragraph (1), the Primary Care Trust shall allow the contractor a period of 30 days, beginning with the day on which it sent the notice, within which to make representations in writing to the Primary Care Trust.

(3) After considering any representations made in accordance with sub-paragraph (2), the Primary Care Trust may determine to-

- (a) continue its approval;
- (b) withdraw its approval following a period of notice; or
- (c) if it appears to it that it is necessary in the interests of the contractor's patients, withdraw its approval immediately.

(4) Except in the case of an immediate withdrawal of approval, the Primary Care Trust shall not withdraw its approval without first consulting the Local Medical Committee (if any) for its area.

- (5) Where the Primary Care Trust determines to withdraw its approval immediately, it shall notify the Local Medical Committee (if any) for its area.
- (6) The Primary Care Trust shall give notice to the contractor of its determination under sub-paragraph (3).
- (7) Where the Primary Care Trust withdraws its approval, whether immediately or on notice, it shall include with the notice a statement in writing of the reasons for its determination.
- (8) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Primary Care Trust's notification under sub-paragraph (6) was sent.
- (9) Where the Primary Care Trust determines to withdraw its approval following a period of notice, the withdrawal shall take effect at the end of the period of two months beginning with-
- (a) the date on which the notice referred to in sub-paragraph (6) was sent; or
 - (b) where there has been a dispute which has been referred under the NHS dispute resolution procedure and the dispute is determined in favour of withdrawal, the date on which the contractor receives notice of the determination.
- (10) Where the Primary Care Trust determines to withdraw its approval immediately, the withdrawal shall take effect on the day on which the notice referred to in sub-paragraph (6) is received by the contractor.

Suspension of approval

5 - (1) Where the Primary Care Trust suspends its approval of an accredited service provider under regulation 9 of the Out of Hours Regulations or receives notice of suspension of such approval under regulation 11 of those Regulations, it shall forthwith suspend its approval of any out of hours arrangement made by the contractor with that accredited service provider.

(2) A suspension of approval under sub-paragraph (1) shall take effect on the day on which the contractor receives notice of suspension of approval of the accredited service provider under regulation 11 of the Out of Hours Regulations.

Immediate withdrawal of approval other than following review

6 - (1) The Primary Care Trust shall withdraw its approval of an out of hours arrangement immediately-

(a) in the case of an arrangement with a person referred to in paragraph 1(5)(a), if it withdraws its approval of the accredited service provider under regulation 8 of the Out of Hours Regulations or receives notice of withdrawal of such approval under regulation 11 of those Regulations;

(b) in the case of an arrangement with a person referred to in paragraph 1(5)(b), if the person with whom it is made ceases to hold a general medical services contract with the Primary Care Trust which includes the provision of out of hours services; or

(c) where, without any review having taken place under paragraph 4, it appears to the Primary Care Trust that it is necessary in the interests of the contractor's patients to withdraw its approval immediately.

(2) The Primary Care Trust shall give notice to the contractor of a withdrawal of approval under sub-paragraph (1)(b) or (c) and shall include with the notice a statement in writing of the reasons for its determination.

(3) An immediate withdrawal of approval under sub-paragraph (1) shall take effect-

(a) in the case of a withdrawal under sub-paragraph (1)(a), on the day on which the contractor receives notice of withdrawal of approval of the accredited service provider under Regulation 11 of the Out of Hours regulations; or

(b) in the case of a withdrawal under sub-paragraph (1)(b) or (c), on the day on which the notice referred to in sub-paragraph (2) is received by the contractor.

(4) The Primary Care Trust shall notify the Local Medical Committee (if any) for its area of a withdrawal of approval under sub-paragraph (1)(c).

(5) A contractor which wishes to refer a withdrawal of approval under sub-paragraph (1)(c) in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Primary Care Trust's notification under sub-paragraph (2) was sent.

Suspension or termination of an out of hours arrangement

7 - (1) The contractor shall suspend an arrangement made with an accredited service provider under paragraph 1(2) on receipt of the notice of suspension of approval of that provider under regulation 11 of the Out of Hours Regulations.

(2) The contractor shall terminate an out of hours arrangement made under paragraph 1(2) with effect from the date of the taking effect of the withdrawal of the Primary Care Trust's approval of that arrangement under paragraph 4 or 6.

SCHEDULE 8

CLOSURE NOTICE

Schedule 6, paragraph 29(8)

Application for List Closure	
From: <i>Name of Contractor</i>	To: <i>Name of Primary Care Trust</i>
	Date:

In accordance with paragraph 29 of Schedule 6 to the National Health Service (General Medical Services Contract) Regulations 2004, on behalf of the above named contractor I/we wish to make formal application for our list to be closed to new patients and assignments, as follows:

(1) Length of period of closure (which may not exceed 12 months and, in the absence of any agreement, shall be 12 months)	
(2) Date from which closure will take effect	
(3) Date from which closure will cease to have effect	
(4) Current number of registered patients	
(5) Reduction in terms of either a percentage of the number indicated in (4) above or an actual number of patients which would trigger a re-opening (or suspension of list closure) of the list	
(6) Increase in terms of either a percentage of the	

number indicated in (4) above or an actual number of patients which would trigger a re-closure (or lifting of the suspension of list closure) of the list	
(7) Any withdrawal or reduction of additional or enhanced services	

Signed.
For: [Name of contractor]

SCHEDULE 9

... [NB: Revoked.]

SCHEDULE 10

INFORMATION TO BE INCLUDED IN PRACTICE LEAFLETS

Schedule 6, paragraph 76

A practice leaflet shall include-

- 1 - The name of the contractor.
- 2 - In the case of a contract with a partnership-
 - (a) whether or not it is a limited partnership; and
 - (b) the names of all the partners and, in the case of a limited partnership, their status as a general or limited partner.
- 3 - In the case of a contract with a company-
 - (a) the names of the directors, the company secretary and the shareholders of that company; and
 - (b) the address of the company's registered office.
- 4 - The full name of each person performing services under the contract.
- 5 - In the case of each health care professional performing services under the contract his professional qualifications.
- 6 - Whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals.
- 7 - The contractor's practice area, by reference to a sketch diagram, plan or postcode.
- 8 - The address of each of the practice premises.
- 9 - The contractor's telephone and fax numbers and the address of its website (if any).

10 - Whether the practice premises have suitable access for disabled patients and, if not, the alternative arrangements for providing services to such patients.

11 - How to register as a patient.

12 - The right of patients to express a preference of practitioner in accordance with paragraph 18 of Schedule 6 and the means of expressing such a preference.

13 - The services available under the contract.

14 - The opening hours of the practice premises and the method of obtaining access to services throughout the core hours.

15 - The criteria for home visits and the method of obtaining such a visit.

16 – The consultations available to patients under paragraphs 5 and 6 of Schedule 6.

17 - The arrangements for services in the out of hours period (whether or not provided by the contractor) and how the patient may contact such services.

18 - If the services in paragraph 17 are not provided by the contractor, the fact that the Primary Care Trust referred to in paragraph 28 is responsible for commission the services.

19 - The name and address of any local walk-in centre.

20 - The telephone number of NHS Direct and details of NHS Direct online.

21 - The method by which patients are to obtain repeat prescriptions.

22 - If the contractor offers repeatable prescribing services, the arrangements for providing such services.

23 - If the contractor is a dispensing contractor, the arrangements for dispensing prescriptions.

24 - How patients may make a complaint or comment on the provision of service.

25 - The rights and responsibilities of the patient, including keeping appointments.

26 - The action that may be taken where a patient is violent or abusive to the contractor, its staff, persons present on the practice premises or in the place where treatment is provided under the contract or other persons specified in paragraph 21(2) of Schedule 6.

27 - Details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information.

28 - The name, address and telephone number of the Primary Care Trust which is a party to the contract and from whom details of primary medical services in the area may be obtained.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set out, for England, the framework for general medical services contracts under section 28Q of the National Health Service Act 1977 ("the Act").

Part 2 of the Regulations prescribes the conditions which, in accordance with section 28S of the Act, must be met by a contractor before the Primary Care Trust may enter into a general medical services contract with it.

Part 3 of the Regulations prescribes the procedure for pre-contract dispute resolution, in accordance with section 28W(2) of the Act. Part 3 applies to cases where the contractor is not a health service body. In cases where the contractor is such a body, the procedure for dealing with pre-contract disputes is set out in section 4 of the National Health Service and Community Care Act 1990.

Part 4 of the Regulations sets out the procedures, in accordance with section 28W(3) of the Act, by which the contractor may obtain health service body status.

Part 5 of (and Schedules 2 to 6, and 8 to 10 to) the Regulations prescribe the terms which, in accordance with sections 28V and 28W of the Act, must be included in a general medical services contract (in addition to those contained in the Act). It includes, in regulation 15, a description of the services which must be provided to patients under general medical services contracts pursuant to section 28R of the Act.

The prescribed terms include terms relating to-

- (a) the type and duration of the contract (regulations 12 to 14);
- (b) the services to be provided (regulations 15, 16 and 18 to 20 and Schedule 2), the manner in which they are to be provided (Part 1 of Schedule 6) and the procedures for opting out of additional and out of hours services (regulation 17 and Schedule 3);
- (c) the issuing of medical certificates (regulation 21 and Schedule 4);
- (d) finance, fees and charges (regulations 22 to 24 and Schedule 5);
- (e) patient registration and removal, lists closures and assignments (Schedule 6, Part 2, and Schedule 8);
- (f) prescribing and dispensing (Schedule 6, Part 3);
- (g) the conditions to be met by those who perform services or are employed or engaged by the contractor (Schedule 6, Part 4);
- (h) patient records, the provision of information and rights of entry (Schedule 6, Part 5, and Schedule 10);
- (i) complaints (Schedule 6, Part 6);
- (j) procedures for dispute resolution (Schedule 6, Part 7); and
- (k) procedures for variation and termination of contracts (Schedule 6, Part 8).

Part 6 of the Regulations prescribes functions for Local Medical Committees.

Part 7 of the Regulations and Schedule 7 make transitional provision.