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STATUTORY INSTRUMENTS

2015 No. 1862

The National Health Service (General Medical Services Contracts) Regulations 2015

PART 1

General

Citation and commencement

- 1.—(1) These Regulations may be cited as the National Health Service (General Medical Services Contracts) Regulations 2015.
 - (2) They come into force on 7th December 2015.

Application

- 2. These Regulations apply to a contract—
 - (a) to which the National Health Service (General Medical Services Contracts) Regulations 2004 M1 applied immediately before the date on which these Regulations come into force; or
 - (b) which is entered into between a contractor and the Board on or after that date.

Marginal Citations

M1 S.I. 2004/291; as amended by S.I. 2004/906 and 2694, S.I. 2005/893 and 3315, S.I. 2006/1501, S.I. 2007/3491, S.I. 2008/528 and 1700, S.I. 2009/309, 2205 and 2230, S.I. 2010/22, 231 and 578, S.I. 2012/970, 1479, 1909, 1916 and 2404, S.I. 2013/363, S.I. 2014/465, 1887 and 2721 and S.I. 2015/196 and 915. S.I. 2004/291 is revoked by regulation 98 of, and Schedule 5 to, these Regulations.

Interpretation

- 3. In these Regulations—
 - "the Act" means the National Health Service Act 2006;
 - "2004 Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2004;
 - "2010 Order" means the Postgraduate Medical Education and Training Order of Council 2010 M2.
 - "additional services" means one or more of the following—
 - (a) cervical screening services;
 - (b) contraceptive services;
 - (c) childhood vaccines and immunisations;

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- (d) vaccines and immunisations;
- (e) child health surveillance services;
- (f) maternity medical services; and
- (g) minor surgery;

"adjudicator" means the Secretary of State or one or more people appointed by the Secretary of State under section 9(8) of the Act M3 (NHS contracts) or under regulation 83(5)(b);

[F1"advanced electronic signature" means an electronic signature which meets the following requirements—

- (a) it is uniquely linked to the signatory;
- (b) it is capable of identifying the signatory;
- (c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under the signatory's sole control; and
- (d) it is linked to the data signed in such a way that any subsequent change in the 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 126 of the Act M4 (arrangements for pharmaceutical services);

"armed forces of the Crown" means the forces that are "regular forces" or "reserve forces" within the meaning given in section 374 of the Armed Forces Act 2006 M5;

"assessment panel" means the panel appointed by the Board for the purpose of making determinations under paragraph 41(7) of Schedule 3;

"bank holiday" means any day that is specified or proclaimed as a bank holiday in England and Wales under section 1 of the Banking and Financial Dealings Act 1971 M6 (bank holidays);

"batch issue" means a form, in the format required by the Board and approved by the Secretary of State, which—

- (a) is issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a chemist or person who provides dispensing services to receive payment for the provision of repeat dispensing services;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is generated by a computer and not signed by a repeatable prescriber;
- (d) 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
- (e) has included on it a number denoting its place in the sequence referred to in paragraph (d);

"the Board" means the National Health Service Commissioning Board M7;

"Care Quality Commission" means the body established under section 1 of the Health and Social Care Act 2008 M8 (The Care Quality Commission);

"CCG" means a clinical commissioning group M9;

"CCT" means a certificate of completion of training awarded under section 34L(1) of the Medical Act 1983 M10 (award and withdrawal of a Certificate of Completion of Training) including any such certificate awarded in pursuance of the competent authority functions of

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the General Medical Council specified in section 49B of, and Schedule 4A to, that Act MII (The Directive: designation of competent authority etc.);

"cervical screening services" means the services described in paragraph 2(2) of Schedule 1;

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

"chemist" means-

- (a) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968 M12 (general provisions); or
- (b) a supplier of appliances,

who is included in the list held by the Board under section 129 of the Act M13 (regulations as to pharmaceutical services), or a local pharmaceutical services scheme made under Schedule 12 to the Act (LPS Schemes);

"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 1;

"childhood vaccines and immunisations" means the services described in paragraph 5(2) of Schedule 1;

"chiropodist or podiatrist independent prescriber" means a person—

- (a) who is engaged or employed by the contractor or is a party to the contract; and
- (b) who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 M14 (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropodist or podiatrist is qualified to order drugs, medicines and appliances as a chiropodist or podiatrist independent prescriber;

"clinical services" means medical services under the contract which relate to the actual observation and treatment of patients;

"closed", in relation to a 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 1;

"contract", except in regulation 96, means a general medical services contract made under section 84(2) of the Act M15 (general medical services contracts: introductory);

"contractor", except in regulation 6, has the meaning given in section 84(5) of the Act (general medical services contracts: introductory);

"contractor's list of patients" means the list prepared and maintained by the Board under paragraph 17 of Schedule 3;

"core hours" means the period beginning at 8.00am 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 the patient's 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 under section 126 (arrangements for pharmaceutical services) and section 132 (persons authorised to provide pharmaceutical services) of the Act M16;

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"Drug Tariff" means the publication known as the Drug Tariff which is published by the Secretary of State and which is referred to in section 127(4) of the Act M17 (arrangements for additional pharmaceutical services);

"electronic communication" has the meaning given in section 15 of the Electronic Communications Act 2000 M18 (general interpretation);

"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 Prescription Service" means the service of that name which is managed by the Health and Social Care Information Centre M19;

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

[F2" electronic signature" means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;

"electronic signature creation data" means unique data which is used by the signatory to create an electronic signature;]

"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 that service;

"essential services" means the services required to be provided in accordance with regulation 17;

"financial year" has the meaning given in section 275(1) of the Act (interpretation);

"general medical practitioner" means a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council under section 2 of the Medical Act 1983 M20 (registration of medical practitioners);

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

"GMS Statement of Financial Entitlements" M21 means the directions given by the Secretary of State under section 87 of the Act M22 (GMS contracts: payments);

"GP Specialty Registrar" means a general medical practitioner who is being trained in general practice by a general medical practitioner who is approved under section 34I(1)(c) of the Medical Act 1983 M23 (postgraduate education and training: approvals) for the purpose of providing training in accordance with that section, whether as part of training leading to a CCT or otherwise;

"Health and Social Services Board" means a Health and Social Services Board established under article 16 of the Health and Social Services (Northern Ireland) Order 1972 M24 (establishment of Health and Social Services Boards);

"Health and Social Services Trust" means a Health and Social Services Trust established under article 10 of the Health and Personal Services (Northern Ireland) Order 1991 M25 (ancillary services);

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"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978 M26 (Health Boards);

"health care professional" has the meaning given in section 108 of the Act M27 (participants in section 107 arrangements) and "health care profession" is to be construed accordingly;

"health service body" has the meaning given in section 9(4) of the Act M28 (NHS contracts);

"home oxygen order form" means a form provided by the Board 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 whose relationship with the registered patient has the characteristics of the relationship between spouses;
- (c) a parent or step-parent;
- (d) a son or daughter;
- (e) 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 M29; or
- (f) a grandparent;

"independent nurse prescriber" means a person—

- (a) who is either engaged or employed by the contractor or who is a 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 that person is qualified to order drugs, medicines or appliances as a community practitioner nurse prescriber, a nurse independent prescriber or as a nurse independent/supplementary prescriber;

"licensing body" means a body that licenses or regulates a profession;

"limited partnership" means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907 M30 (registration of limited partnerships required);

"listed medicines" means the drugs mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015 M31;

"listed medicines voucher" means a form provided by the Board for use for the purpose of ordering a listed medicine;

"Local Health Board" means a body established under section 11 of the National Health Service (Wales) Act 2006 M32 (Local Health Boards);

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"Local Medical Committee" means a committee recognised by the Board under section 97 of the Act M33 (local medical committees);

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

"medical card" means a card issued by the Board or a Local Health Board, Health Authority, Health Board or Health and Social Services Board to a person for the purpose of enabling that person to obtain, or to establish entitlement to receive, primary medical services;

"medical performers list" means the list of medical practitioners maintained and published by the Board in accordance with section 91 of the Act M34 (persons performing primary medical services);

"Medical Register" means the registers kept under section 2 of the Medical Act 1983 M35 (registration of medical practitioners);

"minor surgery" means the services described in paragraph 8(2) of Schedule 1;

"national disqualification" means—

- (a) a decision made by the First Tier Tribunal under section 159 of the Act M36 (national disqualification) or under regulations corresponding to that section made under—
 - (i) section 91(3) of the Act (persons performing primary medical services),
 - (ii) section 106(3) of the Act (persons performing primary dental services),
 - (iii) section 123(3) of the Act (persons performing primary ophthalmic services), and
 - (iv) sections 145, 146, 147A or 149 (performers of pharmaceutical services and assistants),

of the Act M37; or

(b) a decision under provisions in force in Wales, Scotland or Northern Ireland corresponding to section 159 of the Act (national disqualification);

"NHS contract" has the meaning given in section 9 of the Act M38 (NHS contracts);

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

- (a) in Part 12; or
- (b) in a case to which paragraph 42 of Schedule 3 applies, in that paragraph;

"NHS foundation trust" has the meaning given in section 30 of the Act M39 (NHS foundation trusts):

"NHS trust" means a body established under section 25 of the Act M40 (NHS trusts);

"nominated dispenser" means a chemist, medical practitioner or contractor who has been nominated in respect of a patient where the details of that nomination are held in respect of that patient in the Patient Demographics Service which is managed by the Health and Social Care Information Centre M41;

"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 form for the purpose of ordering a drug, medicine or appliance which—

- (a) is provided by the Board, a local authority or the Secretary of State;
- (b) is issued, or is to be issued, by the prescriber;
- (c) indicates that the drug, medicine or appliance ordered may be provided more than once; and

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(d) specifies, or is to specify, the number of occasions on which the drag, medicine or appliance may be provided;

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

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 M42 (establishment and maintenance of register);

"open", in relation to a contractor's list of patients, means open to applications from patients in accordance with paragraph 18 of Schedule 3;

"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 M43 (register of opticians); and
- against whose name in that register is recorded an annotation signifying that that 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 8.00am on the following day;
- (b) the period beginning at 6.30pm on Friday and ending at 8.00am 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 the 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 their 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 17(7) or (9) respectively;
- (d) any other person to whom the contractor has agreed to provide services under the contract; and
- (e) any person in respect of whom the contractor is responsible for the provision of out of hours services;

"performer" means a performer of medical services under the contract to whom the provisions of Part 7 of these Regulations apply;

"pharmacist independent prescriber" means a person—

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

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- (b) who is registered in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010 M44 (establishment, maintenance of and access to the register) or the register maintained under article 6 (the Register) and article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976 M45; and
- (c) against whose name in that register is recorded an annotation signifying that that person is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"physiotherapist independent prescriber" means a person who is—

- (a) engaged or employed by the contractor or is a party to the contract; and
- (b) registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001 M46 (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that that physiotherapist is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"post registration programme" means a programme that is for the time being recognised by the General Medical Council under regulation 10A of the Medical Act 1983 M47 (programmes for provisionally registered doctors) as providing provisionally registered doctors with an acceptable foundation for future practise as a fully registered medical practitioner;

"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 20(1)(d);

"practice leaflet" means a leaflet drawn up in accordance with regulation 78;

"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 chiropodist or podiatrist independent prescriber;
- (b) an independent nurse prescriber;
- (c) a medical practitioner;
- (d) an optometrist independent prescriber;
- (e) a pharmacist independent prescriber;
- (f) a physiotherapist independent prescriber; F3...
- (g) a supplementary [F4prescriber; and]
- (h) [F5 a therapeutic radiographer independent prescriber,]

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

"prescription form" means—

- (a) a form for the purpose of ordering a drug, medicine or appliance which—
 - (i) is provided by the Board, a local authority or the Secretary of State and is in the format required by the NHS Business Services Authority M48,
 - (ii) is issued, or is to be issued, by the prescriber, and
 - (iii) does not indicate that the drug, medicine or appliance ordered may be provided more than once; or
- (b) in the case of an electronic prescription to which regulation 57 applies, data created in an electronic form for the purpose of ordering a drug, medicine or appliance, which—

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- (i) is signed, or is to be signed, with a prescriber's advanced electronic signature,
- (ii) is transmitted, or is to be transmitted, as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service, and
- (iii) does not indicate that the drug, medicine or appliance ordered may be provided more than once;

"prescription only medicine" means a medicine referred to in regulation 5(3) of the Human Medicines Regulations 2012 M49 (classification of medicinal products);

"primary care list" means—

- (a) a list of persons performing primary medical services, primary dental services, primary ophthalmic services or pharmaceutical services prepared in accordance with regulations made under—
 - (i) section 91 of the Act (persons performing primary medical services),
 - (ii) section 106 of the Act (persons performing primary dental services),
 - (iii) section 123 of the Act (persons performing primary ophthalmic services), or
 - (iv) sections 145, 146, 147A or 149 (performers of pharmaceutical services and assistants),

of the Act M50;

- (b) a list of persons undertaking to provide, or assist in the provision of—
 - (i) primary medical services in accordance with regulations made under Part 4 of the Act (primary medical services),
 - (ii) primary dental services in accordance with regulations made under Part 5 of the Act (primary dental services),
 - (iii) primary ophthalmic services in accordance with regulations made under Part 6 of the Act (primary ophthalmic services), and
 - (iv) pharmaceutical services in accordance with regulations made under Part 7 of the Act (pharmaceutical services and local pharmaceutical services); or
- (c) a list corresponding to any of the above in Wales, Scotland or Northern Ireland;

"Primary Care Trust" means the Primary Care Trust which was a party to the contract immediately before the coming into force of section 34 of the Health and Social Care Act 2012 M51 (abolition of primary care trusts);

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

"primary medical services" means medical services provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the Act applies;

"registered patient" means—

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

"relevant register" means—

- (a) in relation to a nurse, the Nursing and Midwifery Register;
- (b) in relation to a pharmacist, Part 1 of the register maintained under article 19 of the Pharmacy Order 2010 M52 (establishment, maintenance of and access to the register) or

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- the register maintained under article 6 (the Register) and article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976 M53;
- (c) in relation to an optometrist, the register maintained by the General Optical Council in pursuance of section 7(a) of the Opticians Act 1989 M54 (register of opticians); and
- (d) the part of the register maintained by the Health and Care Professions Council under article 5 of the Health and Social Work Professions Order 2001 M55 (establishment and maintenance of register) relating to—
 - (i) chiropodists and podiatrists,
 - (ii) physiotherapists, or
 - (iii) radiographers;

"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 regulation 59; 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) a form provided by the Board, a local authority or the Secretary of State for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS
- (b) Business Services Authority M56 and which—
 - is issued, or is to be issued, by a repeatable prescriber to enable a chemist or person providing dispensing services to receive payment for the provision of repeat dispensing services,
 - (ii) indicates, or is to indicate, that the drug, medicine or appliance ordered may be provided more than once, and
 - (iii) specifies, or is to specify, the number of occasions on which the drug, medicine or appliance may be provided; or
- (c) in the case of an electronic prescription to which regulation 57 applies, data created in an electronic form for the purpose of ordering a drug, medicine or appliance, which—
 - (i) is signed, or is to be signed, with a prescriber's advanced electronic signature,
 - (ii) is transmitted, or is to be transmitted, as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service, and
 - (iii) indicates, or is to indicate, that the drug, medicine or appliance ordered may be provided more than once and specifies, or is to specify, the number of occasions on which the drug, medicine or appliance may be provided;

"restricted availability appliance" means an appliance which is approved for particular categories of persons or for 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 88 of the Act (GMS contracts: prescription of drugs etc.) 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

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(b) except where the conditions in regulation 61(3) are satisfied, a drug, medicine or other substance which is specified in any directions given by the Secretary of State under section 88 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes;

"section 92 provider" means a person who is providing services in accordance with arrangements under section 92 of the Act M57 (arrangements for the provision of primary medical services);

"service provider" has the meaning given in regulation 2 of the Care Quality Commission (Registration) Regulations 2009 M58 (interpretation);

[F6" signatory" means a natural person who creates an electronic signature;]

"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 maintained under article 19 of the Pharmacy Order 2010 M59 (establishment, maintenance of and access to the register),
 - (iii) the register maintained under article 6 (the Register) and article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976 M60,
 - (iv) the part of the register maintained by the Health Professions Council under of article 5 of the Health Professions Order 2001 M61 (establishment and maintenance of register) relating to—
 - (aa) chiropodists and podiatrists,
 - (bb) physiotherapists, F7...
 - (cc) radiographers, or
 - (dd) [F8 dietitians, or]
 - (v) the register of optometrists maintained by the General Optical Council under section 7(a) of the Opticians Act 1989 M62 (register of opticians); and
- (c) against whose name is recorded in the relevant register an annotation or entry signifying that that person 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 20 of Schedule 3 and for whom the contractor's responsibility has not been terminated in accordance with that paragraph;

I^{F9} "therapeutic radiographer independent prescriber" means a radiographer—

- (a) who is registered in Part 11 of the register maintained under article 5 of the Health and Social Work Professions Order 2001; and
- (b) against whose name in that register is recorded—
 - (i) an entitlement to use the title "therapeutic radiographer", and
 - (ii) an annotation signifying that the radiographer is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;

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

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"writing", except in paragraph 57 of Schedule 3, includes electronic mail and "written" is to be construed accordingly.

Textual Amendments

- Words in reg. 3 substituted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, Sch. 3 para. 15(1)(a)
- **F2** Words in reg. 3 inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, Sch. 3 para. 15(1)(b)
- **F3** Word in reg. 3(1) omitted (5.12.2016) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), 23(a) (i)
- **F4** Words in reg. 3(1) substituted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **23(a)(ii)**
- F5 Words in reg. 3(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), 23(a)(iii)
- **F6** Words in reg. 3 inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 15(1)(c)**
- Word in reg. 3(1) omitted (5.12.2016) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), 23(b) (i)
- **F8** Words in reg. 3(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **23(b)(ii)**
- F9 Words in reg. 3(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), 23(c)

Marginal Citations

- M2 S.I. 2010/473; as amended by S.I. 2012/344 and 2013/3036.
- M3 Section 9 of the Act was amended by section 95 of, and paragraph 82 of Schedule 5 to, the Health and Social Care Act 2008 (c.14); paragraph 6 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act"); paragraphs 1, 4, 17 and 18 of Schedule 14, and paragraph 10 of Schedule 17 to, the 2012 Act; paragraph 9 of Schedule 19 to the 2012 Act; paragraphs 5 and 6 of Schedule 21 to the 2012 Act; and paragraph 16 of Schedule 5 to the Care Act 2014 (c. 23).
- M4 Section 126 was amended by sections 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the 2012 Act.
- M5 2006 c.52; a relevant amendment to section 374 was made by section 44(3) and (4) of the Defence Reform Act 2014 (c.20).
- **M6** 1971 c.80.
- M7 The National Health Service Commissioning Board (known as "NHS England") was established by section 1H of the Act. Section 1H was inserted into the Act by section 9(1) of the 2012 Act.
- M8 2008 c.14
- **M9** Clinical commissioning groups were established by virtue of sections 1I and 14A to 14D of the Act, as inserted by sections 10 and 25(1) of the 2012 Act.
- M10 1983 c.54. Section 34L was inserted by S.I. 2010/234.
- M11 Section 49B was inserted by S.I. 2007/3101 and was amended by S.I. 2008/1774 and S.I. 2010/234.
- M12 1968 c.67. Section 69 was amended by section 1(1) of the Statute Law Repeals Act 1993 (c.50), and by S.I. 2007/289 and 3101 and S.I. 2010/231.
- M13 Section 129 was amended by sections 26, 27 and 38 of, and Schedule 6 to, the Health Act 2009 (c.21); section 207(1) to (9) of, and paragraph 66 of Schedule 4 to, the Health and Social Care Act 2012 (c.7); section 115 of, and paragraph 120 and 121 of Schedule 9 to, the Protection of Freedoms Act 2012 (c.9); and by S.I. 2010/231.

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- M14 S.I. 2002/254; as amended by section 127 of the Health and Social Care Act 2008 (c.14), section 81(5) of the Policing and Crime Act 2009 (c.26), sections 213, 214(2) to (4), 215, 216, 218 and 219 of the Health and Social Care Act 2012, section 5(2) of, and paragraph 6 of the Schedule to, the Health and Social Care (Safety and Quality) Act 2015 (c.28), and by S.I. 2003/3148, S.I. 2004/1947 and 2033, S.I. 2007/3101, S.I. 2009/1182, S.I. 2010/233, S.I. 2011/1043, S.I. 2012/1479 and 2672 and S.I. 2014/1887.
- M15 Section 84 of the Act was amended by paragraph 31 of Schedule 4 to the Health and Social Care Act 2012.
- M16 2006 c.41. Section 126 was amended by section 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). Section 132 was amended by paragraph 69 of Schedule 4 to the 2012 Act, paragraphs 120 and 122 of Schedule 9 to the Protection of Freedoms Act 2012 (c.9), and by S.I. 2007/289 and S.I. 2010/22 and 231.
- M17 Section 127 was amended by paragraph 64 of Schedule 4 to the 2012 Act. *See* also regulation 89(1) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349) in relation to the publication known as the Drug Tariff.
- M18 2000 c.7. Section 15(1) was amended by section 406(1) of, and paragraph 158 of Schedule 17 to, the Communications Act 2003 (c.21).
- **M19** The Health and Social Care Information Centre is a body corporate established by section 252(1) of the 2012 Act.
- **M20** 1983 c.54. Section 2 was amended by S.I. 2002/3135, **S.I**. 2006/1914, S.I. 2007/3101, **S.I**. 2008/1774 and S.I. 2014/1101.
- M21 See the General Medical Services Statement of Financial Entitlements Directions 2013 which were signed on 27th March 2013, as amended, for the directions given by the Secretary of State under section 87 of the Act. Copies are available at: https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013. Copies of these directions, and of the subsequent amendments to them, may also be obtained from the Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS.
- M22 Section 87 was amended by paragraph 33 of Schedule 4 to the 2012 Act.
- M23 1983 c.54. Section 34I was inserted by S.I. 2010/234.
- **M24** S.I. 1972/1265 (N.I.14).
- M25 S.I. 1991/194 (N.I.1); as amended by section 11 of, and paragraph 13 of Schedule 6 to, the Health and Social Care Reform Act (Northern Ireland) 2009 (c.1) (N.I.) and S.I. 1997/1177.
- M26 1978 c.29. Section 2 was amended by paragraph 1 of Schedule 7 to S.I. 1991/194) (N.I. 1); section 14(2) of, and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications Act 1983 (c.41); paragraph 1(2)(a) and (b) of Schedule 1 to the National Health Service Reform (Scotland) Act 2004 (asp 7); sections 2(1)(a) and 28(a)(ii), (b), and (c) of Schedule 1, and paragraph 19(1) of Schedule 9 and paragraph 1 of Schedule 10 to, the National Health Service and Community Care Act 1990 (c.19); paragraph (2)(2) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13); and sections 2(1), 4, 6(2) and (3), 7 and 11(1) of the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5).
- M27 Section 108 was amended by section 204 of, and paragraph 49 of Schedule 4 to, the Health and Social Care Act 2012 (c.7) ("the 2012 Act").
- M28 2006 c.41. Section 9 was amended by section 95 of, and paragraph 82 of Schedule 5 to the Health and Social Care Act 2008 (c.14); paragraph 6 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act"); paragraphs 1, 4, 17 and 18 of Schedule 14, and paragraph 10 of Schedule 17 to, the 2012 Act; paragraph 9 of Schedule 19 to the 2012 Act; paragraphs 5 and 6 of Schedule 21 to the 2012 Act; and paragraph 16 of Schedule 5 to the Care Act 2014 (c. 23).
- **M29** 1989 c.41.
- M30 1907 c.24. Section 5 was amended by S.I. 2009/1940.
- **M31** S.I. 2015/570.
- M32 2006 c.42.
- M33 2006 c.41. Section 97 was amended by paragraph 41 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act").

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- M34 Section 91 was amended by paragraph 35 of Schedule 4 to the 2012 Act.
- **M35** 1983 c.54. Section 2 was amended by S.I. 2002/3135, **S.I**. 2006/1914, S.I. 2007/3101, **S.I**. 2008/1774 and S.I. 2014/1101.
- M36 Section 159 was amended by section 306(1)(d) of, and paragraph 85 of Schedule 4 to, the 2012 Act and by S.I. 2010/22.
- M37 Sections 91(3), 106(3) and 123(3) were respectively amended by paragraphs 35(1) and (2)(b) and (4), 47 (1) and (4) and 60(1), (2)(b) and (4) of Schedule 4 to the 2012 Act. Sections 146 and 149 are repealed by section 208(1) of the 2012 Act from a date to be appointed. Section 147A was inserted by section 208(2) of the 2012 Act, and was amended by paragraphs 120 and 123 of Schedule 9 to the Protection of Freedoms Act 2012 (c.9). Section 208 of the 2012 Act is to be commenced from a day to be appointed. No regulations have yet been made under section 147A of the Act.
- M38 Section 9 was amended by section 95 of, and paragraph 82 of Schedule 5 to, the Health and Social Care Act 2008 (c.14); paragraph 6(1), (2)(a) and (2)(c) of Schedule 4 to, the 2012 Act; paragraphs 1, 4, 17 and 18 of Schedule 14, and paragraph 10 of Schedule 17 to, the 2012 Act; paragraph 9 of Schedule 19 to the 2012 Act; paragraphs 5 and 6 of Schedule 21 to the 2012 Act; and paragraph 16 of Schedule 5 to the Care Act 2014 (c. 23).
- M39 Section 30 was amended by section 159(1) of the Health and Social Care Act 2012 (c.7) ("the 2012 Act").
- M40 Section 25 is repealed by section 179(2) of the 2012 Act from a date to be appointed.
- M41 The Health and Social Care Information Centre is a body corporate established by section 252(1) of the 2012 Act.
- M42 S.I. 2002/253; article 5 was amended by S.I. 2009/1182.
- M43 1989 c.44. Section 7 was amended by S.I. 2005/848.
- **M44** S.I. 2010/231; as amended by S.I. 2011/1043 and 2159, S.I. 2012/1909, 2672 and 3006, S.I. 2013/50, 235, 349 and 1478, S.I. 2014/1887 and S.I. 2015/806 and 968.
- M45 S.I. 1976/1231 (N.I.22). Article 6(1) was substituted by regulation 5 of S.R. 2008/192, and article 9(2) was amended by regulation 9 of that instrument.
- M46 S.I. 2002/254; as amended by section 127 of the Health and Social Care Act 2008 (c.14), section 81(5) of the Policing and Crime Act 2009 (c.26), sections 213, 214(2) to (4), 215, 216, 218 and 219 of the Health and Social Care Act 2012, section 5(2) of, and paragraph 6 of the Schedule to, the Health and Social Care (Safety and Quality) Act 2015 (c.28), and by S.I. 2003/3148, S.I. 2004/1947 and 2033, S.I. 2007/3101, S.I. 2009/1182, S.I. 2010/233, S.I. 2011/1043, S.I. 2012/1479 and 2672 and S.I. 2014/1887.
- M47 1983 c.54. Section 10A was inserted by S.I. 2006/1914, and was amended by S.I. 2008/3131.
- M48 The NHS Business Services Authority was established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005 (S.I. 2005/2414). S.I. 2005/2414 was amended by S.I. 2006/632, S.I. 2007/1201 and S.I. 2013/235.
- **M49** S.I. 2012/1916; as amended by S.I. 2013/235, 1855 and 2593 and S.I. 2014/490 and 1887, S.I. 2015/323, 570, 903 and 1503.
- M50 Sections 146 and 149 are repealed by section 208(1) of the Health and Social Care Act 2012 (c.7) from a date to be appointed. Section 147A was inserted by section 208(2) of that Act and was amended by paragraphs 120 and 132 of Schedule 9 to the Protection of Freedoms Act 2012 (c.).
- M51 2012 c.7.
- **M52** S.I. 2010/231; as amended by S.I. 2011/1043 and 2159, S.I. 2012/1909, 2672 and 3006, S.I. 2013/50, 235, 349 and 1478, S.I. 2014/1887 and S.I. 2015/806 and 968.
- **M53** S.I. 1976/1231 (N.I.22). Article 6(1) was substituted by regulation 5 of S.R. 2008/192, and article 9(2) was amended by regulation 9 of that instrument.
- M54 1989 c.44. Section 7 was amended by S.I. 2005/848.
- M55 S.I. 2002/254; as amended by section 127 of the Health and Social Care Act 2008 (c.14), section 81(5) of the Policing and Crime Act 2009 (c.26), sections 213, 214(2) to (4), 215, 216, 218 and 219 of the Health and Social Care Act 2012, section 5(2) of, and paragraph 6 of the Schedule to, the Health and Social Care (Safety and Quality) Act 2015 (c.28), and by S.I. 2003/3148, S.I. 2004/1947 and 2033,

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- S.I. 2007/3101, **S.I**. 2009/1182, S.I. 2010/233, **S.I**. 2011/1043, S.I. 2012/1479 and 2672 and S.I. 2014/1887.
- **M56** The NHS Business Services Authority was established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005 (S.I. 2005/2414). S.I. 2005/2414 was amended by S.I. 2006/632, **S.I**. 2007/1201 and S.I. 2013/235.
- M57 Section 92 was amended by paragraph 36 of Schedule 4 to the Health and Social Care Act 2012 (c.7).
- M58 S.I. 2009/3112. There are no relevant amendments to regulation 2.
- **M59** S.I. 2010/231; as amended by S.I. 2011/1043 and 2159, S.I. 2012/1909, 2672 and 3006, S.I. 2013/50, 235, 349 and 1478, S.I. 2014/1887 and S.I. 2015/806 and 968.
- **M60** S.R. 1976/1213 (N.I. 22). Article 6(1) was substituted by regulation 5 of S.R. 2008/192 and article 9(2) was amended by regulation 9 of S.R. 2008/192.
- M61 S.I. 2002/254; as amended by section 127 of the Health and Social Care Act 2008 (c.14), section 81(5) of the Policing and Crime Act 2009 (c.26), sections 213, 214(2) to (4), 215, 216, 218 and 219 of the Health and Social Care Act 2012, section 5(2) of, and paragraph 6 of the Schedule to, the Health and Social Care (Safety and Quality) Act 2015 (c.28), and by S.I. 2003/3148, S.I. 2004/1947 and 2033, S.I. 2007/3101, S.I. 2009/1182, S.I. 2010/233, S.I. 2011/1043, S.I. 2012/1479 and 2672 and S.I. 2014/1887.
- M62 1989 c.44. Section 7 was amended by S.I. 2005/848.

PART 2

Contractors: conditions and eligibility

Conditions: general

- **4.**—(1) The Board may only enter into a contract if the conditions specified in regulations 5 and 6 are met.
- (2) Paragraph (1) is subject to the provisions of any scheme made by the Secretary of State under section 300 (transfer schemes) and section 303 (power to make consequential provision) of the Health and Social Care Act 2012 M63.

Marginal Citations

M63 2012 c.7.

Conditions relating solely to medical practitioners

- **5.**—(1) Where the Board enters, or is proposing to enter, into a contract with—
 - (a) a medical practitioner, that medical practitioner must be a general medical practitioner;
 - (b) two or more persons practising in partnership—
 - (i) at least one partner (who must not be a limited partner) must be a general medical practitioner, and
 - (ii) any other partner who is a medical practitioner must be—
 - (aa) a general medical practitioner, or
 - (bb) employed by 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; or
 - (c) a company limited by shares—

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- (i) at least one share in the company must be both legally and beneficially owned by a general medical practitioner, and
- (ii) any other share or shares in the company that are both legally and beneficially owned by a medical practitioner must be so owned by—
 - (aa) a general medical practitioner, or
 - (bb) a medical practitioner who is employed by 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.
- (2) In paragraph (1)(a), (b)(i) and (c)(i) "general medical practitioner" does not include a medical practitioner whose name is included in the General Practitioner Register by virtue of being a medical practitioner to whom paragraph (3), (4) or (5) applies.
- (3) This paragraph applies to a medical practitioner referred to in article 4(3) of the 2010 Order (general practitioners eligible for entry in the General Practitioner Register) who was exempt from the requirement to have the prescribed experience under—
 - (a) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) Regulations 1997 M64;
 - (b) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998 M65; or
 - (c) regulation 5(1)(d) of the Medical Practitioners (Vocational Training) Regulations (Northern Ireland) 1998 M66.
- (4) This paragraph applies to a medical practitioner who has an acquired right for the purposes of article 6(2) of the 2010 Order (persons with acquired rights) by virtue of—
 - (a) having been a restricted services principal; and
 - (b) that medical practitioner's name being included, as at 31st December 1994, in—
 - (i) a medical list which was, at that date, kept by a Family Health Services Authority M67, or
 - (ii) any corresponding list which was, at that date, kept by a Health Board or by the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland.
- (5) This paragraph applies to a medical practitioner who has an acquired right for the purposes of article 6(6) of the 2010 Order (which relates to persons engaged or provided as a deputy or employed as an assistant) because, on at least ten days in the period of four years ending with 31st December 1994, or on at least 40 days in the period of ten years ending with that date, that medical practitioner was—
 - (a) engaged as a deputy by, or provided as a deputy to, a medical practitioner whose name was included in—
 - (i) the medical list which was, at that date, kept by a Family Health Services Authority, or
 - (ii) any corresponding list kept, at that date, by a Health Board or by the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland; or
 - (b) employed as an assistant (other than as a trainee general practitioner) by such a medical practitioner.
- (6) In paragraph (4)(a), "restricted services principal" means a medical practitioner who provided general medical services limited to child health surveillance, contraceptive services, maternity medical services or minor surgery.

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Marginal Citations

M64 S.I. 1997/2817; as amended by S.I. 1998/669 and revoked by S.I. 2003/1250.

M65 S.I. 1998/669 (S.2); as amended by S.I.1998/669 and S.S. I 2000/23 and revoked by S.I. 2003/1250.

M66 S.R. 1998/13; as revoked by S.I. 2003/1250.

M67 Family Health Services Authorities no longer exist. They were merged with Health Authorities in 1994. Health Authorities have now been abolished.

General condition relating to all contracts

- **6.**—(1) The Board must not enter into a contract with—
 - (a) a medical practitioner to whom paragraph (2) applies; or
 - (b) two or more persons practising in partnership, where paragraph (2) applies to any person who is a partner in the partnership; or
 - (c) a company limited by shares where paragraph (2) applies to—
 - (i) the company,
 - (ii) any person both legally and beneficially owning a share in the company, or
 - (iii) any director or secretary of the company.
- (2) This paragraph applies if—
 - (a) the contractor is the subject of a national disqualification;
 - (b) subject to paragraph (3), the contractor is disqualified or suspended (other than by interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
 - (c) the contractor has, within the period of five years before the signing of the contract or commencement of the contract (whichever is the earlier), been dismissed (otherwise than by reason of redundancy) from any employment by a health service body, unless—
 - (i) if the contractor was employed as a member of a health care profession at the time of the dismissal, the contractor has not subsequently been employed by that health service body or by another health service body, and
 - (ii) the dismissal was the subject of a finding of unfair dismissal by any competent tribunal or a court;
 - (d) the contractor has, within the period of five years before the signing of the contract or commencement of the contract (whichever is the earlier), been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 151(2), (3) and (4) of the Act M68 (disqualification of practitioners)), or a performers list held by the Board by virtue of regulations made under section 91(3) (persons performing primary medical services) of the Act, unless the contractor's name has subsequently been included in such a list;
 - (e) the contractor has been convicted in the United Kingdom of murder;
 - (f) the contractor 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 longer than six months;
 - (g) subject to paragraph (3), the contractor has been convicted outside of the United Kingdom of an offence which would, if committed in England and Wales, constitute murder and—
 - (i) the offence was committed on or after 14th December 2001, and
 - (ii) the contractor was sentenced to a term of imprisonment of longer than six months;

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- (h) the contractor has been convicted of an offence, referred to in Schedule 1 to the Children and Young Persons Act 1933 M69 (offences against children and young persons, with respect to which special provisions of this Act apply), or in Schedule 1 to the Criminal Procedure (Scotland) Act 1995 M70 (offences against children under the age of 17 years to which special provisions apply), committed on or after 1st March 2004;
- (i) the contractor has at any time been included in—
 - (i) any barred list within the meaning of section 2 of the Safeguarding Vulnerable Groups Act 2006 M71 (barred lists), or
 - (ii) any barred list within the meaning of article 6 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007 M72 (barred lists).
 - unless the contractor was removed from the list either on the grounds that it was not appropriate for the contractor to have been included in it or as the result of a successful appeal;
- (j) the contractor has, within the period of five years before the signing of the contract or commencement of the contract (whichever is the earlier), been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission, the Charity Commission for Northern Ireland or the High Court, and that order was made on the grounds of misconduct or mismanagement in the administration of a charity for which the contractor was responsible or to which the contractor was privy, or which was contributed to, or facilitated by, the contractor's conduct;
- (k) the contractor has, within the period of five years before the signing of the contract or commencement of the contract (whichever is the earlier), been removed from being concerned with the management or control of any body in a case where the removal was by virtue of section 34(5)(e) of the Charities and Trustee Investment (Scotland) Act 2005 M⁷³ (powers of Court of Session);
- (1) the contractor—
 - (i) has been [F10made] bankrupt and has not been discharged from the bankruptcy or the bankruptcy order has not been annulled, or
 - (ii) has had sequestration of the contractor's estate awarded and has not been discharged from the sequestration;
- (m) the contractor is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986 M74 (bankruptcy restrictions order and undertaking), Schedule 2A to the Insolvency (Northern Ireland) Order 1989 M75 (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985 M76 (bankruptcy restrictions order, interim bankruptcy restrictions order and bankruptcy restrictions undertaking), unless the contractor has been discharged from that order or that order has been annulled;
- (n) the contractor—
 - (i) is subject to moratorium period under a debt relief order under Part VIIA of the Insolvency Act 1986 M77 (debt relief orders), or
 - (ii) is the subject of a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4ZB to that Act M78 (debt relief restrictions orders and undertakings);
- (o) the contractor has made a composition agreement or arrangement with, or granted a trust deed for, the contractor's creditors and the contractor has not been discharged in respect of it;

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- (p) the contractor is subject to—
 - (i) a disqualification order under section 1 of the Company Directors Disqualification Act 1986 M⁷⁹ (disqualification orders: general) or a disqualification undertaking under section 1A of that Act M⁸⁰ (disqualification undertakings: general),
 - (ii) a disqualification order or disqualification undertaking under article 3 (disqualification orders: general) or article 4 (disqualification undertakings: general) of the Company Directors Disqualification (Northern Ireland) Order 2002 M81, or
 - (iii) a disqualification order under section 429(2) of the Insolvency Act 1986 M82 (disabilities on revocation of an administration order against an individual);
- (q) the contractor has had an administrator, administrative receiver or receiver appointed in respect of the contractor;
- (r) the contractor has had an administration order made in respect of the contractor under Schedule B1 to the Insolvency Act 1986 M83 (administration); or
- (s) the contractor 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.
- (3) Paragraph (2)(b) or, as the case may be, paragraph (2)(g), does not apply to a person where—
 - (a) that person—
 - (i) has been disqualified or suspended from practising by a licensing body outside of the United Kingdom, or
 - (ii) has been convicted outside of the United Kingdom of a criminal offence; and
 - (b) the Board is satisfied that the disqualification, suspension or, as the case may be, the conviction does not make that person unsuitable to be—
 - (i) a contractor,
 - (ii) a partner, in the case of a contract with two or more persons practising in partnership, or
 - (iii) in the case of a company limited by shares—
 - (aa) a person who both legally and beneficially owns a share in the company, or (bb) a director or secretary of the company.
- (4) For the purposes of paragraph (2)(c)—
 - (a) 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; and
 - (b) a health service body includes a Strategic Health Authority or a Primary Care Trust which was established before the coming into force of section 33 (abolition of Strategic Health Authorities) or 34 (abolition of Primary Care Trusts) of the Health and Social Care Act 2012 M84.
- (5) In this regulation, "contractor" includes a person with whom the Board is proposing to enter into a contract with.

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Textual Amendments

F10 Word in reg. 6(2)(l)(i) substituted (6.4.2016) by The Enterprise and Regulatory Reform Act 2013 (Consequential Amendments) (Bankruptcy) and the Small Business, Enterprise and Employment Act 2015 (Consequential Amendments) Regulations 2016 (S.I. 2016/481), reg. 1, **Sch. 2 para. 13**

Marginal Citations

- M68 Section 151 was amended by paragraph 79 of Schedule 4 to the Health and Social Care Act 2012 (c.7).
- M69 1933 c.12. Schedule 1 was amended by section 51 of, and Schedule 4 to, the Sexual Offences Act 1956 (c.99); paragraph 8 of Schedule 15 to, and section 170(2) of, and Schedule 16 to, the Criminal Justice Act 1988 (c.33); section 139 of, and paragraph 7 of Schedule 6 to, the Sexual Offences Act 2003 (c.42); section 58(1) of, and Schedule 10 to, the Domestic Violence, Crime and Victims Act 2004 (c.28); paragraph 53 of Schedule 21 to the Coroners and Justice Act 2009 (c.25); section 115(1) of, and paragraph 136(a) and (b) of Schedule 9 to, the Protection of Freedoms Act 2012 (c.9); and section 57(1) of, and paragraph 1 of Schedule 5 to, the Modern Slavery Act 2015 (c.30).
- M70 1995 c.46. Schedule 1 was amended by paragraph 2(8)(a) of Schedule 5 to the Sexual Offences (Scotland) Act 2009 (asp 9).
- M71 2006 c.47. Section 2 was amended by articles 3(a) and 4 of S.I. 2012/3006.
- M72 S.I. 2007/1351 (N.I. 11); as amended by section 81(2) and (3)(o)(i) of the Policing and Crime Act 2009 (c.26).
- M73 2005 asp. 10. Section 34 was amended by section 122 of the Public Services Reform (Scotland) Act 2010 (asp 8).
- M74 1986 c.45. Schedule 4A was inserted by Schedule 20 of the Enterprise Act 2002 (c.40), and was amended by section 71(3) of, and paragraph 63(1), (3)(a), (2)(a) and (b) to, the Enterprise and Regulatory Reform Act 2013 (c.24).
- M75 S.I. 1989/2405 (N.I.19). Schedule 2A was inserted by article 13(2) of, and Schedule 5 to, S.I. 2005/1455 (N.I. 10).
- M76 1985 c.66. Sections 56A to 56K were inserted by section 2(1) of the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).
- M77 1986 c.45. Part VIIA was inserted by section 108(1) of, and Schedule 17 to, the Tribunals, Courts and Enforcement Act 2007 (c.15).
- **M78** Schedule 4ZB was inserted by section 108(2) of, and Schedule 19 to, the Tribunals, Courts and Enforcement Act 2007.
- M79 1986 c.46. Section 1 was amended by sections 5(1) and (2) and 8 of the Insolvency Act 2000 (c.40), section 204(1) and (3) of the Enterprise Act 2002 (c.40), and sections 111 and 164(1) of, and paragraphs 1 and 2 of Schedule 7 to, the Small Business, Enterprise and Employment Act 2015 (c.26).
- **M80** Section 1A was inserted by section 6(1) and (2) of the Insolvency Act 2000 (c.39), and was amended by section 111 of, and paragraphs 1, 3(1) and (2) of Schedule 7 to, the Small Business Enterprise and Employment Act 2015.
- M81 S.I. 2002/3150 (N.I. 4).
- M82 1986 c.45. Section 429 was amended by section 269 of, and Schedule 23 to, the Enterprise Act 2002, and by section 106 of, and Schedule 16 to, the Tribunals, Courts and Enforcement Act 2007 (c.15).
- M83 1986 c.45. Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002.
- M84 2012 c.7. Sections 33 and 34 of the Health and Social Care Act 2012 (c.7) were commenced by article 2 of the Health and Social Care Act 2012 (Commencement No.4, Transitional, Savings and Transitory Provisions) Order 2013 (S.I. 2013/160 (C.9)) on 1st April 2013.

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Notice of conditions not being met and reasons

- 7.—(1) Where the Board considers that the conditions specified in regulation 5 or 6 for entering into a contract are not met, it must give notice in writing to the person or persons intending to enter into the contract of—
 - (a) its view and the reasons for that view; and
 - (b) the right of appeal under regulation 8.
- (2) The Board must also give notice in writing of its view and the reasons for that view to any person who both legally and beneficially owns a share in, or who is a director or secretary of, a company that is given notice under paragraph (1) in any case where its reason for the decision relates to such a person.

Right of appeal

8. A person who has been given a notice by the Board under regulation 7(1) may appeal to the First-tier Tribunal M85 against the decision of the Board that the conditions in regulation 5 or 6 are not met.

Marginal Citations

M85 An appeal may be made to the First-tier Tribunal (Primary Health Lists) against a decision by the National Health Service Commissioning Board to refuse to enter a person in a list, to remove them from a list, or regarding conditions relating to their entry in a list. The First-tier Tribunal was established in 2008 by Part 1 of the Tribunals, Courts and Enforcement Act 2007 (c.15). The Health, Education and Social Chamber is responsible for hearing appeals concerning matters relating to the health service in England and Wales.

PART 3

Pre-contract dispute resolution

Pre-contract disputes

- **9.**—(1) If, in the course of negotiations intending to lead to a contract, the parties to the proposed contract ("the prospective parties") 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.
- (2) Where the prospective parties are health service bodies, any dispute which arises in the course of the negotiation of the proposed contract may be referred to the Secretary of State for determination under section 9 of the Act (NHS contracts).
- (3) Any dispute referred to the Secretary of State in accordance with paragraph (1), or to which section 9 of the Act applies by virtue of paragraph (2), must be considered and determined in accordance with the provisions of regulations 83(3) to (15) and 84(1) and, where applicable, paragraph (4) of this regulation.
- (4) Where the Secretary of State determines a dispute referred under paragraph (1), the determination—
 - (a) may specify terms to be included in the proposed contract;
 - (b) may require the Board to proceed with the proposed contract, but may not require the intended contractor to proceed with the proposed contract; and
 - (c) is binding upon the prospective parties.

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PART 4

Health service body status

Health service body status: election

- **10.**—(1) A person who proposes to enter into a contract with the Board (a "proposed contractor") may elect, by giving notice in writing to the Board prior to entering into the contract, to be regarded as a health service body for the purposes of section 9 of the Act (NHS contracts).
- (2) An election made by a proposed contractor under paragraph (1) has effect from the date on which the contract is entered into.
- (3) If, by virtue of paragraph (1), a proposed contractor elects to be regarded as a health service body, the nature of, or any rights or liabilities under, any other contract previously entered into by that proposed contractor with a health service body before the date of that election remains unaffected.
 - (4) Paragraph (5) applies where—
 - (a) a contractor who is an individual medical practitioner enters, or two or more persons practising in a partnership enter, into a contract with the Board; and
 - (b) that contractor is to be regarded as a health service body in accordance with paragraph (1).
- (5) Subject to regulation 11, the contractor is to be regarded as a health service body for the purposes of section 9 of the Act (NHS contracts) for as long as the contract continues irrespective of any change in the—
 - (a) partners in the partnership;
 - (b) status of the contractor from that of an individual medical practitioner to that of a partnership; or
 - (c) status of the contractor from that of a partnership to that of an individual medical practitioner.

Health service body status: variation of contracts

- 11.—(1) A contractor may at any time request in writing a variation of the contract to include in, or remove from, the contract provision to the effect that the contract is an NHS contract and, if it does so—
 - (a) the Board must agree to the variation; and
 - (b) the procedure specified in regulation 29 and Part 8 of Schedule 3 for the variation of contracts applies.
- (2) If, by virtue of a request under paragraph (1), the contractor is to be regarded as a health service body—
 - (a) any rights or liabilities under any other contract with a health service body entered into by the contractor before the date on which the contractor is so regarded remain unaffected; and
 - (b) the contractor is to be regarded as a health service body for the purposes of section 9 of the Act (NHS contracts) from the date on which the variation takes effect in accordance with regulation 29 and Part 8 of Schedule 3.
- (3) Where the Board agrees to the variation of the contract, the contractor is to be regarded or, subject to regulation 12, is to cease to be regarded, as a health service body for the purposes of section 9 of the Act (NHS contracts) from the date on which the variation takes effect in accordance with regulation 29 and Part 8 of Schedule 3.

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Cessation of health service body status

- **12.**—(1) A contractor ceases to be regarded as a health service body for the purposes of section 9 of the Act (NHS contracts) if the contract terminates.
- (2) Where, by virtue of paragraph (1), a contractor ceases to be regarded as a health service body in relation to a contract ("the relevant contract"), the contractor is to continue to be regarded as a health service body for the purposes of any other NHS contract to which it became a party between the date on which it entered into the relevant contract and the date on which it ceased to be regarded as a health service body for the purposes of that contract (but it ceases to be a health service body for the purposes of such other NHS contract on the termination of that contract).
 - (3) Where—
 - (a) a contractor ceases to be regarded as a health service body in relation to a contract by reason of a variation of the contract by virtue of regulation 11(1); and
 - (b) the contractor or the Board—
 - (i) has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with regulation 82, after it ceases to be a health service body,

the contractor is to continue to be regarded as a health service body (and accordingly the contract is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute.

- (4) Where a contractor ceases to be regarded as a health service body by virtue of regulation 11(1) but continues to be regarded as a health service body for the purposes of the NHS dispute resolution procedure where that procedure was commenced—
 - (a) before the termination of the contract; or
 - (b) after the termination of the contract (whether in connection with or arising out of the termination of the contract or otherwise),

the contractor ceases to be regarded as a health service body for those purposes on the conclusion of that procedure.

PART 5

Contracts: required terms

Parties to the contract

- 13. A contract must specify—
 - (a) the names of the parties to the contract;
 - (b) in the case of each party to the contract, the address to which official correspondence and notices should be sent; and
 - (c) in the case of a party to the contract which is a partnership—
 - (i) the names of the partners,
 - (ii) whether or not the partnership is a limited partnership, and
 - (iii) in the case of a limited partnership, the status of each partner as a general or a limited partner.

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Health service contract

14. If, by virtue of regulation 10 or 11, a contractor is to be regarded as a health service body, the contract must state that it is an NHS contract.

Contracts with individuals practising in partnership

- 15. Where a contract is with two or more individuals practising in partnership—
 - (a) the contract is to be treated as made with the partnership as it is from time to time constituted, and the contract must make specific provision to this effect; and
 - (b) the terms of the contract must require the contractor to ensure that any person who becomes a partner in the partnership after the contract has come into force is automatically bound by the contract whether by virtue of a partnership deed or otherwise.

Duration

- **16.**—(1) Except as provided in paragraph (2), a contract must provide for it to subsist until it is terminated in accordance with the terms of the contract or by virtue of the operation of any other legal provision.
- (2) The Board may enter into a temporary contract for a period not exceeding 12 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 so desires, invite the Local Medical Committee (if any) for the area in which it is intended that primary medical services are to be provided by the prospective contractor, to participate in the negotiations intending to lead to such a contract.

Essential services

- 17.—(1) Subject to paragraph (2), for the purposes of section 85(1) of the Act (requirement to provide certain medical services), the services which must be provided under a contract ("essential services") are the services described in paragraphs (4), (6), (7) and (9).
- (2) Essential services are not required to be provided by the contractor during any period in respect of which the Care Quality Commission has suspended the contractor as a service provider under section 18 of the Health and Social Care Act 2008 M86 (suspension of registration).
- (3) Subject to regulation 20(2)(b) and (c), a contractor must provide the services described in paragraphs (4) and (6) throughout the core hours.
- (4) The services described in this paragraph are services required for the management of a contractor's 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,

which are delivered in the manner determined by the contractor's practice in discussion with the patient.

(5) For the purposes of paragraph (4)—

"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 M87; and

[&]quot;management" includes—

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- (a) offering consultation and, where appropriate, physical examination for the purposes of identifying the need, if any, for treatment or further investigation; and
- (b) making available 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.
- (6) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all of the contractor's registered patients and temporary residents taking account of their specific needs including—
 - (a) advice in connection with the patient's health and relevant health promotion advice; and
 - (b) the referral of a patient for other services under the Act.
- (7) 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 the contractor's practice area.
- (8) In paragraph (7), "emergency" includes any medical emergency whether or not related to services provided under the contract.
- (9) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person to whom paragraph (10) applies who requests such treatment for the period specified in paragraph (11).
 - (10) This paragraph applies to a person if—
 - (a) that person's application for inclusion in the contractor's list of patients has been refused in accordance with paragraph 21 of Schedule 3, and that person is not registered with another provider of essential services (or their equivalent);
 - (b) that person's application for acceptance as a temporary resident has been refused under paragraph 21 of Schedule 3; or
 - (c) that person is present in the contractor's practice area for a period of less than 24 hours.
 - (11) The period specified in this paragraph is, in the case of a person to whom—
 - (a) paragraph (10)(a) applies, 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) paragraph (10)(b) applies, 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; or
 - (c) paragraph (10)(c) applies, 24 hours or such shorter period as the person is present in the contractor's practice area.

Marginal Citations

M86 2008 c.14.

M87 The tenth revision of the International Statistical Classification of Diseases and Related Health Problems is available from the World Health Organisation at http://www.who.int/classifications/icd/en. Hard copies are available from the WHO bookshop which is able take orders online at http://bookorders.who.int/bookorders/index.htm and can provide a list of distributors in the UK.

Out of hours services

18.—(1) Subject to paragraphs (2) and (3), a contract must provide for the provision by a contractor of out of hours services.

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- (2) A contractor whose contract includes the provision of out of hours services—
 - (a) is only required to provide out of hours services to a patient if, in the contractor's reasonable opinion having regard to the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait to obtain those services; and
 - (b) must, in the provision of out of hours services—
 - (i) 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 M88, and
 - (ii) comply with any requests for information which it receives from, or on behalf of, the Board about the provision by the contractor of out of hours services to its registered patients in such manner, and before the end of such period, as is specified in the request.
- (3) Where a contractor is not required to provide out of hours services under a contract or, by virtue of Part 6, has opted out of the provision of such services under the contract, the contractor must—
 - (a) monitor the quality of the out of hours services which are offered or provided to the contractor's registered patients having regard to the National Quality Standards referred to in paragraph (2)(b), and record, and act appropriately in relation to, any concerns arising;
 - (b) record any patient feedback received, including any complaints;
 - (c) report to the Board, either at the request of the Board or otherwise, any concerns arising about the quality of the out of hours services which are offered or provided to patients having regard to—
 - (i) any patient feedback received, including any complaints, and
 - (ii) the quality requirements set out in the National Quality Standards referred to in subparagraph (2)(b).

Marginal Citations

M88 The document entitled National Quality Standards in the Delivery of Out of Hours Services published on 20th July 2006 is available at http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137271. Hard copies may be obtained from Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

Additional services

- **19.**—(1) Subject to Part 6, a contract may provide for the provision by a contractor of additional services.
 - (2) A contract which includes the provision of any additional services must, in relation to—
 - (a) all such services as are included in the contract, contain a term which has the same effect as paragraph 1 of Schedule 1; and
 - (b) each such service as is included in the contract, contain terms which have the same effect as those specified in Schedule 1 in so far as they are relevant to that service.

Services: general

20.—(1) A contract must specify—

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- (a) the services to be provided;
- (b) subject to paragraph (4), the address of each of the premises to be used by the contractor or any sub-contractor for the provision of such services;
- (c) the persons to whom such services are to be provided;
- (d) the area (the contractor's "practice area") as respects which persons resident in it are, subject to any other terms of the contract relating to patient registration, 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) A contract must also—
 - (a) state the period (if any) for which the services are to be provided except where those services are—
 - (i) essential services,
 - (ii) additional services funded under the global sum, and
 - (iii) out of hours services;
 - (b) contain a term which requires the contractor 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 patients; and
 - (c) contain a term which requires the contractor to have in place arrangements for its patients to access essential services and additional services funded under the global sum throughout the core hours in case of emergency.
- (3) A contract—
 - (a) may also specify an area, other than the contractor's practice area, which is to be known as the outer-boundary area as respects which a patient who—
 - (i) moves into that outer-boundary area to reside, and
 - (ii) would like to remain on the contractor's list of patients,
 - may remain on that list, if the contractor so agrees, notwithstanding that the patient no longer resides in the contractor's practice area; and
 - (b) which specifies an outer-boundary area must also specify that, where a patient remains on the contractor's list of patients as a consequence of sub-paragraph (a), the outer boundary area is to be treated as part of the contractor's practice area for the purposes of the application of any other terms and conditions of the contract in respect of that patient.
- (4) 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.
- (5) Where, on the date on which the contract is signed, the Board 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 3, the contract must include a plan, drawn up jointly by the Board and the contractor, which specifies—
 - (a) the steps to be taken by the contractor to bring the premises up to the relevant standard;

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- (b) any financial support that may be available from the Board; and
- (c) the timescale on which the steps referred to in sub-paragraph (a) are to be taken.

Membership of a CCG

- 21. A contract must contain a term which has the effect of requiring the contractor to—
 - (a) be a member of a CCG; and
 - (b) appoint at least one individual who is a health care professional to act on the contractor's behalf in the dealings between the contractor and the CCG to which the contractor belongs.

Certificates

- **22.**—(1) Subject to paragraphs (2) and (3), a contract must contain a term which has the effect of requiring the contractor to issue any medical certificate of a description prescribed in column 1 of Schedule 2 under, or for the purposes of, the enactments specified in relation to that certificate in column 2 of that Schedule if that certificate is reasonably required under or for the purposes of the enactments specified in relation to that certificate.
- (2) A certificate referred to in paragraph (1) must be issued free of charge to a patient or to a patient's personal representatives.
- (3) A certificate must not be issued where, for the condition to which the certificate relates, the patient is—
 - (a) being attended by a medical practitioner who is not—
 - (i) engaged or employed by the contractor,
 - (ii) in the case of a contract with two or more persons practising in a partnership, one of those persons, 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) not being treated by or under the supervision of a health care professional.
- (4) The exception in paragraph (3)(a) does not apply where the certificate is issued in accordance with regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976 M89 (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985 M90 (medical information).

Marginal Citations

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M89 S.I. 1976/615; as amended by S.I. 1987/409, S.I. 1994/2975, S.I. 1999/3109, S.I. 2001/2931, S.I. 2008/1554 and S.I. 2010/137.
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M90 S.I. 1985/1604; as amended by S.I. 1992/247 and S.I. 2010/137.

Finance

- **23.**—(1) The contract must contain a term which has the effect of requiring payments under the contract to be made promptly and in accordance with—
 - (a) the terms of the contract; and
 - (b) any other conditions relating to payment contained in directions given by the Secretary of State under section 87 of the Act (GMS contracts: payments) M91.

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- (2) The contract must contain a term to the effect that where, in accordance with directions given by the Secretary of State under section 87 (GMS contracts: payments) or section 98A of the Act M92 (exercise of functions), the Board is required to make a payment to a contractor under a contract but subject to conditions, those conditions must be a term of the contract.
- (3) The obligation referred to in paragraph (1) is subject to any right that the Board may have to set off against an amount payable to the contractor under the contract any amount that—
 - (a) is owed by the contractor to the Board under the contract; or
 - (b) the Board 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 87 of the Act (GMS contracts: payments).

Marginal Citations

M91 See the General Medical Services Statement of Financial Entitlements Directions 2013 which were signed on 27th March 2013, as amended, for the directions given by the Secretary of State under section 87 of the Act. Copies are available at:

https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013. These directions, and the subsequent amendments, may also be obtained in hard copy form from the Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS.

M92 Section 98A was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7).

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 must not, either itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person in respect of—
 - (a) the provision of any treatment whether under the contract or otherwise; or
- (b) a prescription or repeatable prescription for any drug, medicine or appliance, except in the circumstances set out in regulation 25.
 - (3) Subject to paragraph (4), where—
 - (a) a person—
 - (i) applies to a contractor for the provision of essential services,
 - (ii) claims to be on that contractor's list of patients, and
 - (iii) fails to produce a medical card relating to that person on request; and
 - (b) the contractor has reasonable doubts about that person's claim,

the contractor must give any necessary treatment to that person and may demand and accept from that person a reasonable fee in accordance with regulation 25(e).

- (4) Where—
 - (a) a person from whom the contractor has received a fee under regulation 25(e) applies to the Board for a refund within 14 days from the date of payment of the fee (or within such longer period not exceeding one month as the Board may allow if it is satisfied that the failure to apply within 14 days was reasonable); and
 - (b) the Board is satisfied that that person was on the contractor's list of patients when the treatment was given,

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the Board may recover the amount of the fee from the contractor, by deduction from the contractor's remuneration or otherwise, and must pay the amount recovered to the person who paid the fee.

Circumstances in which fees and charges may be made

- 25. The contractor may demand or accept (directly or indirectly) a fee or other remuneration—
 - (a) from a statutory body for services rendered for the purposes of that body's statutory functions;
 - (b) from a body, employer or school for—
 - (i) a routine medical examination of persons for whose welfare the body, employer or school is responsible, or
 - (ii) an examination of such persons for the purpose of advising the body, employer or school of any administration action that they might take;
 - (c) for treatment which is not primary medical services or is otherwise required under the contract and which is given—
 - (i) at accommodation made available in accordance with the provisions of paragraph 11 of Schedule 6 to the Act (accommodation and services for private patients), or
 - (ii) in a registered nursing home which is not providing services under the 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 seven days of giving the treatment, the contractor or the person giving the treatment supplies the Board, on a form provided by the Board for that purpose, with such information as the Board may require;
 - (d) under section 158 of the Road Traffic Act 1988 M93 (payment for emergency treatment of traffic casualties):
 - (e) when the contractor treats a patient under regulation 24(3), in which case the contractor is entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if the contractor gives the patient a receipt;
 - (f) for attending and examining (but not otherwise treating) a patient—
 - (i) at a police station, at the patient's request, in connection with possible criminal proceedings against the patient,
 - (ii) for the purpose of creating a medical report or certificate, at the request of a commercial, educational or not for profit organisation,
 - (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 Board 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 their possession solely in anticipation of the onset of an ailment or occurrence of an injury while that patient is outside of the United Kingdom but for which that patient is not requiring treatment when the drug, medicine or appliance 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—

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- (aa) relating to a road traffic accident or criminal assault, or
- (bb) that offers an opinion as to whether the patient is fit to travel;
- (j) for testing the sight of a person to whom none of paragraphs (a) to (e) of section 115(2) of the Act (primary ophthalmic services) applies (including by reason of regulations made under section 115(7) of the Act) M94;
- (k) where the contractor is authorised or required in accordance with arrangements made with the Board under section 126 of the Act M95 (arrangements for pharmaceutical services) and in accordance with regulations made under section 129 of the Act M96 (regulations as to pharmaceutical services) to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of dispensing services, any Scheduled drug; and
- (l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

Marginal Citations

- M93 1988 c.52. Section 158 was amended by section 20(2) of the Community Care and Health (Scotland) Act 2002 (asp 5) and by S.I. 1995/889.
- **M94** Section 115 was amended by paragraph 54 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act").
- M95 Section 126 was amended by sections 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the 2012 Act.
- M96 Section 129 was amended by section sections 26, 27 and 38 of, and Schedule 6 to, the Health Act 2009 (c.21); section 207(1) to (9) of, and paragraph 66 of Schedule 4 to, the 2012 Act; paragraph 121 of Schedule 9 to the Protection of Freedoms Act 2012 (c.9); and by S.I. 2007/289 and S.I. 2010/231.

Patient participation

- **26.**—(1) The contractor must establish and maintain a group known as a "Patient Participation Group" comprising some of its registered patients for the purposes of—
 - (a) obtaining the views of patients who have attended the contractor's practice about the services delivered by the contractor; and
 - (b) enabling the contractor to obtain feedback from its registered patients about those services.
- (2) The contractor is not required to establish a Patient Participation Group if such a group has already been established by the contractor in accordance with any directions about enhanced services which were given by the Secretary of State under section 98A of the 2006 Act M97 (exercise of functions) before 1st April 2015.
- (3) The contractor must make reasonable efforts during each financial year to review the membership of its Patient Participation Group in order to ensure that the Group is representative of its registered patients.
 - (4) The contractor must—
 - (a) engage with its Patient Participation Group, at such frequent intervals throughout the financial year as the contractor must agree with that Group, with a view to obtaining feedback from the contractor's registered patients, in an appropriate and accessible manner which is designed to encourage patient participation, about the services delivered by the contractor; and
 - (b) review any feedback received about the services delivered by the contractor, whether by virtue of sub-paragraph (a) or otherwise, with its Patient Participation Group with a view to agreeing with that Group the improvements (if any) which are to be made to those services.

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(5) The contractor must make reasonable efforts to implement such improvements to the services delivered by the contractor as are agreed between the contractor and its Patient Participation Group.

Marginal Citations

M97 Section 98A was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7).

Publication of earnings information

- 27.—(1) The contractor must publish each year on its practice website (if it has one) the information specified in paragraph (2).
 - (2) The information specified in this paragraph is—
 - (a) the mean net earnings in respect of the previous financial year of—
 - (i) every general medical practitioners who was a party to the contract for a period of at least six months during that financial year, and
 - (ii) every general medical practitioners who was employed or engaged by the contractor to provide services under the contract in the contractor's practice, whether on a fulltime or a part-time basis, for a period of at least six months during that financial year; and
 - (b) the—
 - (i) total number of any general medical practitioners to whom the earnings information referred to in sub-paragraph (a) relates, and
 - (ii) (where applicable) the number of those practitioners who were employed or engaged by the contractor to provide services under the contract in the contractor's practice whether on a full-time or a part-time basis, for a period of at least six months during the financial year to which that information relates.
 - (3) The information specified in paragraph (2) must be—
 - (a) published by the contractor before the end of the financial year following the financial year to which that information relates; and
 - (b) made available by the contactor in hard copy form on request.
- (4) For the purposes of this regulation, mean net earnings are to be calculated by reference to the earnings of a general medical practitioner that, in the opinion of the Board, are attributable to the performance or provision by the practitioner under the contract of primary medical services, after having disregarded any expenses properly incurred in the course of performing or providing those services.

Sub-contracting

28. A contract must contain terms which prevent a contractor from sub-contracting any of its obligations to provide clinical services under the contract except in the circumstances provided for by Part 5 of Schedule 3.

Variation of contracts

- **29.**—(1) Subject to paragraph (2), a variation of, or amendment to, the contract may only be made in the circumstances provided for in Part 8 of Schedule 3.
- (2) Paragraph (1) does not prevent a variation of, or amendment to, a contract in the circumstances provided for in—

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- (a) regulation 30;
- (b) Part 6; and
- (c) paragraphs 44(8), 45(9), 57, 58 and 72 of Schedule 3.

Variation of contracts: registered patients from outside practice area

- **30.**—(1) A contractor may accept onto its list of patients a person who resides outside of the contractor's practice area.
- (2) Subject to paragraphs (5) and (6), the terms of the contractor's contract specified in paragraph (3) must be varied so as to require the contractor to provide to the person any services which the contractor is required to provide to its registered patients under the contract as if the person resided within the contractor's practice area.
 - (3) The terms of the contract specified in this paragraph are—
 - (a) the terms under which the contractor is to provide essential services;
 - (b) the terms under which the contractor is required to provide for arrangements to access services throughout core hours;
 - (c) the terms under which the contractor is required to provide out of hours services; and
 - (d) the terms which give effect to the following provisions of Schedule 3 (other contractual terms)—
 - (i) paragraph 4(1) (attendance at practice premises),
 - (ii) paragraph 5(2)(a) (attendance outside practice premises), and
 - (iii) paragraph 21(2) (refusal of applications for inclusion in list of patients).
- (4) Where, under paragraph (1), a contractor accepts onto its list of patients a person who resides outside of the contractor's practice area and the contractor subsequently considers that it is not clinically appropriate or practical to continue to provide that patient with services in accordance with the terms specified in paragraph (3), or to comply with those terms, the contract must be varied so as to include a term which has the effect of modifying the application of paragraph 24 of Schedule 3 (which relates to the removal of a patient from the list at the contractor's request) in relation to that patient so that—
 - (a) in sub-paragraph (1), the reference to the patient's disability or medical condition is removed; and
 - (b) sub-paragraph (4) applies as if, after paragraph (a), there were inserted the following paragraph—
 - "(aa) the reason for the removal is that the contractor considers that it is not clinically appropriate or practical to continue to provide services under the contract to the patient which do not include the provision of such services at the patient's home address.".
- (5) Where the contractor is required to provide services to a patient in accordance with arrangements made under paragraph (1), the contract must also be varied so as to include terms which have the effect of releasing the contractor and the Board from all obligations, rights and liabilities relating to the terms specified in paragraph (3) (including any right to enforce those terms) where, in the opinion of the contractor, it is not clinically appropriate or practical under those arrangements to—
 - (a) provide the services in accordance with those terms; or
 - (b) comply with those terms.
- (6) The contract must also include a term which has the effect of requiring the contractor to give notice in writing to a person, where the contractor is minded to accept that person on its list of

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registered patients in accordance with arrangements made under paragraph (1), that the contractor is under no obligation to provide—

- (a) essential services if, at the time treatment is required, it is not clinically appropriate or practical to provide primary medical services given the particular circumstances of the patient;
- (b) out of hours services if, at the time treatment is required, it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient; or
- (c) additional services to the patient if it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient.

Termination of a contract

- **31.**—(1) A contract may only be terminated in the circumstances provided for by Part 8 of Schedule 3.
- (2) A contract must make suitable provision for the arrangements which are to have effect on termination of the contract, including the consequences (whether financial or otherwise) of the contract ending.

Other contractual terms

- **32.**—(1) Subject to paragraph (2), a contract must also contain provisions which are equivalent in their effect to the provisions set out in Parts 6 to 14 of, and Schedules 1 to 3 to, these Regulations, unless the contract is of a type or nature to which a particular provision does not apply.
 - (2) The requirement in paragraph (1) does not apply to the provisions specified in—
 - (a) regulation 83(5) to (15);
 - (b) regulation 84; and
 - (c) paragraphs 41(5) to (9) and 42(5) to (17) of Schedule 3,

which are to have effect in relation to the matters set out in those provisions.

PART 6

Opt outs: additional and out of hours services

Opt outs: interpretation

33. In this Part—

"opt out notice" means a notice given under regulation 35(1) to opt out permanently or temporarily of the provision of an additional service;

"out of hours opt out notice" means a notice given under regulation 38(1) to opt out permanently of the provision of out of hours services;

"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" is to 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 regulation 35(1) that a contractor wants to temporarily opt out or permanently opt out of the provision of an additional service;

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"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 12 months and includes an extension of a temporary opt out, and "temporarily opted out" is to be construed accordingly; and

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

Opt outs: general

- 34. Where a contract provides for the contractor to provide—
 - (a) an additional service; or
 - (b) out of hours services,

to be funded through the global sum, the contract must contain terms relating to the procedure for opting out of the provision of any such service which have the same effect as those specified in the following provisions of this Part.

Opt outs: additional services

- **35.**—(1) Where a contractor wants to permanently or temporarily opt out of the provision of additional services, the contractor must give to the Board in writing a preliminary opt out notice which must state the reasons for the contractor wanting to opt out.
 - (2) The Board must enter into discussions with the contractor concerning—
 - (a) the support which the Board is able to give to the contractor; or
 - (b) other changes which the Board or the contractor may make,

that would enable the contractor to continue to provide the additional service.

- (3) The Board and the contractor must use reasonable endeavours in order to achieve the aim specified in paragraph (2).
 - (4) The discussions referred to in paragraph (2) must be—
 - (a) entered into as soon as is reasonably practicable but before the end of the period of seven days beginning with the date on which the preliminary opt out notice was received by the Board; and
 - (b) completed before the end of the period of ten days beginning with the date on which the preliminary opt out notice was received by the Board or as soon as reasonably practicable thereafter.
- (5) If, following the discussions referred to in paragraph (2), the contractor still wants to opt out of the provision of the additional service, the contractor must send an opt out notice to the Board.
 - (6) An opt out notice must specify—
 - (a) the additional service concerned;
 - (b) whether, in relation to that service, the contractor wants to—
 - (i) permanently opt out, or
 - (ii) temporarily opt out;
 - (c) the reasons for the contractor wanting 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 the service of the opt out notice, and

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- (ii) in the case of a permanent opt out, 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, before the end of the period of three years ending with the date on which the opt out notice was given to the Board, a contractor has given two previous temporary opt out notices (whether or not the same additional service is concerned), the latest opt out notice is to be treated as a permanent opt out notice (even if the opt out notice states that the contractor wishes to temporarily opt out).

Additional services: temporary opt outs and permanent opt outs following temporary opt outs

- **36.**—(1) Where the Board has given a temporary opt out notice or a temporary opt out notice which, by virtue of regulation 35(7), is treated as a permanent opt out notice, the Board must, as soon as is reasonably practicable and, in any event, before the end of the period of seven days beginning with the date on which the Board receives a notice given under regulation 35(5)—
 - (a) approve the opt out notice and specify, in accordance with paragraphs (4) and (5), the date on which the temporary opt out is to commence, and the date on which it is to come to an end ("the end date"); or
 - (b) reject the opt out notice in accordance with paragraph (3).
- (2) The Board must give notice to the contractor of its decision under paragraph (1) as soon as practicable, including the reasons for its decision.
 - (3) The Board 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 to opt out temporarily having regard to its ability to deliver the additional service.
- (4) The date specified by the Board for the commencement of the temporary opt out must, where reasonably practicable, be the date requested by the contractor in the contractor's opt out notice.
- (5) Before determining the end date, the Board must make reasonable efforts to reach agreement with the contractor.
- (6) Where the Board approves an opt out notice, the contractor's obligation to provide the additional service specified in the notice is to be suspended from the date specified by the Board in its decision under paragraph (1) and is to remain suspended until the end date unless—
 - (a) the contractor and the Board agree in writing an earlier date, in which case the suspension comes to an end on the earlier date agreed;
 - (b) the Board specifies a later date under paragraph (7) in which case the suspension comes to an end on the later date specified;
 - (c) paragraph (9) applies and the contractor refers the matter to the NHS dispute resolution procedure or the court, in which case the suspension comes to an end—
 - (i) where the outcome of the dispute is to uphold the decision of the Board, on the day after the date of the decision of the Secretary of State or the court,
 - (ii) where the outcome is to overturn the decision of the Board, 28 days after the date of 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 on which the contractor withdraws its claim or the proceedings are otherwise terminated by the Secretary of State or the court;

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- (d) paragraph (11) applies and—
 - (i) the Board refuses the contractor's request for a permanent opt out before the end of the period of 28 days ending with the end date, in which case the suspension comes to an end 28 days after the end date, or
 - (ii) the Board refuses the contractor's request for a permanent opt out after the end date, in which case the suspension comes to an end 28 days after the date of service of the notice.
- (7) Before the end date, the Board may, in exceptional circumstances and with the agreement of the contractor, give notice in writing to the contractor of a later date on which the temporary opt out is to come to an end, being a date which is no more than six months later than the end date.
 - (8) Where the Board 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 paragraph (7) 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 Board may give notice in writing to the contractor at least 28 days before the end date that a permanent opt out is to follow a temporary opt out.

- (9) Where the Board gives notice to the contractor under paragraph (8) that a permanent opt out is to follow a temporary opt out, the permanent opt out is to take effect immediately after the end of the temporary opt out.
- (10) A contractor who has temporarily opted out may, at least three months prior to the end date, give notice in writing to the Board that it wants to permanently opt out of the additional service in question.
- (11) Where the contractor has given notice to the Board under paragraph (10) that it wants to permanently opt out, the temporary opt out is to be followed by a permanent opt out beginning on the day after the end date of the temporary opt out notice unless the Board refuses the contractor's request to permanently opt out by giving notice in writing to the contractor to this effect.
- (12) A temporary opt out or a permanent opt out commences, and a temporary opt out ends, at 8.00am on the relevant day unless—
 - (a) the day is Saturday, Sunday, Good Friday, Christmas Day or a bank holiday in which case the opt out is to take effect on the next working day at 8.00am; or
 - (b) the Board and the contractor agree a different day or time.

Additional services: permanent opt outs

- **37.**—(1) In this regulation—
 - "A day" is the day specified by the contractor in the permanent opt out notice which the contractor gives to the Board for the commencement of the permanent opt out;
 - "B day" is the day six months after the date on which the permanent opt out notice was given to the Board; and
 - "C day" is the day nine months after the date on which the permanent opt out notice was given to the Board.
- (2) The Board must, as soon as is reasonably practicable and in any event before the end of the period of 28 days beginning with the date on which the Board receives a permanent opt out notice under regulation 35(5) (or temporary opt out notice which is treated as a permanent opt out notice under regulation 35(7))—

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- (a) approve the opt out notice; or
- (b) reject the opt out notice in accordance with paragraph (4).
- (3) The Board must give notice to the contractor of its decision under paragraph (2) as soon as possible, including the reasons for its decision where that decision is to reject the opt out notice.
- (4) The Board 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.
- (5) A contractor may not withdraw an opt out notice once that notice has been approved by the Board in accordance with paragraph (2)(a) without the Board's agreement.
- (6) If the Board approves the opt out notice under paragraph (2)(a), the Board must use reasonable endeavours to make arrangements for the contractor's patients to receive the additional service from an alternative provider from A day.
- (7) The contractor's duty to provide the additional service terminates on A day unless the Board gives notice to the contractor under paragraph (8) (extending A day to B day or C day).
- (8) If the Board is not successful in finding an alternative provider to take on the provision of the additional service from A day, then the Board must give notice in writing to the contractor of that fact no later than one month before A day, and in a case where A day is—
 - (a) three months after the date on which the opt out notice was given, the contractor must continue to provide the additional service until B day unless, at least one month before B day, the contractor is given notice in writing by the Board under paragraph (9) to the effect that, despite using reasonable endeavours, the Board has not been able to find an alternative provider to take on the provision of the additional service from B day;
 - (b) six months after the opt out notice was given, the contractor must continue to provide the additional service until C day.
- (9) Where, in accordance with paragraph (8)(a), the permanent opt out is to commence on B day and the Board, despite using reasonable endeavours, has not been able to find an alternative provider to take on the provision of the additional service from that day, the Board must give notice in writing to the contractor of that fact at least one month before B day, in which case the contractor must continue to provide the additional service until C day.
- (10) As soon as is practicable and, in any event, within seven days of the Board giving notice to the contractor under paragraph (9), the Board must enter into discussions with the contractor concerning the support that the Board is able to give to the contractor or other changes which the Board or the contractor may make in relation to the provision of the additional service until C day.
- (11) Nothing in the preceding paragraphs prevents the contractor and the Board 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 regulation 29 and Part 8 of Schedule 3.
 - (12) The permanent opt out takes effect at 8.00am on the relevant day unless—
 - (a) the day is Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday in which case the opt out is to take effect on the next working day at 8.00am; or
 - (b) the Board and the contractor agree a different day or time.

Out of hours services: opt outs

38.—(1) Where a contractor wants to terminate its obligation under the contract to provide out of hours services, the contractor must give an out of hours opt out notice in writing to the Board to that effect.

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- (2) An out of hours opt out notice must specify the date on which the contractor would like the out of hours opt out to take effect, which must be either three or six months after the date on which that notice is given.
- (3) The Board must approve the out of hours opt out notice and specify, in accordance with paragraph (6), the date on which the out of hours opt out is to commence ("OOH day") as soon as is reasonably practicable and in any event before the end of the period of 28 days beginning with the date on which the Board receives the out of hours opt out notice.
 - (4) The Board must give notice to the contractor of its decision as soon as possible.
 - (5) The OOH day is the date that is specified in the out of hours opt out notice.
- (6) A contractor may not withdraw an out of hours opt out notice once it has been approved by the Board under paragraph (3) without the Board's agreement.
- (7) Following receipt of the out of hours opt out notice, the Board must use reasonable endeavours to make arrangements for the contractor's registered patients to receive out of hours services from an alternative provider from OOH day.
 - (8) Paragraphs (7) to (10) of regulation 37 apply in respect of an out of hours opt out—
 - (a) as they apply to a permanent opt out; and
 - (b) as if the reference to "A day" was a reference to "OOH day".

Informing patients of opt outs

- **39.**—(1) Before any opt out takes effect, the Board and the contractor must discuss how to inform the contractor's patients of the proposed opt out.
- (2) The contractor must, if requested by the Board, inform its registered patients of an opt out and of the arrangements made for those patients to receive the additional service or out of hours services by—
 - (a) placing a notice in the contractor's practice waiting rooms; or
 - (b) including the information in the contractor's practice leaflet.
- (3) In this regulation, "opt out" means an out of hours opt out, a permanent opt out or a temporary opt out.

PART 7

Persons who perform services

Qualifications of performers: medical practitioners

- **40.**—(1) Subject to paragraph (2), a medical practitioner may not perform clinical services under the contract unless that medical practitioner is—
 - (a) included in the medical performers list;
 - (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 M98 (interim orders).
- (2) Paragraph (1) does not apply to any medical practitioner who is an exempt medical practitioner within the meaning of paragraph (3) but only in so far as any medical services that the medical practitioner performs constitute part of a post-registration programme.
 - (3) For the purposes of this regulation, an "exempt medical practitioner" is—

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- (a) a medical practitioner employed by an NHS trust, an NHS foundation trust, a Health Board, or 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 M99 (provisional registration), 15A M100 (provisional registration for EEA nationals) or 21 M101 (provisional registration) of the Medical Act 1983, and who is acting in the course of that person's employment in a resident medical capacity in a programme;
- (c) a GP Specialty Registrar who has applied to the Board to be included in its medical performers list until the occurrence of the first of the following events—
 - (i) the Board gives notice to the GP Specialty Registrar of its decision in respect of that application, or
 - (ii) the end of a period of three months, beginning with the date on which that GP Specialty Registrar begins a postgraduate medical education and training scheme necessary for the award of a CCT; or
- (d) a medical practitioner who-
 - (i) is not a GP Specialty Registrar,
 - (ii) is undertaking a post-registration programme of clinical practice supervised by the General Medical Council,
 - (iii) has given notice to the Board of the intention to undertake part or all of a postregistration programme in England at least 24 hours before commencing any part of that programme, and
 - (iv) has, with the notice given, provided the Board with evidence sufficient for the Board to satisfy itself that the medical practitioner is undergoing a post-registration programme.

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      Marginal Citations

      M98
      1983 c.54. Section 41A was inserted by S.I. 2015/794.

      M99
      1983 c.54. Section 15 was substituted by S.I. 2006/1914.

      M100 1983 c.54. Section 15A was inserted by S.I. 2000/3041, and was amended by S.I. 2006/1914, S.I. 2007/3101 and S.I. 2011/1043.

      M101 1983 c.54. Section 21 was amended by S.I. 1996/1591, S.I. 2002/3135, S.I. 2006/1914 and S.I. 2007/3101.
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Qualifications of performers: health care professionals

- **41.** A health care professional (other than one to whom regulation 40 applies) may not perform clinical services under the contract unless—
 - (a) that person is registered with the professional body relevant to that person's profession; and
 - (b) that registration is not subject to a period of suspension.

Conditional registration or inclusion in primary care list

42. Where the registration of a health care professional or, in the case of a medical practitioner, the inclusion of that practitioner's name in a primary care list, is subject to conditions, the contractor must ensure compliance with those conditions in so far as they are relevant to the contract.

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Clinical experience

43. A health care professional may not perform any clinical services under the contract unless that person has such clinical experience and training as are necessary to enable the person to properly perform such services.

Conditions for employment and engagement: medical practitioners

- **44.**—(1) Subject to paragraphs (2) and (3), a contractor may not employ or engage a medical practitioner (other than an exempt medical practitioner within the meaning of regulation 40(3)) unless—
 - (a) the practitioner has provided the contractor with documentary evidence that the practitioner is entered in the medical performers list; and
 - (b) the contractor has checked that the practitioner meets the requirements of regulation 43.
 - (2) Where—
 - (a) the employment or engagement of a medical practitioner is urgently needed; and
 - (b) it is not possible for the contractor to check the matters referred to in regulation 43 in accordance with paragraph (1)(b) before employing or engaging the practitioner,

the contractor may employ or engage the practitioner on a temporary basis for a single period of up to seven days while such checks are undertaken.

- (3) Where the prospective employee is a GP Specialty Registrar, the requirements in paragraph (1) apply with modifications so that—
 - (a) the GP Specialty Registrar is treated as having provided documentary evidence of the GP Specialty Registrar's application to the Board for inclusion on the medical performers list; and
 - (b) confirmation that the GP Specialty Registrar's name appears on that list is not required until the end of the first two months of the GP Specialty Registrar's training period.

Conditions for employment or engagement: health care professionals

- **45.**—(1) Subject to paragraph (2), a contractor may not employ or engage a health care professional to perform clinical services under the contract unless—
 - (a) the contractor has checked that the health care professional meets the requirements of regulation 41; and
 - (b) the contractor has taken reasonable steps to satisfy itself that the health care professional meets the requirements of regulation 43.
 - (2) Where—
 - (a) the employment or engagement of a health care professional is urgently needed; and
 - (b) it is not possible for the contractor to check that the health care professional meets the requirements referred to in regulation 41 before employing or engaging the health care professional,

the contractor may employ or engage the health care professional on a temporary basis for a single period of up to seven days while such checks are undertaken.

- (3) When considering a health care professional's experience and training for the purposes of paragraph (1)(b), the contractor must, in particular, have regard to—
 - (a) any post-graduate or post-registration qualification held by the health care professional; and

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(b) any relevant training undertaken, and any relevant clinical experience gained, by the health care professional.

Clinical references

- **46.**—(1) The contractor may not employ or engage a health care professional to perform clinical services under the contract (other than an exempt medical practitioner to whom regulation 40(3)(d) applies) 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 of why this is the case and details of alternative referees; and
 - (b) the contractor has checked and is satisfied with the references.
 - (2) Where—
 - (a) the employment or engagement of a health care professional is urgently needed; and
 - (b) it is not possible for the contractor to obtain and check the references in accordance with paragraph (1)(b) before employing or engaging that health care professional,

the contractor may employ or engage the health care professional on a temporary basis for a single period of up to 14 days while the references are checked and considered, and for an additional period of a further seven days if the contractor believes that 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, the contractor may rely on the references provided on the first occasion, provided that those references are not more than 12 months old.

Verification of qualifications and competence

- 47.—(1) The contractor must, before employing or engaging any person to assist it in the provision of services under the contract, take reasonable steps to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which that person is to be employed or engaged.
- (2) The duty imposed on the contractor by paragraph (1) is in addition to the duties imposed by regulations 44 to 46.
- (3) When considering the competence and suitability of any person for the purposes of paragraph (1), the contractor must, in particular, have regard to that person's—
 - (a) academic and vocational qualifications;
 - (b) education and training; and
 - (c) previous employment or work experience.

Training

- **48.**—(1) The contractor must 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 the skills and knowledge of that health care professional in relation to the services which that health care professional is performing or assisting in the performance of.

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(2) The contractor must afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

Terms and conditions

49. The contractor may only offer employment to a general medical practitioner on terms which are no less favourable than those contained in the document entitled "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 GMS contract 2003 M102.

Marginal Citations

M102 This document is available at: http://bma.org.uk/sessionalgps. Hard copies may be requested from The British Medical Association, BMA House, Tavistock Square, London WC1H 9JP.

Arrangements for GP Specialty Registrars

- **50.**—(1) The contractor may only employ a GP Specialty Registrar subject to the conditions specified in paragraph (2).
- (2) The conditions specified in this paragraph are that the contractor must not, by reason only of having employed a GP Specialty 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 those practitioners in the performance of those services.
 - (3) Where a contractor employs a GP Specialty Registrar, the contractor must—
 - (a) offer that GP Specialty Registrar terms of employment in accordance with such rates, and subject to such conditions, as are approved by the Secretary of State concerning the grants, fees, travelling and other allowances payable to GP Specialty Registrars; and
 - (b) take into account the guidance contained in the document entitled "A Reference Guide For Postgraduate Specialty Training in the UK" M103.

Marginal Citations

M103 This guidance, last published in May 2014, is available at http://specialtytraining.hee.nhs.uk/files/2013/10/A-Reference-Guide-for-Postgraduate-Specialty-Training-in-the-UK.pdf. Hard copies are available from Health Education England, 1st Floor, Blenheim House, Duncombe Street, Leeds, LS1 4PL.

Notice requirements in respect of relevant prescribers

- **51.**—(1) For the purposes of this regulation, "a relevant prescriber" is—
 - (a) a chiropodist or podiatrist independent prescriber;
 - (b) an independent nurse prescriber;
 - (c) a pharmacist independent prescriber;
 - (d) a physiotherapist independent prescriber; or
 - (e) a supplementary prescriber.
- (2) The contractor must give notice to the Board where—

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- (a) a relevant prescriber is employed or engaged by a contractor to perform functions which include prescribing;
- (b) a relevant prescriber is a party to the contract whose functions include prescribing; or
- (c) the functions of a relevant prescriber whom the contractor already employs or has already engaged are extended to include prescribing.
- (3) The notice under paragraph (2) must be given in writing to the Board before the expiry of the period of seven days beginning with the date on which—
 - (a) the relevant prescriber was employed or engaged by the contractor or, as the case may be, became a party to the contract (unless immediately before becoming such a party, paragraph (2)(a) applied to that relevant prescriber); or
 - (b) the functions of the relevant prescriber were extended to include prescribing.
 - (4) The contractor must give notice to the Board where—
 - (a) the contractor ceases to employ or engage a relevant prescriber in the contractor's practice whose functions include prescribing in the contractor's practice;
 - (b) a relevant prescriber ceases to be a party to the contract;
 - (c) the functions of a relevant prescriber employed or engaged by the contractor in the contractor's practice are changed so that they no longer include prescribing in the contractor's practice; or
 - (d) the contractor becomes aware that a relevant prescriber whom it employs or engages has been removed or suspended from the relevant register.
- (5) The notice under paragraph (4) must be given in writing to the Board before the end of the second working day after the day on which an event described in sub-paragraphs (a) to (d) occurred in relation to the relevant prescriber.
- (6) The contractor must provide the following information when it gives notice to the Board in accordance with paragraph (2)—
 - (a) the person's full name;
 - (b) the person's professional qualifications;
 - (c) the person's identifying number which appears in the relevant register;
 - (d) the date on which the person's entry in the relevant register was annotated to the effect that the person was qualified to order drugs, medicines and appliances for patients;
 - (e) the date on which—
 - (i) the person was employed or engaged (if applicable),
 - (ii) the person became a party to the contract (if applicable), or
 - (iii) the functions of the person were extended to include prescribing in the contractor's practice.
- (7) The contractor must provide the following information when it gives notice to the Board in accordance with paragraph (4)—
 - (a) the person's full name;
 - (b) the person's professional qualifications;
 - (c) the person's identifying number which appears in the relevant register;
 - (d) the date on which—
 - (i) the person ceased to be employed or engaged in the contractor's practice,
 - (ii) the person ceased to be a party to the contract,

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- (iii) the functions of the person were changed so as to no longer include prescribing in the contractor's practice, or
- (iv) the person was removed or suspended from the relevant register.

Signing of documents

- **52.**—(1) The contractor must ensure—
 - (a) that the documents specified in 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 the document is signed; and
 - (b) that the documents specified in paragraph (3) include the clinical profession of the health care professional who signed the document.
- (2) The documents specified in this paragraph are—
 - (a) certificates issued in accordance with regulation 22, unless regulations relating to particular certificates provide otherwise; and
 - (b) any other clinical documents apart from—
 - (i) home oxygen order forms, and
 - (ii) the documents specified in paragraph (3).
- (3) The documents specified in this paragraph are batch issues, prescription forms and repeatable prescriptions.
- (4) This regulation is in addition to any other requirements relating to the documents specified in paragraphs (2) and (3) whether in these Regulations or elsewhere.

Level of skill

53. The contractor must carry out its obligations under the contract with reasonable care and skill.

Appraisal and assessment

- **54.**—(1) The contractor must ensure that any medical practitioner performing services under the contract—
 - (a) participates in the appraisal system provided by the Board unless that medical practitioner participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and
 - (b) co-operates with the Board in relation to the Board's patient safety functions.
- (2) The Board must provide an appraisal system for the purposes of paragraph (1)(a) after consultation with the Local Medical Committee (if any) for the area in which the practitioner provides services under the contract and such other persons as appear to it to be appropriate.
- (3) In 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 armed forces of the Crown.

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PART 8

Prescribing and dispensing

Prescribing: general

- **55.**—(1) The contractor must ensure that—
 - (a) any prescription form or repeatable prescription issued or created by a prescriber;
 - (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 regulations 56, 57 and 59 to 63.

(2) For the purposes of regulations 56, 57 and 59 to 63 in their application to a contractor whose contract includes the provision of contraceptive services, a reference to "drugs" includes contraceptive substances and a reference to "appliances" includes contraceptive appliances.

Orders for drugs, medicines or appliances

- **56.**—(1) Subject to paragraphs (2) and (3) and to the restrictions on prescribing in regulations 61 and 62, a prescriber must 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 the patient a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with paragraph (6); or
 - (b) creating and transmitting an electronic prescription in circumstances to which regulation 57(1) applies,

and a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription that is for health service use must not be used in any other circumstances.

- (2) A healthcare professional must order any home oxygen services which are needed for the treatment of a patient who is receiving treatment under the contract by issuing a home oxygen order form.
- (3) During an outbreak of an illness for which a listed medicine may be used for a treatment or for prophylaxis, if—
 - (a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine 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 order that listed medicine by using a listed medicines voucher and must sign that listed medicines voucher if one is used.

- (4) During an outbreak of an illness for which a listed medicine may be used for a treatment or for prophylaxis, if—
 - (a) the Secretary of State or the Board has made arrangements for the distribution of a listed medicine 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 of that disease or for or prophylaxis;

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- (c) a person acting on behalf of the contractor, who is not a prescriber but who is authorised by the Board to order listed medicines, has applied the criteria referred to in sub-paragraph (b) to a patient who is receiving treatment under the contract; and
- (d) having applied the criteria, that person has concluded that the listed medicine is needed for the treatment or prophylaxis of the patient,

that person may order that listed medicine by using a listed medicines voucher and must sign that listed medicines voucher if one is used.

- (5) A prescriber may only order drugs, medicines or appliances on a repeatable prescription where the drugs, medicines or appliances are to be provided more than once.
- (6) In issuing a non-electronic prescription form or a non-electronic repeatable prescription, the prescriber must—
 - (a) sign the prescription form or repeatable prescription in ink in the prescriber's own handwriting, and not by means of a stamp, with the prescriber's initials, or forenames, and surname; and
 - (b) only sign the prescription or repeatable prescription after particulars of the order have been inserted in the prescription form or repeatable prescription.
- (7) A prescription form or repeatable prescription must not refer to any previous prescription form or repeatable prescription form.
- (8) A separate prescription form or repeatable prescription must be used for each patient, except where a bulk prescription is issued for a school or institution under regulation 63.
 - (9) A home oxygen order form must be signed by a health care professional.
- (10) Where a prescriber orders the drug buprenorphine or diazepam or a drug specified in Part 1 of Schedule 2 to the Misuse of Drugs Regulations 2001 M104 (controlled drugs to which regulations 14 to 16, 18 to 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, the prescriber must—
 - (a) use only the prescription form provided specially for the purposes of supply by instalments;
 - (b) 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.
- (11) The prescription form provided specially for the purpose of supply by instalments must not be used for any purpose other than ordering drugs in accordance with paragraph (10).
- (12) In an urgent case, a prescriber may only request a chemist to dispense a drug or medicine before a prescription form or repeatable prescription is issued or created if—
 - (a) the drug or medicine is not a Scheduled drug;
 - (b) the drug is not a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 M105 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Part 1 of Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23, 26 and 27) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001 M106; and
 - (c) the prescriber undertakes to—

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- (i) provide the chemist within 72 hours from the time of the request with a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with paragraph (6), or
- (ii) transmit by the Electronic Prescription Service within 72 hours from the time of the request an electronic prescription.
- (13) In an urgent case, a prescriber may only request a chemist to dispense an appliance before a prescription form or repeatable prescription form is issued or created if—
 - (a) the appliance does not contain a Scheduled drug, or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26);
 - (b) if the appliance is a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
 - (c) the prescriber undertakes to—
 - (i) provide the chemist within 72 hours from the time of the request with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with paragraph (6), or
 - (ii) transmit by the Electronic Prescription Service within 72 hours from the time of the request an electronic prescription.

Marginal Citations

M104 S.I. 2001/3998. Schedule 2 was amended by S.I. 2003/1432, **S.I**. 2009/3136, S.I. 2011/448, **S.I**. 2014/1275 and 3277 and S.I. 2015/891.

M105 1971 c.38. Section 2 was amended by paragraphs 1 and 2 of Schedule 17 to the Police Reform and Social Responsibility Act 2011 (c. 13).

M106 S.I. 2001/3998. Schedule 4 was amended by S.I. 2003/1432, **S.I**. 2005/3372, S.I. 2007/2154, **S.I**. 2009/3136, S.I. 2013/625, **S.I**. 2014/1275 and 3277 and S.I. 2015/891. Schedule 5 was amended by S.I. 2005/2864.

Electronic prescriptions

- **57.**—(1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if—
 - (a) the Board authorises the contractor to use the Electronic Prescription Service;
 - (b) the patient to whom the prescription relates has—
 - (i) nominated one or more dispensers,
 - (ii) confirmed the intention 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) consented 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 section 2 of the Misuse of Drugs Act 1971 M107 (which relates to controlled drugs and their classification for the purposes

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of that Act), other than a drug which is for the time being specified in Schedules 2 to 5 to the Misuse of Drugs Regulations 2001, or

- (ii) a bulk prescription issued for a school or institution under regulation 63.
- (2) A health care professional may not order home oxygen services by means of an electronic prescription.
- (3) In relation to a patient who is a child or an adult who lacks capacity to nominate a dispenser, paragraph (1)(b) applies as if the reference to the patient to whom the prescription relates included a reference to—
 - (a) where the patient is a child—
 - (i) either parent, or in the absence of both parents, the guardian or other adult who has care of the patient,
 - (ii) a person duly authorised by a local authority to whose care the patient has been committed under the Children Act 1989 M108, or
 - (iii) a person duly authorised by a voluntary organisation by which the patient is being accommodated under the Children Act 1989; or
 - (b) where the patient is an adult who lacks capacity to make such a request, the 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 a court under the Mental Capacity Act 2005 M109.
- (4) A prescriber who orders drugs, medicines or appliances by means of an electronic prescription must, in the case of—
 - (a) an electronic repeatable prescription, issue the patient, if the patient so requests, with a form provided by the Board for the purpose of recording details of that prescription and linked to that prescription by a number contained on the form; and
 - (b) an electronic prescription form, issue the patient, if the patient so requests, with a written record of the prescription which has been created.

Marginal Citations

M107 1971 c.38. Section 2 was amended by paragraphs 1 and 2 of Schedule 17 to the Police Reform and Social Responsibility Act 2011 (c. 13).

M108 1989 c.41.

M109 2005 c.9.

Nomination of dispensers for the purposes of electronic prescriptions

- **58.**—(1) A contractor authorised to use the Electronic Prescription Service for its patients must enter into the particulars relating to the patient which are held in the Patient Demographic Service managed by the Health and Social Care Information Centre MIIO—
 - (a) where the patient does not have a nominated dispenser, the dispenser chosen by the patient; and
 - (b) where the patient does have a nominated dispenser—
 - (i) a replacement dispenser, or
 - (ii) a further dispenser,

chosen by the patient.

(2) Paragraph (1)(b)(ii) does not apply if the number of the nominated dispensers would thereby exceed the maximum number permitted by the Electronic Prescription Service.

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- (3) A request for the nomination of a dispenser may be made—
 - (a) where the patient is a child, on behalf of the patient—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult who has care of the patient,
 - (ii) by a person duly authorised by a local authority to whose care the patient has been committed under the Children Act 1989 MIII, or
 - (iii) by a person duly authorised by a voluntary organisation by which the patient is being accommodated under the Children Act 1989; or
 - (b) where the patient is an adult who lacks capacity to make such a request, by a relative or a primary carer of the patient, a done of a lasting power of attorney granted by the patient or a deputy appointed for the patient by the court under the Mental Capacity Act 2005.
- (4) A contractor must—
 - (a) not seek to persuade a patient to nominate a dispenser recommended by the prescriber or the contractor; and
 - (b) if asked by a patient to recommend a chemist whom the patient might nominate as the patient's dispenser, provide the patient with the list given to the contractor by the Board of all chemists in the area who provide an Electronic Prescription Service.

Marginal Citations

M110 The Health and Social Care Information Centre is a body corporate established by section 252(1) of the Health and Social Care Act 2012 (c.7).

M111 1989 c.41.

Repeatable prescribing services

- **59.**—(1) The contractor may only provide repeatable prescribing services to a person on its list of patients if the contractor—
 - (a) satisfies the conditions specified in paragraph (2); and
 - (b) has given notice in writing to the Board of its intention to provide repeatable prescribing services in accordance with paragraphs (3) and (4).
 - (2) The conditions specified in this paragraph are that—
 - (a) the contractor has access to computer systems and software which enable it to issue nonelectronic repeatable prescriptions and batch issues; and
 - (b) the practice premises at which the repeatable prescribing services are to be provided are located in a local authority area in which there is also located the premises of at least one chemist who has undertaken to provide, or has entered into arrangements to provide, repeat dispensing services.
 - (3) The notice given under paragraph (1)(b) must confirm that the contractor—
 - (a) wants to provide repeatable prescribing services;
 - (b) intends to begin providing those services from a specified date; and
 - (c) satisfies the conditions specified in paragraph (2).
- (4) The date specified by the contractor under paragraph (3)(b) must be at least ten days after the date on which the notice under paragraph (1)(b) was given.
- (5) Nothing in this regulation requires a contractor or a prescriber to provide repeatable prescribing services to any person.

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- (6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if—
 - (a) the 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 person on its list of patients to whom any person specified in paragraph (8) is authorised or required by the Board to provide pharmaceutical services in accordance with arrangements under section 126 M112 (arrangements for pharmaceutical services) and section 132 M113 (persons authorised to provide pharmaceutical services) of the Act.
 - (8) The persons specified in this paragraph 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 persons practising in a partnership, any medical practitioner who is a partner in the partnership;
 - (c) in the case of a contract with a company limited by shares, any medical practitioner who is both a legal and beneficial shareholder in that company; or
 - (d) any medical practitioner employed or engaged by the contractor.

Marginal Citations

M112 Section 126 was amended by sections 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the Health and Social Care Act 2012 (c.7).

M113 Section 132 was amended by paragraph 69 of Schedule 4 to the Health and Social Care Act 2012 (c.7), section 115 (1) of, and paragraphs 120 and 121 of Schedule 9 to, the Protection of Freedoms Act 2012 (c. 9), and by S.I. 2007/289 and S.I. 2010/22 and 231.

Repeatable prescriptions

- **60.**—(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 wants to make a change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription, the prescriber must—
 - (a) in the case of a non-electronic repeatable prescription—
 - (i) give notice to the person, and
 - (ii) make reasonable efforts to give notice to the chemist providing repeat dispensing services to the 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 the person; or

- (b) in the case of an electronic repeatable prescription—
 - (i) arrange with the Electronic Prescription Service for the cancellation of the original repeatable prescription, and
 - (ii) create a replacement prescription relating to the person and give notice to the person that this has been done.

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- (3) Where a prescriber has created an electronic repeatable prescription for a person, the prescriber must, as soon as practicable, arrange with the Electronic Prescription Service for its cancellation if, before the expiry of that prescription—
 - (a) the prescriber considers that it is no longer safe or appropriate for the person to receive the drugs, medicines or appliances ordered on the person's electronic repeatable prescription or it is no longer safe or appropriate for the person to continue to receive repeatable prescribing services;
 - (b) the prescriber has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription; or
 - (c) it comes to the prescriber's notice that the 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 an electronic repeatable prescription relating to a person in accordance with paragraph (3), the prescriber must give notice of the cancellation to the person as soon as possible.
- (5) A prescriber who has issued a non-electronic repeatable prescription in relation to a person must, as soon as possible, make reasonable efforts to give notice to 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) the prescriber considers that it is no longer safe or appropriate for the person to receive the drugs, medicines or appliances ordered on the person's repeatable prescription or that it is no longer safe or appropriate for the person to continue to receive repeatable prescribing services;
 - (b) the prescriber 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 paragraph (2)(a) (for example, because the person wants to obtain the drugs, medicines or appliances from a different chemist); or
 - (c) it comes to the prescriber's notice that the person has been removed from the list of patients of the contractor on whose behalf the prescription was issued.
- (6) Where the circumstances in paragraph (5)(a) to (c) apply in respect of a person, the prescriber must as soon as possible give notice to that person that their repeatable prescription should no longer be used to obtain repeat dispensing services.

Restrictions on prescribing by medical practitioners

- **61.**—(1) A medical practitioner, in the course of treating a patient to whom the practitioner is providing treatment under the contract, must comply with the following paragraphs.
- (2) The medical practitioner must not order on a listed medicines voucher, prescription form or a repeatable prescription a drug, medicine or other substance specified in any directions given by the Secretary of State in regulations made under section 88 of the Act MII4 (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.
- (3) The medical practitioner must 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 88 of the Act (GMS contracts: prescription of drugs etc) as being a drug, medicine or other substance which can only be ordered for specified patients and for specified purposes unless—
 - (a) the patient is a person of the specified description;
 - (b) the drug, medicine or other substance is prescribed for that patient only for the specified purpose; and

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- (c) if the order is on a prescription form, the practitioner includes on the form—
 - (i) the reference "SLS", or
 - (ii) if the order is under arrangements made by the Secretary of State or the Board for the distribution of a listed medicine free of charge, the reference "ACP".
- (4) The medical practitioner must 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".
- (5) The medical practitioner must not order on a repeatable prescription a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 MIIS (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 4 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001 MII6.
- (6) Subject to regulation 24(2)(b) and to paragraph (7), nothing in the preceding paragraphs prevents a medical practitioner, in the course of treating a patient to whom this regulation refers, from prescribing a drug, medicine or other substance or, as the case may be, a restricted availability appliance or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), for the treatment of that patient under a private arrangement.
- (7) Where, under paragraph (6), a drug, medicine or other substance is prescribed under a private arrangement, if the order is to be transmitted as an electronic communication to a chemist for the drug, medicine or appliance to be dispensed—
 - (a) if the order is not for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001 MII7, it may be transmitted by the Electronic Prescription Service; but
 - (b) if the order is for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001, it must be transmitted by the Electronic Prescription Service.

Marginal Citations

M114 See the National Health Service (General Medical Services Contracts) (Prescription of Drugs, Medicines and Appliances etc) Regulations 2004 (S.I. 2004/639) for the Directions given by the Secretary of State under section 88 of the Act. S.I. 2004/639 was amended by S.I. 2004/3215, S.I. 2009/2230, S.I. 2010/2389, S.I. 2011/680 and 1043, S.I. 2013/363 and 2494 and S.I. 2014/1625.

M115 1971 c.38.

M116 S.I. 2001/3998. Schedule 4 was amended by S.I. 2003/1432, **S.I**. 2005/3372, S.I. 2007/2154, **S.I**. 2009/3136, S.I. 2013/625, **S.I**. 2014/1275 and 3277 and S.I. 2015/891. Schedule 5 was amended by S.I. 2005/2864.

M117 S.I. 2001/3998. Schedules 2 and 3 were amended by S.I. 2003/1432, **S.I**. 2007/2154, S.I. 2009/3136, **S.I**. 2011/448, S.I. 2012/1311, **S.I**. 2014/1275 and 3277 and S.I. 2015/891.

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Restrictions on prescribing by supplementary prescribers

- **62.**—(1) The contractor must have arrangements in place to secure that a supplementary prescriber may only—
 - (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 under the conditions set out in paragraph (2).

- (2) The conditions set out in this paragraph are that—
 - (a) the person satisfies the conditions in regulation 215 of the Human Medicines Regulations 2012 MII8 (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 those Regulations;
 - (b) the medicine is not specified in any directions given by the Secretary of State in regulations under section 88 of the Act MII9 (GMS contracts: prescription of drugs etc) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;
 - (c) the medicine is not specified in any directions given by the Secretary of State under section 88 of the Act (GMS contracts: prescription of drugs etc) 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—
 - (aa) the reference "SLS", or
 - (bb) in the case of a listed medicine ordered under arrangements made by the Secretary of State or the Board for the medicine's distribution free of charge, the reference "ACP".
- (3) Where the functions of a supplementary prescriber include prescribing, the contractor must have arrangements in place to secure that the person may 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 paragraph (4).

- (4) The conditions set out in this paragraph are that—
 - (a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time when that prescriber acts and which contains the following particulars—
 - (i) the name of the patient to whom the plan relates,
 - (ii) the illness or conditions which may be treated by the supplementary prescriber,
 - (iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan,
 - (iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,

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- (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 giving notice of—
 - (aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan, and
 - (bb) incidents occurring with the appliance that might lead, might have led or have led to the death or serious deterioration of the state of health of the patient, and
- (viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of the medical practitioner or dentist who is a party to the plan;
- (b) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by a medical practitioner or dentist who is a party to the plan;
- (c) if it is a prescription for a prescription only medicine, that prescription only medicine is not specified in any directions given by the Secretary of State in regulations made under section 88 of the Act M120 (GMS contracts: prescription of drugs etc.) as being a medicine which may not be ordered for patients in the provision of medical services under the contract;
- (d) if it is a prescription for a prescription only medicine which is not specified in any directions given by the Secretary of State under section 88 of the Act (GMS contracts: prescription of drugs etc) as being a medicine 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, the supplementary prescriber includes on the prescription form the reference "SLS";
- (e) if it is prescription for an appliance, the appliance is listed in Part IX of the Drug Tariff; and
- (f) if it is a prescription for a restricted availability appliance—
 - (i) the patient is a person of the 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, the supplementary prescriber includes on the prescription form the reference "SLS".
- (5) In 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.

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Marginal Citations

M118 S.I. 2012/1916. There are no amendments to regulation 215.

M119 See the National Health Service (General Medical Services Contracts) (Prescription of Drugs, Medicines and Appliances etc) Regulations 2004 (S.I. 2004/639) for the Directions given by the Secretary of State under section 88 of the Act. S.I. 2004/639 was amended by S.I. 2004/3215, S.I. 2009/2230, S.I. 2010/2389, S.I. 2011/680 and 1043, S.I. 2013/363 and 2494 and S.I. 2014/1625.

M120 See the National Health Service (General Medical Services Contracts) (Prescription of Drugs, Medicines and Appliances etc) Regulations 2004 (S.I. 2004/639) for the Directions given by the Secretary of State under section 88 of the Act. S.I. 2004/639 was amended by S.I. 2004/3215, S.I. 2009/2230, S.I. 2010/2389, S.I. 2011/680 and 1043, S.I. 2013/363 and 2494 and S.I. 2014/1625.

Bulk prescribing

- **63.**—(1) A prescriber may use a single non-electronic prescription form where—
 - (a) a contractor is responsible under the contract for the treatment of ten or more persons in a school or other institution in which at least 20 persons normally reside; and
 - (b) the prescriber orders, for any two or more of those persons for whose treatment the contractor is responsible, drugs, medicines or appliances to which this regulation applies.
- (2) Where a prescriber uses a single non-electronic prescription form for the purpose mentioned in paragraph (1)(b), the prescriber must (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 other institution in which those persons reside; and
 - (b) the number of persons residing there for whose treatment the contractor is responsible.
- (3) This regulation applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which in the case of—
 - (a) a drug or medicine, is not a prescription only medicine; or
 - (b) an appliance, does not contain such a product.

Excessive prescribing

- **64.**—(1) The contractor must not prescribe drugs, medicines or appliances the cost or quantity of which, in relation to a 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 the patient.
- (2) In considering whether a contractor has breached its obligations under paragraph (1), the Board must seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.

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

- **65.**—(1) Subject to paragraphs (2) and (3), a contractor—
 - (a) must provide to a patient a drug, medicine or appliance, which is not a Scheduled drug, where such provision is needed for the immediate treatment of the patient before provision can otherwise be obtained; and
 - (b) may provide to a patient a drug, medicine or appliance, which is not a Scheduled drug, which the contractor personally administers or applies to the patient.

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- (2) A contractor must only provide a restricted availability appliance under paragraph (1)(a) or (b) if it is for a person or a purpose specified in the Drug Tariff.
- (3) Nothing in paragraph (1) or (2) authorises a person to supply a prescription only medicine to a patient otherwise than in accordance with Part 12 of the Human Medicines Regulations 2012 M121 (which relates to dealings with medicinal products).

Marginal Citations

M121 S.I. 2012/1916; as amended by S.I. 2013/235, 1855 and 2593, S.I. 2014/490 and 1887, and S.I. 2015/323, 570, 903 and 1503.

PART 9

Prescribing and dispensing: out of hours services

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

66.—(1) In this Part—

"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 having regard to the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait to obtain them;

"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 meaning given in the regulation 213(1) of the Human Medicines Regulations 2012 M122 (interpretation); and

- "supply form" means a form provided by the Board 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 Board 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 must comply with the requirements of paragraphs (3) to (5).
 - (3) The contractor must 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 to treat the patient; and
 - (c) does not supply—
 - (i) drugs, medicines or appliances which the contractor 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

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- (iv) a drug, medicine or other substance listed in Schedule 1 to the National Health Service (General Medical Services Contract) (Prescription of Drugs etc) Regulations 2004 M123 (drugs, medicines and other substances not to be ordered under a general medical services contract), or a drug listed in Schedule 2 to those Regulations M124 (drugs, medicines and other substances that may be ordered only in certain circumstances), other than in the circumstances specified in that Schedule.
- (4) The out of hours performer—
 - (a) must, except where paragraph (b) applies, record on a separate supply form for each patient any drugs, medicines or appliances supplied to the patient; and
 - (b) may complete a single supply form in respect of the supply of any necessary drugs, medicines or appliances to two or more persons in a school or other institution in which at least 20 persons normally reside, in which case the out of hours performer may write on the supply form the name of the school or institution rather than the name of each individual patient.
- (5) The out of hours performer must ask any person to produce satisfactory evidence of entitlement where that person makes a declaration that a patient does not have to pay any of the charges specified in regulations made under section 172 of the Act (charges for drugs, medicines or appliances, or pharmaceutical services) or section 174 of the Act (pre-payment certificates) M125 in respect of dispensing services to the patient by virtue of either—
 - (a) entitlement to exemption under regulations made under section 172 or 174 of the Act; or
 - (b) entitlement to full remission of charges under regulations made under section 182 (remission and repayment of charges) or 183 M126 (payment of travelling expenses) of the Act.
- (6) Paragraph (5) does not apply if, at the time of the declaration, satisfactory evidence of entitlement is already available to the out of hours performer.
- (7) If, in accordance with paragraphs (5) and (6), no satisfactory evidence of entitlement is produced or no such evidence is otherwise already available to the out of hours performer, the out of hours performer must endorse the supply form to that effect.
- (8) Subject to paragraph (9), nothing in this regulation prevents an out of hours performer from supplying a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.
- (9) The provisions of regulation 24(2)(b) which relate to fees and charges apply in respect of the supply of any necessary drugs, medicines and appliances under this regulation as they apply in respect of prescriptions for any drugs, medicines and appliances.

Marginal Citations

M122 S.I. 2012/1916. There are no relevant amendments to regulation 213.

M123 S.I. 2004/629. There are no amendments to Schedule 1.

M124 Schedule 2 was amended by S.I. 2004/3215, **S.I**. 2009/2230, S.I. 2010/2389, **S.I**. 2011/680 and 1043, S.I. 2012/2389, **S.I**. 2013/363 and 2194, and S.I. 2014/1625.

M125 The Regulations made under sections 172 and 174 are the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 (S.I. 2003/2382) and the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570). S.I. 2003/2382 was amended by S.I. 2004/633 and 936, S.I. 2005/26, 578 and 2114, S.I. 2006/562, 675 and 2171, S.I. 2007/1898, S.I. 2008/571, 1697, 1700 and 2868, S.I. 2009/411, S.I. 2010/620, S.I. 2011/1587, S.I. 2013/458, 475 and 1600, and S.I. 2015/417, 643, 570, 993 and 1776.

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M126 Section 183 was amended paragraph 98 of Schedule 4 to the Health and Social Care Act 2012 (c.7) and by S.I. 2010/915 and S.I. 2013/2269.

PART 10

Records and information

Patient records

- **67.**—(1) The contractor must keep adequate records of its attendance on and treatment of its patients and must do so—
 - (a) on forms supplied to it for the purpose by the Board; or
- (b) with the written consent of the Board, by way of computerised records, or in a combination of those two ways.
- (2) The contractor must include in the records referred to in paragraph (1), clinical reports sent in accordance with paragraph 12 of Schedule 3 or from any other health care professional who has provided clinical services to a person on the contractor's list of patients.
- (3) The consent of the Board required by paragraph (1)(b) may not be withheld or withdrawn provided the Board 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 by another person acting on the Secretary of State's behalf in accordance with "General Practice Systems of Choice Level 2". M127;
 - (b) the security measures, audit and system management functions incorporated into the computer system as accredited in accordance with sub-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 "The Good Practice Guidelines for GP electronic patient records" (Version 4) published on 21st March 2011 M128.
- (4) Where the patient's records are computerised records, the contractor must, as soon as possible following a request from the Board, allow the Board to access the information recorded on the computer system on which those records are held by means of the audit function referred to in paragraph (3)(b) to the extent necessary for the Board to confirm that the audit function is enabled and functioning correctly.
- [F11(5)] Where a patient on the contractor's list of patients dies, the contractor must send the complete records relating to that patient to the Board—
 - (a) in a case where the contractor was informed by the Board of that patient's death, before the end of the period of 14 days beginning with the date on which the contractor was so informed; or
 - (b) in any other case, before the end of the period of one month beginning with the date on which the contractor learned of that patient's death.
- (5A) Where a patient on a contractor's list of patients has registered with another provider of primary medical services and the contractor receives a request from that provider for the complete records relating to that patient, the contractor must send to the Board—
 - (a) the complete records, or any part of the records, sent via the GP2GP facility in accordance with regulation 69 for which the contractor does not receive confirmation of safe and effective transfer via that facility; and

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- (b) any part of the records held by the contractor only in paper form.
- (5B) Where a patient on a contractor's list of patients—
 - (a) is removed from that list at that patient's request under paragraph 23 of Schedule 3, or by reason of the application of any of paragraphs 24 to 31 of that Schedule; and
 - (b) the contractor has not received a request from another provider of medical services with which that patient has registered for the transfer of the complete records relating to that patient,

the contractor must send a copy of those records to the Board.

- (5C) Where a contractor's responsibility for a patient terminates in accordance with paragraph 32 of Schedule 3, the contractor must send any records relating to that patient that it holds to—
 - (a) if known, the provider of primary medical services with which that patient is registered; or
 - (b) in all other cases, the Board.
- (5D) For the purposes of this regulation, "GP2GP facility" has the same meaning as in paragraph (2) of regulation 69.]

$^{\text{F12}}(6)$																
F13(7)																

- (8) A contractor whose patient records are computerised records must not disable, or attempt to disable, either the security measures or the audit system management functions referred to in paragraph (3).
- (9) In this regulation, "computerised records" means records created by way of entries on a computer.

Textual Amendments

- F11 Reg. 67(5)-(5D) substituted for reg. 67(5) (3.10.2016) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2016 (S.I. 2016/875), regs. 1(2), 2(a)
- **F12** Reg. 67(6) omitted (3.10.2016) by virtue of The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2016 (S.I. 2016/875), regs. 1(2), **2(b)**
- F13 Reg. 67(7) omitted (3.10.2016) by virtue of The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2016 (S.I. 2016/875), regs. 1(2), 2(c)

Marginal Citations

- M127 GP Systems of Choice is a scheme by which the National Health Service funds the cost of GP clinical IT systems in England. Guidance about this scheme is available from the Health and Social Care Information Centre, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE.
- M128 This guidance is available at http://www.gov.uk/government/publications/the-good-practice-guidelines-for-gp-electronic-patient-records-version-4-2011. Hard copies are available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

Summary Care Record

68.—(1) A contractor must, in any case where there is a change to the information included in a patient's medical record, enable the automated upload of summary information to the Summary Care Record, [F14] when the change occurs], using approved systems provided to it by the Board.

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(2) In this regulation—

"Summary Care Record" means the system approved by the Board for the automated uploading, storing and displaying of patient data relating to medications, allergies, adverse reactions and, where agreed with the contractor and subject to the patient's consent, any other data taken from the patient's electronic record; and

"summary information" means items of patient data that comprise the Summary Care Record.

Textual Amendments

F14 Words in reg. 68(1) substituted (3.10.2016) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2016 (S.I. 2016/875), regs. 1(2), 3

Electronic transfer of patient records between GP practices

- **69.**—(1) A contractor must use the facility known as "GP2GP" for the safe and effective transfer of any patient records—
 - (a) in a case where a new patient registers with the contractor's practice, to the contractor's practice from the practice of another provider of primary medical services (if any) with which the patient was previously registered; or
 - (b) in a case where the contractor receives a request from another provider of primary medical services with which the patient has registered, in order to respond to that request.
- (2) In this regulation, "GP2GP facility" means the facility provided by the Board to a contractor's practice which enables the electronic health records of a registered patient which are held on the computerised clinical systems of a contractor's practice to be transferred securely and directly to another provider of primary medical services with which the patient has registered.
 - (3) The requirements of this regulation do not apply in the case of a temporary resident.

Clinical correspondence: requirement for NHS number

- **70.**—(1) A contractor must include the NHS number of a registered patient as the primary identifier in all clinical correspondence issued by the contractor which relates to that patient.
- (2) The requirement in paragraph (1) does not apply where, in exceptional circumstances outside of the contractor's control, it is not possible for the contractor to ascertain the patient's NHS number.
 - (3) In this regulation—
 - "clinical correspondence" means all correspondence in writing, whether in electronic form or otherwise, between the contractor and other health service providers concerning or arising out of patient attendance and treatment at practice premises including referrals made by letter or by any other means; and
 - "NHS number", in relation to a registered patient, means the number, consisting of ten numeric digits, which serves as the national unique identifier used for the purpose of safely, accurately and efficiently sharing information relating to that patient across the whole of the health service in England.

Patient online services

- 71.—(1) A contractor must promote and offer to its registered patients the facility for a patient to—
 - (a) book, view, amend, cancel and print appointments online;

Changes to legislation: The National Health Service (General Medical Services Contracts) Regulations 2015 is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (b) order repeat prescriptions for drugs, medicines or appliances online; and
- (c) view and print a list of any drugs, medicines or appliances in respect of which the patient has a repeat prescription,

in a manner which is capable of being electronically integrated with the computerised clinical systems of the contractor's practice using appropriate systems authorised by the Board.

- (2) The requirements in paragraph (1) do not apply where the contractor does not have access to computer systems and software which would enable it to offer the online services described in that paragraph to its registered patients.
- (3) A contractor must, when complying with the requirement in paragraph (1)(a), consider whether it is necessary, in order to meet the reasonable needs of its registered patients, to take action to increase the proportion of appointments which are available for its registered patients to book online and, if so, take such action.
- (4) A contractor must promote and offer to its registered patients, in circumstances where the medical records of its patients are held on the contractor's computerised clinical systems, the facility for a patient to—
 - (a) access online any summary information derived from the patient's medical records and any other data which the contractor has agreed that the patient may access; and
 - (b) view online, electronically export or print any summary information derived from the patient's medical records and any other data which the contractor has agreed that the patient may access.
- (5) A contractor must promote and offer to its registered patients, in circumstances where the medical records of its registered patients are held on the contractor's computerised clinical systems, the facility for any such patient to access online all information from the patient's medical record which is held in coded form unless—
 - (a) in the reasonable opinion of the contractor, access to such information would not be in the patient's best interests because it is likely to cause serious harm to—
 - (i) the patient's physical or mental health, or
 - (ii) the physical or mental health of any other person;
 - (b) the information includes a reference to any third party who has not consented to its disclosure; or
 - (c) the information in the patient's medical record contains a free text entry and it is not possible under the contractor's computerised clinical systems to separate that free text entry from other information in that medical record which is held in coded form.
 - (6) The requirements in paragraph (4)—
 - (a) do not apply where the contractor does not have access to computer systems and software which would enable it to offer the online services described in that paragraph; and
 - (b) only apply until such time as the contractor is able to fully comply with the requirements in paragraph (5).
 - (7) The requirements in paragraph (5) do not apply where the contractor—
 - (a) does not have access to GPSOC accredited computer systems and software which would enable it to offer the online services described in that paragraph to its registered patients; and
 - (b) has, by 30th September 2015, publicised its plans to achieve that requirement by 31st March 2016 by displaying a statement of intent on the practice premises and, where the contractor has a website, on the practice website.

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- (8) Where the contractor has a practice website, the contractor must also promote and offer to its registered patients the facility referred to in paragraph (1)(a) and (b) on that practice website.
 - (9) In this regulation—
 - (a) "GPSOC accredited computer systems and software" means computer systems and software which have been accredited by the Secretary of State or by another person in accordance with "General Practice Systems of Choice Level 2 M129; and
 - (b) "summary information" has the meaning given in regulation 68(2).

Marginal Citations

M129 GP Systems of Choice is a scheme by which the National Health Service funds the cost of GP clinical IT systems in England. Guidance about this scheme is available from the Health and Social Care Information Centre, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE.

Confidentiality of personal data: nominated person

72. The contractor must nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it.

Provision of information on practice website

73. Where a contractor has a practice website, the contractor must publish on that website details of the contractor's practice area, including the area known as the outer boundary area (within the meaning given in regulation 20(3)) by reference to a sketch, diagram, plan or postcode.

Provision of information

- **74.**—(1) Subject to paragraph (2), the contractor must, at the request of the Board, produce to the Board, or to a person authorised in writing by the Board, or allow the Board, or a person authorised in writing by it, to access—
 - (a) any information which is reasonably required by the Board for the purposes of or in connection with the contract; and
 - (b) any other information which is reasonably required in connection with the Board's functions.
- (2) The contractor is not required to comply with any request made under paragraph (1) unless it has been made by the Board in accordance with directions relating to the provision of information by contractors given to the Board by the Secretary of State under section 98A of the Act M130 (exercise of functions).
- (3) The contractor must produce the information requested, or, as the case may be, allow the Board access to such information—
 - (a) by such date as has been agreed as reasonable between the contractor and the Board; or
 - (b) in the absence of such agreement, before the end of the period of 28 days beginning with the date on which the request is made.

Marginal Citations

M130 Section 98A was inserted by section 49(1) of the Health and Social care Act 2012 (c.7).

Changes to legislation: The National Health Service (General Medical Services Contracts) Regulations 2015 is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

[F15Provision of information: GP access data

- **74A.**—(1) Subject to paragraph (4), a contractor must collect such information relating to patient access to primary medical services at the contractor's practice ("GP access data") as the Board may reasonably require for the purposes of, or in connection with, the contract.
- (2) The contractor must submit an online return to the Board in respect of any GP access data collected by it using the Primary Care Web Tool ("PCWT") facility which is provided by the Board to the contractor for this purpose.
- (3) The contractor must submit an online return of GP access data to the Board twice in every financial year—
 - (a) by 31st October 2016 and 31st March 2017 in respect of the financial year that ends on 31st March 2017; and
 - (b) by 30th September and 31st March respectively for each subsequent financial year until 31st March 2021.
- (4) The requirements of this regulation do not apply where the contractor does not have access to computer systems and software which would enable it to use the PCWT facility to submit an online return of GP access data to the Board.]

Textual Amendments

F15 Reg. 74A inserted (3.10.2016) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2016 (S.I. 2016/875), regs. 1(2), 4

[F16] National Diabetes Audit

- **74B.**—(1) A contractor must record any data required by the Board for the purposes of the National Diabetes Audit in accordance with paragraph (2).
- (2) The data referred to in paragraph (1) must be appropriately coded by the contractor and uploaded onto the contractor's computerised clinical systems in line with the requirements of guidance published by NHS Employers for these purposes.
- (3) The contractor must ensure that the coded data is uploaded onto its computerised clinical systems and available for collection by the Health and Social Care Information Centre at such intervals during each financial year as are notified to the contractor by NHS Digital.

Textual Amendments

F16 Regs. 74B-74F inserted (6.10.2017) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2017 (S.I. 2017/908), regs. 1(2), 2

Information relating to indicators no longer in the Quality and Outcomes Framework

74C. A contractor must allow the extraction from the contractor's computerised clinical systems by the Health and Social Care Information Centre of the information specified in the Table relating to clinical indicators which are no longer in the Quality and Outcomes Framework at such intervals during each financial year as are notified to the contractor by NHS Digital.

Changes to legislation: The National Health Service (General Medical Services Contracts) Regulations 2015 is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Table Quality and Outcomes Framework – indicators no longer in the Quality and Outcomes Framework

Indicator ID	Indicator Description
Clinical domain	
CHD003	The percentage of patients with coronary heart disease whose last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
CKD002	The percentage of patients on the CKD register in whom the last blood pressure reading (measured in the preceding 12 months) is 140/85 mmHg or less
CKD004	The percentage of patients on the CKD register whose notes have a record of a urine albumin:creatinine ratio (or protein:creatinine ratio) tes in the preceding 12 months
NM84	The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with renin-angiotensin system antagonists
DEP001	The percentage of patients aged 18 or over with a new diagnosis of depression in the preceding 1st April to 31st March, who have had a bio-psychosocial assessment by the point of diagnosis. The completion of the assessment is to be recorded on the same day as the diagnosis is recorded
DM005	The percentage of patients with diabetes, on the register, who have a record of an albumin:creatinine ratio test in the preceding 12 months
DM011	The percentage of patients with diabetes, on the register, who have a record of retinal screening in the preceding 12 months
DM016	The percentage of male patients with diabetes, on the register, who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 12 months.
EP002	The percentage of patients aged 18 or over on drug treatment for epilepsy who have been seizure free for the last 12 months recorded in the preceding 12 months
EP003	The percentage of women aged 18 or over and who have not attained the age of 55 who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy in the preceding 12 months
HYP003	The percentage of patients aged 79 or under with hypertension in whom the last blood pressure reading (measured in the preceding 9 months) is 140/90 mmHg or less
HYP004	The percentage of patients with hypertension aged 16 or over and who have not attained the age of 75 in whom there is an assessment of physical activity, using GPPAQ, in the preceding 12 months
HYP005	The percentage of patients with hypertension aged 16 or over and who have not attained the age of 75 who score 'less than active' on

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Indicator ID	Indicator Description
	GPPAQ in the preceding 12 months, who also have a record of a brief intervention in the preceding 12 months
LD002	The percentage of patients on the learning disability register with Down's Syndrome aged 18 or over who have a record of blood TSH in the preceding 12 months (excluding those who are on the thyroid disease register)
MH004	The percentage of patients aged 40 or over with schizophrenia, bipolar affective disorder and other psychoses who have a record of total cholesterol:hdl ratio in the preceding 12 months
MH005	The percentage of patients aged 40 or over with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood glucose or HbA1c in the preceding 12 months
MH006	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of BMI in the preceding 12 months
PAD003	The percentage of patients with peripheral arterial disease in whom the last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
RA003	The percentage of patients with rheumatoid arthritis aged 30 or over and who have not attained the age of 85 who have had a cardiovascular risk assessment using a CVD risk assessment tool adjusted for RA in the preceding 12 months
RA004	The percentage of patients aged 50 or over and who have not attained the age of 91 with rheumatoid arthritis who have had an assessment of fracture risk using a risk assessment tool adjusted for RA in the preceding 24 months
STIA004	The percentage of patients with stroke or TIA who have a record of total cholesterol in the preceding 12 months
STIA005	The percentage of patients with a stroke shown to be non-haemorrhagic, or a history of TIA whose last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
THY001	The contractor establishes and maintains a register of patients with hypothyroidism who are currently treated with levothyroxine
THY002	The percentage of patients with hypothyroidism, on the register, with thyroid function tests recorded in the preceding 12 months
Public Health Domain	
CVD-PP002	The percentage of patients diagnosed with hypertension (diagnosed after on or after 1st April 2009) who are given lifestyle advice in the preceding 12 months for smoking cessation, safe alcohol consumption and healthy diet
CON002	The percentage of women, on the register, prescribed an oral or patch contraceptive method in the preceding 12 months who have also received information from the contractor about long acting reversible methods of contraception in the preceding 12 months

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Indicator ID	Indicator Description
SMOK001	The percentage of patients aged 15 or over whose notes record smoking status in the preceding 24 months

Textual Amendments

F16 Regs. 74B-74F inserted (6.10.2017) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2017 (S.I. 2017/908), regs. 1(2), 2

Information relating to alcohol related risk reduction and dementia diagnosis and treatment

- **74D.**—(1) A contractor must allow the extraction by the Health and Social Care Information Centre of the information specified in—
 - (a) paragraph (2) in relation to alcohol related risk reduction; and
 - (b) paragraph (3) in relation to dementia diagnosis and treatment,

from the record that the contractor is required to keep in respect of each registered patient under regulation 67 by such means, and at such intervals during each financial year, as are notified to the contractor by the Health and Social Care Information Centre.

- (2) The information specified in this paragraph is information required in connection with the requirements under paragraph 7 of Schedule 3.
- (3) The information specified in this paragraph is information relating to any clinical interventions provided by the contractor in the preceding 12 months in respect of a patient who is suffering from, or who is at risk of suffering from, dementia.

Textual Amendments

F16 Regs. 74B-74F inserted (6.10.2017) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2017 (S.I. 2017/908), regs. 1(2), **2**

NHS Digital Workforce Census

- **74E.**—(1) A contractor must record and submit any data required by the Health and Social Care Information Centre for the purposes of the NHS Digital Workforce Census (known as the "Workforce Minimum Data Set") in accordance with paragraph (2).
- (2) The data referred to in paragraph (1) must be appropriately coded by the contractor in line with agreed standards set out in guidance published by NHS Employers and must be submitted to the Health and Social Care Information Centre by using the workforce module on the Primary Care Web Tool which is a facility provided by the Board to the contractor for this purpose.
- (3) The contractor must ensure that the coded data is available for collection by the Health and Social Care Information Centre at such intervals during each financial year as are notified to the contractor by the Health and Social Care Information Centre.

Changes to legislation: The National Health Service (General Medical Services Contracts) Regulations 2015 is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Textual Amendments

F16 Regs. 74B-74F inserted (6.10.2017) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2017 (S.I. 2017/908), regs. 1(2), 2

Information relating to overseas visitors

74F.—(1) A contractor must—

- (a) record the information specified in paragraph (2) relating to overseas visitors, where that information has been provided to it by a newly registered patient on a form supplied to the contractor by the Board for this purpose; and
- (b) where applicable in the case of a patient, record the fact that the patient is the holder of a European Health Insurance Card or S1 Healthcare Certificate which has not been issued to or in respect of the patient by the United Kingdom,

in the medical record that the contractor is required to keep under regulation 67 in respect of the patient.

- (2) The information specified in this paragraph is—
 - (a) in the case of a patient who holds a European Health Insurance Card which has not been issued to the patient by the United Kingdom, the information contained on that card in respect of the patient; and
 - (b) in the case of a patient who holds a Provisional Replacement Certificate issued in respect of the patient's European Health Insurance Card, the information contained on that certificate in respect of the patient.
- (3) The information referred to in paragraph (2) must be submitted by the contractor to NHS Digital—
 - (a) electronically at NHSDIGITAL-EHIC@nhs.net; or
 - (b) by post in hard copy form to EHIC, PDS NBO, NHS Digital, Smedley Hydro, Trafalgar Road, Southport, Merseyside, PR8 2HH.
- (4) Where the patient is the holder of an S1 Healthcare Certificate, the contractor must send that certificate, or a copy of that certificate, to the Department for Work and Pensions—
 - (a) electronically to overseas.healthcare@dwp.gsi.gov.uk; or
 - (b) by post in hard copy form to the Overseas Healthcare Team, Durham House, Washington, Tyne and Wear, NE38 7SF.]

Textual Amendments

F16 Regs. 74B-74F inserted (6.10.2017) by The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2017 (S.I. 2017/908), regs. 1(2), 2

Inquiries about prescriptions and referrals

- **75.**—(1) The contractor must, subject to paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the Board concerning—
 - (a) any prescription form or repeatable prescription form issued or created by a prescriber;

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- (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 paragraph (1) may only be made for the purpose of obtaining information to assist the Board to discharge its functions, or of assisting the contractor in the discharge of its obligations under the contract.
- (3) The contractor is not obliged to answer any inquiry referred to in paragraph (1) unless it is made—
 - (a) in the case of paragraph (1)(a) or (b), by an appropriately qualified health care professional; or
 - (b) in the case of paragraph (1)(c) or (d), by an appropriately qualified medical practitioner.
 - (4) The appropriately qualified person referred to in paragraph (3)(a) or (b) must—
 - (a) be appointed by the Board in either case to assist it in the exercise of its functions under this regulation; and
 - (b) produce, on request, written evidence of that person's authority from the Board to make such an inquiry on the Board's behalf.

Provision of information to a medical officer etc.

- **76.**—(1) The contractor must, if satisfied that the patient consents—
 - (a) supply in writing to a person specified in paragraph (3) (a "relevant person"), before the end of such reasonable period as that person may specify, such clinical information as a person specified in 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 a relevant person 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 a relevant person 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 this regulation, "a relevant person" is—
 - (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 sub-paragraphs (a) to (d).
 - (4) In this regulation—
 - "medical officer" means a medical practitioner who is—
 - (a) employed or engaged by the Department for Work and Pensions; or

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(b) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions;

"nursing officer" means a health care professional who is registered on the Nursing and Midwifery Register and who is—

- (a) employed by the Department for Work and Pensions; or
- (b) provided by an organisation under a contract with the Secretary of State for Work and Pensions:

"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 and Social Work Professions Order 2001 M131 (establishment and maintenance of register) relating to occupational therapists and who is—

- (a) employed or engaged by the Department for Work and Pensions; or
- (b) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions; and

"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 and Social Work Professions Order 2001 (establishment and maintenance of register) relating to physiotherapists and who is—

- (a) employed or engaged by the Department for Work and Pensions; or
- (b) provided by an organisation under a contract entered into with the Secretary of State for Work and Pensions.

Marginal Citations

M131 S.I. 2002/254; as amended by section 127 of the Health and Social Care Act 2008 (c.14), section 81(5) of the Policing and Crime Act 2009 (c.26), sections 213, 214(2) to (4), 215, 216, 218 and 219 of the Health and Social Care Act 2012 (c.7), section 5(2) of, and paragraph 6 of the Schedule to, the Health and Social Care (Safety and Quality) Act 2015 (c.28), and by S.I. 2003/3148, S.I. 2004/1947 and 2033, S.I. 2007/3101, S.I. 2009/1182, S.I. 2010/233, S.I. 2011/1043, S.I. 2012/1479 and 2672 and S.I. 2014/1887.

Annual return and review

- 77.—(1) The contractor must submit to the Board an annual return relating to the contract which must require the same categories of information to be provided by all persons who hold contracts with the Board.
- (2) The Board may request a return relating to the contract 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.
 - (3) The contractor must submit the completed return to the Board—
 - (a) by a date which has been agreed as reasonable between the contractor and the Board; or
 - (b) in the absence of such agreement, before the end of the period of 28 days beginning with the date on which the request was made.
- (4) Following receipt of the return referred to in paragraph (1), the Board must arrange with the contractor an annual review of its performance in relation to the contract.

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- (5) The contractor or the Board may, if desired, invite the Local Medical Committee (if any) for the area in which the contractor is providing services under the contract to participate in the annual review.
- (6) The Board must prepare a draft record of the review referred to in paragraph (4) for comment by the contractor and, having regard to such comments, must produce a final written record of the review.
- (7) The Board must send a copy of the final record of the review referred to in paragraph (6) to the contractor.

Practice leaflet

- **78.**—(1) The contractor must compile a document (a "practice leaflet") which must include the information specified in Part 6 of Schedule 3.
- (2) The contractor must review its practice leaflet at least once in every period of 12 months and make any amendments necessary to maintain its accuracy.
- (3) The contractor must make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

PART 11

Complaints

Complaints procedure

- **79.**—(1) The contractor must establish and operate a complaints procedure to deal with complaints made in relation to any matter that is reasonably connected with the provision of services under the contract.
- (2) The complaints procedure must comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 M132.

Marginal Citations

M132 S.I. 2009/309; as amended by S.I. 2009/1768, S.I. 2012/1909 and S.I. 2013/235 and 349.

Co-operation with investigations

- **80.**—(1) The contractor must co-operate with—
 - (a) the investigation of any complaint made in relation to a matter that is reasonably connected with the provision of services under the contract by—
 - (i) the Board, or
 - (ii) the Health Service Commissioner; and
 - (b) the investigation of any complaint made by an NHS body or local authority which relates to a patient or former patient of the contractor.
- (2) In paragraph (1)—
 - "NHS body" means-
 - (a) in relation to England, the Board or a CCG; and

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(b) in relation to England and Wales, Scotland and Northern Ireland, an NHS trust, an NHS foundation trust, a Local Health Board, a Health Board, a Health and Social Services Board or a Health and Social Services Trust;

"local authority" means-

- (a) a local authority within the meaning of section 1 of the Local Authority Social Services Act 1970 M133 (local authorities);
- (b) the Council of the Isles of Scilly; F17...
- (c) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 Mil (constitution of councils); [Fi8 or]
- (d) [F19the council of a county or county borough in Wales; and]
- "Health Service Commissioner" means the person appointed as Health Service Commissioner for England in accordance with section 1 of, and Schedule 1 to, the Health Service Commissioners Act 1993 M135 (The Commissioner).
- (3) For the purposes of paragraph (1), co-operation includes—
 - (a) answering any questions which are reasonably put to the contractor by the Board;
 - (b) providing any information relating to the complaint which is reasonably required by the Board; and
 - (c) attending any meeting held to consider the complaint (if held at a reasonably accessible place and at a reasonable hour and if due notice has been given) if the contractor's presence at the meeting is reasonably required by the Board.

Textual Amendments

- F17 Word in reg. 80(2) omitted (6.4.2016) by virtue of The Social Services and Well-being (Wales) Act 2014 (Consequential Amendments) (Secondary Legislation) Regulations 2016 (S.I. 2016/211), reg. 1(2), Sch. 3 para. 186(a)
- F18 Word in reg. 80(2) substituted (6.4.2016) by The Social Services and Well-being (Wales) Act 2014 (Consequential Amendments) (Secondary Legislation) Regulations 2016 (S.I. 2016/211), reg. 1(2), Sch. 3 para. 186(b)
- F19 Words in reg. 80(2) inserted (6.4.2016) by The Social Services and Well-being (Wales) Act 2014 (Consequential Amendments) (Secondary Legislation) Regulations 2016 (S.I. 2016/211), reg. 1(2), Sch. 3 para. 186(c)

Marginal Citations

- M133 1970 c.42. Section 1 was amended by the section 195 of Local Government Act 1972 (c.70) and section 22(4) of, and Schedule 10 to, the Local Government (Wales) Act 1994 (c.19).
- M134 1994 c.39. Section 2 was amended by paragraph 232(1) of Schedule 22 to the Environment Act 1995 (c.25).
- M135 1993 c.46. Section 1 was amended by section 224 of, and paragraph 7 of Schedule 7 to, the Local Government (Wales) Act 1994; section 112 of, and paragraph 10 of Schedule 10 to, the Government of Wales Act 1998 (c.38); section 39(1) of, and Schedules 6 and 7 to, the Public Service Ombudsman (Wales) Act 2005 (c.10); and by S.I. 2004/1823. This Act is repealed in relation to Scotland by the Scottish Public Service Ombudsman Act 2002 (asp 11).

Changes to legislation: The National Health Service (General Medical Services Contracts) Regulations 2015 is up to date with all changes known to be in force on or before 20 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

PART 12

Dispute resolution

Local resolution of contract disputes

- **81.**—(1) The contractor and the Board must make reasonable efforts to communicate and cooperate with each other with a view to resolving any dispute which arises out of or in connection with the contract before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).
- (2) Paragraph (1) does not apply to a dispute relating to the assignment of patients to a closed list which falls to be determined under the NHS dispute resolution procedure by virtue of paragraph 42(1) of Schedule 3 where it is not practicable for the parties to attempt local resolution before the expiry of the period of seven days specified in paragraph 42(4) of that Schedule.
- (3) The contractor or the Board may invite the Local Medical Committee (if any) for the area in which the contractor is providing services under the contract to participate in discussions which take place by virtue of paragraph (1).

Dispute resolution: non-NHS contracts

- **82.**—(1) Where a contract is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the complaints procedure under Part 11, may be referred for consideration and determination to the Secretary of State—
 - (a) if it relates to a period when the contractor was treated as a health service body, by the contractor or the Board; or
 - (b) in any other case, by the contractor or, if the contractor agrees in writing, by the Board.
 - (2) Where a dispute is referred to the Secretary of State under paragraph (1)—
 - (a) the procedure to be followed is the NHS dispute resolution procedure; and
 - (b) the parties are to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

- **83.**—(1) The procedure specified in this regulation and in regulation 82 applies to a dispute arising out of, or in connection with, the contract which is referred to the Secretary of State in accordance with—
 - (a) section 9(6) of the Act (where the contract is an NHS contract); or
 - (b) regulation 82(1) (where the contract is not an NHS contract).
- (2) The procedure referred to in paragraph (1) does not apply where the contractor refers a matter for determination in accordance with paragraph 42 of Schedule 3 and, in such a case, the procedure specified in that paragraph applies instead.
- (3) Where a party wants to refer a dispute for determination under the procedure specified in this regulation, it must send to the Secretary of State a written request for dispute resolution which must 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 of the nature of, and circumstances giving rise to, the dispute.
- (4) Where a party wants to refer a dispute, it must send a request under paragraph (3) to the Secretary of State before the end of the period of three years beginning with the date on which the

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matter giving rise to the dispute occurred or should reasonably have come to the attention of that party.

- (5) Where the dispute relates to a contract which is not an NHS contract, the Secretary of State may—
 - (a) determine the dispute; or
 - (b) if the Secretary of State considers it appropriate, appoint one or more persons to consider and determine the dispute.
- (6) Before reaching a decision about who should determine the dispute, either under paragraph (5) or section 9(6) of the Act, the Secretary of State must send a written request to the parties, before the end of the period of seven days beginning with the date on which the dispute was referred, inviting them to make any written representations that they would like to make about the matter under dispute before the end of a specified period.
- (7) The Secretary of State must give to a 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 together with the notice under paragraph (6).
 - (8) The Secretary of State must—
 - (a) give a copy of any representations received from a party to the other party to the dispute; and
 - (b) request in writing each party to whom a copy of the representations is given to make, within a specified period, any written observations which that party would like to make regarding those representations.
- (9) If the Secretary of State decides to appoint a person or persons ("the adjudicator") to hear the dispute the Secretary of State must—
 - (a) inform the parties in writing of the name or names of the adjudicator whom the Secretary of State has appointed; and
 - (b) pass to the adjudicator any documents received from the parties under or by virtue of paragraph (3), (6) or (8).
 - (10) The Secretary of State must comply with the requirement in paragraph (9)—
 - (a) following receipt of any representations received from the parties; or
 - (b) if no such representations are received before the end of the period for making those representations specified in the request sent under paragraph (6) or (8), at the end of that period.
- (11) The adjudicator may, for the purpose of assisting in the consideration of the subject matter of the dispute—
 - (a) invite representatives of the parties to appear before, and make oral representations to, the adjudicator either together or, with the agreement of the parties, separately;
 - (b) in advance of hearing any oral representations, provide the parties with a list of matters or questions that the adjudicator would like the parties to give special consideration to; or
 - (c) consult such other persons whose expertise the adjudicator considers is likely to assist in the consideration of the matter.
- (12) Where the adjudicator consults another person under paragraph (11)(c), the adjudicator must—
 - (a) give notice in writing to the parties accordingly; and
 - (b) where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, give to the parties such opportunity as the

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adjudicator considers reasonable in the circumstances to make observations on those results.

- (13) In considering the matter, the adjudicator must have regard to—
 - (a) any written representations made in response to a request under paragraph (6), but only if they are made before the end of the specified period;
 - (b) any written observations made in response to a request under paragraph (8), but only if they are made before the end of the specified period;
 - (c) any oral representations made in response to an invitation under paragraph (11)(a);
 - (d) the results of any consultation under paragraph (11)(c); and
 - (e) any observations made in accordance with an opportunity given under paragraph (12).
- (14) In this regulation, "specified period" means—
 - (a) such period as the Secretary of State specifies in the request being a period of not less than two or not more than four weeks beginning with the date on which the notice referred to is given; or
 - (b) such longer period as the Secretary of State may allow if the Secretary of State considers that there are good reasons for extending the period referred to in sub-paragraph (a) (even after that period has expired), and where the Secretary of State does so allow, a reference in this regulation to the specified period is to the period as so extended.
- (15) The adjudicator may determine the procedure which is to apply to the dispute resolution in such manner as the adjudicator considers appropriate in order to ensure the just, expeditious, economical and final determination of the dispute subject to—
 - (a) the other provisions of this regulation;
 - (b) regulation 84; and
 - (c) any agreement between the parties.

Determination of the dispute

- **84.**—(1) The adjudicator's determination and the reasons for it must be recorded in writing and the adjudicator must give notice in writing of that determination (including the record of the reasons) to the parties.
- (2) Where a dispute in relation to a contract is referred for determination in accordance with regulation 82(1)—
 - (a) section 9(12) and (13) of the Act apply in the same manner as those provisions apply to a dispute referred for determination in accordance with section 9(6) and (7) of the Act; and
 - (b) section 9(5) of the Act applies to any dispute referred for determination in relation to a contract which is not an NHS contract as if it were referred for determination in accordance with section 9(6) of the Act.

Interpretation of this Part

- **85.**—(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) A term of the contract which makes provision in respect of the requirements of this Part is to survive even where the contract has terminated.

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PART 13

Functions of a Local Medical Committee

Functions of a Local Medical Committee

- **86.**—(1) The functions of a Local Medical Committee which are prescribed for the purposes of section 97(8) of the Act M136 (Local Medical Committees) are—
 - (a) considering a complaint made to it by a medical practitioner against another medical practitioner specified in paragraph (2) who is providing services under a contract in the relevant area involving any question relating to the efficiency of those services;
 - (b) reporting the outcome of the consideration of any such complaint to the Board where that consideration gives rise to concerns relating to the efficiency of the services provided under a contract;
 - (c) making arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the contractor or the Board is concerned that the medical practitioner is incapable of adequately providing services under the contract and the contractor or the Board requests that examination with the agreement of the medical practitioner concerned; and
 - (d) considering the report of any medical examination arranged in accordance with subparagraph (c) and reporting in writing to that medical practitioner, the contractor and the Board about the capability of the medical practitioner to adequately provide services under the 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 persons practising in partnership which holds a contract; or
 - (c) both a legal and beneficial shareholder in a company limited by shares which holds a contract.
- (3) In this regulation "the relevant area" means the area for which the Local Medical Committee is formed.

Marginal Citations

M136 2006 c.41. Section 97 was amended by paragraph 41 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

PART 14

Miscellaneous

Clinical governance

- **87.**—(1) The contractor must have in place an effective system of clinical governance which includes appropriate standard operating procedures in relation to the management and use of controlled drugs.
- (2) The contractor must nominate a person who is to have responsibility for ensuring the effective operation of the system of clinical governance.

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- (3) The person nominated under paragraph (2) must be a person who performs or manages the performance of services under the contract.
 - (4) In this regulation—
 - (a) "controlled drugs" has the meaning given in section 2 of the Misuse of Drugs Act 1971 Mison (which relates to controlled drugs and their classification for the purposes of that Act); and
 - (b) "system of clinical governance" means a framework through which the contractor endeavours continuously to improve the quality of its services and to safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Marginal Citations

M137 1971 c.38. Section 2 was amended by section 151 of, and paragraphs 1 and 2 of Schedule 17 to, the Police Reform and Social Responsibility Act 2011 (c.13).

Friends and Family Test

- **88.**—(1) A contractor must give all patients who use the contractor's practice the opportunity to provide feedback about the service received from the practice through the Friends and Family Test M138.
 - (2) The contractor must—
 - (a) report the results of completed Friends and Family Tests to the Board; and
 - (b) publish the results of such completed Tests M139.
- (3) In this regulation, "Friends and Family Test" means the arrangements that a contractor is required by the Board to implement to enable its patients to provide anonymous feedback about the patient experience at the contractor's practice.

Marginal Citations

- M138 See the guidance for GP practices on the Friends and Family Test, published in July 2014, which is available in full and summary form at: http://www.england.nhs.uk/ourwork/pe/fft/fft-guidance/.

 Hard copies of this guidance are available from Primary Care Commissioning, NHS Employers, 50 Broadway, London SW1H 0DB.
- M139 See pages 7 and 8 of the full Guidance for GP Practices on the Friends and Family Test, published in July 2014, in respect of the requirement on GP practices to submit monthly reports to the Board and to publish the results of completed tests. This guidance is available at: http://www.england.nhs.uk/ourwork/pe/fft/fft-guidance/. Hard copies of this guidance are available from Primary Care Commissioning, NHS Employers, 50 Broadway, London SW1H 0DB.

Co-operation with the Board

89. The contractor must co-operate with the Board in the discharge of any of the Board's obligations, or the obligations of the Board's accountable officers, under the Controlled Drugs (Supervision and Management of Use) Regulations 2013 M140.

Marginal Citations

M140 S.I. 2013/373.

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Co-operation with the Secretary of State and Health Education England

- 90. The contractor must co-operate with—
 - (a) the Secretary of State in the discharge of the Secretary of State's duty under section 1F of the Act M141 (duty as to education and training); or
 - (b) Health Education England M142 where Health Education England is discharging the Secretary of State's duty under section 1F of the Act by virtue of its functions under section 97(1) of the Care Act 2014 M143 (planning education and training for health care workers etc.).

Marginal Citations

- M141 Section 1F was inserted by section 7 of the Health and Social Care Act 2012 (c.7).
- M142 Health Education England is a body corporate established under section 96 of the Care Act 2014 (c.23)
- M143 See section 97 of the Care Act 2014 (c.23) for the duty on Health Education England to exercise the Secretary of State's functions under section 1F of the Act.

Insurance

- **91.**—(1) The contractor must at all times have in force in relation to it an indemnity arrangement which provides appropriate cover.
- (2) The contractor may not sub-contract its obligations to provide clinical services under the contract unless it is satisfied that the sub-contractor has in force in relation to it an indemnity arrangement which provides appropriate cover.
 - (3) In this regulation—
 - (a) "appropriate cover" means cover against liabilities that may be incurred by the contractor in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;
 - (b) "indemnity arrangement" means a contract of insurance or other arrangement made for the purpose of indemnifying the contractor; and
 - (c) a contractor is to be regarded as holding insurance if that insurance is held by a person employed or engaged by the contractor in connection with clinical services which that person provides under the contract or, as the case may be, sub-contract.

Public liability insurance

92. The contractor must 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 indemnity arrangement referred to in regulation 91.

Gifts

- 93.—(1) The contractor must keep a register of gifts which—
 - (a) are given to any of the persons specified in paragraph (2) by or on behalf of—
 - (i) a patient,
 - (ii) a relative of a patient, or
 - (iii) any person who provided or would like to provide services to the contractor or its patients in connection with the contract; and

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- (b) have, in the contractor's reasonable opinion, an individual value of more than £100.00.
- (2) The persons specified in this paragraph are—
 - (a) the contractor;
 - (b) where the contract is with two or more persons practising in partnership, any partner in the partnership;
 - (c) where the contract is with a company limited by shares—
 - (i) any person both legally and beneficially owning 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 sub-paragraphs (b) to (e); or
 - (g) any person whose relationship with the contractor (where the contractor is an individual medical practitioner), or with a person specified in sub-paragraphs (b) to (e), has the characteristics of the relationship between spouses.
- (3) Paragraph (1) does not apply where—
 - (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the contractor;
 - (b) the contractor is not aware of the gift; or
 - (c) the contractor is not aware that the donor would like to provide services to the contractor or its patients.
- (4) The contractor must take reasonable steps to ensure that it is informed of any gifts which fall within paragraph (1) and which are given to the persons specified in paragraph (2)(b) to (g).
 - (5) The register referred to in sub-paragraph (1) must 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, the patient's 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 must make the register available to the Board on request.

Compliance with legislation and guidance

- **94.** The contractor must—
 - (a) comply with all relevant legislation; and
 - (b) have regard to all relevant guidance issued by the Board, the Secretary of State or local authorities in respect of the exercise of their functions under the Act.

Third party rights

95. The contract does not create any right enforceable by any person who is not a party to it.

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PART 15

General transitional provision and saving, consequential amendments and revocations

General transitional provision and saving

- **96.**—(1) This regulation applies to—
 - (a) the exercise by the Board of any of its functions under the 2004 Regulations on or before the commencement date;
 - (b) any rights or liabilities of the Board in respect of the exercise of any of its functions under the 2004 Regulations; and
 - (c) any rights or liabilities of a Primary Care Trust transferred to the Board as a consequence of a property transfer scheme made under section 300 of the Health and Social Care Act 2012 (transfer schemes).
- (2) Subject to paragraph (4), any act or omission concerning a contract to which the 2004 Regulations applied immediately before the commencement date in respect of any of the matters specified in paragraph (1), is to be treated as an act or omission concerning a contract to which these Regulations apply.
- (3) Subject to paragraph (4), anything which, on or before the commencement date, is done or is in the process of being done under the 2004 Regulations concerning a contract to which the 2004 Regulations applied immediately before that date in respect of any of the matters specified in paragraph (1), is to be treated as if done or in the process of being done under these Regulations.
- (4) Notwithstanding paragraphs (2) and (3) and the revocations provided for in Schedule 5, where the 2004 Regulations contain a provision for which there is no equivalent provision in these Regulations ("the relevant provision"), the 2004 Regulations, as they were in force immediately before the commencement date, are to continue to apply to the extent necessary for the purposes of—
 - (a) preserving any rights conferred or liabilities accrued by or under the relevant provision; or
 - (b) the assessment or determination of any rights or liabilities arising under or in accordance with the relevant provision.
 - (5) In this regulation—
 - (a) "the commencement date" means the date on which these Regulations come into force;
 - (b) "contract" includes any contract to which the 2004 Regulations applied immediately before the commencement date under which medical services were provided before 1st January 2005 (whether or not such services continued to be provided after that date); and
 - (c) references to the exercise by the Board of any of its functions include the exercise by the Board of any functions of a Primary Care Trust under Part 4 of the Act.

Consequential amendments

97. Schedule 4 makes provision in respect of the amendments to secondary legislation which are consequential upon the coming into force of these Regulations.

Revocations

98. Schedule 5 makes provision in respect of the revocation of the enactments specified in column 1 of the Table in that Schedule to the extent specified in column 2 of that Table.

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Signed by authority of the Secretary of State for Health.

Department of Health

Alistair Burt Minister of State,

Status:

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