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STATUTORY INSTRUMENTS

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**2015 No. 1862**

**NATIONAL HEALTH SERVICE, ENGLAND**

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

*Made* - - - - *6th November 2015*  
*Laid before Parliament* *13th November 2015*  
*Coming into force* - - *7th December 2015*

The Secretary of State for Health, in exercise of the powers conferred by sections 9(8), 83(3), (6), 85(1), 86(1) and (4), 89(1), (1A)(a) and (b), (3) and (4), 90(1), (3), 91(1), 97(6) and (8), 187 and 272(7) and (8) of the National Health Service Act 2006<sup>(1)</sup>, makes the following Regulations.

**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—

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(1) [2006 c.41](#). Section 9 of the National Health Service Act 2006 (“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](#)). Section 83 of the Act was amended by paragraph 30 of Schedule 4 to the 2012 Act. Section 86 of the Act was amended by section 202(1) of, and paragraph 32 of Schedule 4 to, the 2012 Act. Section 89 of the Act was amended by section 202(2) of the 2012 Act, and sub-section (1A) of that section was inserted by section 28(1) of the 2012 Act. Section 91 was amended by paragraph 35 of Schedule 4 to the 2012 Act. Section 97 was amended by paragraph 41 of Schedule 12 to the 2012 Act. Section 187 was amended by paragraph 101 of Schedule 4 to the 2012 Act. The powers exercised in making these Regulations are exercisable by the Secretary of State only in relation to England, by virtue of section 271(1) of the Act. See section 275(1) of the Act for the meaning given to “prescribed” and “regulations”.

- (a) to which the National Health Service (General Medical Services Contracts) Regulations 2004(2) 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.

### 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(3);

“additional services” means one or more of the following—

- (a) cervical screening services;
- (b) contraceptive services;
- (c) childhood vaccines and immunisations;
- (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(4) (NHS contracts) or under regulation 83(5)(b);

“advanced electronic signature” means an electronic signature which is—

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

“appliance” means an appliance which is included in a list for the time being approved by the Secretary of State for the purposes of section 126 of the Act(5) (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(6);

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

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(2) [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.

(3) [S.I. 2010/473](#); as amended by [S.I. 2012/344](#) and [2013/3036](#).

(4) 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).

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

(6) [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).

“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(7) (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(8);

“Care Quality Commission” means the body established under section 1 of the Health and Social Care Act 2008(9) (The Care Quality Commission);

“CCG” means a clinical commissioning group(10);

“CCT” means a certificate of completion of training awarded under section 34L(1) of the Medical Act 1983(11) (award and withdrawal of a Certificate of Completion of Training) including any such certificate awarded in pursuance of the competent authority functions of the General Medical Council specified in section 49B of, and Schedule 4A to, that Act(12) (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(13) (general provisions); or
- (b) a supplier of appliances,

who is included in the list held by the Board under section 129 of the Act(14) (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;

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(7) 1971 c.80.

(8) 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.

(9) 2008 c.14.

(10) Clinical commissioning groups were established by virtue of sections 11 and 14A to 14D of the Act, as inserted by sections 10 and 25(1) of the 2012 Act.

(11) 1983 c.54. Section 34L was inserted by S.I. 2010/234.

(12) Section 49B was inserted by S.I. 2007/3101 and was amended by S.I. 2008/1774 and S.I. 2010/234.

(13) 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.

(14) 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.

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

“chiropracist 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(15) (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropracist or podiatrist is qualified to order drugs, medicines and appliances as a chiropracist 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(16) (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(17);

“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(18) (arrangements for additional pharmaceutical services);

“electronic communication” has the meaning given in section 15 of the Electronic Communications Act 2000(19) (general interpretation);

“electronic prescription” means an electronic prescription form or an electronic repeatable prescription;

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(15) [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](#).

(16) Section 84 of the Act was amended by paragraph 31 of Schedule 4 to the Health and Social Care Act 2012.

(17) [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.

(18) 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.

(19) [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](#)).

“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<sup>(20)</sup>;

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

“enhanced services” are—

- (a) services other than essential services, additional services or out of hours services; or
- (b) essential services, additional services or out of hours services, or an element of such a service, that a contractor agrees under the contract to provide in accordance with specifications set out in a plan, which requires of the contractor an enhanced level of service provision compared to that which it needs generally to provide in relation to that service or element of 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<sup>(21)</sup> (registration of medical practitioners);

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

“GMS Statement of Financial Entitlements”<sup>(22)</sup> means the directions given by the Secretary of State under section 87 of the Act<sup>(23)</sup> (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<sup>(24)</sup> (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<sup>(25)</sup> (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<sup>(26)</sup> (ancillary services);

“Health Board” means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978<sup>(27)</sup> (Health Boards);

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<sup>(20)</sup> The Health and Social Care Information Centre is a body corporate established by section 252(1) of the 2012 Act.

<sup>(21)</sup> 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.

<sup>(22)</sup> 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.

<sup>(23)</sup> Section 87 was amended by paragraph 33 of Schedule 4 to the 2012 Act.

<sup>(24)</sup> 1983 c.54. Section 34I was inserted by S.I. 2010/234.

<sup>(25)</sup> S.I. 1972/1265 (N.I.14).

<sup>(26)</sup> 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.

<sup>(27)</sup> 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

“health care professional” has the meaning given in section 108 of the Act**(28)** (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**(29)** (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**(30)**; 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**(31)** (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**(32)**;

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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).

**(28)** 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”).

**(29)** 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).

**(30)** 1989 c.41.

**(31)** 1907 c.24. Section 5 was amended by S.I. 2009/1940.

**(32)** S.I. 2015/570.



“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(33) (Local Health Boards);

“Local Medical Committee” means a committee recognised by the Board under section 97 of the Act(34) (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(35) (persons performing primary medical services);

“Medical Register” means the registers kept under section 2 of the Medical Act 1983(36) (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(37) (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(38); 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(39) (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;

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(33) 2006 c.42.

(34) 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”).

(35) Section 91 was amended by paragraph 35 of Schedule 4 to the 2012 Act.

(36) 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.

(37) 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.

(38) 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 date to be appointed. No regulations have yet been made under section 147A of the Act.

(39) 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).

“NHS foundation trust” has the meaning given in section 30 of the Act<sup>(40)</sup> (NHS foundation trusts);

“NHS trust” means a body established under section 25 of the Act<sup>(41)</sup> (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<sup>(42)</sup>;

“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
- (d) specifies, or is to specify, the number of occasions on which the drug, 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<sup>(43)</sup> (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<sup>(44)</sup> (register of opticians); and
- (b) 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—

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<sup>(40)</sup> Section 30 was amended by section 159(1) of the Health and Social Care Act 2012 (c.7) (“the 2012 Act”).

<sup>(41)</sup> Section 25 is repealed by section 179(2) of the 2012 Act from a date to be appointed.

<sup>(42)</sup> The Health and Social Care Information Centre is a body corporate established by section 252(1) of the 2012 Act.

<sup>(43)</sup> S.I. 2002/253; article 5 was amended by S.I. 2009/1182.

<sup>(44)</sup> 1989 c.44. Section 7 was amended by S.I. 2005/848.



(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;

(b) who is registered in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010(45) (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(46); 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(47) (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(48) (programmes for provisionally registered doctors) as providing provisionally registered doctors with an acceptable foundation for future practise as a fully registered medical practitioner;

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(45) 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.

(46) 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.

(47) 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.

(48) 1983 c.54. Section 10A was inserted by S.I. 2006/1914, and was amended by S.I. 2008/3131.

“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; and
- (g) a supplementary prescriber,

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

“prescription form” means—

- (a) a form 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<sup>(49)</sup>,
  - (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—
  - (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<sup>(50)</sup> (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

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<sup>(49)</sup> 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.

<sup>(50)</sup> 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.

- (iv) sections 145, 146, 147A or 149 (performers of pharmaceutical services and assistants),  
of the Act<sup>(51)</sup>;
- (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<sup>(52)</sup> (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<sup>(53)</sup> (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<sup>(54)</sup>;
- (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<sup>(55)</sup> (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<sup>(56)</sup> (establishment and maintenance of register) relating to—

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<sup>(51)</sup> 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. ).

<sup>(52)</sup> 2012 c.7.

<sup>(53)</sup> 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.

<sup>(54)</sup> 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.

<sup>(55)</sup> 1989 c.44. Section 7 was amended by S.I. 2005/848.

<sup>(56)</sup> 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,

- (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(57) and which—
  - (i) 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
- (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

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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.

(57) 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.

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(58) (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(59) (interpretation);

“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(60) (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(61),
  - (iv) the part of the register maintained by the Health Professions Council under of article 5 of the Health Professions Order 2001(62) (establishment and maintenance of register) relating to—
    - (aa) chiropodists and podiatrists,
    - (bb) physiotherapists, or
    - (cc) radiographers, or
  - (v) the register of optometrists maintained by the General Optical Council under section 7(a) of the Opticians Act 1989(63) (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;

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

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

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(58) Section 92 was amended by paragraph 36 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

(59) S.I. 2009/3112. There are no relevant amendments to regulation 2.

(60) 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.

(61) 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.

(62) 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.

(63) 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<sup>(64)</sup>.

#### 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—
  - (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<sup>(65)</sup>;
- (b) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998<sup>(66)</sup>; or

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<sup>(64)</sup> 2012 c.7.

<sup>(65)</sup> S.I. 1997/2817; as amended by S.I. 1998/669 and revoked by S.I. 2003/1250.

<sup>(66)</sup> 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.



(c) regulation 5(1)(d) of the Medical Practitioners (Vocational Training) Regulations (Northern Ireland) 1998<sup>(67)</sup>.

(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<sup>(68)</sup>, 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.

### **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;

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<sup>(67)</sup> S.R. 1998/13; as revoked by S.I. 2003/1250.

<sup>(68)</sup> Family Health Services Authorities no longer exist. They were merged with Health Authorities in 1994. Health Authorities have now been abolished.

- (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<sup>(69)</sup> (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;
- (h) the contractor has been convicted of an offence, referred to in Schedule 1 to the Children and Young Persons Act 1933<sup>(70)</sup> (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<sup>(71)</sup> (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<sup>(72)</sup> (barred lists), or
  - (ii) any barred list within the meaning of article 6 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007<sup>(73)</sup> (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,

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<sup>(69)</sup> Section 151 was amended by paragraph 79 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

<sup>(70)</sup> 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).

<sup>(71)</sup> 1995 c.46. Schedule 1 was amended by paragraph 2(8)(a) of Schedule 5 to the Sexual Offences (Scotland) Act 2009 (asp 9).

<sup>(72)</sup> 2006 c.47. Section 2 was amended by articles 3(a) and 4 of S.I. 2012/3006.

<sup>(73)</sup> 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).

- 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(74) (powers of Court of Session);
- (l) the contractor—
- (i) has been adjudged 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(75) (bankruptcy restrictions order and undertaking), Schedule 2A to the Insolvency (Northern Ireland) Order 1989(76) (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(77) (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(78) (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(79) (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;
- (p) the contractor is subject to—
- (i) a disqualification order under section 1 of the Company Directors Disqualification Act 1986(80) (disqualification orders: general) or a disqualification undertaking under section 1A of that Act(81) (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(82), or

(74) 2005 asp. 10. Section 34 was amended by section 122 of the Public Services Reform (Scotland) Act 2010 (asp 8).

(75) 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).

(76) 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).

(77) 1985 c.66. Sections 56A to 56K were inserted by section 2(1) of the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).

(78) 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).

(79) Schedule 4ZB was inserted by section 108(2) of, and Schedule 19 to, the Tribunals, Courts and Enforcement Act 2007.

(80) 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).

(81) 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.

(82) S.I. 2002/3150 (N.I. 4).

- (iii) a disqualification order under section 429(2) of the Insolvency Act 1986<sup>(83)</sup> (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<sup>(84)</sup> (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<sup>(85)</sup>.
- (5) In this regulation, “contractor” includes a person with whom the Board is proposing to enter into a contract with.

#### **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

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<sup>(83)</sup> 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).

<sup>(84)</sup> 1986 c.45. Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002.

<sup>(85)</sup> 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.

(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<sup>(86)</sup> against the decision of the Board that the conditions in regulation 5 or 6 are not met.

## **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.

## **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).

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<sup>(86)</sup> 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.

(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.

#### **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.

#### **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<sup>(87)</sup> (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<sup>(88)</sup>; and

“management” includes—

- (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.

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<sup>(87)</sup> 2008 c.14.

<sup>(88)</sup> 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.

(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.

### **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.

(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<sup>(89)</sup>, and

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<sup>(89)</sup> 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](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.

- (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).

#### **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—

- (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;
  - (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<sup>(90)</sup> (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985<sup>(91)</sup> (medical information).

## 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)<sup>(92)</sup>.

(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<sup>(93)</sup> (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).

## 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—

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<sup>(90)</sup> 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.

<sup>(91)</sup> S.I. 1985/1604; as amended by S.I. 1992/247 and S.I. 2010/137.

<sup>(92)</sup> 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.

<sup>(93)</sup> Section 98A was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7).



- (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,

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<sup>(94)</sup> (payment for emergency treatment of traffic casualties);

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<sup>(94)</sup> 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.

- (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—
    - (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)<sup>(95)</sup>;
- (k) where the contractor is authorised or required in accordance with arrangements made with the Board under section 126 of the Act<sup>(96)</sup> (arrangements for pharmaceutical services) and in accordance with regulations made under section 129 of the Act<sup>(97)</sup> (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.

### **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.

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<sup>(95)</sup> Section 115 was amended by paragraph 54 of Schedule 4 to the Health and Social Care Act 2012 (c.7) (“the 2012 Act”).

<sup>(96)</sup> Section 126 was amended by sections 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the 2012 Act.

<sup>(97)</sup> 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.

(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(98) (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.

(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.

#### **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 full-time 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 contractor 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

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

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—

- (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 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;

“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
    - (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;
- (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))—

- (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.

(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<sup>(99)</sup> (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—

- (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<sup>(100)</sup> (provisional registration), 15A<sup>(101)</sup> (provisional registration for EEA nationals) or 21<sup>(102)</sup> (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 post-registration 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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<sup>(99)</sup> 1983 c.54. Section 41A was inserted by S.I. 2015/794.

<sup>(100)</sup> 1983 c.54. Section 15 was substituted by S.I. 2006/1914.

<sup>(101)</sup> 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.

<sup>(102)</sup> 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.

### **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.

### **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
- (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.

(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(**103**).

### **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"(**104**).

### **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

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**(103)** 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.

**(104)** 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.



- (e) a supplementary prescriber.
- (2) The contractor must give notice to the Board where—
  - (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,
- (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.

## 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;

- (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(105) (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(106) (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

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(105) 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.

(106) 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).

and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001(107); 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 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.

### 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(108) (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 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.

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(107) 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.

(108) 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).

(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(**109**), 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(**110**).

(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.

### **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(**111**)—

- (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.

(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(**112**), or

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(**109**) 1989 c.41.

(**110**) 2005 c.9.

(**111**) 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).

(**112**) 1989 c.41.

- (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 donee 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.

### **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 non-electronic 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.
- (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(113)

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(113) 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).



(arrangements for pharmaceutical services) and section 132(114) (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.

### **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.

(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.

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**(114)** 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.

(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(**115**) (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
- (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”.

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**(115)** 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.

(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(116) (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(117).

(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(118), 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.

### **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(119) (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;

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(116) 1971 c.38.

(117) 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.

(118) 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.

(119) S.I. 2012/1916. There are no amendments to regulation 215.

- (b) the medicine is not specified in any directions given by the Secretary of State in regulations under section 88 of the Act(120) (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,
    - (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

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(120) 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.

- (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<sup>(121)</sup> (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.

### **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.

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<sup>(121)</sup> 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.

(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.

(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(122) (which relates to dealings with medicinal products).

## **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(**123**) (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
  - (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(**124**) (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(**125**) (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)(**126**) in respect of dispensing services to the patient by virtue of either—

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(123) S.I. 2012/1916. There are no relevant amendments to regulation 213.

(124) S.I. 2004/629. There are no amendments to Schedule 1.

(125) 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.

(126) 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



- (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(127) (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.

## 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"(128);
- (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

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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.

(127) 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.

(128) 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.

- (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(129).
- (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.
- (5) The contractor must send the complete records relating to a patient to the Board—
- (a) where a person on the contractor’s list of patients dies, before the end of the period of 14 days beginning with the date on which the contractor was informed by the Board of that person’s death, or (in any other case) before the end of the period of one month beginning with the date on which the contractor learned of that person’s death; or
  - (b) in any other case where the person is no longer registered with the contractor, as soon as possible at the request of the Board.
- (6) To the extent that a patient’s records are computerised records, the contractor complies with paragraph (5) if it sends to the Board a copy of those records—
- (a) in writing; or
  - (b) with the written consent of the Board, in any other form.
- (7) The consent of the Board to the transmission of information other than in writing for the purposes of paragraph (6)(b) may not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with the following matters—
- (a) the contractor’s proposals as to how the record is to be transmitted;
  - (b) the contractor’s proposals as to the format of the transmitted record;
  - (c) the manner in which the contractor proposes to ensure that the record received by the Board is identical to that transmitted; and
  - (d) the manner in which a written copy of the record may be produced by the Board.
- (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.

### 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, at least on a daily basis, using approved systems provided to it by the Board.

(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.

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(129) 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.

### **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;
- (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.

(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(130); and
- (b) "summary information" has the meaning given in regulation 68(2).

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**(130)** 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(131) (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.

### **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;
- (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

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

- (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
  - (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(**132**) (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.

### **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.

(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.

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(132) 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.

(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(**133**).

#### 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
- (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(**134**) (local authorities);
- (b) the Council of the Isles of Scilly; or
- (c) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**135**) (constitution of councils); 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(**136**) (The Commissioner).

(3) For the purposes of paragraph (1), co-operation includes—

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(**133**) S.I. 2009/309; as amended by S.I. 2009/1768, S.I. 2012/1909 and S.I. 2013/235 and 349.

(**134**) 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).

(**135**) 1994 c.39. Section 2 was amended by paragraph 232(1) of Schedule 22 to the Environment Act 1995 (c.25).

(**136**) 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).



- (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.

## PART 12

### Dispute resolution

#### **Local resolution of contract disputes**

**81.**—(1) The contractor and the Board must make reasonable efforts to communicate and co-operate 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 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 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.

## **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(137) (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.

## 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.

(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(**138**) (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.

#### 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(**139**).

(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(**140**).

(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.

#### 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(**141**).

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

**90.** The contractor must co-operate with—

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(138) 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).

(139) 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.

(140) 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.

(141) S.I. 2013/373.

- (a) the Secretary of State in the discharge of the Secretary of State’s duty under section 1F of the Act(142) (duty as to education and training); or
- (b) Health Education England(143) 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(144) (planning education and training for health care workers etc.).

### **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
- (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—

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(142) Section 1F was inserted by section 7 of the Health and Social Care Act 2012 (c.7) .

(143) Health Education England is a body corporate established under section 96 of the Care Act 2014 (c.23).

(144) 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.

- (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.

## **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.



Signed by authority of the Secretary of State for Health.

6th November 2015

*Alistair Burt*  
Minister of State,  
Department of Health

## SCHEDULE 1

Regulation 19

## Additional services

**Additional services: general**

1. The contractor must provide, in relation to each additional service, such facilities as are necessary to enable the contractor to properly perform that service.

**Cervical screening**

2.—(1) A contractor whose contract includes the provision of cervical screening must—

- (a) provide all the services described in sub-paragraph (2); and
- (b) make the records described in sub-paragraph (3).

(2) The services described in this sub-paragraph are—

- (a) the provision of necessary information and advice to assist women identified by the Board as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Cervical Screening Programme<sup>(145)</sup>;
- (b) the performance of cervical screening tests on women who have agreed to participate in that Programme; and
- (c) ensuring that test results are followed up appropriately.

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

**Contraceptive services**

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

(2) The services described in this sub-paragraph are—

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

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<sup>(145)</sup>The NHS Cervical Screening Programme is a programme intended to reduce the number of women who develop cervical cancer and the number of women who die from that condition. All women aged between 25 and 64 are invited for cervical screening. Further information about the Programme is available at <http://www.nhs.uk/conditions/Cervical-screening-test/Pages/Introduction.aspx> or in hard copy form from Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

- (g) the referral as necessary to specialist sexual health services, including tests for sexually transmitted infections.

### **Vaccines and immunisations**

4.—(1) This paragraph applies to a contractor whose contract includes the provision of vaccines and immunisations but does not apply to the provision of—

- (a) childhood immunisations; and
- (b) the combined Haemophilus influenza type B and Meningitis C booster vaccine.

(2) The contractor must—

- (a) offer to provide to patients all vaccines and immunisations (other than those mentioned in sub-paragraph (1)) of the type, and in the circumstances, specified in the GMS Statement of Financial Entitlements;
- (b) taking into account the individual circumstances of the patient, consider whether immunisation ought to be administered by the contractor or by another health care professional or whether a prescription form ought to be provided for the purpose of self-administration by the patient of the immunisation;
- (c) provide appropriate information and advice to patients about such vaccines and immunisations;
- (d) record, in the patient's record, any refusal of the offer referred to in paragraph (a);
- (e) where the offer is accepted and immunisation is to be administered by the contractor or by another health care professional, include in the patient's record—
  - (i) the patient's consent to immunisation or the name of the person who gave consent to immunisation and that person's relationship to the patient,
  - (ii) the batch numbers, expiry date and title of the vaccine,
  - (iii) the date of administration,
  - (iv) in the case where two vaccines are administered by injections, in close succession, the route of the administration and the injection site of each vaccine,
  - (v) any contraindications to the vaccine, and
  - (vi) any adverse reactions to the vaccine; and
- (f) where the offer is accepted and the immunisation is not to be administered by the contractor or another health care professional, issue a prescription form for the purpose of self-administration by the patient.

(3) The contractor must ensure that all staff involved in the administration of vaccinations and immunisations are trained in the recognition and initial treatment of anaphylaxis.

(4) In this paragraph, "patient's record" means the record which is kept in accordance with regulation 67.

### **Childhood vaccines and immunisations**

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

(2) The contractor must—

- (a) offer to provide to children all vaccines and immunisations of the type specified, and in the circumstances which are set out, in the GMS Statement of Financial Entitlements;

- (b) provide appropriate information and advice to patients and, where appropriate, to the parents of patients, about such vaccines and immunisations;
- (c) record in the patient's record any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the immunisations and include in the patient's record—
  - (i) the name of the person who gave consent to the immunisations and that person's relationship to the patient,
  - (ii) the batch number and expiry date of the vaccine,
  - (iii) the date of administration,
  - (iv) in a case where two vaccines are administered by injections in close succession, the route of administration and the injection site of each vaccine,
  - (v) any contraindications to the vaccine, and
  - (vi) any adverse reactions to the vaccine.
- (3) The contractor must ensure that all staff involved in administering vaccines and immunisations are trained in the recognition and initial treatment of anaphylaxis.
- (4) In this paragraph, "patient's record" has the same meaning as in paragraph 4.

### **Child health surveillance**

- 6.—(1)** A contractor whose contract includes the provision of child health surveillance services must, in respect of any child under the age of five years for whom it has responsibility under the contract—
- (a) provide all the services described in sub-paragraph (2), other than an examination described in that sub-paragraph which the parent refuses to allow the child to undergo, until the date upon which the child attains the age of five years; and
  - (b) maintain the records specified in sub-paragraph (3).
- (2) The services described in this sub-paragraph are—
- (a) monitoring the health, well-being and physical, mental and social development ("development") of the child while under the age of five years with a view to detecting any deviations from normal development—
    - (i) by the consideration of information concerning the child received by or on behalf of the contractor, and
    - (ii) on any occasion when the child is examined or observed by or on behalf of the contractor (whether by virtue of paragraph (b) or otherwise); and
  - (b) examination of the child at the frequency that has been agreed with the Board in accordance with the nationally agreed evidence based programme set out in the fourth edition of "Health for all Children"<sup>(146)</sup>.
- (3) The records specified in this sub-paragraph are an accurate record of—
- (a) the development of the child while under the age of five years, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination; and
  - (b) the responses (if any) to offers made to the child's parent for the child to undergo an examination referred to in sub-paragraph (2)(b).

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<sup>(146)</sup>Health for All Children, Revised 4th Edition by David M B Hall and David Elliman was published by Oxford University Press on 7th September 2006.

### **Maternity medical services**

- 7.—(1) A contractor whose contract includes the provision of maternity medical services must—
- (a) provide to female patients who have been diagnosed as pregnant all necessary maternity medical services throughout the antenatal period;
  - (b) provide to female patients and their babies all necessary maternity medical services throughout the postnatal period other than neonatal checks;
  - (c) subject to sub-paragraph (2), provide all necessary maternity medical services to female patients whose pregnancy has terminated as a result of miscarriage or abortion.
- (2) Where the contractor has a conscientious objection to the termination of pregnancy by abortion, the contractor must promptly refer the patient to another provider of primary medical services who does not have such an objection.
- (3) In this paragraph—
- “antenatal period” means the period beginning with the start of the pregnancy and ending with the onset of labour;
- “maternity medical services” means—
- (a) in relation to female patients (other than babies) all primary medical services relating to pregnancy, excluding intra partum care; and
  - (b) in relation to babies, any primary medical services necessary in their first fourteen days of life; and
- “postnatal period” means the period beginning with the conclusion of the delivery of the baby or the patient’s discharge from secondary care services (whichever is the later) and ending on the fourteenth day after the birth.

### **Minor surgery**

- 8.—(1) A contractor whose contract includes the provision of minor surgery must comply with the requirements in sub-paragraphs (2) and (3).
- (2) The contractor must make available to patients where appropriate—
- (a) curettage;
  - (b) cautery; and
  - (c) cryocautery of warts, verrucae and other skin lesions.
- (3) The contractor must record in the patient’s record—
- (a) details of the minor surgery provided to the patient; and
  - (b) the consent of the patient to that surgery.
- (4) In this paragraph, “patient’s record” has the same meaning as in paragraph 4.

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

## SCHEDULE 2

Regulation 22

## List of prescribed medical certificates

<i>Description of medical certificate</i>	<i>Enactment under or for the purposes of which the certificate is required</i>
1. To support a claim or to obtain a payment either personally or by proxy; to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc.	Naval and Marine Pay and Pensions Act 1865( <b>147</b> )
	Air Force (Constitution) Act 1917( <b>148</b> )
	Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939( <b>149</b> )
	Personal Injuries (Emergency Provisions) Act 1939( <b>150</b> )
	Social Security Administration Act 1992( <b>151</b> )
2. To establish pregnancy for the purpose of obtaining welfare foods	Social Security Contributions and Benefits Act 1992( <b>152</b> )
	Social Security Act 1998( <b>153</b> )
3. To secure registration of still-birth	Section 13 of the Social Security Act 1988( <b>154</b> ) (Benefits under schemes for improving nutrition: pregnant women, mothers and children)
4. To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment from public funds	Section 11 of the Births and Deaths Registration Act 1953( <b>155</b> ) (special provision as to registration of still-birth)
5. To establish unfitness for jury service	Section 142 of the Mental Health Act 1983( <b>156</b> ) (pay, pensions etc. of mentally disordered persons)
	Juries Act 1974( <b>157</b> )

(147) 1865 c.73. Section 3, which makes provision for the payment of naval and marine pay and pensions by Order in Council, was amended by section 4 of the Armed Forces (Pensions and Compensations) Act 2004 (c.32) and by section 378(1) of, and Schedule 16 to, the Armed Forces Act 2006 (c.52).

(148) 1917 c.51.

(149) 1939 c.83.

(150) 1939 c.82.

(151) 1992 c.5.

(152) 1992 c.4.

(153) 1998 c.14.

(154) 1988 c.7. Section 13 was substituted by section 185(1) of the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

(155) 1953 c.20. Section 11 was amended by section 2 of the Population (Statistics) Act 1960 (c.32), section 23(4) of the Nurses, Midwives and Health Visitors Act 1979 (c.36) and by S.I. 1968/1242 and S.I. 1996/2395.

(156) 1983 c.20. Section 142 of the Mental Health Act 1983 was repealed by section 67 of the Mental Capacity Act 2005 (c.9). See paragraph 29 of Schedule 6 to the Mental Capacity Act 2005 which enables payments made under section 142 before the date on which that provision was repealed to continue.

(157) 1974 c.23.

<i>Description of medical certificate</i>	<i>Enactment under or for the purposes of which the certificate is required</i>
6. To support late application for reinstatement in civil employment or notification on non-availability to take up employment owing to sickness	Reserve Forces (Safeguard of Employment) Act 1985( <b>158</b> )
7. To enable a person to be registered as an absent voter on grounds of physical incapacity	Representation of the People Act 1985( <b>159</b> )
8. To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances	National Health Service Act 2006( <b>160</b> )
9. To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable	Local Government and Finance Act 1992( <b>161</b> )

### SCHEDULE 3

Regulation 32

#### Other contractual terms

### PART 1

#### Provision of services

##### Premises

1.—(1) The contractor must ensure that the premises used for the provision of services under the contract are—

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

(2) The requirement in sub-paragraph (1) is subject to any plan included in the contract in accordance with regulation 20(5) which sets out steps to be taken by the contractor to bring the premises up to the required standard.

##### Telephone services

2.—(1) The contractor must not be a party to a contract or other arrangement under which the number for telephone services to be used by—

- (a) patients to contact the contractor's practice for a purpose related to the contract; or
- (b) any other person to contact the contractor's practice in relation to services provided as part of the health service,

(158) 1985 c.17.

(159) 1985 c.50.

(160) 2006 c.41.

(161) 1992 c.14.

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

(2) In this paragraph, “personal number” means a telephone number which starts with 070 followed by a further eight digits.

### **Cost of relevant calls**

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

(2) Where it has not been possible for the contractor to take reasonable steps to ensure that persons will not pay more to make relevant calls to the contractor’s practice than they would to make equivalent calls to a geographical number, the contractor must consider introducing a system under which, if a caller asks to be called back, the contractor will do so at the contractor’s own expense.

(3) In this paragraph—

“geographical number” means a number which has a geographical area code as its prefix; and

“relevant calls” means—

- (a) calls made by patients to the contractor’s practice for any reason related to services provided under the contract; and
- (b) calls made by persons, other than patients, to the contractor’s practice in relation to services provided as part of the health service.

### **Attendance at practice premises**

4.—(1) The contractor must take steps to ensure that a patient who—

- (a) has not previously made an appointment; and
- (b) attends the contractor’s practice premises during the normal hours for essential services,

is provided with such services by an appropriate health care professional during that surgery period.

(2) Sub-paragraph (1) does not apply where—

- (a) it is more appropriate for the patient to be referred elsewhere for the provision of services under the Act; or
- (b) the patient is offered an appointment to attend the contractor’s practice premises again at a time which is appropriate and reasonable having regard to all the circumstances, and the patient’s health would not thereby be jeopardised.

### **Attendance outside practice premises**

5.—(1) Where the medical condition of a patient is such that, in the reasonable opinion of the contractor—

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

the contractor must provide services to the patient at whichever of the places described in sub-paragraph (2) is, in the contractor’s judgement, the most appropriate.

(2) The places described in this sub-paragraph are—

- (a) the place recorded in the patient’s medical records as being the patient’s last home address;



- (b) such other place as the contractor has informed the patient and the Board is the place where the contractor has agreed to visit and treat the patient; or
  - (c) another place in the contractor's practice area.
- (3) Nothing in this paragraph prevents the contractor from—
- (a) arranging for the referral of the patient without first seeing the patient in any case where the patient's medical condition makes that course of action appropriate; or
  - (b) visiting the patient in circumstances where this paragraph does not place the contractor under an obligation to do so.

### **Newly registered patients**

- 6.—(1) Where a patient has been—
- (a) accepted on a contractor's list of patients; or
  - (b) assigned to that list by the Board,

the contractor must invite the patient to participate in a consultation either at the contractor's practice premises or, if the patient's medical condition so warrants, at one of the places described in paragraph 5(2).

(2) An invitation under sub-paragraph (1) must be issued by the contractor before the end of the period of six months beginning with the date of the acceptance of the patient on, or assignment of the patient to, the contractor's list of patients.

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

(4) This paragraph does not affect the contractor's other obligations under the contract in respect of the patient.

### **Newly registered patients – alcohol dependency screening**

- 7.—(1) Where a patient has been—
- (a) accepted onto a contractor's list of patients; or
  - (b) assigned to that list by the Board,

the contractor must, whether as part of the consultation which the contractor is required to offer the patient under paragraph 6(1) or otherwise, take action to identify any such patient over the age of 16 who is drinking alcohol at increasing or higher risk levels with a view to seeking to reduce the alcohol related risks to that patient.

(2) The contractor must comply with the requirement in sub-paragraph (1) by screening the patient using either of the two shortened versions of the World Health Organisations Alcohol Use Disorders Identification ("AUDIT") questionnaire<sup>(162)</sup> which are known as—

- (a) FAST (which has four questions); or
- (b) AUDIT-C (which has three questions).

(3) Where, under paragraph (2), the contractor identifies a patient as positive using one of the shortened versions of the AUDIT questionnaire specified in sub-paragraph (2), the remaining

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<sup>(162)</sup>The World Health Organisation Alcohol Use Disorders Identification Test (AUDIT) questionnaire can be accessed at [http://www.who.int/substance\\_abuse/activities/sbi/en/](http://www.who.int/substance_abuse/activities/sbi/en/). Further information about the Test, and the questionnaires themselves, is available in hard copy from NHS England, PO Box 16738, Redditch, B97 7PT.

questions of the full ten question AUDIT questionnaire are to be used by the contractor to determine increasing risk, higher risk or likely dependent drinking.

(4) Where a patient is identified as drinking at increasing or higher risk levels, the contractor must—

- (a) offer the patient appropriate advice and lifestyle counselling;
- (b) respond to any other need identified in the patient which relates to the patient's levels of drinking, including by providing additional support or treatment required for people with mental health issues; and
- (c) in any case where the patient is identified as a dependent drinker, offer the patient a referral to such specialist services as are considered clinically appropriate to meet the needs of the patient.

(5) Where a patient is identified as drinking at increasing or higher risk levels or as a dependent drinker, the contractor must ensure that the patient is—

- (a) assessed for anxiety and depression;
- (b) offered screening for anxiety and depression; and
- (c) where anxiety and depression is diagnosed, provided with any treatment or support which may be required under the contract, including referral for specialist mental health treatment.

(6) The contractor must make relevant entries, including the results of the completed questionnaire referred to in sub-paragraph (2), in the patient's record that the contractor is required to keep under regulation 67.

### **Accountable GP**

**8.—(1)** A contractor must ensure that for each of its registered patients (including those patients under the age of 16) there is assigned an accountable general medical practitioner ("accountable GP").

(2) The accountable GP must take lead responsibility for ensuring that any services which the contractor is required to provide under the contract are, to the extent that their provision is considered necessary to meet the needs of the patient, coordinated and delivered to the patient.

(3) The contractor must—

- (a) inform the patient, as soon as is reasonably practicable and in such manner as is considered appropriate by the contractor's practice, of the assignment to the patient of an accountable GP and must state the name and contact details of the accountable GP and the role and responsibilities of the accountable GP in respect of the patient;
- (b) inform the patient as soon as any circumstances arise in which the accountable GP is not able, for any significant period, to carry out the duties of an accountable GP in respect of the patient; and
- (c) where the contractor's practice considers it to be necessary, assign a replacement accountable GP to the patient and inform the patient accordingly.

(4) The contractor must comply with the requirement in sub-paragraph (3)(a), in the case of any person who is accepted by the contractor as a registered patient on or after the date on which these Regulations come into force, within 21 days from the date on which that person is so accepted.

(5) The requirement in this paragraph does not apply to—

- (a) any patient of the contractor who is aged 75 or over, or who attains the age of 75, on or after the date on which these Regulations come into force; or

(b) any other patient of the contractor if the contractor has been informed that the patient does not wish to have an accountable GP.

(6) Where, under sub-paragraph (3)(a), the contractor informs a patient of the assignment to the patient of an accountable GP, the patient may express a preference as to which general medical practitioner within the contractor's practice the patient would like to have as the patient's accountable GP and, where such a preference has been expressed, the contractor must make reasonable efforts to accommodate the request.

(7) Where, under sub-paragraph (5)(b), the contractor has been informed by, or in relation to, a patient that the patient does not wish to have an accountable GP, the contractor must record that fact in the patient's record that the contractor is required to keep under regulation 67.

(8) The contractor must, by no later than 31st March 2016, include information about the requirement to assign an accountable GP to each of its new and existing registered patients—

- (a) on the contractor's practice website (if it has one); and
- (b) in the contractor's practice leaflet.

(9) Where the contractor does not have a practice website, the contractor must include the information referred to in sub-paragraph (8) on its profile page on NHS Choices<sup>(163)</sup>.

#### **Patients not seen within three years**

**9.—**(1) This paragraph applies where a registered patient who has attained the age of 16 years but has not attained the age of 75 years—

- (a) requests a consultation with the contractor; and
- (b) has not attended either a consultation with, or a clinic provided by, the contractor within the period of three years prior to the date of the request.

(2) The contractor must—

- (a) provide the patient with a consultation; and
- (b) during that consultation, make such inquiries and undertake such examinations of the patient as the contractor considers appropriate in all the circumstances.

(3) This paragraph does not affect the contractor's other obligations under the contract in respect of the patient.

#### **Patients aged 75 and over**

**10.—**(1) Where a registered patient who requests a consultation—

- (a) has attained the age of 75 years; and
- (b) has not participated in a consultation within the 12 month period prior to the date of the request,

the contractor must provide such a consultation during which it must make such inquiries and undertake such examinations as it considers appropriate in all the circumstances.

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

(3) This paragraph does not affect the contractor's other obligations under the contract in respect of the patient.

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<sup>(163)</sup>NHS Choices is the website available at <http://www.nhs.uk> which provides information from the National Health Service on conditions, treatments and local services including GP services.

### **Patients aged 75 and over: accountable GP**

**11.**—(1) A contractor must ensure that for each of its registered patients aged 75 and over there is assigned an accountable general medical practitioner (“accountable GP”).

- (2) The accountable GP must—
- (a) take lead responsibility for ensuring that any services which the contractor is required to provide under the contract are, to the extent that their provision is considered necessary to meet the needs of the patient, delivered to the patient;
  - (b) take all reasonable steps to recognise and appropriately respond to the physical and psychological needs of the patient in a timely manner;
  - (c) ensure that the patient receives a health check if, and within a reasonable period after, one has been requested; and
  - (d) work co-operatively with such other health and social care professionals who may become involved in the care and treatment of the patient to ensure the delivery of a multi-disciplinary care package designed to meet the needs of the patient.
- (3) The contractor must—
- (a) inform the patient, in such manner as is considered appropriate by the contractor’s practice, of the assignment to the patient of an accountable GP;
  - (b) provide the patient with the name and contact details of the accountable GP and information regarding the role and responsibilities of the accountable GP in respect of the patient;
  - (c) inform the patient as soon as any circumstances arise in which the accountable GP is not able, for any significant period, to carry out the duties of an accountable GP in respect of the patient; and
  - (d) where the contractor’s practice considers it to be necessary, assign a replacement accountable GP to the patient and inform the patient accordingly.
- (4) The contractor must comply with the requirement in sub-paragraph (3)(a)—
- (a) in the case of any person aged 75 or over who is accepted by the contractor as a registered patient on or after the date on which these Regulations come into force, before the end of the period of 21 days beginning with the date on which that person was so accepted; or
  - (b) in the case of any person who is included in the contractor’s list of patients immediately before the date on which these Regulations come into force who attains the age of 75 or over on or after that date, before the end of the period of 21 days after the date on which that person attained that age.

(5) In this paragraph, “health check” means a consultation undertaken by the contractor which is of the type which a contractor is required to undertake at a patient’s request under paragraph 10(1).

### **Clinical reports**

**12.**—(1) Where the contractor provides clinical services, other than under a private arrangement, to a patient who is not on its list of patients, the contractor must, as soon as reasonably practicable, provide to the Board a clinical report relating to that consultation and any treatment provided to the patient.

(2) The Board must send a report received in accordance with sub-paragraph (1) to the person with whom the patient is registered for the provision of essential services or their equivalent.

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

### **Storage of vaccines**

13. The contractor must ensure that—
- (a) all vaccines are stored in accordance with the manufacturer's instructions; and
  - (b) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that temperature readings are taken on all working days.

### **Infection control**

14. The contractor must ensure that it has appropriate arrangements in place for infection control and decontamination.

### **Duty of co-operation**

15.—(1) Where a contractor does not provide to its registered patients or to persons whom it has accepted as temporary residents—

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

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

(2) The requirements specified in this sub-paragraph are that the contractor must—

- (a) co-operate, insofar as is reasonable, with any person responsible for the provision of that service or those services;
- (b) comply in core hours with any reasonable request for information from such a person or from the Board relating to the provision of that service or those services; and
- (c) in the case of out of hours services—
  - (i) take reasonable steps to ensure that any patient who contacts the contractor's practice premises during the out of hours period is provided with information about how to obtain services during that period,
  - (ii) ensure that the clinical details of all out of hours consultations received from the out of hours provider are reviewed by a clinician within the contractor's practice on the same working day as those details are received by the practice or, exceptionally, on the next working day,
  - (iii) ensure that any information requests received from the out of hours provider in respect of any out of hours consultations are responded to by a clinician within the contractor's practice on the same day as those requests are received by the contractor's practice, or on the next working day,
  - (iv) take all reasonable steps to comply with any systems which the out of hours provider has in place to ensure the rapid, secure and effective transmission of patient data in respect of out of hours consultations, and
  - (v) agree with the out of hours provider a system for the rapid, secure and effective transmission of information about registered patients who, due to chronic disease or terminal illness, are predicted as more likely to present themselves for treatment during the out of hours period.

(3) Nothing in this paragraph requires a contractor whose contract does not include the provision of out of hours services to make itself available during the out of hours period.

### **Cessation of service provision: information requests**

16. Where a contractor is to cease to be required to provide to its patients—
- (a) a particular additional service;
  - (b) a particular enhanced service; or
  - (c) out of hours services, either at all or in respect of some periods or some services,

the contractor must comply with any reasonable request for information relating to the provision of that service, or those services, made by the Board or by any person with whom the Board intends to enter into a contract for the provision of such services.

## **PART 2**

### **Patients: general**

#### **List of patients**

17. The Board must prepare and keep up to date a list of the patients—
- (a) who have been accepted by the contractor for inclusion in the contractor's list of patients under paragraph 18 and who have not subsequently been removed from that list under paragraphs 23 to 31; and
  - (b) who have been assigned by the Board to the contractor's list of patients—
    - (i) under paragraph 39(1)(a), or
    - (ii) under paragraph 39(1)(b) (by virtue of a determination of the assessment panel under paragraph 41(8) which has not subsequently been overturned by a determination of the Secretary of State under paragraph 42 or by a court).

#### **Application for inclusion in a list of patients**

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

(2) If the contractor's list of patients is closed, the contractor may only accept an application for inclusion in that list made by or on behalf of a person who is an immediate family member of a registered patient whether or not that person is resident in the contractor's practice area or is included, at the time of the application, in the list of patients of another contractor or provider of primary medical services.

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

- (4) An application may be made—
- (a) where the patient is a child, on behalf of the patient by—
    - (i) either parent, or in the absence of both parents, the guardian or other adult who has care of the child,

- (ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989(164), or
- (iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of the Children Act 1989; or
- (b) where the patient is an adult who lacks capacity to make such an application, or to authorise such an application to be made on their behalf, by—
  - (i) a relative of that person,
  - (ii) the primary carer of that person,
  - (iii) a donee of a lasting power of attorney granted by that person, or
  - (iv) a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005(165).
- (5) Where a contractor accepts an application for inclusion in the contractor’s list of patients, the contractor must give notice in writing to the Board of that acceptance as soon as possible.
- (6) The Board must, on receipt of a notice given under sub-paragraph (5)—
  - (a) include the applicant in the contractor’s list of patients from the date on which the notice is received; and
  - (b) give notice in writing to the applicant (or, in the case of a child or an adult who lacks capacity, the person making the application on their behalf) of that acceptance.

#### **Inclusion in list of patients: armed forces personnel**

**19.**—(1) The contractor may, if the contractor’s list of patients is open, include a person to whom sub-paragraph (2) applies in that list for a period of up to two years and paragraph 29(1)(b) does not apply in respect of any person who is included in the contractor’s list of patients by virtue of this paragraph.

- (2) This sub-paragraph applies to a person who is—
  - (a) a serving member of the armed forces of the Crown who has received written authorisation from Defence Medical Service(166) to receive primary medical services from the contractor’s practice; and
  - (b) living or working within the contractor’s practice area during the period in respect of which that written authorisation is given.
- (3) Where the contractor has accepted a person to whom sub-paragraph (2) applies onto its list of patients, the contractor must—
  - (a) obtain a copy of the patient’s medical record, or a summary of that record, from Defence Medical Services; and
  - (b) provide regular updates to Defence Medical Services, at such intervals as are agreed with Defence Medical Services, about any care and treatment which the contractor has provided to the patient.
- (4) At the end of the period of two years, or on such earlier date as the contractor’s responsibility for the patient has come to an end, the contractor must—
  - (a) notify Defence Medical Services in writing that its responsibility for the patient has come to an end; and

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(164) 1989 c.41.

(165) 2005 c.9.

(166) Defence Medical Services is an umbrella organisation within the Ministry of Defence which is responsible for the provision of medical, dental and nursing services in the United Kingdom to members of the armed forces of the Crown.

- (b) update the patient's medical record, or summary of that record, and return it to Defence Medical Services.

### **Temporary residents**

**20.**—(1) The contractor may, if the contractor's list of patients is open, accept a person as a temporary resident provided the contractor is satisfied that the person is—

- (a) temporarily resident away from their normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where that person is temporarily residing; or
- (b) moving from place to place and not for the time being resident in any place.

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

(3) Where a contractor wants to terminate its responsibility for a person accepted by it as a temporary resident before the end of—

- (a) three months; or
- (b) such shorter period for which the contractor agreed to accept that person as a temporary resident,

the contractor must give notice of that fact to the person either orally or in writing and the contractor's responsibility for that person is to cease seven days after the date on which notice is given.

(4) Where the contractor's responsibility for a person as a temporary resident comes to an end, the contractor must give notice in writing to the Board of its acceptance of that person as a temporary resident—

- (a) at the end of the period of three months beginning with the date on which the contractor accepted that person as a temporary resident; or
- (b) if the contractor's responsibility for that person as a temporary resident came to an end earlier than at the end of the three month period referred to in paragraph (a), at the end of that period.

### **Refusal of applications for inclusion in list of patients or for acceptance as temporary resident**

**21.**—(1) The contractor may only refuse an application made under paragraph 18 or 20 if the contractor has reasonable grounds for doing so which do not relate to the applicant's age, appearance, disability or medical condition, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sexual orientation or social class.

(2) The reasonable grounds referred to in sub-paragraph (1) may, in the case of an application made under paragraph 18, include the ground that the applicant—

- (a) does not live in the contractor's practice area; or
- (b) lives in the outer boundary area (the area referred to in regulation 20(3)).

(3) Where a contractor refuses an application made under paragraph 18 or 20, the contractor must give notice in writing of that refusal and the reasons for it to the applicant (or, in the case of a child or an adult who lacks capacity, to the person who made the application on their behalf) before the end of the period of 14 days beginning with the date of its decision to refuse.

- (4) The contractor must—
  - (a) keep a written record of—



- (i) the refusal of any application made under paragraph 18, and
  - (ii) the reasons for that refusal; and
- (b) make such records available to the Board on request.

### **Patient preference of a practitioner**

**22.**—(1) Where the contractor has accepted an application made under paragraph 18 or 20, the contractor must—

- (a) give notice in writing to the person (or, in the case of a child or an adult who lacks capacity, to the person who made the application on the applicant’s behalf) of that person’s right to express a preference to receive services from a particular performer or class of performer either generally or in relation to any particular condition; and
- (b) record in writing any such preference expressed by or on behalf of that person.

(2) The contractor must endeavour to comply with any reasonable preference expressed under sub-paragraph (1) but need not do so if the preferred performer—

- (a) has reasonable grounds for refusing to provide services to the person who expressed the preference; or
- (b) does not routinely perform the service in question within the contractor’s practice.

### **Removal from the list at the request of the patient**

**23.**—(1) The contractor must give notice in writing to the Board of a request made by any person who is a registered patient to be removed from the contractor’s list of patients.

(2) Where the Board—

- (a) receives a notice given by the contractor under sub-paragraph (1); or
- (b) receives directly a request from a person to be removed from the contractor’s list of patients,

the Board must remove that person from the contractor’s list of patients.

(3) The removal of a person from a contractor’s list of patients in accordance with sub-paragraph (2) takes effect on whichever is the earlier of—

- (a) the date on which the Board is given notice of the registration of that person with another provider of essential services (or their equivalent); or
- (b) 14 days after the date on which the notice given under sub-paragraph (1) or the request made under sub-paragraph (2) is received by the Board.

(4) The Board must, as soon as practicable, give notice in writing to—

- (a) the person who requested the removal; and
- (b) the contractor,

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

(5) In this paragraph, and in paragraphs 24(1)(b) and (10), 25(6) and (7), 27 and 30, a reference to a request received from or advice, information or notice required to be given to, a person includes a request received from or advice, information or notice required to be given to—

- (a) in the case of a child—
  - (i) either parent, or in the absence of both parents, the guardian or other adult who has care of the child,

- (ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989<sup>(167)</sup>, or
- (iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the Children Act 1989; or
- (b) in the case of an adult patient who lacks capacity to make the relevant request or receive the relevant advice, information or notice—
  - (i) a relative of that person,
  - (ii) the primary carer of that person,
  - (iii) a donee of a lasting power of attorney granted by that person, or
  - (iv) a deputy appointed for that person by the court under the Mental Capacity Act 2005<sup>(168)</sup>.

### **Removal from the list at the request of the contractor**

**24.**—(1) Subject to paragraph 25, where a contractor has reasonable grounds for wanting a person to be removed from its list of patients which do not relate to the person's age, appearance, disability or medical condition, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sexual orientation or social class the contractor must—

- (a) give notice in writing to the Board that it wants to have that person removed; and
- (b) subject to sub-paragraph (2), give notice in writing to that person of its specific reasons for requesting the removal of that person.
- (2) Where, in the reasonable opinion of the contractor—
  - (a) the circumstances of the person's removal are such that it is not appropriate for a more specific reason to be given; and
  - (b) there has been an irrevocable breakdown in the relationship between the relevant person and the contractor,

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

(3) Except in the circumstances specified in sub-paragraph (4), a contractor may only request the removal of a person from its list of patients under sub-paragraph (1) if, before the end of the period of 12 months beginning with the date of the contractor's request to the Board, the contractor has—

- (a) warned that person of the risk of being removed from that list; and
- (b) explained to that person the reasons for this.
- (4) The circumstances specified in this sub-paragraph are that—
  - (a) the reason for the removal relates to a change of address;
  - (b) the contractor has reasonable grounds for believing that the giving of such a warning would—
    - (i) be harmful to the person's physical or mental health, or
    - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (5); or
  - (c) the contractor considers that it is not otherwise reasonable or practical for a warning to be given.
- (5) The persons referred to in sub-paragraph (4) are—

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<sup>(167)</sup>1989 c.41.

<sup>(168)</sup>2005 c.9.

- (a) the contractor, where the contractor is an individual medical practitioner;
  - (b) in the case of a contract with two or more persons practising in a partnership, a partner in the partnership;
  - (c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company;
  - (d) a member of the contractor's staff;
  - (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
  - (f) any other person present—
    - (i) on the practice premises, or
    - (ii) in the place where services are being provided to the patient under the contract.
- (6) The contractor must keep a written record—
- (a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the person concerned; or
  - (b) the reason why no such warning was given.
- (7) The contractor must keep a written record of the removal of any person from its list of patients under this paragraph which must include—
- (a) the reason given for the removal;
  - (b) the circumstances of the removal; and
  - (c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate,

and the contractor must make this record available to the Board on request.

(8) The removal of a person from the contractor's list of patients must, subject to sub-paragraph (9), take effect from whichever is the earlier of—

- (a) the date on which the Board is given notice of the registration of that person with another provider of essential services (or their equivalent); or
- (b) the eighth day after the Board is given notice under sub-paragraph (1)(a).

(9) Where, on the date on which the removal of a person would take effect under sub-paragraph (8), the contractor is treating that person at intervals of less than seven days, the contractor must give notice in writing to the Board of that fact and the removal is to take effect on whichever is the earlier of—

- (a) the eighth day after the Board is given notice by the contractor that the person no longer needs such treatment; or
- (b) the date on which the Board is given notice of the registration of the person with another provider of essential services (or their equivalent).

(10) The Board must give notice in writing to—

- (a) the person in respect of whom the removal is requested; and
- (b) the contractor,

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

### **Removal from the list of patients who are violent**

**25.—**(1) Where a contractor wants a person to be removed from its list of patients with immediate effect on the grounds that—

- (a) the person has committed an act of violence against any of the persons specified in sub-paragraph (2) or has behaved in such a way that any of those persons has feared for their safety; and
  - (b) the contractor has reported the incident to the police,
- the contractor must give notice to the Board in accordance with sub-paragraph (3).
- (2) The persons specified in this sub-paragraph are—
- (a) the contractor, where the contractor is an individual medical practitioner;
  - (b) in the case of a contract with two or more persons practising in partnership, a partner in the partnership;
  - (c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company;
  - (d) a member of the contractor’s staff;
  - (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
  - (f) any other person present—
    - (i) on the contractor’s practice premises, or
    - (ii) in the place where services were provided to the person under the contract.
- (3) Notice under sub-paragraph (1) may be given by any means but, if not in writing, must subsequently be confirmed in writing before the end of a period of seven days beginning with the date on which notice was given.
- (4) The Board must acknowledge in writing receipt of a request for removal from the contractor under sub-paragraph (1).
- (5) A removal requested in accordance with sub-paragraph (1) takes effect at the time at which the contractor—
- (a) makes a telephone call to the Board; or
  - (b) sends or delivers the notice to the Board.
- (6) Where, under this paragraph, the contractor has given notice to the Board that it wants to have a person removed from its list of patients, the contractor must inform that person of that fact unless—
- (a) it is not reasonably practicable for the contractor to do so; or
  - (b) the contractor has reasonable grounds for believing that to do so would—
    - (i) be harmful to that person’s physical or mental health, or
    - (ii) put the safety of any person specified in sub-paragraph (2) at risk.
- (7) Where a person is removed from the contractor’s list of patients under this paragraph, the Board must give that person notice in writing of that removal.
- (8) The contractor must record the removal of any person from its list of patients under this paragraph and the circumstances leading to that removal in the medical records of the person removed.

### **Removal from the list of patients registered elsewhere**

- 26.—(1) The Board must remove a person from the contractor’s list of patients if—
- (a) the person has subsequently been registered with another provider of essential services (or their equivalent) in England; or

- (b) the Board has been given notice by a Local Health Board, a Health Board or a Health and Social Services Board that the person has subsequently been registered with a provider of essential services (or their equivalent) outside of England.
- (2) A removal in accordance with sub-paragraph (1) takes effect—
  - (a) on the date on which the Board is given notice of the person’s registration with the new provider; or
  - (b) with the consent of the Board, on such other date as has been agreed between the contractor and the new provider.
- (3) The Board must give notice in writing to the contractor of any person removed from its list of patients under sub-paragraph (1).

**Removal from the list of patients who have moved**

27.—(1) Subject to sub-paragraph (2), where the Board is satisfied that a person on the contractor’s list of patients has moved and no longer resides in the contractor’s practice area, the Board must—

- (a) inform both the person and the contractor that the contractor is no longer obliged to visit and treat that person;
- (b) advise the person in writing to either obtain the contractor’s agreement to that person’s continued inclusion on the contractor’s list of patients or to apply for registration with another provider of essential services (or their equivalent); and
- (c) inform the person that if, after the end of the period of 30 days beginning with the date on which the advice mentioned in paragraph (b) was given, that person has not acted in accordance with that advice and informed the Board accordingly, that person will be removed from the contractor’s list of patients.

(2) If, at the end of the period of 30 days mentioned in sub-paragraph (1)(c), the Board has not been informed by the person of the action taken, the Board must remove that person from the contractor’s list of patients and inform that person and the contractor of that removal.

**Removal from the list of patients whose address is unknown**

28. Where the address of a person who is on the contractor’s list of patients is no longer known to the Board, the Board must—

- (a) give notice in writing to the contractor that it intends, at the end of the period of six months beginning with the date on which the notice was given, to remove the person from the contractor’s list of patients; and
- (b) at the end of the period referred to in sub-paragraph (a), remove the person from the contractor’s list of patients unless, before the end of that period, the contractor satisfies the Board that the person is a patient to whom it is still responsible for providing essential services.

**Removal from the list of patients absent from the United Kingdom etc.**

29.—(1) The Board must remove a person from a contractor’s list of patients where it receives notice to the effect that the person—

- (a) intends to be away from the United Kingdom for a period of at least three months;
- (b) is in the armed forces of the Crown (except in the case of a patient to which paragraph 19 applies);

- (c) is serving a term of imprisonment of more than two years or more than one term of imprisonment totalling, in the aggregate, more than two years;
  - (d) has been absent from the United Kingdom for a period of more than three months; or
  - (e) has died.
- (2) The removal of a person from a contractor's list of patients under this paragraph takes effect from—
- (a) where sub-paragraph (1)(a) to (c) applies—
    - (i) the date of the person's departure, enlistment or imprisonment, or
    - (ii) the date on which the Board first receives notice of the person's departure, enlistment or imprisonment,
 whichever is the later; or
  - (b) where sub-paragraph (1)(d) and (e) applies, the date on which the Board is given notice of the person's absence or death.
- (3) The Board must give notice in writing to the contractor of the removal of any person from the contractor's list of patients under this paragraph.

#### **Removal from the list of patients accepted elsewhere as temporary residents**

- 30.**—(1) The Board must remove a person from a contractor's list of patients where the person has been accepted as a temporary resident by another contractor or other provider of essential services (or their equivalent) in any case where the Board is satisfied, after due inquiry, that—
- (a) the person's stay in the place of temporary residence has exceeded three months; and
  - (b) the person has not returned to their normal place of residence or to any other place within the contractor's practice area.
- (2) The Board must give notice in writing of the removal of a person from a contractor's list of patients under this paragraph—
- (a) to the contractor; and
  - (b) where practicable, to that person.
- (3) A notice given under sub-paragraph (2)(b) must inform the person of—
- (a) that person's entitlement to make arrangements for the provision to that person of essential services (or their equivalent), including by the contractor by which that person has been treated as a temporary resident; and
  - (b) the name, postal and electronic mail address and telephone number of the Board.

#### **Removal from the list of pupils etc. of a school**

- 31.**—(1) Where the contractor provides essential services under the contract to persons on the grounds that they are pupils at, or staff or residents of, a school, the Board must remove any person from a contractor's list of patients who does not appear on the particulars provided by that school of persons who are pupils at, or staff or residents of, that school.
- (2) Where the Board has requested a school to provide the particulars referred to in sub-paragraph (1) and has not received those particulars, the Board must consult the contractor as to whether it should remove from the contractor's list of patients any persons appearing in that list as pupils at, or staff or residents of, that school.
- (3) The Board must give notice in writing to the contractor of the removal of any person from the contractor's list of patients under this paragraph.

### **Termination of responsibility for patients not registered with the contractor**

**32.**—(1) Where the contractor has—

- (a) received an application for the provision of medical services other than essential services—
  - (i) from a person who is not included in the contractor’s list of patients,
  - (ii) from a person that the contractor has not accepted as a temporary resident, or
  - (iii) made on behalf of a person referred to in paragraph (i) or (ii) by a person specified in paragraph 18(4); and
- (b) accepted the person making the application or on whose behalf the application is made as a patient for the provision of the service in question,

the contractor’s responsibility for that person terminates in the circumstances described in sub-paragraph (2).

(2) The circumstances described in this sub-paragraph are that—

- (a) the contractor is informed that the person no longer wishes the contractor to be responsible for the provision of the service in question;
- (b) in a case where the contractor has reasonable grounds for terminating its responsibility to provide the service to the person which do not relate to the person’s age, appearance, disability or medical condition, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sexual orientation or social class, the contractor informs the person that it no longer wants to be responsible for providing that person with the service in question; or
- (c) it comes to the contractor’s attention that the person—
  - (i) no longer resides in the area for which the contractor has agreed to provide the service in question, or
  - (ii) is no longer included in the list of patients of another contractor to whose registered patients the contractor has agreed to provide that service.

(3) Where a contractor wants to terminate its responsibility for a person under sub-paragraph (2)(b), the contractor must give notice to that person of the termination and the reason for it.

(4) The contractor must keep a written record of terminations under this paragraph and of the reasons for those terminations and must make this record available to the Board on request.

(5) A termination under sub-paragraph (2)(b) takes effect—

- (a) where the grounds for termination are those specified in paragraph 25(1), from the date on which the notice is given; or
- (b) in any other case, 14 days after the date on which the notice is given.

## **PART 3**

### **Lists of patients: closure etc.**

#### **Application for closure of list of patients**

**33.**—(1) Where a contractor wants to close its list of patients, the contractor must send a written application to that effect (“the application”) to the Board.

(2) The application must include the following information—

- (a) the options which the contractor has considered, rejected or implemented in an attempt to alleviate the difficulties which the contractor has encountered in respect of its open list and, if any of the options were implemented, the level of success in reducing or extinguishing such difficulties;
  - (b) details of any discussions between the contractor and its patients and a summary of those discussions including whether or not, in the opinion of those patients, the list of patients should be closed;
  - (c) details of any discussions between the contractor and the other contractors in the contractor's practice area and a summary of the opinion of the other contractors as to whether or not the list of patients should be closed;
  - (d) the period of time, being a period of not less than three months and not more than 12 months, during which the contractor wants its list of patients to be closed;
  - (e) any reasonable support from the Board which the contractor considers would enable its list of patients to remain open or would enable the period of the proposed closure to be minimised;
  - (f) any plans which the contractor may have to alleviate the difficulties mentioned in the application during the period of the proposed closure in order for that list to re-open at the end of that period without the existence of those difficulties; and
  - (g) any other information which the contractor considers ought to be drawn to the attention of the Board.
- (3) The Board must acknowledge receipt of the application before the end of the period of seven days beginning with the date on which the Board received the application.
- (4) The Board must consider the application and may request such other information from the contractor as the Board requires in order to enable it to determine the application.
- (5) The Board must enter into discussions with the contractor concerning—
- (a) the support which the Board may give to the contractor; or
  - (b) any changes which the Board or the contractor may make,
- which would enable the contractor to keep its list of patients open.
- (6) The Board and the contractor must, throughout the period of the discussions referred to in sub-paragraph (5), use reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.
- (7) The Board or the contractor may, at any stage during the discussions, invite the Local Medical Committee (if any) for the area in which the contractor provides services under the contract to attend any meetings arranged between the Board and the contractor to discuss the application.
- (8) The Board may consult such persons as it appears to the Board may be affected by the closure of the contractor's list of patients and, if the Board does so, it must provide to the contractor a summary of the views expressed by those persons consulted in respect of the application.
- (9) The Board must enable the contractor to consider and comment on all the information before the Board makes a decision in respect of the application.
- (10) A contractor may withdraw the application at any time before the Board makes a decision in respect of that application.
- (11) The Board must, before the end of the period of 21 days beginning with the date on which the application was received by the Board (or within such longer period as the parties may agree), make a decision to—
- (a) approve the application and determine the date from which the closure of the contractor's list is to take effect; or



- (b) reject the application.
- (12) The Board must give notice in writing to the contractor of its decision to—
  - (a) approve the application in accordance with paragraph 34; or
  - (b) reject the application in accordance with paragraph 35.
- (13) A contractor may not submit more than one application to close its list of patients in any period of 12 months beginning with the date on which the Board makes its decision on the application unless—
  - (a) paragraph 36 applies; or
  - (b) there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

#### **Approval of an application to close a list of patients**

- 34.—**(1) Where the Board approves an application to close a contractor’s list of patients, the Board must—
- (a) give notice in writing to the contractor of its decision as soon as possible and the notice (“the closure notice”) must include the details specified in sub-paragraph (2); and
  - (b) at the same time as the Board gives notice to the contractor, send a copy of the closure notice to—
    - (i) the Local Medical Committee (if any) for the area in which the contractor provides services under the contract, and
    - (ii) any person who the Board consulted in accordance with paragraph 33(8).
- (2) The closure notice must include—
- (a) the period of time for which the contractor’s list of patients is to be closed which must be—
    - (i) the period specified in the application, or
    - (ii) where the Board and the contractor have agreed in writing to a different period, that different period,and, in either case, the period must not be less than three months and not more than 12 months;
  - (b) the date on which the closure of the list of patients is to take effect (“the closure date”); and
  - (c) the date on which the list of patients is to re-open.
- (3) Subject to paragraph 37, a contractor must close its list of patients with effect from the closure date and the list of patients must remain closed for the duration of the closure period as specified in the closure notice.

#### **Rejection of an application to close a list of patients**

- 35.—**(1) Where the Board rejects an application to close a contractor’s list of patients it must—
- (a) give notice in writing to the contractor of its decision as soon as possible, including the Board’s reasons for rejecting the application; and
  - (b) at the same time as it gives notice to the contractor, send a copy of the notice to—
    - (i) the Local Medical Committee (if any) for the area in which the contractor provides services under the contract, and
    - (ii) any person who the Board consulted in accordance with paragraph 33(8).

(2) Subject to sub-paragraph (3), if the Board rejects an application from a contractor to close its list of patients, the contractor must not make a further application to close its list of patients until whichever is the later of—

- (a) the end of the period of three months beginning with the date on which the Board's decision to reject the application was made; or
- (b) in a case where a dispute arising from the Board's decision to reject the application has been referred to the NHS dispute resolution procedure, the end of the period of three months beginning with the date on which a final determination to reject the application was made in accordance with that procedure (or any court proceedings).

(3) A contractor may make a further application to close its list of patients where there has been a change in the circumstances of the contractor which affects the contractor's ability to deliver services under the contract.

### **Application for an extension of a closure period**

**36.**—(1) A contractor may apply to extend the closure period by sending a written application (“the application”) to that effect to the Board no later than eight weeks before the date on which the closure period is due to expire.

(2) The application must include the following information—

- (a) details of the options which the contractor has considered, rejected or implemented in an attempt to alleviate the difficulties which have been encountered during the closure period or which may be encountered when the closure period expires;
- (b) the period of time during which the contractor wants its list of patients to remain closed (which may not be longer than 12 months);
- (c) details of any reasonable support from the Board which the contractor considers would enable the contractor's list of patients to re-open or would enable the proposed extension to the closure period to be minimised;
- (d) details of any plans which the contractor may have to alleviate the difficulties mentioned in the application to extend the closure period in order for the list of patients to re-open at the end of the proposed extension of that period without the existence of those difficulties; and
- (e) any other information which the contractor considers ought to be drawn to the attention of the Board.

(3) The Board must acknowledge receipt of the application before the end of the period of seven days beginning with the date on which the Board received the application.

(4) The Board must consider the application and may request such other information from the contractor as it requires in order to enable it to decide the application.

(5) The Board may enter into discussions with the contractor concerning—

- (a) the support which the Board may give to the contractor; or
- (b) any changes which the Board or the contractor may make,

which would enable the contractor to re-open its list of patients.

(6) The Board must determine the application before the end of the period of 14 days beginning with the date on which the Board received that application (or before the end of such longer period as the parties may agree).

(7) The Board must give notice in writing to the contractor of its decision to approve or reject the application to extend the closure period as soon as possible after making that decision.

(8) Where the Board approves an application, the Board must—

- (a) give notice in writing to the contractor of its decision (“the extended closure notice”) which must include the details referred to in sub-paragraph (9); and
  - (b) at the same time as it gives notice in writing to the contractor, send a copy of the extended closure notice to—
    - (i) the Local Medical Committee (if any) for the area in which the contractor provides services under the contract, and
    - (ii) any person who the Board consulted in accordance with paragraph 33(8).
- (9) The extended closure notice must include—
- (a) the period of time for which the contractor’s list of patients is to remain closed which must be—
    - (i) the period specified in the application, or
    - (ii) where the Board and contractor have agreed in writing a different period to the period specified in that application, that agreed period,and, in either case, the period (“the extended closure period”) must not be less than three months and not more than 12 months beginning with the date on which the extended closure period is to take effect;
  - (b) the date on which the extended closure period is to take effect; and
  - (c) the date on which the contractor’s list of patients is to re-open.
- (10) Where the Board rejects an application, it must—
- (a) give notice in writing to the contractor of its decision including its reasons for rejecting the application; and
  - (b) at the same time as it gives notice to the contractor, send a copy of the notice to the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.
- (11) Where an application is made in accordance with sub-paragraphs (1) and (2), the contractor’s list of patients is to remain closed pending whichever is the later of—
- (a) the determination by the Board of that application; or
  - (b) in a case where a dispute arising from the Board’s decision to reject the application to extend the closure period has been referred to the NHS dispute resolution procedure, the contractor ceasing to pursue that dispute through that procedure (or any court proceedings).

### **Re-opening of list of patients**

**37.** The contractor may re-open its list of patients before the expiry of the closure period if the Board and the contractor agree that the contractor should do so.

## **PART 4**

### **Assignment of patients to lists**

#### **Application of this Part**

**38.** This Part applies in respect of the assignment by the Board of a person as a new patient to a contractor’s list of patients where that person—

- (a) has been refused inclusion in a contractor’s list of patients or has not been accepted as a temporary resident by a contractor; and

- (b) would like to be included in the list of patients of a contractor in whose outer boundary area (as specified in accordance with regulation 20(1)(d)) that person resides.

#### **Assignment of patients to list of patients: open and closed lists**

- 39.**—(1) Subject to paragraph 40, the Board may—
- (a) assign a new patient to a contractor whose list of patients is open; and
  - (b) only assign a new patient to a contractor whose list of patients is closed in the circumstances specified in sub-paragraph (2).
- (2) The circumstances specified in this sub-paragraph are where—
- (a) the assessment panel has determined under paragraph 41(7) that new patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Secretary of State under paragraph 42(13) or (where applicable) by a court; and
  - (b) the Board has entered into discussions with the contractor in question regarding the assignment of new patients if such discussions are required under paragraph 43.

#### **Factors relevant to assignments**

**40.** When assigning a person as a new patient to a contractor's list of patients under paragraph 39(1)(a) or (b), the Board must have regard to—

- (a) the preferences and circumstances of the person;
- (b) the distance between the person's place of residence and the contractor's practice premises;
- (c) any request made by a contractor to remove the person from its list of patients within the preceding period of six months beginning with the date on which the application for assignment is received by the Board;
- (d) whether, during the preceding period of six months beginning with the date on which the application for assignment is received by the Board, the person has been removed from a list of patients on the grounds referred to in—
  - (i) paragraph 24 (relating to the circumstances in which a person may be removed from a contractor's list of patients at the request of the contractor),
  - (ii) paragraph 25 (relating to the removal from the contractor's list of patients of persons who are violent), or
  - (iii) the equivalent provisions to those paragraphs in relation to arrangements made under section 83(2)(**169**) of the Act or section 92(**170**) of the Act (which relate to arrangements for the provision of primary medical services);
- (e) in a case to which sub-paragraph (d)(ii) applies (or equivalent provisions as mentioned in sub-paragraph (d)(iii) apply), whether the contractor has appropriate facilities to deal with such patients; and
- (f) such other matters as the Board considers relevant.

#### **Assignments to closed lists: composition and determinations of the assessment panel**

**41.**—(1) Where the Board wants to assign a new patient to a contractor which has closed its lists of patients, the Board must prepare a proposal to be considered by the assessment panel.

- (2) The Board must give notice in writing to—

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(**169**) Section 83 was amended by paragraph 30 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act").

(**170**) Section 92 was amended by paragraph 36 of Schedule 4 to the 2012 Act.

- (a) contractors, including those contractors who provide primary medical services under arrangements made under section 83(2) of the Act(171) or 92 of the Act (which relate to arrangements for the provision of primary medical services) which—
  - (i) have closed their lists of patients, and
  - (ii) may, in the opinion of the Board, be affected by the determination of the assessment panel; and
- (b) the Local Medical Committee (if any) for the area in which the contractors referred to in paragraph (a) provide essential services (or their equivalent),

that it has referred the matter to the assessment panel.

(3) The Board must ensure that the assessment panel is appointed to consider and determine the proposal made under sub-paragraph (1), and the composition of the assessment panel must be as described in sub-paragraph (4).

(4) The members of the assessment panel must be—

- (a) a member of the Board who is a director;
- (b) a patient representative who is a member of the Local Health and Wellbeing Board(172) or Local Healthwatch organisation(173);
- (c) a member of a Local Medical Committee, but not a member of the Local Medical Committee (if any) for the area in which the contractors who may be assigned patients as a consequence of the assessment panel's determination provide services.

(5) In reaching its determination, the assessment panel must have regard to all relevant factors including—

- (a) whether the Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of assignment to a contractor with a closed list; and
- (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.

(6) The assessment panel must reach a determination before the end of the period of 28 days beginning with the date on which the panel was appointed.

(7) The assessment panel must—

- (a) determine whether the Board may assign new patients to a contractor which has a closed list of patients; and
- (b) if it determines that the Board may make such an assignment, determine, where there is more than one contractor, the contractors to which patients may be assigned.

(8) The assessment panel may determine that the Board may assign new patients to contractors other than any of the contractors specified in its proposals under sub-paragraph (1), as long as the contractors were given notice in writing under sub-paragraph (2)(a).

(9) The assessment panel's determination must include its comments on the matters referred to in sub-paragraph (5), and notice in writing of that determination must be given to those contractors referred to in sub-paragraph (2)(a).

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(171) Section 151 was amended by paragraph 79 of Schedule 4 to the 2012 Act.

(172) See section 194 of the 2012 Act which requires a local authority to establish a Health and Wellbeing Board for its area.

(173) Local Healthwatch organisations are bodies corporate with which a local authority may enter into arrangements under section 222 of the Local Government and Public Involvement in Health Act 2007 (c.28) for the purpose of discharging their functions. Section 222 was amended by section 183 of, and Schedules 5 and 14 to, the Health and Social Care Act 2012 (c.7).

### **Assignment to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel**

42.—(1) Where an assessment panel makes a determination under paragraph 41(7)(a) that the Board may assign new patients to contractors who have closed their lists of patients, any contractor specified in the determination may refer the matter to the Secretary of State to review that determination.

(2) Where a matter is referred to the Secretary of State under sub-paragraph (1), it must be reviewed in accordance with the procedure specified in the following sub-paragraphs.

(3) Where more than one contractor specified in the determination would like to refer the matter for dispute resolution, those contractors may, if they all agree, refer the matter jointly and, in that case, the Secretary of State must review the matter in relation to those contractors together.

(4) The contractor (or contractors) must send to the Secretary of State, before the end of the period of seven days beginning with the date of the determination of the assessment panel in accordance with paragraph 41(7), 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 (or contracts); and
- (c) a brief statement describing the nature of and circumstances giving rise to the dispute.

(5) The Secretary of State must, before the end of the period of seven days beginning with the date on which the matter was referred to the Secretary of State—

- (a) give notice in writing to the parties that the Secretary of State is dealing with the matter; and
- (b) include with the notice a written request to the parties to make, in writing before the end of a specified period, any representations which those parties would like to make about the dispute.

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

(7) The Secretary of State must, upon receiving any representations from a party—

- (a) give a copy of those representations to each other party; and
- (b) request, in writing, that each party to which a copy of those representations is given makes, before the end of a specified period, any written observations which the party would like to make about those representations.

(8) The Secretary of State may—

- (a) invite representatives of the parties to appear before, and make oral representations to, the Secretary of State either together or, with the agreement of the parties, separately, and may, in advance, provide the parties with a list of matters or questions to which the Secretary of State would like them to give special consideration; or
- (b) consult other persons whose expertise the Secretary of State considers is likely to assist the Secretary of State's consideration of the dispute.

(9) Where the Secretary of State consults another person under sub-paragraph (8)(b), the Secretary of State must—

- (a) give notice in writing to that effect to the parties; and
- (b) where the Secretary of State considers that the interests of any party might be substantially affected by the results of the consultation, give to the parties such opportunity as the

Secretary of State considers reasonable in the circumstances to make observations about those results.

- (10) In considering the dispute, the Secretary of State must take into account—
- (a) any written representations made in response to a request under sub-paragraph (5)(b), but only if those representations are made before the end of the specified period;
  - (b) any written observations made in response to a request under sub-paragraph (7), but only if those written observations are made before the end of the specified period;
  - (c) any oral representations made in response to an invitation under sub-paragraph (8)(a);
  - (d) the results of any consultation under sub-paragraph (8)(b); and
  - (e) any observations made in accordance with an opportunity given under sub-paragraph (9).

(11) Subject to the other provisions of this paragraph and to any agreement between the parties, the Secretary of State may determine the procedure which is to apply to the dispute resolution in such manner as the Secretary of State considers appropriate in order to ensure the just, expeditious, economical and final determination of the dispute.

- (12) In this paragraph, “specified period” means—
- (a) such period as the Secretary of State specifies in the request being a period of not less than one week and not more than two 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 for the determination of the dispute where the period for determination of the dispute has been extended in accordance with sub-paragraph (16), and where the Secretary of State does so allow, a reference in this paragraph to the specified period is to the period as so extended.

- (13) Subject to sub-paragraph (16), the Secretary of State must—
- (a) determine the dispute before the end of the period of 21 days beginning with the date on which the matter was referred to the Secretary of State;
  - (b) determine whether the Board may assign new patients to contractors which have closed their lists of patients; and
  - (c) if the Secretary of State determines that the Board may assign new patients to such contractors, determine the contractors to which such new patients may be assigned.

(14) The Secretary of State must not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 41(7)(b).

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

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

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

- (17) The Secretary of State must—
- (a) record the determination, and the reasons for it, in writing; and
  - (b) give notice in writing of the determination (including the record of the reasons) to the parties.

### **Assignments to closed lists: assignments of patients by the Board**

**43.**—(1) Before the Board assigns a new patient to a contractor, the Board must, subject to sub-paragraph (3)—

- (a) enter into discussions with the contractor regarding the additional support that the Board can offer the contractor; and
- (b) use its best endeavours to provide such appropriate support.

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

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

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

## **PART 5**

### **Sub-contracting**

#### **Sub-contracting of clinical matters**

**44.**—(1) Subject to sub-paragraph (2), the contractor must not sub-contract any of its rights or duties under the contract in relation to clinical matters to any person unless—

- (a) in all cases, including those duties relating to out of hours services to which paragraph 45 applies, it has taken reasonable steps to satisfy itself that—
  - (i) it is reasonable in all the circumstances to do so, and
  - (ii) the person to whom any of those rights or duties is sub-contracted is qualified and competent to provide the service; and
- (b) except in cases to which paragraph 45 applies, the contractor has given notice in writing to the Board of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into effect.

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

(3) A notice given under sub-paragraph (1)(b) must include—

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

(4) On receipt of a notice given under sub-paragraph (1)(b), the Board may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the contractor must supply such information to the Board promptly.

(5) The contractor must not proceed with a sub-contract or, if the sub-contract has already taken effect, the contractor must take steps to terminate it, where—



- (a) the Board gives notice in writing of its objection to the sub-contract on the grounds that the sub-contract would—
    - (i) put the safety of the contractor’s patients at serious risk, or
    - (ii) put the Board at risk of material financial loss,and notice is given by the Board before the end of the period of 28 days beginning with the date on which the Board received a notice from the contractor under sub-paragraph (1) (b); or
  - (b) the sub-contractor would be unable to meet the contractor’s obligations under the contract.
- (6) A notice given by the Board under sub-paragraph (5)(a) must include a statement of the reasons for the Board’s objection.
- (7) Sub-paragraphs (1) and (3) to (6) also apply in relation to any renewal or material variation of a sub-contract in relation to clinical matters.
- (8) Where the Board does not give notice of an objection under sub-paragraph (5), the parties to the contract are deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises any premises the address of which was notified to the Board under sub-paragraph (3)(d) and, in these circumstances, paragraph 57(1) of Schedule 3 does not apply.
- (9) A sub-contract entered into by a contractor must prohibit the sub-contractor from sub-contracting any of the clinical services that it has agreed with the contractor to provide under the sub-contract.
- (10) The contractor must not sub-contract any of its rights or duties under the contract in relation to the provision of essential services to a company or firm that is—
  - (a) wholly or partly owned by the contractor, or by any former or current employee of, or partner or shareholder in, the contractor;
  - (b) formed by or on behalf of the contractor, or from which the contractor derives or may derive a pecuniary benefit; or
  - (c) formed by or on behalf of a former or current employee of, or partner or shareholder in, the contractor, or from which such a person derives or may derive a pecuniary benefit,where sub-paragraph (11) applies to that company or firm.
- (11) This sub-paragraph applies to a company or firm which is or was formed wholly or partly for the purpose of avoiding the restrictions on the sale of goodwill of a medical practice in section 259 of the Act(174) (sale of medical practices), and Schedule 21 to the Act (prohibition of sale of medical practices), or any regulations made wholly or partly under those provisions of the Act.

### **Sub-contracting out of hours services**

- 45.—**(1) A contractor must not sub-contract all or part of its duty to provide out of hours services under the contract to a person other than those specified in sub-paragraph (2) without the prior written approval of the Board.
- (2) The persons specified in this sub-paragraph are—
  - (a) a person who holds a general medical services contract with the Board which includes out of hours services;
  - (b) a section 92 provider who is required to provide the equivalent of essential services to its patients during all or part of the out of hours period;
  - (c) a health care professional, not falling within paragraph (a) or (b), who is to provide the out of hours services personally under a contract for services; or

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(174) Section 259 was amended by paragraph 131 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

(d) a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota agreements.

(3) The requirement in sub-paragraph (1) to obtain prior written approval does not apply in any case where a contractor sub-contracts all or part of its duty to provide out of hours services under the contract on a short term or occasional basis.

(4) An application for approval under sub-paragraph (1) may be made by the contractor in writing to the Board and must state—

- (a) the name and address of the proposed sub-contractor;
- (b) the address of any premises to be used for the provision of services under the sub-contract;
- (c) the duration of the proposed sub-contract;
- (d) the services to be covered by the sub-contract; and
- (e) the manner in which the sub-contractor proposes to meet the contractor's obligations under the contract in respect of the services to be covered by the sub-contract.

(5) The Board may request such further information relating to arrangements under the proposed sub-contract as appears to it to be reasonable before the end of the period of seven days beginning with the date on which the Board received the application under sub-paragraph (4).

(6) Where the Board receives an application which meets the requirements specified in sub-paragraph (4), or receives any further information requested under sub-paragraph (5) in relation to an application, the Board must, before the end of the period of 28 days beginning with the date on which it received the application or that information (whichever is the latest)—

- (a) approve the application;
- (b) approve the application subject to conditions; or
- (c) refuse the application.

(7) The Board must not refuse the application if it is satisfied that the arrangements covered by the proposed sub-contract would, in respect of the services to be provided, enable the contractor to satisfactorily meet its obligations under the contract and would not—

- (a) put the safety of the contractor's patients at serious risk; or
- (b) put the Board at risk of material financial loss.

(8) The Board must give notice in writing to the contractor of its decision on the application and, where it refuses an application, it must include in the notice a statement of the reasons for its refusal.

(9) Where the Board approves an application under this paragraph, the parties to the contract are deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises, for the purposes of the provision of services in accordance with that application, any premises the address of which was notified to the Board under sub-paragraph (4)(b) and, in these circumstances, paragraph 57(1) of Schedule 3 does not apply.

(10) Sub-paragraphs (1) to (9) also apply in relation to any renewal or material variation of a sub-contract in relation to out of hours services.

(11) A sub-contract entered into by a contractor must prohibit the sub-contractor from sub-contracting the out of hours services that it has agreed with the contractor to provide under the sub-contract.

#### **Withdrawal and variation of approval under paragraph 45**

**46.**—(1) Subject to paragraph 47, where the Board approves an application made under paragraph 45, the Board may subsequently give notice in writing to the contractor withdrawing or varying that approval from a date specified in the notice if it is no longer satisfied that the arrangements

covered by the sub-contract would enable the contractor to satisfactorily meet its obligations under the contract.

(2) The date specified in the notice given under sub-paragraph (1) may be such date as appears to the Board to be reasonable in all the circumstances.

(3) A notice given under sub-paragraph (1) takes effect on whichever is the later of—

- (a) the date specified in the notice; or
- (b) in a case where a dispute arising in relation to the notice given by the Board under sub-paragraph (1) is referred to the NHS dispute resolution procedure, the date of the final determination of the dispute under that procedure (or any court proceedings) in favour of the Board.

(4) This paragraph does not affect any other remedies which the Board may have under the contract.

### **Withdrawal or variation of approval with immediate effect**

47.—(1) Where the Board approves an application made under paragraph 45, the Board may subsequently give notice in writing to the contractor withdrawing or varying that approval with immediate effect if the Board is—

- (a) no longer satisfied that the arrangements covered by the sub-contract would enable the contractor to satisfactorily meet its obligations under the contract; and
- (b) satisfied that the immediate withdrawal or variation of the approval is necessary to protect the safety of the contractor's patients.

(2) A notice given under sub-paragraph (1) takes effect on the date on which it is received by the contractor.

(3) This paragraph does not affect any other remedies which the Board may have under the contract.

## **PART 6**

### **Provision of information: practice leaflet**

#### **Information to be included in practice leaflets**

48. A practice leaflet must include—

- (a) the name of the contractor;
- (b) the address of each of the contractor's practice premises;
- (c) the contractor's telephone and fax number and its website address (if any);
- (d) in the case of a contract with a partnership—
  - (i) whether or not the partnership is a limited partnership, and
  - (ii) the names of all the partners in the partnership and, in the case of a limited partnership, the status of the partners as either a general or a limited partner;
- (e) in the case of a contract with a company limited by shares—
  - (i) the names of the directors, the company secretary and the shareholders of that company, and
  - (ii) the address of the company's registered office;
- (f) the full name of each person performing services under the contract;

- (g) the professional qualifications of each health care professional providing services under the contract;
- (h) whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals;
- (i) the contractor's practice area, including the area known as the outer boundary area (within the meaning given by regulation 20(3)) by reference to a sketch diagram, plan or postcode;
- (j) the access arrangements which the contractor's premises has for providing services to disabled patients and, if none, the alternative arrangements for providing services to such patients;
- (k) how to register as a patient;
- (l) information about the assignment by the contractor to its new and existing patients of an accountable GP in accordance with paragraph 8;
- (m) information about the assignment by the contractor to its patients aged 75 and over of an accountable GP in accordance with paragraph 11;
- (n) the right of patients to express a preference of practitioner in accordance with paragraph 22 and the means of expressing such a preference;
- (o) the services available under the contract;
- (p) the opening hours of the practice premises and the method of obtaining access to services throughout the core hours;
- (q) the criteria for home visits and the method of obtaining such visits;
- (r) the consultations available to patients under paragraphs 9 and 10;
- (s) the arrangements for services in the out of hours period (whether or not provided by the contractor) and how the patient may access such services;
- (t) if services during the out of hours period are not provided by the contractor, the fact that the Board is responsible for the commissioning of those services;
- (u) the method by which patients may obtain repeat prescriptions;
- (v) if the contractor offers repeatable prescribing services, the arrangements for providing such services;
- (w) if the contractor is a dispensing contractor, the arrangements for dispensing prescriptions;
- (x) how patients may make a complaint or comment on the provision of services;
- (y) the rights and responsibilities of the patient, including keeping appointments;
- (z) the action that may be taken under paragraph 25 where a patient is violent or abusive to the contractor, the contractor's staff, persons present on the practice premises or in the place where treatment is provided under the contract;
- (aa) details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information;
- (bb) the full name, postal and electronic mail address and telephone number of the Board.

## PART 7

### Notice requirements and rights of entry

#### Notices to the Board

**49.**—(1) In addition to any requirements to give notice elsewhere in these Regulations, the contractor must give notice in writing to the Board as soon as reasonably practicable of—

- (a) any serious incident that, in the reasonable opinion of the contractor, affects or is likely to affect the contractor's performance of its obligations under the contract;
- (b) any circumstances which give rise to the Board's right to terminate the contract under paragraph 65, 66 or 67;
- (c) any appointments system which the contractor proposes to operate and the proposed discontinuance of any such system;
- (d) any change in the address of a registered patient of which the contractor is aware; and
- (e) the death of any patient of which the contractor is aware.

(2) The contractor must give notice in writing to the Board about any person, other than a registered patient or a person whom the contractor has accepted as a temporary resident, to whom the contractor has provided essential services in the form of immediately necessary treatment as described in regulation 17(7) or (9).

(3) The contractor must give notice to the Board under sub-paragraph (2) before the end of the period of 28 days beginning with the date on which the services described in that sub-paragraph were provided.

#### Notice provisions specific to a contract with a company limited by shares

**50.**—(1) Where a contractor is a company limited by shares, the contractor must give notice in writing to the Board as soon as—

- (a) any share in the company is transmitted or transferred (whether legally or beneficially) to another person on a date after the date on which the contract was entered into;
- (b) a new director or secretary of the company is appointed;
- (c) circumstances arise which may entitle a creditor or a court to appoint a receiver, administrator or administrative receiver in respect of the company;
- (d) circumstances arise which would enable the court to make a winding up order in respect of the company;
- (e) a company resolution is passed, or a court of competent jurisdiction makes an order, that the company is to be wound up; or
- (f) the company is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986<sup>(175)</sup> (definition of inability to pay debts).

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

- (a) is—
  - (i) a medical practitioner, or

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<sup>(175)</sup> 1986 c.45. Section 123 was modified by section 90 of, and Schedule 15 to, the Building Societies Act 1986 (c.53), and by section 23 of, and Schedule 10 to, the Friendly Societies Act 1992 (c.40).

- (ii) a person who satisfies the conditions specified in section 86(2)(b)(i) to (iv) of the Act(176) (persons eligible to enter into GMS contracts); and
  - (b) meets the further conditions imposed on shareholders by virtue of regulations 5 and 6.
- (3) A notice under sub-paragraph (1)(b) must confirm that the new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 6.

### **Notice provisions specific to a contract with two or more individuals practising in a partnership**

**51.**—(1) Where a contractor is a partnership, the contractor must give notice in writing to the Board as soon as—

- (a) any partner in the partnership—
  - (i) leaves the partnership, or
  - (ii) informs the other partners in the partnership that they intend to leave the partnership;
 or
- (b) a new partner joins the partnership.

(2) A notice under sub-paragraph (1)(a) must confirm the date on which the partner left or proposes to leave the partnership.

(3) A notice under sub-paragraph (1)(b) must—

- (a) state the date on which the new partner joined the partnership;
- (b) confirm that the new partner is—
  - (i) a medical practitioner, or
  - (ii) a person who satisfies the conditions specified in section 86(2)(b)(i) to (iv) of the Act (persons eligible to enter into GMS contracts);
- (c) confirm that the new partner meets the conditions imposed by regulations 5 and 6; and
- (d) state whether the new partner is a general or a limited partner in the partnership.

### **Notice of deaths**

**52.**—(1) The contractor must give notice in writing to the Board of the death on its practice premises of a patient no later than the end of the first working day after the day on which that death occurred.

(2) The notice given under sub-paragraph (1) must include—

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

### **Notices given to patients following variation of the contract**

**53.**—(1) This paragraph applies where a contract is varied in accordance with regulation 29 and Part 8 of this Schedule and, as a result of that variation—

- (a) there is to be a change in the range of services provided to the contractor’s registered patients; or
  - (b) patients who are on the contractor’s list of patients are to be removed from that list.
- (2) Where this paragraph applies, the Board must—
- (a) give notice in writing to those patients of the variation and of its effect; and
  - (b) inform those patients of the steps that they may take to—
    - (i) obtain the services in question elsewhere, or
    - (ii) register elsewhere for the provision to them of essential services (or their equivalent).

### **Entry and inspection by the Board**

**54.**—(1) Subject to the conditions specified in sub-paragraph (2), the contractor must allow any person authorised in writing by the Board to enter and inspect the contractor’s practice premises at any reasonable time.

- (2) The conditions specified in this sub-paragraph are that—
- (a) reasonable notice of the intended entry has been given;
  - (b) written evidence of the authority of the person seeking entry is produced to the contractor on request; and
  - (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) The contractor or the Board or a person authorised in writing by the Board may invite the Local Medical Committee (if any) for the area in which the contractor provides services under the contract to be present at any inspection of the contractor’s practice premises which takes place under this paragraph.

### **Entry and inspection by the Care Quality Commission**

**55.** The contractor must allow persons authorised by the Care Quality Commission to enter and inspect the contractor’s practice premises in accordance with section 62 of the Health and Social Care Act 2008(177) (entry and inspection).

### **Entry and inspection by Local Healthwatch organisations**

**56.** The contractor must comply with the requirement to allow an authorised representative to enter and view premises and observe the carrying on of activities on those premises in accordance with regulations made under section 225 of the Local Government and Public Involvement in Health Act 2007(178) (duties of services-providers to allow entry by Local Healthwatch organisations or contractors).

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(177)2008 c.14.

(178)2007 c.28. See section 225(5) of that Act for the meaning of “authorised representative”. Section 225 was amended by section 179 of, and Schedule 14 to, the Health and Social Care Act 2014 (c.7) (“the 2012 Act”); section 186(6) to (11) of the 2012 Act; and paragraphs 148 to 151 of Schedule 5 to the 2012 Act.

## PART 8

### Variation and termination of contracts

#### Variation: general

**57.**—(1) Subject to Part 6, and to paragraphs 44(8), 45(9), 58, 59 and 72, a variation of, or amendment to, a contract is not effective unless it is made in writing and signed by or on behalf of the Board and the contractor.

(2) The Board may vary a contract without the contractor's consent where—

- (a) it is reasonably satisfied that the variation is necessary in order to comply with the Act, any regulations made under or by virtue of the Act or any direction given by the Secretary of State under or by virtue of the Act; and
- (b) it gives notice in writing to the contractor of the wording of the proposed variation and the date on which that variation is to take effect.

(3) The date on which the proposed variation referred to in sub-paragraph (2)(b) is to take effect must, unless it is not reasonably practicable, be a date which falls at least 14 days after the date on which notice under that sub-paragraph is given to the contractor.

#### Variation provisions specific to a contract with an individual medical practitioner

**58.**—(1) Where a contractor who is an individual medical practitioner proposes to practise in partnership with one or more persons, the contractor must give notice in writing to the Board of—

- (a) the name of the person or persons with whom the contractor proposes to practise in partnership; and
- (b) the date on which the contractor would like to change its status as a contractor from that of an individual medical practitioner to that of a partnership, which must be at least 28 days after the date on which the contractor gives notice to the Board under this sub-paragraph.

(2) A notice given under sub-paragraph (1) must—

- (a) in respect of each person with whom the contractor is proposing to practise in partnership confirm that the person—
  - (i) is either—
    - (aa) a medical practitioner, or
    - (bb) a person who satisfies the conditions specified in section 86(2)(b)(i) to (iv) of the Act(179) (persons eligible to enter into GMS contracts); and
  - (ii) satisfies the conditions imposed by regulations 5 and 6; and
- (b) state whether the partnership is to be a general partnership or a limited partnership and give the names of the limited partners and the general partners in the partnership.

(3) A notice given under sub-paragraph (1) must be signed by the individual medical practitioner and by the person, or each of the persons, with whom the practitioner is proposing to practise in partnership.

(4) The contractor must ensure that any person with whom it is to practise in partnership is bound by the contract, whether by virtue of a partnership deed or otherwise.

(5) If the Board is satisfied as to the accuracy of the matters specified in a notice given under sub-paragraph (1), the Board must give notice in writing to the contractor confirming that the contract

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(179) Section 86 was amended by section 202(1) of, and paragraph 32 of Schedule 4 to, the Health and Social Care Act 2012 (c.7).



is to continue with the partnership entered into by the contractor and its partners, from a date that the Board specifies in the notice.

- (6) The date to be specified by the Board under sub-paragraph (5) is—
- (a) the date requested in the notice given by the contractor under sub-paragraph (1); or
  - (b) where that date is not reasonably practicable, a date that is as close as is reasonably practicable to the requested date.

(7) Where the contractor has given notice to the Board under sub-paragraph (1), the Board may vary the contract but only to the extent that the Board is satisfied is necessary to reflect the change in the status of the contractor from that of an individual medical practitioner to a partnership.

(8) If, under sub-paragraph (7), the Board proposes to vary the contract, it must include in the notice given to the contractor under sub-paragraph (5) the wording of the proposed variation and the date upon which that variation is to take effect.

### **Variation provisions specific to a contract with two or more persons practising in partnership**

**59.**—(1) Subject to sub-paragraph (4), where a contractor consists of two or more persons practising in partnership and that partnership is terminated or dissolved, the contract may only continue with one of the former partners if that partner is—

- (a) nominated in accordance with sub-paragraph (3); and
- (b) a medical practitioner who satisfies the condition in regulation 5(1)(a),

and only if the requirements in sub-paragraphs (2) and (3) are met.

(2) A contractor must give notice in writing to the Board of the intention to change its status from that of a partnership to that of an individual medical practitioner under sub-paragraph (1) at least 28 days before the date on which the contractor proposes to change its status.

- (3) A notice given under sub-paragraph (2) must—
- (a) specify the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner;
  - (b) specify the name of the medical practitioner with whom the contract is to continue, which must be one of the partners in the partnership; and
  - (c) be signed by each partner in the partnership.

(4) Where a contractor consists of two persons practising in partnership and the partnership is terminated or dissolved because one of the partners has died, the remaining partner in the partnership must give notice in writing to the Board of that death as soon as is reasonably practicable and, in that case, sub-paragraphs (5) and (6) apply.

(5) If the remaining partner in the partnership is a general medical practitioner, the contract is to continue with that general medical practitioner.

- (6) If the remaining partner in the partnership is not a general medical practitioner, the Board—
- (a) must enter into discussions with that partner and use reasonable endeavours to reach an agreement to enable the provision of clinical services to continue under the contract;
  - (b) may, if it considers it appropriate, consult the Local Medical Committee (if any) for the area in which the partnership was providing clinical services under the contract or such other person as the Board considers necessary;
  - (c) may, if it considers it appropriate to enable the provision of clinical services under the contract to continue, offer the remaining partner in the partnership reasonable support; and

- (d) must give notice to the remaining partner in the partnership if agreement has been reached in accordance with sub-paragraph (7) or, in the event that agreement cannot be reached, in accordance with sub-paragraph (8).

(7) If the Board reaches an agreement, the Board must give notice in writing to the remaining partner in the partnership confirming—

- (a) the terms upon which the Board agrees to the contract continuing with that partner including the period, as specified by the Board, during which the contract is to continue (“the interim period”) and such a period must not exceed six months;
- (b) that the partner agrees to the employment or engagement of a general medical practitioner for the interim period to assist in the provision of clinical services under the contract; and
- (c) the support, if any, which the Board is to provide to enable the provision of clinical services under the contract to continue during the interim period.

(8) If—

- (a) the remaining partner in the partnership does not wish to employ or engage a medical practitioner;
- (b) an agreement in accordance with sub-paragraph (6) cannot be reached; or
- (c) the remaining partner in the partnership would like to withdraw from the agreed arrangements at any stage during the interim period,

the Board must give notice in writing to that partner terminating the contract with immediate effect.

(9) If, at the end of the interim period, the contractor has not entered into partnership with a general medical practitioner who is not a limited partner in the partnership, the Board must give notice in writing to the contractor terminating the contract with immediate effect.

(10) Where a contractor gives notice to the Board under sub-paragraph (2) or (4), the Board must—

- (a) acknowledge receipt of the notice in writing; and
- (b) in relation to a notice given under sub-paragraph (2), acknowledge receipt of the notice before the date specified in accordance with sub-paragraph (3)(a).

(11) Where a contractor gives notice to the Board under sub-paragraph (2) or (4), the Board may vary the contract but only to the extent that it is satisfied is necessary to reflect the change in status of the contractor from that of a partnership to an individual medical practitioner.

(12) If the Board varies the contract under sub-paragraph (11), the Board must give notice in writing to the contractor of the wording of the proposed variation and the date upon which that variation is to take effect.

(13) In this paragraph “general medical practitioner” has the same meaning as in regulation 5(2).

(14) Sub-paragraphs (5) to (9) do not affect any other right which the Board may have under the contract to vary or terminate the contract.

### **Termination by agreement**

**60.** The Board and the contractor may agree in writing to terminate the contract, and if the parties so agree, they must agree the date upon which that termination is to take effect and any further terms upon which the contract is to be terminated.

### **Termination on the death of an individual medical practitioner**

**61.**—(1) Where the contractor is an individual medical practitioner and the contractor dies, the contract terminates at the end of the period of seven days beginning with the date of the contractor’s death unless, before the end of that period sub-paragraph (2) applies.

(2) This sub-paragraph applies where—

- (a) the Board agrees in writing with the contractor’s personal representatives that the contract is to continue for a further period, not exceeding 28 days, from the end of the period of seven days; and
- (b) the contractor’s personal representatives confirm in writing to the Board that they wish to employ or engage one or more general medical practitioners to assist in the continuation of the provision of clinical services under the contract and, after discussion with the Board—
  - (i) the Board agrees to provide reasonable support which would enable clinical services under the contract to continue,
  - (ii) the Board and the contractor’s personal representatives agree the terms on which the provision of clinical services can continue,
  - (iii) the Board and the contractor’s personal representatives agree the period during which clinical services must be provided being a period of not more than 28 days beginning on the day after the end of the period of seven days referred to in sub-paragraph (1).

(3) This paragraph does not affect any other rights to terminate the contract which the contractor may have.

### **Termination by the contractor**

**62.**—(1) A contractor may terminate the contract at any time by giving notice in writing to the Board.

(2) Where a contractor gives notice to the Board under sub-paragraph (1), the contract terminates six months after the date on which the notice was given (“the termination date”) unless the termination date does not fall on the last calendar day of a month, in which case the contract terminates instead on the last calendar day of the month in which the termination date falls.

(3) If the contractor is an individual medical practitioner, sub-paragraph (2) applies to the contractor as if the references to “six months” were instead references to “three months”.

(4) This paragraph does not affect any other rights to terminate the contract that the contractor may have.

### **Late payment notices**

**63.**—(1) The contractor may give notice in writing (a “late payment notice”) to the Board if the Board has failed to make payments due to the contractor in accordance with any term of the contract regarding prompt payment which has the effect specified in regulation 23(1), and the contractor must specify in the late payment notice the payments that the Board has failed to make in accordance with that term.

(2) Subject to sub-paragraph (3), the contractor may, at least 28 days after the date on which a late payment notice under sub-paragraph (1) was given, terminate the contract by giving a further written notice to the Board in the event of the Board’s continuing failure to make the payments that are due to the contractor as specified in the late payment notice.

(3) Sub-paragraph (4) applies if, following receipt of a late payment notice, the Board—

- (a) refers the matter to the NHS dispute resolution procedure before the end of a period of 28 days beginning with the date on which the Board received the late payment notice; and
  - (b) gives notice in writing to the contractor that it has done so before the end of that period.
- (4) Where this sub-paragraph applies, the contractor may not terminate the contract under sub-paragraph (2) until—
- (a) there has been a final determination of the dispute under the NHS dispute resolution procedure (or by a court) and that determination permits the contractor to terminate the contract; or
  - (b) the Board ceases to pursue the NHS dispute resolution procedure,
- whichever is the earlier.
- (5) This paragraph does not affect any other rights to terminate the contract which the contractor may have.

#### **Termination by the Board: general**

**64.** A contract may only be terminated by the Board in accordance with the following provisions of this Part.

#### **Termination by the Board for breach of conditions in regulation 5**

**65.—**(1) Subject to paragraph (2), the Board must give notice in writing to the contractor terminating the contract with immediate effect where, in any case, a contractor who is an individual medical practitioner has ceased to be a general medical practitioner.

(2) Where the contractor referred to in sub-paragraph (1) has ceased to satisfy the condition specified in regulation 5(1)(a) by reason of a suspension of the type described in sub-paragraph (7), the Board is not required to give notice to the contractor under sub-paragraph (1) unless—

- (a) the contractor is unable to satisfy the Board that it has in place adequate arrangements for the provision of clinical services under the contract for so long as the suspension continues; or
  - (b) the Board is satisfied that the circumstances of the suspension are such that if the contract is not terminated with immediate effect—
    - (i) the safety of the contractor’s patients would be at serious risk, or
    - (ii) the Board would be at risk of material financial loss.
- (3) Sub-paragraph (4) applies where—
- (a) except in a case to which paragraph 59(4) applies, the contractor consists of two or more persons practising in partnership and the condition specified in regulation 5(1)(b) is no longer satisfied; or
  - (b) the contractor is a company limited by shares, and the condition specified in regulation 5(1)(c) is no longer satisfied.
- (4) Where this sub-paragraph applies, the Board must—
- (a) give notice in writing to the contractor terminating the contract with immediate effect; or
  - (b) give notice in writing to the contractor confirming that the Board is prepared to allow the contract to continue, for a period specified by the Board, in accordance with sub-paragraph (5) (“the interim period”).
- (5) The period specified by the Board under sub-paragraph (4)(b) must not exceed—
- (a) six months; or

- (b) where the failure of the contractor to continue to satisfy the condition in regulation 5(1)(b) or 5(1)(c), is by reason of a suspension described in sub-paragraph (7), the period for which that suspension continues.
- (6) The Board must, during the interim period and with the consent of the contractor, employ or supply the contractor with one or more general medical practitioners for the interim period to assist the contractor in the provision of clinical services under the contract.
- (7) The suspensions described in this sub-paragraph are suspension—
- (a) by a Fitness to Practise Panel under—
    - (i) section 35D of the Medical Act 1983(**180**) (functions of a fitness to practise panel) in a health case, other than an indefinite suspension under section 35D(6) of that Act, or
    - (ii) section 38(1) of the Medical Act 1983(**181**) (power to order immediate suspension etc. after a finding of impairment of fitness to practise); or
  - (b) by a Fitness to Practise Panel or an Interim Orders Panel under section 41A of the Medical Act 1983(**182**) (interim orders).
- (8) Before deciding which of the options in sub-paragraph (4) to pursue, the Board must, if it is reasonably practicable to do so, consult the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.
- (9) If the contractor does not, in accordance with sub-paragraph (6), consent to the Board employing or supplying a general medical practitioner during the interim period, the Board must give notice in writing to the contractor terminating the contract with immediate effect.
- (10) If, at the end of the interim period, sub-paragraph (3)(a) or (b) continues to apply to the contractor, the Board must give notice in writing to the contractor terminating the contract with immediate effect.
- (11) In this paragraph—
- (a) “health case” has the meaning given in section 35E(4) of the Medical Act 1983(**183**) (provisions supplementary to section 35D); and
  - (b) “general medical practitioner” has the meaning given in regulation 5(2).

#### **Termination by the Board for the provision of untrue etc. information**

**66.**—(1) The Board may give notice in writing to the contractor terminating the contract with immediate effect or from such date as may be specified by the Board in the notice where sub-paragraph (2) applies.

(2) This sub-paragraph applies if, after the contract was entered into, it comes to the Board’s attention that written information—

- (a) provided to the Board by the contractor before the contract was entered into; or
- (b) included in a notice given to the Board by the contractor under paragraph 50(1)(a) or (b) or 51(1),

relating to the conditions set out in regulations 5 and 6 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.

(180) 1983 c.54. Section 35D was substituted by S.I. 2002/3135, and was amended by section 99 of, and Schedule 7 to, the Health and Social Care Act 2008 (c.14) and by S.I. 2014/1101 and S.I. 2015/794.

(181) Section 38 was substituted by S.I. 2002/3135 and was amended by S.I. 2015/794.

(182) Section 41A was substituted by S.I. 2002/3135 and was amended by S.I. 2006/1914 and S.I. 2015/794.

(183) 1983 c.54. Section 35D was substituted by S.I. 2002/3135 and was amended by section 99 of, and Schedule 7 to, the Health and Social Care Act 2008, and by S.I. 2006/1914, S.I. 2014/1101, and S.I. 2015/794.

### Other grounds for termination by the Board

**67.**—(1) The Board may give notice in writing to a contractor terminating the contract with immediate effect, or from such date as may be specified in the notice, if sub-paragraph (3) applies to the contractor—

- (a) during the existence of a contract; or
  - (b) if later, on or after the date on which a notice in respect of the contractor's compliance with the condition in regulation 6 was given under paragraph 50(1)(a) or (b) or 51(1).
- (2) Sub-paragraph (3) applies—
- (a) where the contract is with a general medical practitioner, to that general medical practitioner;
  - (b) where the contract is with two or more persons practising in partnership, to the partnership or any partner in the partnership; and
  - (c) where the contract is with a company limited by shares 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.
- (3) This sub-paragraph applies if—
- (a) the contractor does not satisfy the conditions prescribed in sections 86(2) or 86(3) of the Act<sup>(184)</sup> (persons eligible to enter into GMS contracts);
  - (b) the contractor is the subject of a national disqualification;
  - (c) subject to sub-paragraph (5), the contractor has been disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill health) from practising by a licensing body anywhere in the world;
  - (d) subject to sub-paragraph (6), the contractor has been dismissed (otherwise than by reason of redundancy) from employment by a health service body unless, before the Board has given notice to the contractor terminating the contract under this paragraph, the contractor is employed by the health service body from which the contractor was dismissed or by another health service body;
  - (e) the contractor has 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<sup>(185)</sup> respectively) unless the contractor's name has subsequently been included in such a list;
  - (f) the contractor has been convicted in the United Kingdom of murder;
  - (g) the contractor has been convicted in the United Kingdom of a criminal offence other than murder and has been sentenced to a term of imprisonment of longer than six months;
  - (h) subject to sub-paragraph (7), the contractor has been convicted elsewhere of an offence which would, if it were 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;
  - (i) the contractor has been convicted of an offence, referred to in Schedule 1 to the Children and Young Persons Act 1933<sup>(186)</sup> (offences against children and young persons, with

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<sup>(184)</sup> Section 86(3) was amended by section 202 of, and paragraph 32 of Schedule 4 to, the Health and Social Care Act 2012 (c.7).

<sup>(185)</sup> Section 151 was amended by paragraph 79 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

<sup>(186)</sup> 1933 c.12. Schedule 1 was amended by section 51 of, and Schedule 4 to, the Sexual Offences Act 1956 (c.69); section 170 of, and Schedule 16 to, the Criminal Justice Act 1988 (c.33); section 139 of, and Schedule 6 to, the Sexual Offences Act

respect to special provisions of this Act apply), or in Schedule 1 to the Criminal Procedure (Scotland) Act 1995(**187**) (offences against children under the age of 17 years to which special provisions apply);

- (j) the contractor has at any time been included in—
- (i) any barred list within the meaning of the Safeguarding Vulnerable Groups Act 2006(**188**), or
  - (ii) any barred list within the meaning of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007(**189**) (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;
- (k) the contractor has, within the period of five years before the signing of the contract, 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;
- (l) the contractor has, within the period of five years before the signing of the contract or commencement of the contract (whichever is earlier), been removed from being concerned with the management or control of a body in any case where removal was by virtue of section 34(5)(e) of the Charities and Trustees Investment (Scotland) Act 2005(**190**) (powers of Court of Session); or
- (m) the contractor—
- (i) has been adjudged 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;
- (n) the contractor is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(**191**) (bankruptcy restrictions order and undertaking), or Schedule 2A to the Insolvency (Northern Ireland) Order 1989(**192**) (bankruptcy restrictions order and undertaking) or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(**193**) (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;
- (o) the contractor—
- (i) is subject to a moratorium period under a debt relief order under Part VIIA of the Insolvency Act 1986(**194**) (debt relief orders) applies, or

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2003 (c.42); section 58(1) of, and Schedule 10 to, the Domestic Violence, Crime and Victims Act 2004 (c.28); section 177(1) of, and Schedule 21 to, the Coroners and Justice Act 2009 (c.25); section 115(1) of, and Schedule 10 to, the Protection of Freedoms Act 2012 (c.9); and section 57(1) of, and Schedule 5 to, the Modern Slavery Act 2015 (c.30).

(187) 1995 c.46.

(188) 2006 c.47.

(189) S.I. 2007/1351 (N.I. 11).

(190) 2005 asp. 10.

(191) 1986 c.45. Schedule 4A was inserted by section 257(2) of, and Schedule 20 to, the Enterprise Act 2002 (c.40).

(192) S.I. 1985/2405 (N.I.19). Schedule 2A was inserted by S.I. 2005/1455 (N.I.10).

(193) 1985 c.66. Sections 56A to 56K were inserted by the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).

(194) Part VIIA was inserted by section 108(1) of, and Schedule 17 to, the Tribunals, Courts and Enforcement Act 2007 (c.15).

- (ii) is the subject of a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4ZB to that Act<sup>(195)</sup> (debt relief restrictions orders and undertakings), unless that order has ceased to have effect or has been annulled;
  - (p) the contractor has made a composition agreement or arrangement with, or a trust deed has been granted for, the contractor's creditors and the contractor has not been discharged in respect of it;
  - (q) the contractor is a company which has been wound up under Part IV of the Insolvency Act 1986<sup>(196)</sup> (winding up of companies registered under the Companies Acts);
  - (r) the contractor has had an administrator, administrative receiver or receiver appointed in respect of it;
  - (s) the contractor has had an administration order made in respect of the contractor under Schedule B1 to the Insolvency Act 1986<sup>(197)</sup> (administration);
  - (t) 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;
  - (u) the contractor is subject to—
    - (i) a disqualification order under section 1 of the Company Directors Disqualification Act 1986<sup>(198)</sup> (disqualification orders: general) or a disqualification undertaking under section 1A of that Act<sup>(199)</sup> (disqualification undertakings: general),
    - (ii) a disqualification order or disqualification undertaking under article 3 (disqualification orders) or article 4 (disqualification undertakings: general) of the Company Directors Disqualification (Northern Ireland) Order 2002<sup>(200)</sup>, or
    - (iii) a disqualification order under section 429(2) of the Insolvency Act 1986<sup>(201)</sup> (disabilities on revocation of administration order against an individual); or
  - (v) the contractor has refused to comply with a request by the Board for the contractor to be medically examined because the Board is concerned that the contractor is incapable of adequately providing services under the contract and, in a case where the contract is with two or more individuals practising in partnership or with a company, the Board is satisfied that the contractor is taking adequate steps to deal with the matter.
- (4) The Board must not terminate the contract under sub-paragraph (3)(c) where the Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—
- (a) a contractor;
  - (b) a partner, in the case of a contract with two or more persons practising in a partnership; or
  - (c) in the case of a contract with a company limited by shares—

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<sup>(195)</sup> Schedule 4ZB was inserted by section 108(2) of, and Schedule 19 to, the Tribunals, Courts and Enforcement Act 2007.

<sup>(196)</sup> 1986 c.45. Part IV was substituted by S.I. 2009/1941.

<sup>(197)</sup> 1986 c.45. Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002.

<sup>(198)</sup> 1986 c.46. Section 1 was amended by sections 5(1) and (2) and 8 of the Insolvency Act 2000 (c.39), section 204(1) and (3) of the Enterprise Act 2002, 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).

<sup>(199)</sup> Section 1A was inserted by section 6(1) and (2) of the Insolvency Act 2000, 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.

<sup>(200)</sup> S.I. 2002/3150 (N.I. 4); as amended by S.I. 2004/347, S.I. 2005/1454 and 1455.

<sup>(201)</sup> 1986 c.45. Section 429 was amended by section 269 of, and Schedule 3 to, the Enterprise Act 2002 (c.40), and section 106 of, and Schedule 16 to, the Tribunals, Courts and Enforcement Act 2007 (c.15).



- (i) a person legally and beneficially holding a share in the company, or
- (ii) a director or secretary of the company,

as the case may be.

- (5) The Board may not terminate the contract under sub-paragraph (3)(d)—
  - (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or
  - (b) if, during the period specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

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

(6) The Board must not terminate the contract under sub-paragraph (3)(h) where the Board is satisfied that the conviction does not make the person unsuitable to be—

- (a) a contractor;
- (b) a partner, in the case of a contract with two or more persons practising in partnership; or
- (c) in the case of a contract with a company limited by shares—
  - (i) a person both legally and beneficially holding a share in the company, or
  - (ii) a director or secretary of the company,

as the case may be.

#### **Termination by the Board where patients' safety is seriously at risk or where there is risk of material financial loss to Board**

**68.** The Board may give notice in writing to the contractor terminating the contract with immediate effect or with effect from such date as may be specified in the notice if—

- (a) the contractor has breached a term of the contract and, as a result of that breach, the safety of the contractor's patients would be at serious risk if the contract is not terminated; or
- (b) the Board considers that contractor's financial situation is such that the Board would be at risk of material financial loss.

#### **Termination by the Board for unlawful sub-contracting**

**69.—(1)** This paragraph applies if the contractor breaches the condition specified in paragraph 44(10) relating to the sub-contracting of clinical services under the contract and it comes to the Board's attention that the contractor has done so.

- (2) Where this paragraph applies the Board must give notice in writing to the contractor—
  - (a) terminating the contract with immediate effect; or
  - (b) instructing the contractor to terminate with immediate effect the sub-contracting arrangements that give rise to the breach, and, if the contractor fails to comply with that instruction, the Board must give notice in writing to the contractor terminating the contract with immediate effect.

#### **Termination by the Board: remedial notices and breach notices**

**70.—(1)** Where a contractor's breach of the contract is not one to which any of paragraphs 65 to 69 apply and that breach is capable of remedy, the Board must, before taking any action it is

otherwise entitled to take by virtue of the contract, give notice in writing to the contractor requiring it to remedy the breach (a “remedial notice”).

- (2) A remedial notice must specify—
- (a) details of the breach;
  - (b) the steps that the contractor must take to the satisfaction of the Board in order to remedy the breach; and
  - (c) the period during which those steps must be taken (the “notice period”).

(3) The notice period must not be less than a period of 28 days beginning with the date on which the notice is given unless the Board is satisfied that a shorter period is necessary to protect—

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

(4) Where the Board is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Board may give a further notice in writing to the contractor terminating the contract with effect from such date as the Board specifies in the notice.

(5) Where the contractor’s breach of the contract is not one to which any of paragraphs 65 to 69 apply and the breach is not capable of remedy, the Board may give notice in writing to the contractor requiring the contractor not to repeat the breach (a “breach notice”).

- (6) If, following a breach notice or a remedial notice, the contractor—
- (a) repeats the breach that was the subject of the breach notice or the remedial notice; or
  - (b) otherwise breaches the contract resulting in either a remedial notice or a further breach notice,

the Board may give notice in writing to the contractor terminating the contract with effect from such date as the Board specifies in the notice.

(7) The Board may not exercise its right to terminate the contract under sub-paragraph (6) unless the Board is satisfied that the cumulative effect of the breaches is such that to allow the contract to continue would prejudice the efficiency of the services to be provided under the contract.

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

**Termination by the Board: additional provisions specific to contracts with two or more persons practising in partnership and companies limited by shares**

**71.—**(1) If the Board becomes aware that a contractor which is a company limited by shares is carrying on any business which the Board considers to be detrimental to the contractor’s performance of its obligations under the contract—

- (a) the Board may give notice in writing to the contractor requiring it to cease carrying on that business before the end of a period of at least 28 days beginning with the date on which the notice is given (“the notice period”); and
- (b) if the contractor has not satisfied the Board that it has ceased carrying on that business by the end of the notice period, the Board may give a further notice in writing to the contractor terminating the contract with immediate effect or from such date as may be specified in the notice.

(2) Where the contractor consists of two or more persons practising in partnership and one or more of those persons has or have left the partnership during the existence of the contract, the Board may give notice in writing to the contractor terminating the contract on such date as may be specified

in the notice if, in the Board's reasonable opinion, the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Board to perform its obligations under the contract.

- (3) A notice given to the contractor under sub-paragraph (2) must specify—
  - (a) the date on which the contract is to terminate; and
  - (b) the Board's reasons for considering that the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Board to perform its obligations under the contract.

### **Contract sanctions**

**72.**—(1) In this paragraph and in paragraph 73, “contract sanction” means—

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

(2) Where the Board is entitled to terminate the contract under paragraphs 66, 67, 68, 69 70(4) or (6) or 71, it may instead impose any of the contract sanctions if the Board is reasonably satisfied that the contract sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Board's entitlement to terminate the contract.

(3) The Board may not, under sub-paragraph (2), impose any contract sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

(4) If the Board decides to impose a contract sanction, the Board must—

- (a) give notice in writing to the contractor of the contract sanction that it proposes to impose and the date upon which that sanction is to be imposed; and
- (b) include in the notice an explanation of the effect of the imposition of the sanction.

(5) Subject to paragraph 73 the Board may not impose the contract sanction until the end of a period of at least 28 days beginning with the date on which the Board gives notice to the contractor under sub-paragraph (4) unless the Board is satisfied that it is necessary to do so in order to protect—

- (a) the safety of the contractor's patients; or
- (b) itself from material financial loss.

(6) Where the Board imposes a contract sanction, the Board may charge the contractor the reasonable costs of any additional administration that the Board has incurred in order to impose, or as a result of imposing, the contract sanction.

### **Contract sanctions and the NHS dispute resolution procedure**

**73.**—(1) If there is a dispute between the Board and the contractor in relation to a contract sanction that the Board is proposing to impose, the Board may not, subject to sub-paragraph (5), impose the contract sanction except in the circumstances specified in sub-paragraphs (2) and (3).

(2) The circumstances specified in this sub-paragraph are if the contractor—

- (a) refers the dispute relating to the contract sanction to the NHS dispute resolution procedure before the end of a period of 28 days beginning with the date on which the contractor was given notice in accordance with paragraph 72(4) (or such longer period as may be agreed in writing with the Board); and
- (b) gives notice to the Board in writing that it has done so.

(3) Where the circumstances specified in sub-paragraph (2) apply, the Board may not impose the contract sanction unless—

- (a) there has been a final determination of the dispute in accordance with regulation 83 (or by a court) and that determination permits the Board to impose the contract sanction; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(4) If the contractor does not invoke the NHS dispute resolution procedure before the end of the period specified in sub-paragraph (2)(a), the Board may impose the contract sanction with immediate effect.

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

- (a) the safety of the contractor's patients; or
- (b) itself from material financial loss,

the Board may impose the contract sanction with immediate effect, pending the outcome of that procedure (or any court proceedings).

### **Termination and the NHS dispute resolution procedure**

**74.**—(1) Where the Board is entitled to give notice in writing to the contractor terminating the contract under paragraphs 66, 67, 68, 70(4) or (6) or 71, the Board must, in the notice given to the contractor under those provisions, specify a date on which the contract terminates that is at least 28 days after the date on which the Board gives notice to the contractor, unless sub-paragraph (2) applies.

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

- (a) the safety of the contractor's patients; or
- (b) itself from material financial loss.

(3) Where—

- (a) sub-paragraph (1) applies, but the exceptions in sub-paragraph (2) do not apply; and
- (b) the contractor invokes the NHS dispute resolution procedure before the end of the notice period referred to in sub-paragraph (1) and gives notice in writing to the Board that it has done so,

the contract does not terminate at the end of the notice period but instead only terminates in the circumstances described in sub-paragraph (4).

(4) The circumstances described in this sub-paragraph for the termination of the contract are if and when—

- (a) there has been a final determination of the dispute under the NHS dispute resolution procedure (or by a court) and that determination permits the Board to terminate the contract; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the earlier.

(5) If the Board is satisfied that it is necessary to terminate the contract before the NHS dispute resolution procedure is (or any court proceedings are) concluded in order to protect—

- (a) the safety of the contractor's patients; or
- (b) itself from material financial loss,

sub-paragraphs (3) and (4) do not apply and the Board may confirm, by giving notice in writing to the contractor, that the contract will nevertheless terminate at the end of the period of the notice given under paragraphs 66, 67, 68, 70(4) or (6) or 71.

### **Consultation with the Local Medical Committee**

**75.**—(1) If the Board is considering—

- (a) terminating the contract under paragraphs 66, 67, 68, 70(4) or (6) or 71;
- (b) whether a remedial notice or a breach notice under paragraph 70 should be given in writing to the contractor; or
- (c) imposing a contract sanction,

the Board must, if it is reasonably practicable to do so, consult the Local Medical Committee (if any) for the area in which the contractor is providing services under the contract before it terminates the contract or imposes a contract sanction.

(2) Whether or not the Local Medical Committee has been consulted under sub-paragraph (1), if the Board imposes a contract sanction on a contractor or terminates a contract in accordance with this Part, it must, as soon as reasonably practicable, give notice in writing to the Local Medical Committee of the contract sanction imposed or of the termination of the contract (as the case may be).

## SCHEDULE 4

Regulation 97

### Consequential amendments

#### **Amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004**

**1.** In the National Health Service (General Medical Service Contracts) (Prescription of Drugs etc) Regulations 2004(**202**), in Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances: interpretation)—

- (a) for the definition of “general medical practitioner” substitute—

““general medical practitioner” has the meaning given in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015;”, and
- (b) for the definition of “patient” substitute—

““patient” has the meaning given in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015;”.

#### **Amendment of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004**

**2.** In regulation 2 of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004(**203**) (interpretation), for the definition of “GMS Contracts Regulations” substitute—

““GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2015;”.

(202) S.I. 2004/629. The relevant amending instruments are S.I. 2004/3215 and SI. 2010/2389.

(203) S.I. 2004/906. There are no relevant amending instruments.

### **Amendment of the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) Establishment and Constitution) Order 2005**

3. In article 3 of the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) Establishment and Constitution Order 2005(204) (functions of the Authority), for “the National Health Service (General Medical Services Contracts) Regulations 2004” in paragraph (fa) substitute “the National Health Service (General Medical Services Contracts) (Consolidation) Regulations 2015”.

### **Amendment of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009**

4. In regulation 2(1) of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(205) (interpretation), for paragraph (b)(i) of the definition of “relevant complaints procedure” substitute—

“(i) regulation 79 of the National Health Service (General Medical Services Contracts) Regulations 2015;”.

### **Amendment of the National Health Service (Functions of the First-tier Tribunal relating to Primary Medical, dental and Ophthalmic Services) Regulations 2010**

5. In regulation 2 of the National Health Service (Functions of the First-tier Tribunal relating to Primary Medical, Dental and Ophthalmic Services) Regulations 2010(206) (interpretation), for the definition of “GMS Contracts Regulations” substitute—

““GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2015;”.

### **Amendment of the National Health Service (Clinical Commissioning Groups) Regulations 2012**

6. In regulation 2 of the National Health Service (Clinical Commissioning Groups) Regulations 2012(207) (CCG membership requirement), for the definition of “essential primary medical services” substitute—

““essential primary medical services” means the services described in regulation 17(4), (6), (7) and (9) of the National Health Service (General Medical Services Contracts) Regulations 2015 (essential services);”.

### **Amendment of the National Health Service (Performers Lists) (England) Regulations 2013**

7. In regulation 26 of the National Health Service (Performers Lists) (England) Regulations 2013(208) (application for inclusion in the medical performers list), for “paragraph 124 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004 (gifts)” in paragraph (3)(b) substitute “regulation 93 of the National Health Service (General Medical Services Contracts) Regulations 2015”.

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(204) S.I. 2005/2414. The relevant amending instruments are S.I. 2006/632 and S.I. 2013/235.

(205) S.I. 2009/309. Paragraphs (a)(i), (ia), (ii) and (iii) of the definition of “relevant complaints procedure” were substituted by regulation 120 of, and paragraph 7(a) of Schedule 10 to S.I. 2013/349.

(206) S.I. 2010/76. The definition of “PMS Agreements Regulations” was amended by article 11 of, and Part 1 of Schedule 2 to, S.I. 2013/235.

(207) S.I. 2012/1631. There are no relevant amending instruments.

(208) S.I. 2013/335. There are no relevant amending instruments.

### **Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013**

8. In regulation 2 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(209) (interpretation), for the definition of “GMS Regulations” substitute—

““GMS Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2015;”.

### **Amendment of the National Health Service (Clinical Commissioning Groups – Disapplication of Responsibility) Regulations 2013**

9. In regulation 2 of the National Health Service (Clinical Commissioning Groups – Disapplication of Responsibility Regulations 2013(210) (persons for whom a CCG does not have responsibility in relation to its duty to commission services), for “paragraph 16 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004” in paragraph (4) (a), substitute “paragraph 20 of Schedule 3 to the National Health Service (General Medical Services Contracts) Regulations 2015”.

### **Amendment of the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013**

10. In regulation 11 of the National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013(211) (patient choice: primary medical services), for paragraph (2)(a) substitute—

“(a) Part 2 of Schedule 3 to the National Health Service (General Medical Services Contracts) Regulations 2015 (other contractual terms - patients: general),”.

## SCHEDULE 5

Regulation 98

### List of enactments to be revoked

1. The enactments listed in column 1 of the Table are revoked to the extent specified in column 2 of that table.

#### Table

<i>Title of instrument</i>	<i>Extent of revocation</i>
The National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291)	The whole instrument
The General Medical Services Transitional and Consequential Provisions Order 2004 (S.I. 2004/433)	The whole instrument
The General Medical Services and Personal Medical Services Transitional and	The whole instrument

(209) S.I. 2013/349. There are no relevant amending instruments.

(210) S.I. 2013/350. There are no relevant amending instruments.

(211) S.I. 2013/500. There are no relevant amending instruments.

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

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<i>Title of instrument</i>	<i>Extent of revocation</i>
Consequential Provisions Order 2004 ( <a href="#">S.I. 2004/865</a> )	
The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2004 ( <a href="#">S.I. 2004/2694</a> )	The whole instrument
The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005 ( <a href="#">S.I. 2005/893</a> )	Regulations 2 to 5 and regulation 14
The National Health Service (Primary Medical Services) (Miscellaneous Amendments) (No.2) Regulations 2005 ( <a href="#">S.I. 2005/3315</a> )	Regulations 2 to 7
The National Health Service (Primary Medical Services and Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2006 ( <a href="#">S.I. 2006/1501</a> )	The whole instrument
The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2007 ( <a href="#">S.I. 2007/3491</a> )	The whole instrument
The Local Involvement Networks (Miscellaneous Amendments) Regulations 2008 ( <a href="#">S.I. 2008/1514</a> )	Regulation 3
The Primary Ophthalmic Services Amendment, Transitional and Consequential Provisions Regulations 2008 ( <a href="#">S.I. 2008/1700</a> )	Schedule 1, paragraph 12
The Local Authority Social Services and NHS (Complaints) (England) Regulations 2009 ( <a href="#">S.I. 2009/309</a> )	Schedule, paragraph 3
The National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009 ( <a href="#">S.I. 2009/2205</a> )	Regulation 35
The National Health Service (Prescribing and Charging Amendments Relating to Pandemic Influenza) Regulations 2009 ( <a href="#">S.I. 2009/2230</a> )	Regulation 3
The Value Added Tax Order 2009 ( <a href="#">S.I. 2009/2972</a> )	Paragraph (i) of Note (2D) of the inserted text
The Transfer of Tribunal Functions Order ( <a href="#">S.I. 2010/22</a> )	Schedule 3, paragraphs 42 to 44
The Pharmacy Order 2010 ( <a href="#">S.I. 2010/231</a> )	Schedule 4, paragraph 40
The General Specialist Medical Practice (Education, Training and Qualifications) Order 2010 ( <a href="#">S.I. 2010/234</a> )	Schedule 3, paragraph 10



<i>Title of instrument</i>	<i>Extent of revocation</i>
The National Health Service Primary Medical Services (Miscellaneous Amendments) Regulations 2010 ( <a href="#">S.I. 2010/578</a> )	The whole instrument
The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2012 ( <a href="#">S.I. 2012/970</a> )	The whole instrument
The Health and Social Care Act (Consequential Provision – Social Workers) Order 2012 ( <a href="#">S.I. 2012/1479</a> )	Schedule, paragraph 35
The Human Medicines Regulations 2012 ( <a href="#">S.I. 2012/1916</a> )	Schedule 34, paragraph 85
The Tribunals, Courts and Enforcement Act 2007(Consequential Amendments) Order 2012 ( <a href="#">S.I. 2012/2404</a> )	Schedule 3, paragraph 31
The National Health Service (Primary Medical Services) (Miscellaneous Amendments and Transitional Provisions) Regulations 2013 ( <a href="#">S.I. 2013/363</a> )	Part 2
The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) Amendment Regulations 2014 ( <a href="#">S.I. 2014/465</a> )	The whole instrument
The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 ( <a href="#">S.I. 2014/1887</a> )	Schedule 2, paragraph 1
The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment No.2) Regulations 2014 ( <a href="#">S.I.2014/2721</a> )	The whole instrument
The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2015 ( <a href="#">S.I. 2015/196</a> )	The whole instrument
The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015 ( <a href="#">S.I. 2015/915</a> )	Regulation 2

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations consolidate provisions previously contained in the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291) (“the 2004 Regulations”), as amended, which are revoked by regulation 98 and Schedule 5. They set out, in relation to England, the framework for general medical services contracts made under section 84 (general medical services contracts: introductory) of the National Health Service Act 2006 (c.41) (“the Act”).

Part 2 (contractors: conditions and eligibility) prescribes the conditions which, in accordance with section 86 of the Act (persons eligible to enter into GMS contracts), must be met by a contractor before the contractor may enter into a general medical services contract.

Part 3 (pre-contract dispute resolution) prescribes the procedure for pre-contract dispute resolution, in accordance with section 90 of the Act (GMS contracts: disputes and enforcement). Part 3 applies to cases where the contractor is not a health service body. In cases where the contractor is such a body, the procedure for dealing with pre-contract disputes is set out in section 9 of the Act (NHS contracts).

Part 4 (health service body status) sets out the procedures, in accordance with regulations made under section 90(3) of the Act, by which the contractor may obtain health service body status.

Part 5 and Schedule 3 (contracts: required terms) prescribe the terms which, in accordance with section 89 (GMS contracts: other required terms) and section 90 (GMS contracts: disputes and enforcement) of the Act, must be included in a general medical services contract (in addition to those contained in the Act). It includes, in regulation 17, a description of the services which must be provided to patients under general medical services contracts under section 85(1) and (2) (requirement to provide certain primary medical services) of the Act. It also makes provision for the services which may be provided by way of additional services under the contract (regulation 19 and Schedule 1).

The required terms include terms relating to:

- the type and duration of the contract (regulations 13 to 16);
- the services to be provided (regulations 17 to 20 and Part 1 of Schedule 3), the manner in which they are to be provided (Schedule 3) and the procedures for opting out of additional and out of hours services (Part 6);
- membership of a clinical commissioning group (regulation 21);
- the issuing of medical certificates (regulation 22 and Schedule 2);
- finance, fees and charges (regulations 23 to 25);
- the requirement to establish Patient Participation Groups and to publish mean net earnings (regulations 26 and 27);
- the sub-contracting, variation and termination of contracts and consequences of termination of contracts (regulations 28 to 31); and
- other required general terms (regulation 32 and Schedule 3).

Part 6 (opt outs: additional and out of hours services) provides for a contractor to be able to “opt out” of the provision of additional services and out of hours service under a general medical services contract in certain circumstances.

Part 7 (persons who perform services) prescribes the required qualifications, conditions, experience and professional verification required in respect of persons employed or engaged by a general medical services contractor to perform services under the contract.

Part 8 (prescribing and dispensing) prescribes the terms in accordance with which a person, prescriber or health care worker may prescribe and dispense drugs, medicines or appliances under a general medical services contract.

Part 9 (prescribing and dispensing: out of hours services) prescribes terms additional to those in Part 6 in relation to contractors providing out of hours services.

Part 10 (records and information) prescribes the manner in which a contractor is to provide and store all records and data including that associated with patients.

Part 11 (complaints) requires a contractor to establish and operate a complaints procedure to deal with complaints in relation to any matter reasonably connected with the provision of services under a general medical services contract. The complaints procedure must comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 (S.I. 2009/309).

Part 12 (dispute resolution) prescribes the procedures which are to apply for the purposes of dispute resolution.

Part 13 (functions of a Local Medical Committee) sets out the functions of Local Medical Committees.

Part 14 of the Regulations (miscellaneous) sets out miscellaneous provisions which must be complied with by a contractor.

Part 15 (general transitional provision and saving, consequential amendments and revocations) makes a general transitional provision and saving and also revokes various enactments included in secondary legislation as a result of the coming into force of these Regulations, including the revocation of the 2004 Regulations. The effect of the 2004 Regulations is saved for limited purposes.