
STATUTORY INSTRUMENTS

2015 No. 1879

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Personal Medical
Services Agreements) 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 93(2), 94(1), (2) (3), (3A)(a) and (6) to (9) and 272(7) and (8) of the National Health Service Act 2006(1), makes the following Regulations.

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the National Health Service (Personal Medical Services Agreements) Regulations 2015.

(2) They come into force on 7th December 2015.

Application

2. These Regulations apply to an agreement—

- (a) to which the National Health Service (Personal Medical Services Agreements) Regulations 2004(2) applied immediately before the date on which these Regulations come into force; or

(1) 2006 c.41. Section 93 of the National Health Service Act 2006 (“the Act”) was amended by paragraph 37 of Schedule 4 to the Health and Social Care Act 2012 (c.7) (“the 2012 Act”). Section 94 of the Act was amended by section 28(2) of, and paragraph 38(1) and (2) to, the 2012 Act, and by section 17(5) of, and paragraph 2(1)(b) and (2) of Schedule 9 to, the Crime and Courts Act 2013 (c.22). 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 of “prescribed” and “regulations”.

(2) S.I. 2004/627; as amended by S.I. 2004/906 and 2694, S.I. 2005/893, 3315 and 3491, S.I. 2006/1501, S.I. 2007/3491, S.I. 2008/1700, S.I. 2009/309, 2205 and 2230, S.I. 2010/22, 231|, 234, 578 and 1621, S.I. 2012/970, 1479, 190, 1916 and 2404,

- (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 (Personal Medical Services Agreements) Regulations 2004;

“adjudicator” means the Secretary of State or a person or persons appointed by the Secretary of State under section 9(8) of the Act(3) (NHS contracts) or under regulation 76(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;

“agreement”, except in regulation 88, means an agreement for primary medical services made under section 92 of the Act(4) (arrangements by the Board for the provision of primary medical services);

“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 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;

“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 purposes of making determinations under paragraph 40(3) of Schedule 2;

“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;

S.I. 2013/363, S.I.2014/465, 1887 and 2721 and S.I. 2015/196 and 915. S.I. 2004/627 is revoked by regulation 90 of, and Schedule 4 to, these Regulations.

- (3) 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).
- (4) Section 92 was amended by paragraph 36 of Schedule 4 to the 2012 Act.
- (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).
- (7) 1971 c.80.

- (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⁾;

“CCG” means a clinical commissioning group⁽⁹⁾;

“CCT” means a certificate of completion of training awarded under section 34L(1) of the Medical Act 1983 (award and withdrawal of a Certificate of Completion of Training)⁽¹⁰⁾ 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⁽¹¹⁾;

“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⁽¹²⁾ (general provisions); or

(b) a supplier of appliances,

who is included in the list held by the Board under section 129 of the Act⁽¹³⁾ (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;

“chiroprapist or podiatrist independent prescriber” means a person who—

(a) is engaged or employed by a party to the agreement; and

(b) is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001⁽¹⁴⁾ (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiroprapist or podiatrist is qualified to order drugs, medicines and appliances as a chiroprapist or podiatrist independent prescriber;

“clinical services” means medical services under the agreement 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;

“contractor”, except in regulation 5, means a person or persons other than the Board who is a party, or who are parties, to the agreement;

⁽⁸⁾ The National Health Service Commissioning Board (known as “NHS England”) was established by section 1H of the Act. Section 1H was inserted by section 9 of the Health and Social Care Act 2012 (“the 2012 Act”).

⁽⁹⁾ Clinical commissioning groups were established by virtue of provision in sections 11 and 14A to 14D of the Act as inserted by sections 10 and 25(1) of the 2012 Act.

⁽¹⁰⁾ 1983 c.54. Section 34L was inserted by S.I. 2010/234.

⁽¹¹⁾ Section 49B was inserted by S.I. 2007/3101 and was amended by S.I. 2008/1774 and S.I. 2010/234 and 478.

⁽¹²⁾ 1968 c.67. Section 69 was amended by S.I. 2007/289 and 3101 and S.I. 2010/231.

⁽¹³⁾ Section 129 was amended by sections 26 and 27 of, and paragraph 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; section 115 of, and Schedule 9 to, the Protection of Freedoms Act 2012 (c.9) and by S.I. 2010/231.

⁽¹⁴⁾ 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.

“contractor’s list of patients” means the list prepared and maintained by the Board under paragraph 13 of Schedule 2;

“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 would like 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⁽¹⁵⁾;

“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⁽¹⁶⁾ (arrangements for additional pharmaceutical services);

“electronic communication” has the meaning given in section 15 of the Electronic Communications Act 2000⁽¹⁷⁾ (general interpretation);

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

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

“Electronic Prescription Service” means the service of that name which is managed by the Health and Social Care Information Centre⁽¹⁸⁾;

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

“essential services” means the services required to be provided in accordance with regulation 17 of the General Medical Services Contracts Regulations;

“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⁽¹⁹⁾ (registration of medical practitioners);

“General Medical Services Contracts Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2015⁽²⁰⁾;

“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⁽²¹⁾ (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;

(15) 2006 c.41. Section 126 was amended by 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. 2008/289 and S.I. 2010/22 and 231.

(16) 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.

(17) 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).

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

(19) 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.

(20) S.I.2015/1862.

(21) 1983 c.54. Section 34I was inserted by S.I. 2010/234.

“Health and Social Services Board” means a Health and Social Services Board established under article 16 the Health and Social Services (Northern Ireland) Order 1972(22) (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(23) (ancillary services);

“Health Board” means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(24) (Health Boards);

“health care professional” has the meaning given in section 108 of the Act(25) (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(26) (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(27); or
- (f) a grandparent;

“independent nurse prescriber” means a person—

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- (22) [S.I. 1972/1265 \(N.I.14\)](#). Article 16 was repealed by the Health and Social Care (Reform) Act 2009 (c.1) (N. I.), paragraph 6 of Schedule 3 and Schedule 7.
- (23) [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 and by [S.I. 1997/1177](#).
- (24) [1978 c.29](#). Section 2 was amended by paragraph 1 of Schedule 7 to [S.I. 1991/194 \(N.I. 1\)](#); and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications Act 1983 (c.41); paragraph 1(2)(a) and (b) of Schedule 1 to the National Health Service Reform (Scotland) Act 2004 (asp 7); sections 2(1)(a) and 28(a)(ii), (b) and (c) of Schedule 1, and paragraph 19(1) of Schedule 9 and paragraph 1 of Schedule 10 to, the National Health Service and Community Care Act 1990 (c.19); paragraph 2(2) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), and sections 2(1), 4, 6(2) and (3), 7 and 11(1) of the Health Boards (Membership and Elections) (Scotland) Act 2005 (asp 5).
- (25) Section 108 was amended by section 204 of, and paragraph 49 of Schedule 4 to, the Health and Social Care Act 2012 (“the 2012 Act”).
- (26) [2006 c.41](#). 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).
- (27) [1989 c.41](#).

- (a) who is either engaged or employed by the contractor or who is a party to the agreement;
- (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 and 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;

“listed medicines” means a medicine mentioned in regulation 7C(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015⁽²⁸⁾ (exemption from charges in respect of listed or emergency medicines);

“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⁽²⁹⁾ (Local Health Boards);

“Local Medical Committee” means a committee recognised by the Board under section 97 of the Act⁽³⁰⁾ (local medical committees);

“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⁽³¹⁾ (persons performing medical services);

“Medical Register” means the registers kept under section 2 of the Medical Act 1983⁽³²⁾ (registration of medical practitioners);

“national disqualification” means—

- (a) a decision made by the First-tier Tribunal under section 159 of the Act⁽³³⁾ (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) section 145, 146 or 147A (performers of pharmaceutical services and assistants), of the Act⁽³⁴⁾; 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⁽³⁵⁾ (NHS contracts);

⁽²⁸⁾ S.I. 2000/620. Regulation 7C was inserted by S.I. 2009/2230 and was amended by S.I. 2012/1909.

⁽²⁹⁾ 2006 c.42.

⁽³⁰⁾ 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”).

⁽³¹⁾ Section 91 was amended by paragraph 35 of Schedule 4 to the 2012 Act.

⁽³²⁾ 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.

⁽³³⁾ Section 159 was amended by section 306(1)(d) of, and paragraph 85(1)(d) of Schedule 4 to, the 2012 Act.

⁽³⁴⁾ Sections 91(3), 106(3) and 123(3) were respectively amended by paragraph 35(1) and (2)(b) and (4), 45 and 60(1) and (2)(b) of Schedule 4 to, the 2012 Act. Sections 146 and 149 of the Act are repealed by section 208(1) of the 2012 Act. 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 on a day to be appointed. No regulations have been made under section 147A of the Act.

⁽³⁵⁾ 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

“NHS dispute resolution procedure” means the procedure for the resolution of disputes specified—

- (a) in Part 13; or
- (b) in a case to which paragraph 41 of Schedule 2 applies, in that paragraph;

“NHS foundation trust” has the meaning given in section 30 of the Act⁽³⁶⁾ (NHS foundation trusts);

“NHS trust” means a body established under section 25 of the Act⁽³⁷⁾ (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 operated by the Health and Social Care Information Centre⁽³⁸⁾;

“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 agreement are normally made available and may be different for different services;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001⁽³⁹⁾ (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 17 of Schedule 2;

“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⁽⁴⁰⁾ (register of opticians); and
- (b) against whose name 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,

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).

⁽³⁶⁾ Section 30 was amended by section 159(1) of the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”).

⁽³⁷⁾ Section 25 of the Act is repealed by section 179(2) of the 2012 Act from a date to be appointed.

⁽³⁸⁾ The Health and Social Care Information Centre is a body corporate established by section 252(1) of the 2012 Act.

⁽³⁹⁾ S.I. 2002/253; article 5 was amended by S.I. 2009/182.

⁽⁴⁰⁾ 1989 c.44. Section 7 was amended by S.I. 2005/848.

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 would be essential services if provided by a contractor to its registered patients in core hours;

“parent” includes, in relation to any child, an 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 as part of its obligation to provide essential services; and
- (d) any other person to whom the contractor has agreed to provide services under the agreement; 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 agreement to whom the provisions of Part 8 of these Regulations applies;

“pharmacist independent prescriber” means a person who—

- (a) is either engaged or employed by the contractor or is a party to the agreement;
- (b) is registered in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010(41) (establishment, maintenance and access to the Register), or the register maintained under article 6 (the registers) and 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976(42); 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 agreement; and
- (b) registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(43) (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that that person 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(44) (programmes for provisionally registered doctors) as providing registered doctors with an acceptable foundation for future practise as a fully registered medical practitioner;

(41) S.I. 2010/231; as amended by S.I. 2011/1043, S.I. 2012/3006, S.I. 2013/235 and S.I. 2014/1887.

(42) 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.

(43) 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.

(44) 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 agreement;

“practice area” means the area specified in the agreement as the area in which essential services are to be provided;

“practice leaflet” means a leaflet drawn up in accordance with regulation 71;

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

“prescriber” means—

- (a) a 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 agreement;

“prescription form” means—

- (a) a form for the purpose of ordering a drug, medicine or appliance which is—
 - (i) provided by the Board, a local authority or the Secretary of State which is in the form required by the NHS Business Services Authority⁽⁴⁵⁾,
 - (ii) 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 50 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 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⁽⁴⁶⁾ (classification of medicinal products);

“primary care list” means—

- (a) a list of persons performing primary medical services, primary dental services or 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), and

⁽⁴⁵⁾ 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.

⁽⁴⁶⁾ 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⁽⁴⁷⁾;
- (b) a list of persons undertaking to provide, or assist in the provision of—
- (i) primary medical services, prepared in accordance with regulations made under Part 4 of the Act (primary medical services),
 - (ii) primary dental services, prepared in accordance with regulations made under Part 5 of the Act (primary dental services),
 - (iii) primary ophthalmic services prepared in accordance with regulations made under Part 6 of the Act (persons performing primary ophthalmic services),
 - (iv) pharmaceutical services, prepared 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 agreement immediately before the coming into force of section 34 of the Health and Social Care Act 2012⁽⁴⁸⁾ (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 Part 4 of the Act applies;

“registered patient” means a person—

- (a) who is recorded by the Board as being included in the contractor’s list of patients; or
- (b) 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⁽⁴⁹⁾ (establishment, maintenance 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⁽⁵⁰⁾;
- (c) in relation to an optometrist, the register maintained by the General Optical Council under section 7(a) of the Opticians Act 1989⁽⁵¹⁾ (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⁽⁵²⁾ (establishment and maintenance of register) relating to—

⁽⁴⁷⁾ Sections 91(3), 106(3) and 123(3) were respectively amended by paragraph 35(1) and (2)(b) and (4), 45 and 60(1) and (2)(b) of Schedule 4 to, the 2012 Act. Sections 146 and 149 of the Act are repealed by section 208(1) of the 2012 Act. 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 on a day to be appointed. No regulations have been made under section 147A of the Act.

⁽⁴⁸⁾ 2012 c.7.

⁽⁴⁹⁾ 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 and S.I. 2014/1887 and S.I. 2015/806 and 968.

⁽⁵⁰⁾ 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 S.I. 2008/192.

⁽⁵¹⁾ 1989 c.44. Section 7 was amended by S.I. 2005/848.

⁽⁵²⁾ 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)

- (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 agreement which give effect to regulation 52; or
- (b) a party to an agreement 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 Business Services Authority(53), 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
- (b) in the case of an electronic prescription to which regulation 50 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 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 agreement; or
- (b) except where the conditions set out in regulation 54(3) are satisfied, a drug, medicine or other substance which is specified in any directions given by the Secretary of State

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.

(53) 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.

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;

“supplementary prescriber” means a person—

- (a) who is either engaged or employed by the contractor or is a party to the agreement;
- (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⁽⁵⁴⁾ (establishment, maintenance of and access to the register),
 - (iii) the register maintained under articles 6 (the Register) and article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976⁽⁵⁵⁾,
 - (iv) the part of the register maintained by the Health Professions Council under article 5 of the Health and Social Work Professions Order 2001⁽⁵⁶⁾ (establishment and maintenance of register) relating to—
 - (aa) chiropodists or 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⁽⁵⁷⁾ (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 19 of Schedule 2 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 52(1) of Schedule 2, includes electronic mail and “written” is to be construed accordingly.

(54) 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 and S.I. 2014/1887 and S.I. 2015/806 and 968.

(55) S.I. 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 that instrument.

(56) 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.

(57) 1989 c.44. Section 7 was amended by S.I. 2005/848.

PART 2

Agreements

Conditions: general

4.—(1) The Board may only enter into an agreement if the conditions specified in regulation 5 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⁽⁵⁸⁾.

General condition relating to all agreements

5.—(1) The Board must not enter into an agreement with—

- (a) a person falling within section 93(1)(b) to (d) of the Act (persons with whom agreements may be made under section 92), to whom paragraph (2) applies;
- (b) a qualifying body if paragraph (2) applies to—
 - (i) the qualifying body,
 - (ii) any person both legally and beneficially owning a share in the qualifying body, and
 - (iii) any director or secretary of the qualifying body.

(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 a licensing body anywhere in the world;
- (c) the contractor has, within the period of five years before the signing of the agreement or commencement of the agreement (whichever is the earlier) been dismissed (otherwise than by reason of redundancy) from any employment with 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 agreement or commencement of the agreement (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⁽⁵⁹⁾ (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 1st April 2002 and has been sentenced to a term of imprisonment of longer than six months;

⁽⁵⁸⁾ 2012 c.7.

⁽⁵⁹⁾ Section 151 was amended by paragraph 79 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

- (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 3rd November 2003; 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(60) (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(61) (offences against children under the age of 17 years to which special provisions apply) committed on or after 1st April 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(62) (barred lists), or
 - (ii) any barred list within the meaning of article 6 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007(63) (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 agreement or commencement of the agreement (whichever is the earlier), been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission, the Charity Commission for Northern Ireland or the High Court, and that order was made on the grounds of misconduct or mismanagement in the administration of a charity for which the contractor was responsible or to which the contractor was privy, or which was contributed to, or facilitated by, the contractor's conduct;
- (k) the contractor has, within the period of five years before the signing of the agreement or commencement of the agreement (whichever is the earlier), been removed from being concerned with the management or control of any body in any case where removal was by virtue of section 34(5)(e) of the Charities and Trustees Investment (Scotland) Act 2005(64) (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(65) (bankruptcy restrictions order and undertaking), or Schedule 2A to the Insolvency (Northern

(60) 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, 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 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 7(1) of, and paragraph 1 of Schedule 5 to, the Modern Slavery Act 2015 (c.30).

(61) 1995 c.46. Schedule 1 was amended by paragraph 2(8)(a) of Schedule 5 to the Sexual Offences (Scotland) Act 2009 (asp 9) which inserted paragraphs 1A to 1D into that Schedule.

(62) 2006 c.47. Section 2 was amended by articles 3(a) and 4 of S.I. 2012/3006

(63) S.I. 2007/1351 (N.I. 11); as amended by section 81(2) and (3)(o)(i) and 116(5)(a) of the Policing and Crime Act 2009 (c.26).

(64) 2005 asp 10. Section 34 was amended by section 122 of the Public Services Reform (Scotland) Act 2010 (asp 8).

(65) 1986 c.45. Schedule 4A was inserted by Schedule 20 to the Enterprise Act 2002 (c.40) and was amended by section 71(3) of, and paragraph 63(1), (3), (2)(a) and (b) to, the Enterprise and Regulatory Reform Act 2013 (c.24).

- Ireland) Order 1989(66) (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(67) (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 a moratorium period under a debt relief order under Part VIIA of the Insolvency Act 1986(68) (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(69) (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(70) (disqualification orders: general) or a disqualification undertaking under section 1A of that Act(71) (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(72), or
 - (iii) a disqualification order under section 429(2) of the Insolvency Act 1986(73) (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; or
- (r) the contractor has had an administration order made in respect of the contractor under Schedule B1 to the Insolvency Act 1986(74) (administration).
- (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 the person unsuitable to be—
- (i) a party to the agreement; or
 - (ii) in the case of an agreement with a qualifying body—

(66) 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).

(67) 1985 c.66. Sections 56A to 56K were inserted by section 2(1) of the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).

(68) 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).

(69) 1986 c.45. Schedule 4ZB was inserted by section 108(2) of and Schedule 19 to the Tribunals, Courts and Enforcement Act 2007.

(70) 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).

(71) 1986 c.46. 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 and 3(1) and (2) of Schedule 7 to, the Small Business Enterprise and Employment Act 2015.

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

(73) 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.

(74) 1986 c.45. Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002.

- (aa) a person who both legally and beneficially owns a share in the qualifying body, or
 - (bb) a director or secretary of the qualifying body.
- (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 section 34 (abolition of Primary Care Trusts) of the Health and Social Care Act 2012⁽⁷⁵⁾.
- (5) In this regulation, “contractor” includes a person with whom the Board is proposing to enter into an agreement.

Notice of conditions not being met and reasons

6.—(1) Where the Board considers that the conditions in regulation 5 for entering into an agreement are not met, it must give notice in writing to the person or persons intending to enter into the agreement of—

- (a) its view and the reasons for that view; and
- (b) the right of appeal under regulation 7.

(2) The Board must 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 qualifying body that is given notice under paragraph (1) in any case where its reason for the decision relates to such a person.

Right of appeal

7. A person who has been given a notice by the Board under regulation 6(1) may appeal to the First-tier Tribunal⁽⁷⁶⁾ against the decision of the Board that the conditions in regulation 5 are not met.

PART 3

Pre-agreement dispute resolution

Pre-agreement disputes

8.—(1) If, in the course of negotiations intending to lead to an agreement, the parties to the proposed agreement (“the prospective parties”) are unable to agree on a particular term of the agreement, 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 agreement may be referred to the Secretary of State for determination under section 9 of the Act (NHS contracts).

⁽⁷⁵⁾ 2012 c.7.

⁽⁷⁶⁾ 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 a person from a list or regarding the conditions relating to that person’s 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.

(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 76(3) to (14) and 77(1) and, where it applies, paragraph (4) of this regulation.

- (4) Where a dispute is referred to the Secretary of State under paragraph (1), the determination—
- (a) may specify terms to be included in the proposed agreement;
 - (b) may require the Board to proceed with the proposed agreement, but may not require the intended contractor to proceed with the proposed agreement; and
 - (c) is binding upon the prospective parties.

PART 4

Health Service Body Status

Health service body status

9.—(1) A 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 it enters into an agreement unless, in the case of—

- (a) an agreement with a contractor who is an individual or which is a qualifying body, that individual or qualifying body; or
- (b) any other agreement, any of the proposed parties to the agreement (other than the Board), objects by giving notice in writing to the Board at any time prior to the agreement being made.

(2) If, by virtue of paragraph (1), a contractor is to be regarded as a health service body, any change in the parties comprising the contractor does not affect the status of the contractor as a health service body.

(3) If, by virtue of paragraph (1) or regulation 10, a contractor is to be regarded as a health service body, the nature of, or any rights or liabilities under, any other agreement or contract previously entered into by the contractor with a health service body remain unaffected.

Health service body status: variation of agreements

10.—(1) A contractor may at any time request in writing a variation of the agreement to include in, or remove from, the agreement provision to the effect that the agreement is an NHS contract and, if it does so—

- (a) the Board must agree to the variation; and
- (b) the procedure specified in regulation 24 and Part 8 of Schedule 2 for the variation of agreements applies.

(2) If, by virtue of a request under paragraph (1), the agreement is varied so as to remove provision from it to the effect that it is an NHS contract, the contractor is, subject to regulation 11, to cease to be regarded as a health service body for the purposes of section 9 of the Act from the date on which that variation takes effect.

(3) If, by virtue of a request under paragraph (1), the agreement is varied so as to include provision in it to the effect that it is an NHS contract, the contractor is to be regarded as a health service body for the purposes of section 9 of the Act from the date on which that variation takes effect.

(4) Where the Board agrees to the variation of the agreement, the contractor is to be regarded, or, subject to regulation 11, 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 by virtue of paragraph 52(1) of Schedule 2.

Cessation of health service body status

11.—(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 agreement terminates.

(2) Where, by virtue of paragraph (1), a contractor ceases to be regarded as a health service body in relation to an agreement (“the relevant agreement”), the contractor is to—

- (a) 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 the relevant agreement and the date on which it ceased to be regarded as a health service body for the purposes of that agreement; but
- (b) cease to be regarded as a health service body for these purposes upon the termination of any such other NHS contracts.

(3) Where—

- (a) a contractor ceases to be regarded as a health service body in relation to an agreement by reason of a variation of the agreement by virtue of regulation 10(1); and
- (b) the contractor or the Board—
 - (i) has referred any matter to the NHS dispute resolution procedure before the contractor ceases to be regarded as a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with regulation 76, after the contractor ceases to be regarded as a health service body,

the contractor is to continue to be regarded as a health service body (and accordingly the agreement 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 10(1) but the contractor 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 agreement; or
- (b) after the termination of the agreement (whether in connection with or arising out of the termination of the agreement or otherwise),

the contractor ceases to be regarded as such a body on the conclusion of that procedure.

PART 5

Agreements: required terms

Health service contract

12. If, by virtue of regulation 9 or 10 the contractor is to be regarded as a health service body, the agreement must state that it is an NHS contract.

Agreements: general

13.—(1) An agreement must specify—

- (a) the services to be provided under the agreement;

- (b) subject to paragraph (3), the address of each of the premises to be used by the contractor or by any sub-contractor for the provision of such services;
 - (c) the persons to whom such services are to be provided under the agreement; and
 - (d) where the agreement requires the contractor to provide essential services, the area as respects which persons resident in it are, subject to any other terms of the agreement relating to patient registration, entitled to—
 - (i) register with the contractor, or
 - (ii) seek acceptance by the contractor as a temporary resident; and
 - (e) where the agreement requires the contractor to provide essential services, whether, at the date on which the agreement comes into effect, the contractor's list of patients is open or closed.
- (2) An agreement—
- (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 must 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 agreement in respect of that patient.
- (3) 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.

Membership of a CCG

- 14.** An agreement must contain a term which has the effect of requiring the contractor—
- (a) if that contractor provides essential services to patients on its list of patients, to be a member of a CCG; and
 - (b) to 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

15.—(1) Subject to paragraphs (2) and (3), an agreement which requires a contractor to provide essential services 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 1 under, or for the purposes of, the enactments specified in relation to the 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) a party to the agreement, or
 - (iii) a shareholder in a qualifying body which is a party to the agreement; 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⁽⁷⁷⁾ (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985⁽⁷⁸⁾ (medical information).

Finance

16.—(1) The agreement must contain a term which has the effect of requiring payments to be made under the agreement promptly and in accordance with—

- (a) the terms of the agreement;
- (b) any other terms based on which the payment is made; and
- (c) any other conditions relating to the payment contained in regulations made by the Secretary of State under section 94(4) (regulations about section 92 arrangements) or directions given by the Secretary of State under section 98A (exercise of functions) of the Act⁽⁷⁹⁾.

(2) The obligation referred to in paragraph (1) is subject to any right that the Board may have to set off against any amount payable to the contractor under the agreement any amount that—

- (a) is owed by the contractor to the Board under the agreement; or
- (b) the Board may withhold from the contractor in accordance with the terms of the agreement or any other applicable provisions contained in regulations made by the Secretary of State under section 94(4) of the Act (regulations about section 92 arrangements) or directions given by the Secretary of State under section 98A of the Act (exercise of functions).

Conditions about payments

17. Where, as a consequence of regulations made under section 94(4) of the Act (regulations about section 92 arrangements) or in accordance with directions given by the Secretary of State under section 98A of the Act (exercise of functions), the Board is required to make a payment to a contractor under an agreement which is subject to conditions, the agreement must contain a term which requires those conditions to be a term of the agreement.

Fees and charges

18.—(1) The agreement 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 may not, either itself or through any other person, demand or accept from any patient of the contractor a fee or other remuneration, for its own or another's benefit, for—

- (a) the provision of any treatment whether under the agreement or otherwise; or

⁽⁷⁷⁾ S.I. 1976/615; as amended by S.I. 1982/699, S.I.1987/409, S.I. 1989/1686, S.I. 1991/2284, S.I.1994/2975, S.I.1999/3109, S.I.2001/2931, S.I. 2002/881 and 2469, S.I. 2004/1771, S.I. 2008/1554, S.I. 2010/137, S.I. 2013/235 and 630.

⁽⁷⁸⁾ S.I. 1985/1604; as amended by S.I. 1992/247 and S.I. 2010/137.

⁽⁷⁹⁾ Sections 92 was amended by paragraphs 36 of Schedule 4 to the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). Section 94 was amended by section 28(2) of, and paragraph 38(1) and (2) to, the 2012 Act, and by section 17(5) of, and paragraph 2(1)(b) and (2) of Schedule 9 to, the Crime and Courts Act 2013 (c.22). Section 98A was inserted by section 49(1) of the 2012 Act.

(b) a prescription or repeatable prescription for any drug, medicine or appliance, except in circumstances set out in regulation 19.

(3) Subject to paragraph (4), where—

- (a) a person applies to a contractor for the provision of services;
- (b) claims to be entitled to be treated by the contractor without paying a fee or other remuneration; and
- (c) 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 accordingly in accordance with regulation 19(e).

(4) Where—

- (a) a person from whom a contractor received a fee under regulation 19(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 the person was entitled to be treated by the contractor without paying a fee or other remuneration 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

19. 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 administrative action that they might take;
- (c) for treatment which is not primary medical services or is otherwise required to be provided under the agreement 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 it for that purpose, with such information about the treatment as the Board may require;
- (d) under section 158 of the Road Traffic Act(80) (payment for emergency treatment of traffic casualties);
- (e) when the contractor treats a patient under regulation 18(3), in which case the contractor is entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 18(4)) for any treatment given, if it gives the patient a receipt;

(80) 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.

- (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, or
 - (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 drugs, medicines or appliances in the form of a travel kit) which are required to be in the possession of a patient solely in anticipation of the onset of an ailment or occurrence of an injury while the patient is outside the United Kingdom but for which the patient is not requiring treatment when the medicine is prescribed;
- (i) for a medical examination—
 - (i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or
 - (ii) for the purpose of creating a report—
 - (aa) relating to a road traffic accident or criminal assault, or
 - (bb) that offers an opinion as to whether a patient is fit to travel;
- (j) for testing the sight of a person to whom none of paragraphs (a) to (e) of section 115(2) of the Act (primary ophthalmic services) applies (including by virtue of regulations made under section 115(7) of the Act⁽⁸¹⁾);
- (k) where the contractor is authorised or required in accordance with arrangements made with the Board under section 126 of the Act⁽⁸²⁾ (arrangements for pharmaceutical services) and in accordance with regulations made under section 129 of the Act⁽⁸³⁾ (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; or
- (l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

Patient participation

20.—(1) A contractor which provides essential services must establish and maintain a group known as a “Patient Participation Group” comprising some of its registered patients for the purposes of—

- (a) obtaining the views of patients who have attended the contractor’s practice about the services delivered by the contractor; and
- (b) enabling the contractor to obtain feedback from its registered patients about those services.

(2) The contractor is not required to establish a Patient Participation Group if such a group has already been established by the contractor in accordance with the provisions of any directions about

⁽⁸¹⁾ Section 115 was amended by paragraph 54 of Schedule 4 to the Health and Social Care Act 2012 (c.7) (“the 2012 Act”).

⁽⁸²⁾ Section 126 was amended by sections 213(7)(k) and 220(7) of, and paragraph 63 of Schedule 4 to, the 2012 Act.

⁽⁸³⁾ Section 129 was amended by section 26, 27 and 38 of, and Schedule 6 to, the Health Act 2009 (c.7); 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.

enhanced services which were given by the Secretary of State under section 98A of the Act⁽⁸⁴⁾ (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 each 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, about the services delivered by the contractor; and
- (b) review any feedback received about the services delivered by the contractor, whether in accordance with 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

21.—(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 practitioner who was a party to the agreement for a period of at least six months during that financial year, and
 - (ii) every general medical practitioner who was employed or engaged by the contractor to provide services under the agreement 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 have been employed or engaged by the contractor to provide services under the agreement in the contractor's practice on a full-time or a part-time basis and for a period of at least six months during the financial year in respect of which that information relates.

(3) The information specified in sub-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 agreement of medical services to which Part 4 of the Act applies, after having disregarded any expenses properly incurred in the course of performing or providing those services.

⁽⁸⁴⁾ Section 98A was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7).

Out of hours services

22.—(1) Subject to paragraphs (2) and (3), an agreement under which essential services are to be provided must provide for the provision of out of hours services throughout the out of hours period unless—

- (a) the Board has accepted in writing, prior to the signing of the agreement, a written request from the contractor that the agreement should not require the contractor to make such provision;
- (b) the contractor has opted out of providing such services in the out of hours period in accordance with Part 6; or
- (c) the agreement has been otherwise varied to exclude a requirement to make such provision.

(2) Except to the extent that the agreement otherwise provides, a contractor whose agreement includes the provision of out of hours services is only required to provide such services 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 such services.

(3) Paragraph (4) applies to a contractor which—

- (a) provides out of hours services to registered patients of another contractor or provider of essential services (or their equivalent); or
- (b) has contracted to provide out of hours services to patients to whom it provides essential services.

(4) The contractor must, in the provision of those services—

- (a) meet the quality requirements set out in the document entitled "National Quality Requirements in the Delivery of Out of Hours Services" published on 29th July 2006⁽⁸⁵⁾; and
- (b) 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.

(5) Where a contractor is a provider of essential services but is not required to provide out of hours services under the agreement or, under Part 6, has opted out of the provision of such services under the agreement, the contractor must—

- (a) monitor the quality of the out of hours services which are offered or provided to its registered patients having regard to the National Quality Standards referred to in subparagraph (4) and record, and act appropriately in relation to, any concerns arising;
- (b) record any patient feedback received, including complaints; and
- (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 to its registered 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 paragraph (4).

⁽⁸⁵⁾ The document entitled National Quality Standards in the Delivery of Out of Hours Services published on 20th July 2006 is available at http://www.dh.gov.uk/en/PublicationsAndStatistics/Publications/PolicyAndGuidance/DH_4137271. Hard copies of this document may be obtained from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

Sub-contracting

23. An agreement must contain terms which prevent a contractor from sub-contracting any of its obligations to provide clinical services under the agreement except in the circumstances provided for in Part 5 of Schedule 2.

Variation of agreements

24.—(1) Subject to paragraph (2), a variation of, or amendment to, the agreement may only be made in the circumstances provided for in Part 8 of Schedule 2.

(2) Paragraph (1) does not prevent a variation of, or amendment to, an agreement in the circumstances provided for in—

- (a) regulation 25;
- (b) Part 6; and
- (c) paragraphs 43(3) and 52 of Schedule 2.

Variation of agreements: registered patients from outside practice area

25.—(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 (4) and (5), the terms of the contractor's agreement 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 agreement as if the person resided within the contractor's practice area.

(3) The terms of the agreement specified in this paragraph are—

- (a) the terms under which the contractor is to provide essential services and any other service;
- (b) the terms under which the contractor is required to provide out of hours services to patients to whom it provides essential services; and
- (c) the terms which give effect to the following provisions of Schedule 2 (other contractual terms)—
 - (i) paragraph 1 (services to registered patients),
 - (ii) paragraph 5(1) (attendance at practice premises),
 - (iii) paragraph 6(2)(a) (attendance outside practice premises) , and
 - (iv) paragraph 20(2) (refusal of applications for inclusion 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 agreement must be varied so as to include a term which has the effect of modifying the application of paragraph 23 of Schedule 2 (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 agreement 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 agreement 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 services in accordance with those terms; or
- (b) comply with those terms.

(6) The agreement must also include a term which has the effect of requiring the contractor to notify a person in writing, where the contractor is minded to accept that person on its list of patients in accordance with arrangements made under paragraph (1), that the contractor is under no obligation to provide—

- (a) essential services, and any other service in core hours, if, at the time the treatment is required, it is not clinically appropriate or practical to provide primary medical services given the particular circumstances of the patient; or
- (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.

Termination of agreements

26.—(1) An agreement may only be terminated in the circumstances provided for by Part 8 of Schedule 2.

(2) An agreement must make suitable provision for arrangements which are to have effect on termination of the agreement, including the consequences (whether financial or otherwise) of the agreement ending.

Other required terms

27.—(1) Subject to paragraph (2), an agreement must also contain provisions which are equivalent in their effect to the provisions set out in Parts 6 to 14 of, and Schedules 1 and 2 to, these Regulations, unless the agreement 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 76(5) to (14);
- (b) regulation 77; and
- (c) paragraph 40(5) to (9) and 41(5) to (17) of Schedule 2,

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

PART 6

Out of hours services: opt outs

Opt outs: interpretation

28. In this Part—

“out of hours opt out notice” means a notice given under regulation 30(1) to opt out permanently of the provision of out of hours services;

“OOH day” is the day specified by the contractor in the out of hours opt out notice which the contractor gives to the Board for the commencement of the out of hours opt out;

“B day” is the day six months after the date on which the out of hours opt out notice was given; and

“C day” is the day nine months after the date on which the out of hours opt out notice was given.

Opt outs: general

29. Where—

- (a) an agreement requires the contractor to provide out of hours services in accordance with regulation 22; and
- (b) the contractor has contracted to provide out of hours services only to patients to which it is required to provide essential services under the agreement,

the agreement must contain terms relating to the procedure for opting out of the provision of those services which have the same effect as those specified in the following provisions of this Part.

Opting out of out of hours service provision

30.—(1) Where a contractor wants to terminate its obligation under the agreement 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 OOH day, which must be either three or six months after the date on which that notice was given.

(3) The Board must approve the out of hours opt out notice and specify, in accordance with paragraph (5), the 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 in writing of its decision as soon as possible.

(5) 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.

(6) 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 the out of hours services from an alternative provider from OOH day.

(7) The contractor’s duty to provide the out of hours services terminates on OOH day unless the Board gives notice in writing to the contractor under paragraph (7) (extending OOH 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 out of hours services from OOH day, the Board must give notice in writing to the contractor of this fact no later than one month before OOH day, and—

- (a) in a case where OOH day is three months after service of the opt out notice, the contractor must continue to provide the out of hours services until B day unless, at least one month before B day, it receives a notice in writing from the Board under paragraph (8) that, despite using reasonable endeavours, it has failed to find an alternative provider to take on the provision of the out of hours services from B day;
- (b) in a case where OOH day is six months after the date on which the opt out notice was served, the contractor must continue to provide the out of hours services until C day.

(9) Where, in accordance with paragraph (9)(a), the opt out is to commence on B day and the Board, despite using reasonable endeavours, has failed to find an alternative provider to take on the provision of the out of hours services from that day, the Board must give notice in writing to the contractor of this fact at least one month before B day, in which case the contractor must continue to provide the out of hours services until C day.

(10) The opt out takes effect at 8.00am on the relevant day unless—

- (a) the day is a Saturday, Sunday, Good Friday, Christmas Day, or a bank holiday, in which case the opt out takes effect on the next working day at 8.00am; or
- (b) the Board and the contractor agree a different day or time.

(11) As soon as reasonably practicable and, in any event, before the end of the period of seven days beginning with the date on which the Board gives notice under paragraph (10), the Board must enter into discussions with the contractor concerning the support that the Board may give to the contractor or other changes which the Board or the contractor may make in relation to the provision of out of hours services until C day.

Informing patients of opt outs

31.—(1) Before any out of hours 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 the arrangements made for them to receive the out of hours services by—

- (a) placing a notice in the contractor's waiting rooms; or
- (b) including the information in the contractor's practice leaflet.

PART 7

Right to a general medical services contract

Right to a general medical services contract

32.—(1) Where a contractor is providing essential services under the agreement and would like to enter into a general medical services contract by virtue of this regulation, the contractor must give notice in writing to the Board to that effect at least three months before the date on which the contractor would like to enter into the general medical services contract.

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

- (a) state that the contractor wants to terminate the agreement and the date on which the contractor would like the agreement to terminate, which must be at least three months after the date on which the notice was given;
- (b) subject to paragraph (3), give the names of the person or persons with whom the contractor wants the Board to enter into a general medical services contract; and
- (c) confirm that the person or persons so named meet the conditions set out in section 86 of the Act⁽⁸⁶⁾ (persons eligible to enter into GMS contracts) and regulations 5 (conditions relating solely to general medical practitioners) and 6 (general condition relating to all contracts) of the General Medical Services Contracts Regulations or, where the contractor is not able so to confirm, provide the reason why it is not able to do so together with

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

confirmation that the person or persons will, immediately prior to entering into the general medical services contract, meet those conditions.

(3) A person's name may only be given in a notice referred to in paragraph (1) if that person is a party to the agreement.

(4) The Board must acknowledge receipt of the notice given under paragraph (1) before the end of the period of seven days beginning with the date on which the Board received the notice.

(5) Provided that the conditions set out in section 86 of the Act (persons eligible to enter into GMS contracts) and regulations 5 and 6 of the General Medical Services Contracts Regulations are met, the Board must enter into a general medical services contract with the person or persons named in the notice given under paragraph (1).

(6) In addition to the terms required by the Act and the General Medical Services Contracts Regulations, a general medical services contract entered into by virtue of this regulation must provide for—

- (a) the general medical services contract to commence immediately after the termination of the agreement;
- (b) the names of the patients included in the contractor's list of patients immediately before the termination of the agreement to be included in the first list of patients to be prepared and maintained by the Board under paragraph 17 of Schedule 3 to the General Medical Services Contracts Regulations;
- (c) the same services to be provided under the general medical services contract as were provided under the agreement immediately before it was terminated unless the parties otherwise agree; and
- (d) the opt out of the provision of out of hours services referred to in paragraph (7) in accordance with the terms specified in Part 6 of the General Medical Services Contracts Regulations (opt outs: additional and out of hours services).

(7) The out of hours services are the services which the contractor was providing under the agreement in accordance with regulation 22 immediately before its termination and which the general medical services contract continues to require the contractor to provide.

(8) An agreement is to terminate on the date stated in the notice given by the contractor under paragraph (1) unless a different date is agreed by the contractor and the Board or no general medical services contract is entered into by the Board by virtue of this regulation.

(9) Where there is a dispute as to whether or not a person satisfies the conditions set out in section 86 of the Act (persons eligible to enter into a GMS contract), or of regulations 5 and 6 of the General Medical Services Contracts Regulations, the contractor may appeal to the First-tier Tribunal⁽⁸⁷⁾ under this regulation and the Board is to be the respondent.

(10) Any other dispute relating to this regulation is to be determined by the Secretary of State in accordance with regulation 9(2) and (3) of the General Medical Services Contracts Regulations.

(11) The parties to a dispute referred to the Secretary of State in accordance with paragraph (10) are the contractor and the Board.

⁽⁸⁷⁾ The First-tier Tribunal was established in 2008 by Part 1 of the Tribunals, Courts and Enforcement Act 2007 (c.15). The Health, Education and Social Chamber is responsible for hearing appeals concerning matters relating to the Health Service in England and Wales.

PART 8

Persons who perform services

Qualifications of performers: medical practitioners

33.—(1) Subject to paragraph (2), a medical practitioner may not perform medical services under the agreement 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⁽⁸⁸⁾ (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 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⁽⁸⁹⁾ (provisional registration), 15A⁽⁹⁰⁾ (provisional registration for EEA nationals) or 21⁽⁹¹⁾ (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 post-registration 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;
- (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 undertaking a post-registration programme.

⁽⁸⁸⁾ 1983 c.54. Section 41A was inserted by S.I. 2015/794.

⁽⁸⁹⁾ 1983 c.54. Section 15 was substituted by S.I. 2006/1914.

⁽⁹⁰⁾ 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.

⁽⁹¹⁾ 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

34.—(1) A health care professional (other than one to whom regulation 33 applies) may not perform clinical services under the agreement unless—

- (a) that health care professional is registered with the professional body relevant to that health care professional's profession; and
- (b) that registration is not subject to a period of suspension.

Conditional registration or inclusion in a primary care list

35. 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 agreement.

Clinical experience

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

Conditions for employment and engagement: medical practitioners

37.—(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 33(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 36.

(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 36 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 in 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

38.—(1) Subject to paragraph (2), a contractor may not employ or engage a health care professional to perform clinical services under the agreement unless—

- (a) the contractor has checked that the health care professional meets the requirements of regulation 34; or
- (b) the contractor has taken reasonable steps to satisfy itself that the health care professional meets the requirements of regulation 36.

(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 the matters referred to in regulation 36 in accordance with paragraph (1) before employing or engaging the healthcare 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 any—

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

Clinical references

39.—(1) The contractor may not employ or engage a health care professional to perform clinical services under the agreement (other than a medical practitioner to whom regulation 33(2)(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

40.—(1) The contractor must, before employing or engaging a person to assist it in the provision of services under the agreement, 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 37 to 39.

(3) When considering the competence and suitability of a 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

41.—(1) The contractor must ensure that for any health care professional who is—

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

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.

Arrangements for GP Specialty Registrars

42.—(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 agreement or for which other staff assist those medical 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 to Postgraduate Specialty Training in the UK”(92).

Doctors with provisional registration

43. A contractor may not, by reason only of having employed or engaged a person who is—

- (a) provisionally registered under section 15, 15A or 21 of the Medical Act 1983(93); and
- (b) acting in the course of that person's employment in a resident medical capacity in a post-registration programme,

reduce the total number of hours in which other staff assist in the performance of medical services under the agreement.

Notice requirements in respect of relevant prescribers

44.—(1) For the purposes of this regulation, “a relevant prescriber” is—

- (a) a chiropodist or podiatrist independent prescriber;
- (b) an independent nurse prescriber;
- (c) a pharmacist independent prescriber;
- (d) a physiotherapist independent prescriber; or
- (e) a supplementary prescriber.

(92) 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.

(93) 1983 c.54. Section 15 was substituted by articles 2 and 26 of S.I. 2006/1914. Section 15A was inserted by regulations 2 and 3 of S.I. 2000/3041, and was amended by S.I. 2006/1914 and S.I. 2007/1043. Section 21 was amended by S.I. 1996/1591, S.I. 2002/3135, S.I. 2006/1914 and S.I. 2007/3101.

- (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 agreement 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 agreement (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 agreement;
 - (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 agreement (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; and
 - (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 agreement,
- (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

45.—(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 15, 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

46. The contractor must carry out its obligations under the agreement with reasonable care and skill.

Appraisal and assessment

47.—(1) The contractor must ensure that any medical practitioner performing services under the agreement—

- (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 is to provide services under the agreement 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 9

Prescribing and dispensing

Prescribing: general

48.—(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 agreement,

complies as appropriate with the requirements in regulations 49, 50 and 52 to 55.

(2) For the purposes of regulations 49, 50 and 52 to 55 in their application to a contractor whose agreement 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

49.—(1) Subject to paragraphs (2) and (3) and to the restrictions on prescribing in regulations 54 and 55, a prescriber must order any drugs, medicines or appliances which are needed for the treatment of a patient who is receiving treatment under the agreement by—

- (a) issuing to the patient a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with paragraph (6);
- (b) creating and transmitting an electronic prescription in circumstances to which regulation 50(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 agreement 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 agreement,

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 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 or prophylaxis of, that disease;

- (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 agreement; 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 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.

(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 54.

(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 Schedule 2 to the Misuse of Drugs Regulations 2001⁽⁹⁴⁾ (controlled drugs to which regulations 14 to 16, 18, 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, that prescriber must—

- (a) use only the non-electronic 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) only order 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⁽⁹⁵⁾ (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 of importation, exportation

⁽⁹⁴⁾ 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.

⁽⁹⁵⁾ 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⁽⁹⁶⁾; 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) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
 - (c) the prescriber undertakes to—
 - (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

50.—(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;
 - (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 (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 subject to the requirements of regulations 22, 23, 26 and 27) or 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, or
 - (ii) a bulk prescription issued for a school or institution under regulation 56.

⁽⁹⁶⁾ 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.

(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 includes 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(97), or
 - (iii) a person duly authorised by a voluntary organisation by which the patient 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 a request, the patient's relative, primary carer, a donee of a lasting power of attorney or a deputy appointed for that person by a court under the Mental Capacity Act 2005(98).

(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 purpose of electronic prescriptions

51.—(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 operated by the Health and Social Care Information Centre(99)—

- (a) where the patient does not have a nominated dispenser, the dispenser chosen by the patient;
- (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 a 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(100), or

(97) 1989 c.41.

(98) 2005 c.9.

(99) 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).

(100) 1989 c.41.

- (iii) by a person duly authorised by a voluntary organisation by which the patient 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 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 provisions of the Mental Capacity Act 2005.
- (4) A contractor must—
- (a) not seek to persuade the patient to nominate a dispenser recommended by the prescriber or the contractor; and
 - (b) if asked by the 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

52.—(1) The contractor may only provide repeatable prescribing services to a person on its lists 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 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 of its patients to whom a person specified in paragraph (8) is authorised or required by the Board to provide pharmaceutical services in accordance with arrangements under section 126(101) (arrangements for pharmaceutical services) and section 132(102) (persons authorised to provide pharmaceutical services) of the Act.

(101)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) (“the 2012 Act”).

- (8) The persons specified in this paragraph are—
- (a) a medical practitioner who is a party to the agreement;
 - (b) in the case of an agreement with a qualifying body, any medical practitioner who is both a legal and beneficial shareholder in that body; or
 - (c) any medical practitioner employed or engaged by the contractor.

Repeatable prescriptions

53.—(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 electronic repeatable 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 to the person as soon as possible to that effect.

(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 attention 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, the prescriber must, as soon as practicable, give notice to a person that the person's repeatable prescription should no longer be used to obtain repeat dispensing services.

Restrictions on prescribing by medical practitioners

54.—(1) A medical practitioner, in the course of treating a patient to whom the practitioner is providing treatment under the agreement, 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 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 a general medical services 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 be ordered for specified patients and 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”.

(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(**103**) (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 subject to the requirements of regulations 22, 23, 26 and 27) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001(**104**).

(103) 1971 c.38.

(104) S.I. 2001/3998. Schedule 4 was amended by S.I. 2003/1432, S.I. 2005/3372, S.I. 2007/2154, S.I. 2012/973, S.I. 2013/625, S.I. 2014/1275 and 3277 and S.I. 2015/1891. Schedule 5 was amended by S.I. 2005/2864.

(6) Subject to regulation 18(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 (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 Schedule 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(**105**), 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 Schedule 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

55.—(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(**106**) (prescribing and administration by supplementary prescribers), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of those Regulations;
- (b) the prescription only 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 may not be ordered for patients in the provision of medical services under a general medical services contract; and
- (c) the prescription only medicine is not specified in any directions given by the Secretary of State under section 88 of the Act (GMS contracts: prescription of drugs) as being a prescription only 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

(**105**) 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.

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

- (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 at which 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
 - (bb) incidents occurring with the appliance that might lead, might have led or has 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 any 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 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 agreement;

- (d) 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 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 a 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 a description mentioned in the entry in Part IX of the Drug Tariff in respect of that appliance,
 - (ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and
 - (iii) when issuing or creating the prescription, 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

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

Excessive prescribing

- 57.**—(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 may, if the contractor consents, seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the agreement.

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

58.—(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 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 any drug or medicine to a patient otherwise than in accordance with Part 12 of the Human Medicines Regulations 2012(**107**).

PART 10

Prescribing and dispensing: out of hours services

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

59.—(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 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 agreement;

“Patient Group Direction” has the meaning given in the regulation 213(1) of the Human Medicines Regulations 2012(**108**) (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 agreement includes the provision of out of hours services has agreed with the Board that its agreement should also include the supply of necessary drugs, medicines or 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—

(**107**) 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.
 (**108**) S.I. 2012/1916. There are no relevant amendments to regulation 213.

- (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 Contracts) (Prescription of Drugs etc) Regulations 2004(109) (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(110) (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 sub-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)(111) in respect of dispensing services to the patient by virtue of either—
 - (a) entitlement to exemption under regulations made under section 172 or 174 of the Act; or
 - (b) entitlement to full remission of charges under regulations made under section 182 (remission and repayment of charges) or 183(112) (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 service 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.

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

(110) S.I. 2001/3998. 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. 2013/363 and 2194, S.I. 2012/2389 and S.I. 2014/1625.

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

(112) Section 183 was amended paragraph 98 of Schedule 4 to the 2012 Act and by S.I. 2010/915 and S.I. 2013/2269.

(9) The provisions of regulation 18 which relates to fees and charges apply in respect of the supply of necessary drugs, medicines and appliances under this regulation as they apply in respect of prescriptions for any drugs, medicines and appliances.

PART 11

Records and information

Patient records

60.—(1) The contractor must keep adequate records of its attendance on and treatment of patients.

(2) A contractor which provides essential services must keep the records referred to in paragraph (1)—

- (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.

(3) A contractor which provides essential services must include in the records referred to in paragraph (1), clinical reports sent in accordance with paragraph 7 of Schedule 2 or from any other health care professional who has provided clinical services to a person on the contractor's list of patients.

(4) The consent of the Board required by paragraph (2)(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"**(113)**;
- (b) the security measures, audit and system management functions incorporated into the computer system as accredited in accordance with sub-paragraph (a) have been enabled; and
- (c) the contractor is aware of, and has signed an undertaking that it will have regard to, the guidelines contained in "The Good Practice Guidelines for GP electronic patient records (Version 4)" published on 21st March 2011**(114)**.

(5) 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 (4)(b) to the extent necessary for the Board to confirm that the audit function is enabled and functioning correctly.

(6) 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

(113) 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, Board Lane, Leeds, LS1 6AE.

(114) 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 of this guidance are available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

- (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.
- (7) To the extent that a patient's records are computerised records, the contractor complies with paragraph (6) 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.
- (8) The consent of the Board to the transmission of information other than in writing for the purposes of paragraph (7)(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.
- (9) 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 (4)(b).
- (10) In this regulation, "computerised records" means records created by way of entries on a computer.

Summary Care Record

- 61.**—(1) A contractor which provides essential services 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.

Electronic transfer of patient records between GP practices

- 62.**—(1) A contractor which provides essential services 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 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 the 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

63.—(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, efficiently and accurately sharing information relating to that patient across the whole of the health service in England.

Patient online services

64.—(1) A contractor which provides essential services 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 comply with the requirement in paragraph (1)(a) so as to increase the proportion of appointments which are available for its registered patients to book online and, if so, to 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—
 - (i) to the patient's physical or mental health, or

- (ii) to the physical or mental health of any other person;;
 - (b) the information includes any reference to a 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 the 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 to its registered patients; and
 - (b) only apply until such time as the contractor is able to fully comply with the requirements of 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 enable it to achieve those requirements by 31st March 2016 by displaying a statement of intent on the practice premises and, where the practice 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 another person in accordance with “General Practice Systems of Choice Level 2(115)”; and
 - (b) “summary information” has the meaning given in regulation 61(2).

Confidentiality of personal data: nominated person

65. 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

66. 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 13(2)) by reference to a sketch, diagram, plan or postcode.

Provision of information

67.—(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 the Board, to access—

- (a) any information which is reasonably required by the Board for the purposes of or in connection with the agreement; and

(115) 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, Board Lane, Leeds, LS1 6AE.

(b) any other information which is reasonably required in connection with the Board's functions.

(2) The contractor is not be 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 it by the Secretary of State under section 98A of the Act (exercise of functions).

(3) The contractor must produce the information requested, or, as the case may be, allow the Board, or a person authorised by 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

68.—(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 agreement.

(3) The contractor is not obliged to answer any inquiry referred to in paragraph (1) unless it is made—

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

(4) The appropriately qualified person referred to in paragraph (3)(a) or (b) must —

- (a) be appointed by the Board to assist it in the exercise of the Board's functions under this regulation; and
- (b) produce on request, written evidence that they are authorised by the Board to make such an inquiry on the Board's behalf.

Provision of information to a medical officer etc.

69.—(1) The contractor must, if satisfied that the patient consents—

- (a) supply in writing to any person specified in paragraph (3), (a "relevant person"), before the end of such reasonable period as that person may specify, such clinical information as any of the persons mentioned 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 purposes 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(**116**) (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.

(116) 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.

Annual return and review

70.—(1) The contractor must submit to the Board an annual return relating to the agreement which must require the same categories of information to be provided by all persons who hold agreements with the Board.

(2) The Board may request a return relating to the agreement 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 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 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 agreement.

(5) The Board must prepare a draft record of the review referred to in paragraph (2) for comment by the contractor and, having regard to such comments, must produce a final written record of the review.

(6) The Board must send a copy of the final record of the review referred to in paragraph (5) to the contractor.

Practice leaflet

71.—(1) A contractor which provides essential services must compile a document (a “practice leaflet”) which must include the information specified in Part 6 of Schedule 2.

(2) The contractor must review its practice leaflet at least once in every period of 12 months and make any amendments necessary to maintain its accuracy.

(3) The contractor must make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

PART 12**Complaints****Complaints procedure**

72.—(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 agreement.

(2) The complaints procedure must comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(117).

Co-operation with investigations

73.—(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 agreement 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 and Wales, 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(**118**) (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(**119**) (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(**120**) (The Commissioner).
- (3) For the purposes of paragraph (1), co-operation includes—
- (a) answering questions which are reasonably put to the contractor by the Board;
 - (b) providing 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 13

Dispute resolution

Local resolution of agreement disputes

74.—(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 agreement 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 dealt with under the NHS dispute resolution procedure by virtue of paragraph 41(1) of Schedule 2 where it is not practicable for the parties to attempt local resolution before the expiry of the period seven days specified in paragraph 41(4) of that Schedule.

(118) 1970 c.42. Section 1 was amended by section 22(4) of, and Schedule 10 to, the Local Government (Wales) Act 1994 (c.19).

(119) 1994 c.39. Section 2 was amended by paragraph 232(1) of Schedule 22 to the Environment Act 1995 (c.25).

(120) 1993 c.46. Section 1 was amended by section 195 of the Local Government Act 1972 (c.70); 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. The Act is repealed in relation to Scotland by the Scottish Public Service Ombudsman Act 2002 (asp 11).

Dispute resolution: non-NHS contracts

75.—(1) Where an agreement is not an NHS contract, a dispute arising out of or in connection with the agreement, except any matter dealt with under the complaints procedure under Part 12, may be referred for consideration and determination by 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 by 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 agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

76.—(1) The procedure specified in this regulation and in regulation 77 applies to a dispute arising out of or in connection with the agreement which is referred to the Secretary of State in accordance with—

- (a) section 9(6) of the Act (where the agreement is an NHS contract); or
- (b) regulation 75(1) (where the agreement 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 38 of Schedule 2 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 agreement; 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 an agreement 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 a person or persons to consider and determine the dispute.

(6) Before reaching a decision about who should determine the dispute, either under paragraph (5) or under 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 may wish to make about the matter under dispute before the end of a specified period.

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

- (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) in each case, request in writing a party to whom a copy of the representations is given to make, within a specified period, any written observations which that party may wish 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 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 other persons whose expertise the adjudicator considers is likely 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 77; and
- (c) any agreement between the parties.

Determination of dispute

77.—(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 the adjudicator makes a direction as to payments under section 9(6) of the Act (as it has effect as a result of section 9 of the Act or regulation 77(1), that direction is to be enforceable in a county court (if the court so orders) as if it were a judgement or order of the court.

(3) Where a dispute is referred for determination in accordance with regulation 75(1)—

- (a) section 9(12) and (13) of the Act apply in the same manner as those provisions apply to an agreement 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 agreement 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

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

(2) A term of the agreement which makes provision in respect of the requirements of this Part is to survive even where the agreement has terminated.

PART 14

Miscellaneous

Clinical governance

79.—(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 agreement.

(4) In this regulation—

- (a) “controlled drugs” has the meaning given in section 2 of the Misuse of Drugs Act 1971(121) (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 safeguards high standards of care by creating an environment in which clinical excellence can flourish.

Friends and Family Test

80.—(1) A contractor which provides essential services must give all patients who use the contractor’s practice the opportunity to provide feedback about the service received from the contractor’s practice through the Friends and Family Test(122).

(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(123).

(3) In this regulation, “Friends and Family Test” means the arrangements that a contractor which provides essential services 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

81. 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(124).

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

82. The contractor must co-operate with—

- (a) the Secretary of State in the discharge of the Secretary of State’s duty under section 1F of the Act(125) (duty as to education and training); and
- (b) Health Education England(126) 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(127) (planning education and training for health workers etc.).

Insurance

83.—(1) The contractor must at all times have in force in relation to it an indemnity arrangement which provides appropriate cover.

(121) 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).

(122) 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-guidance/>. Hard copies of this guidance are available from Primary Care Contracting, NHS Employers, 50 Broadway, London SW1H 0DR.

(123) See pages 7 and 8 of the full Guidance for GP Practices on the Friends and Family Test 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-guidance/>. Hard copies of this guidance are available from Primary Care Contracting, NHS Employers, 50 Broadway, London SW1H 0DR.

(124) S.I. 2013/373.

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

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

(127) 2014 c.23. See section 97 of the Care Act 2014 for the duty on Health Education England to exercise the Secretary of State’s functions under section 1F of the Act.

(2) The contractor may not sub-contract its obligations to provide clinical services under the agreement 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 agreement, 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 it is held by a person employed or engaged by the contractor in connection with clinical services which that person provides under the agreement or, as the case may be, sub-contract.

Public liability insurance

84. 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 agreement which are not covered by the indemnity agreement referred to in regulation 83.

Gifts

85.—(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 agreement; 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 agreement is with a qualifying body—
 - (i) any person both legally and beneficially owning a share in the qualifying body, or
 - (ii) a director or secretary of the qualifying body;
- (c) any person employed by the contractor for the purposes of the agreement;
- (d) any general medical practitioner engaged by the contractor for the purposes of the agreement;
- (e) 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 (d); or
- (f) any person whose relationship with a contractor (where the contractor is an individual medical practitioner) or with a person specified in sub-paragraphs (b) to (d) 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 (f).
- (5) The register referred to in 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

- 86.** 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

- 87.** The agreement 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

- 88.**—(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(**128**) (transfer schemes).
- (2) Subject to paragraph (4), any act or omission concerning an agreement 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 an agreement 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 an agreement 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 by Schedule 4, 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) “agreement” includes any agreement 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

89. Schedule 3 makes provision in respect of the amendment to secondary legislation which are consequential upon the coming into force of these Regulations.

Revocations

90. Schedule 4 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 on behalf of the Secretary of State for Health.

6th November 2015

Alistair Burt
Minister of State,
Department of Health

SCHEDULE 1

Regulation 15

List of prescribed medical certificates

| <i>Description of medical certificate</i> | <i>Enactment under or for the purposes of which 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(129) Air Force (Constitution) Act 1917(130) Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939(131) Personal Injuries (Emergency Provisions) Act 1939(132) Social Security Administration Act 1992(133) Social Security Contributions and Benefits Act 1992(134) Social Security Act 1998(135) |
| 2. To establish pregnancy for the purpose of obtaining welfare foods | Section 13 of the Social Security Act 1988(136) (Benefits under schemes for improving nutrition: pregnant women, mothers and children) |
| 3. To secure registration of still-birth | Section 11 of the Births and Deaths Registration Act 1953(137) (special provision as to registration of still-birth) |
| 4. To enable payment to be made from an institution or other person in case of mental disorder of persons entitled to payment from public funds | Section 142 of the Mental Health Act 1983(138) (pay, pensions etc. of mentally disordered persons) |
| 5. To establish unfitness for jury service | Juries Act 1974(139) |

(129) 1865 c.45. 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).

(130) 1917 c.51.

(131) 1939 c.83.

(132) 1939 c.82.

(133) 1992 c.5.

(134) 1992 c.4.

(135) 1998 c.14.

(136) 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).

(137) 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, S.I. 1968/1242 and S.I. 1996/2395.

(138) 1983 c.20. Section 142 of the Mental Health Act 1983 was repealed by section 67 of the Mental Capacity Act 2005 (c.5). See paragraph 29 of Schedule 26 to the Mental Capacity Act 2005 which enables payments made under section 142 before the date on which it was revoked to continue to be made.

(139) 1974 c.23.

Status: This is the original version (as it was originally made).

| <i>Description of medical certificate</i> | <i>Enactment under or for the purposes of which 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(140) |
| 7. To enable a person to be registered as an absent voter on grounds of physical incapacity | Representation of the People Act 1985(141) |
| 8. To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances | National Health Service Act 2006(142) |
| 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 of the amount of Council Tax payable | Local Government and Finance Act 1992(143) |

SCHEDULE 2

Regulation 27

Other required terms

PART 1

Provision of services

Services to registered patients

1. Where the agreement provides for a contractor to provide essential services, the contractor must—
 - (a) provide those services, and such other services that the contractor is required to provide to its patients, at such times, within core hours, as are appropriate to meet the reasonable needs of those patients; and
 - (b) have in place arrangements for the contractor’s patients to access such services throughout the core hours in case of emergency.

Premises

- 2.—(1) The contractor must ensure that the premises used for the provision of services under the agreement are—
 - (a) suitable for the delivery of those services; and
 - (b) sufficient to meet the reasonable needs of the contractor’s patients.

(140) 1985 c.17.
 (141) 1985 c.50.
 (142) 2006 c.41.
 (143) 1992 c.14.

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

Telephone services

3.—(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 agreement; or
- (b) any other person to contact the contractor’s practice in relation to services provided at the contractor’s practice as part of the health service,

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

4.—(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 at the contractor’s practice under the agreement; and
- (b) calls made by persons, other than patients, to the contractor’s practice in relation to services provided at the contractor’s practice as part of the health service.

Attendance at practice premises

5.—(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.

Status: This is the original version (as it was originally made).

Attendance outside practice premises

6.—(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 a 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.

Clinical reports

7.—(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—

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

(3) This paragraph does not apply in relation to the provision of out of hours services by a contractor which is, by virtue of regulation 22, required to comply with the quality standards or requirements referred to in that regulation.

Storage of vaccines

8. The contractor must ensure that all—

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

Infection control

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

Duty of co-operation

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

- (a) a particular service; or
- (b) 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 in so far 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 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 agreement 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

11. Where a contractor is to cease to be required to provide to its patients—

- (a) a particular service; or
- (b) 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 an agreement for the provision of such services.

PART 2

Patients: general

General provision

12. This Part only applies to a contractor which provides essential services.

List of patients

13. 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 its list of patients under paragraph 17 and who have not subsequently been removed from that list under paragraphs 22 to 30; and
- (b) who have been assigned by the Board to the contractor’s list of patients—
 - (i) under paragraph 38(1)(a), or
 - (ii) under paragraph 38(1)(b) (by virtue of a determination of the assessment panel under paragraph 40(8) which has not subsequently been overturned by a determination of the Secretary of State under paragraph 41 or by a court).

Newly registered patients – alcohol dependency screening

14.—(1) Where a patient has been—

- (a) accepted onto the contractor’s list of patients; or
- (b) assigned to that list by the Board,

the contractor must 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 health risks to that patient.

(2) The contractor must comply with the requirement in sub-paragraph (1) by screening the patient using either one of the two shortened versions of the World Health Organisation Alcohol Use Disorders Identification (“AUDIT”) questionnaires(144) which are known as—

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

(3) Where, under sub-paragraph (2), the contractor identifies a patient as positive using either of the shortened versions of the AUDIT questionnaire specified in sub-paragraph (2), the remaining questions of the full ten question AUDIT questionnaire must 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 any additional support or treatment required for people with mental health issues; and

(144) The World Health Organisation Alcohol Use Disorders Identification Test (AUDIT) questionnaire can be accessed at http://www.who.int/substance_abuse/activities/sbi/en/. Further information about the Test, and the questionnaires themselves, is available in hard copy form from NHS England, PO Box 16738, Redditch, BP97 7PT.

- (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 or depression; and
 - (c) where anxiety or depression is diagnosed, provided with any treatment and support which may be required under the agreement, including a 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 60.

Accountable GP

15.—(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 agreement 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 was 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 them 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 60.

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(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⁽¹⁴⁵⁾.

Patients aged 75 years and over: accountable GP

16.—(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 agreement 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 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 is so accepted; or
- (b) in the case of a person who is included in the contractor’s list of patients immediately before the date on which these Regulations come into force and 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 in the course of which the contractor must make such inquiries and undertake such examinations of the patient as appear to it to be appropriate in all the circumstances.

⁽¹⁴⁵⁾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.

Application for inclusion in a list of patients

17.—(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 (“the applicant”) 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 from 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(146), 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 the 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 Mental Capacity Act 2005(147).

(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, to the person making the application on the applicant’s behalf) of that acceptance.

Inclusion in list of patients: armed forces personnel

18.—(1) The contractor may, if the contractor’s list of patients is open, include a person to whom sub-paragraph (2) applies in its list of patients for a period of up to two years and paragraph 28(1) (b) does not apply in respect of any person included in the contractor’s by virtue of this paragraph.

(2) This sub-paragraph applies to a person who is—

(146) 1989 c.41.

(147) 2005 c.9.

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- (a) a serving member of the armed forces of the Crown who has received written authorisation from Defence Medical Services(148) 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 comes to an end, the contractor must—
- (a) notify Defence Medical Services in writing that its responsibility for that person has come to an end; and
 - (b) update the patient's medical record, or summary of that record, and return it to Defence Medical Services.

Temporary residents

19.—(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 the person's 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) the period of 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 such 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 the end of the three month period referred to in paragraph (a), at the end of that period.

(148) 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.

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

20.—(1) The contractor may only refuse an application made under paragraph 17 or 19 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 17, 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 13(2)).

(3) Where a contractor refuses an application made under paragraph 17 or 19, the contractor must give notice in writing of that refusal and of the reason for it to the applicant (or, in the case of a child or an adult who lacks capacity, the person making the application on the applicant's behalf) before the end of the period of the period of 14 days beginning with the date of the decision to refuse.

(4) The contractor must—

- (a) keep a written record of—
 - (i) the refusal of any application made under paragraph 17,
 - (ii) the reasons for that refusal; and
- (b) make such records available to the Board on request.

Patient preference of a practitioner

21.—(1) Where the contractor has accepted an application made under paragraph 17 of 19, 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

22.—(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 this paragraph takes effect on whichever is the earlier of—

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- (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 23(1)(b) and (9), 24(6) and (7), 25(1), 28(2) and 29(3), 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, on behalf of the patient—
 - (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(149), or
 - (iii) a person duly authorised by a voluntary organisation by whom 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 provisions of the Mental Capacity Act 2005(150).

Removal from the list at the request of the contractor

23.—(1) Subject to paragraph 24, 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 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 person and the contractor,

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

(149) 1989 c.41.

(150) 2005 c.9.

(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 the 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 any party to the agreement who is an individual, any member of the contractor's staff or any other person; or
- (c) the contractor considers that it is not otherwise reasonable or practical for a warning to be given.

(5) The contractor must keep a written record of—

- (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.

(6) 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 a case where sub-paragraph (2) applies, grounds for a more specific reason not being appropriate,

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

(7) The removal of a person from the contractor's list of patients in accordance with this paragraph must, subject to sub-paragraph (8), 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 receives the notice referred to in sub-paragraph (1)(a).

(8) Where, on the date on which the removal of a person would take effect under sub-paragraph (7), 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).

(9) 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 (7) or (8).

Removal from the list of patients who are violent

24.—(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) any party to the agreement who is an individual;
- (b) a member of the contractor’s staff;
- (c) a person engaged by the contractor to perform or assist in the performance of services under the agreement;
- (d) any other person present—
 - (i) on the contractor’s practice premises, or
 - (ii) in the place where services were provided to the patient under the agreement.

(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 the notice was given.

(4) The Board must acknowledge in writing receipt of a request 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 the person’s physical or mental health, or
 - (ii) put the safety of a person specified in sub-paragraph (2) at risk.

(7) Where a person is removed from the contractor’s list of patients in accordance with 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

25.—(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

26.—(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 in 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 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 list of patients whose address is unknown

27. 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 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 the contractor is still responsible for providing essential services.

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

28.—(1) The Board must remove a person from a contractor’s list of patients where it is given 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 whom paragraph 18 applies);

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- (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 is given 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 a person from the contractor's list of patients under this paragraph.

Removal from the list of patients accepted elsewhere as temporary residents

- 29.**—(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 any removal of a person from the contractor's list of patients under this paragraph—
- (a) to the contractor; and
 - (b) where practicable, to that person.
- (3) A notice given to a person under sub-paragraph (2)(b) must inform the person to whom it is given 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 a list of pupils etc. of a school

- 30.**—(1) Where the contractor provides essential services under the agreement to persons on the grounds that they are pupils at, or staff or residents of, a school, the Board must remove any such 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

31.—(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 17(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 of the termination to that person and the reason for it.

(4) The contractor must keep a written record of any 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 24(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

List of patients: closure etc.

Application for closure of list of patients

32.—(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—

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- (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) details of 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 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 application was received by the Board.
- (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 decide 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 agreement 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 it does so, the Board 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 and the date on which the list of patients is to reopen; 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 33; or
 - (b) reject the application in accordance with paragraph 34.
- (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 35 applies; or
 - (b) there has been a change in the circumstances of the contractor which affects its ability to deliver services under the agreement.

Approval of an application to close a list of patients

33.—(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 agreement, and
 - (ii) any person who the Board consulted in accordance with paragraph 32(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 contractor’s 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 36, 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

34.—(1) Where the Board rejects 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 must include the Board’s reasons for rejecting the application; and
- (b) at the same time as the Board 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 agreement, and
 - (ii) any person who the Board consulted in accordance with paragraph 32(8).

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(2) Subject to sub-paragraph (3), if the Board decides to reject an application from a contractor to close its list of patients, the contractor may 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 agreement.

Application for an extension of the closure period

35.—(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 the closure 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 application was received by the Board.

(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 as soon as possible after making that decision.

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

- (a) give notice in writing to the contractor of its decision (“the extended closure notice”) which must include the details specified 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 agreement, and
 - (ii) any person who the Board consulted in accordance with paragraph 32(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, the Board must—
- (a) give notice in writing to the contractor of its decision which must include 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 agreement.
- (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 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

36. 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

37. 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

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- (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 13(2)) that person resides.

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

38.—(1) Subject to paragraph 39, 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 40(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 41(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 42.

Factors relevant to assignments

39. When assigning a person as a new patient to a contractor’s list of patients under paragraph 38(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 23 (relating to circumstances in which a patient may be removed from a contractor’s list of patients at the request of the contractor),
 - (ii) paragraph 24 (relating to circumstances in which a patient who is violent may be removed from a contractor’s list of patients), or
 - (iii) the equivalent provisions to those paragraphs in relation to arrangements made under section 83(2) of the Act(151) (which relates to the provision of primary medical services) or under a contract made in accordance with the General Medical Services Contracts Regulations;
- (e) in a case to which sub-paragraph (d)(ii) applies (or to which the 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

40.—(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.

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

- (2) The Board must give notice in writing to—
- (a) contractors, including those contractors who provide primary medical services in accordance with arrangements made under section 83(2) of the Act (primary medical services) or under a contract made in accordance with the General Medical Services Contracts Regulations, 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⁽¹⁵²⁾ or Local Healthwatch organisation⁽¹⁵³⁾;
 - (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 panel's determination provide essential 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 contractor's referred to in sub-paragraph (2)(a).

⁽¹⁵²⁾ See section 194 of the Health and Social Care Act 2012 which requires a local authority to establish a Health and Wellbeing Board for its area.

⁽¹⁵³⁾ 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 its functions. Section 222 was amended by section 183 of, and Schedules 5 and 14 to, the Health and Social Care Act 2012.

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

41.—(1) Where an assessment panel makes a determination under paragraph 40(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 40(7)(a), 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 agreement (or agreements); 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 they 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 result 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 they 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 they 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 or 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 40(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

42.—(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 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

43.—(1) The contractor must not sub-contract any of its rights or duties under the agreement in relation to clinical matters to any person unless it has taken reasonable steps to satisfy itself that—

- (a) it is reasonable in all the circumstances to do so;
- (b) the person to whom any of those rights or duties is sub-contracted is qualified and competent to provide the service; and
- (c) the person holds adequate insurance in accordance with regulation 83.

(2) Where the contractor sub-contracts any of its rights or duties under the agreement in relation to clinical matters, it must—

- (a) inform the Board of the sub-contract as soon as reasonably practicable; and
- (b) provide the Board with such information in relation to the sub-contract as the Board may reasonably request.

(3) Where the contractor sub-contracts clinical services under sub-paragraph (1), the parties to the agreement are deemed to have agreed a variation to the agreement which has the effect of adding to the list of the contractor's premises any premises which are to be used by the sub-contractor for the purposes of the sub-contract and, in these circumstances, regulation 24(1) does not apply.

(4) A contractor must ensure that any person with whom it sub-contracts is prohibited from sub-contracting the clinical services which that person has agreed with the contractor to provide.

(5) The contractor, if it has a list of registered patients or a list of registered patients is held in respect of it, must not sub-contract any of its rights or duties under the agreement 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 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 (6) applies to that company or firm.

(6) 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(154) of the Act (sale of medical practices) and Schedule 21 to the Act (prohibition of sale of medical practices) or in any regulations made wholly or partly under those provisions.

PART 6

Provision of information: practice leaflet

Information to be included in a practice leaflet

44. A practice leaflet must include—

- (a) the name of the contractor;
- (b) in the case of an agreement with a qualifying body—
 - (i) the names of the directors, the company secretary and the shareholders of that qualifying body, and
 - (ii) the address of that qualifying body's registered office;
- (c) the contractor's telephone, fax number and website address (if any);
- (d) the full name of each person performing services under the agreement;
- (e) the professional qualifications of each health care professional providing services under the agreement;
- (f) whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals;
- (g) whether the contractor provides essential services in its practice area, including the area known as the outer boundary area (within the meaning given in regulation 13(2)) by reference to a sketch diagram, plan or postcode;
- (h) the address of each of the contractor's premises;
- (i) the access arrangements which the contractor's premises have for providing services to disabled patients and, if none, the alternative arrangements for providing services to such patients;
- (j) how to register as a patient;
- (k) the right of patients to express a preference of practitioner in accordance with paragraph 21 and the means of expressing such a preference;
- (l) the services available under the agreement;
- (m) the opening hours of the contractor's premises and the method of obtaining access to services throughout the core hours;
- (n) the criteria for home visits and the method of obtaining such a visit;
- (o) 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;

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- (p) where the services referred to in sub-paragraph (o) are not provided by the contractor, the fact that the Board is responsible for commissioning the services;
- (q) information about the assignment by the contractor to its new and existing patients of an accountable GP in accordance with paragraph 15;
- (r) information about the assignment by the contractor to its patients aged 75 and over of an accountable GP under paragraph 16;
- (s) the telephone number of the 111 service;
- (t) the method by which patients are to obtain repeat prescriptions;
- (u) if the contractor offers repeatable prescribing services, the arrangements for providing such services;
- (v) if the contractor is a dispensing contractor, the arrangements for dispensing prescriptions;
- (w) how patients may make a complaint or comment on the provision of services;
- (x) the rights and responsibilities of the patient, including keeping appointments;
- (y) the action that may be taken where a patient is violent or abusive to a party to the agreement who is an individual, any member of the contractor's staff or other persons present on the contractor's premises or in the place where treatment is provided under the agreement;
- (z) details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the rights of patients in relation to the disclosure of such information; and
- (aa) the full name, postal and e mail address and telephone number of the Board from whom details of primary medical services in the area may be obtained.

PART 7

Notice requirements and rights of entry

Notices to the Board

45. 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 agreement;
- (b) any circumstances which give rise to the Board's right to terminate the agreement under paragraph 57 or 58;
- (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.

Notice provisions specific to an agreement with a qualifying body

46.—(1) Where a qualifying body is a party to the agreement, the contractor must give notice in writing to the Board as soon as—

- (a) any share in the qualifying body is transmitted or transferred (whether legally or beneficially) to another person on a date after the date on which the agreement was entered into;

- (b) a new director or secretary of the qualifying body is appointed;
 - (c) the qualifying body passes a resolution, or a court of competent jurisdiction makes an order, that the qualifying body be wound up;
 - (d) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the qualifying body;
 - (e) circumstances arise which would enable the court to make a winding up order in respect of the qualifying body; or
 - (f) the qualifying body is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986⁽¹⁵⁵⁾ (definition of inability to pay debts).
- (2) A notice under paragraph (1)(a) must confirm that the new shareholder, or, as the case may be, the personal representative of a deceased shareholder—
- (a) falls within section 93(1) of the Act⁽¹⁵⁶⁾ (persons with whom agreements may be made); and
 - (b) meets the further conditions imposed on shareholders by virtue of regulation 5.
- (3) A notice under 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 5.

Notice of deaths

- 47.**—(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 date on which that death occurred.
- (2) The notice given under sub-paragraph (1) must include—
- (a) the patient's full 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 agreement

- 48.**—(1) This paragraph applies where an agreement is varied in accordance with regulation 24 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 that 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

⁽¹⁵⁵⁾ 1986 c.45. Section 123 was modified by section 90 of, and Schedule 15 to, the Building Societies Act 1986 (c.5), and by the section 23 of, and Schedule 10 to, the Friendly Societies Act 1992 (c.40).

⁽¹⁵⁶⁾ Section 93 was amended by paragraph 37 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

- (ii) register elsewhere for the provision to them of essential services (or their equivalent).

Entry and inspection by the Board

49.—(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.

Entry and inspection by the Care Quality Commission

50. 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(157) (entry and inspection).

Entry and inspection by Local Healthwatch organisations

51. 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(158) (duties of service-providers to allow entry by Local Healthwatch organisations or contractors).

PART 8

Variation and termination of agreements

Variation of an agreement

52.—(1) Subject to Part 6 and to paragraphs 43(3) and 64 of Schedule 2, a variation of, or amendment to, an agreement is not effective unless it is in writing and signed by or on behalf of the Board and the contractor.

(2) The Board may vary the agreement 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.

(157)2008 c.14.

(158)2007 c.28. See section 225(5) 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, and Schedule 5 to, the 2012 Act; and paragraphs 148 to 151 of Schedule 5 to the 2012 Act.

(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 the notice under that sub-paragraph is given to the contractor.

Termination by agreement

53. The Board and the contractor may agree in writing to terminate the agreement, 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 agreement is to be terminated.

Termination on death of the contractor

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

(2) This sub-paragraph applies where, before the end of the period of seven days referred to in sub-paragraph (1), the Board agrees in writing with the contractor's personal representatives that the agreement should continue for a further period, not exceeding 28 days, from the end of the period of seven days.

(3) This paragraph does not affect any other rights to terminate the agreement which the Board may have under paragraphs 57 to 60.

Termination by giving notice

55.—(1) The contractor or the Board may at any time terminate the agreement by giving notice in writing to the other party or parties to the agreement.

(2) Subject to sub-paragraphs (3) and (4), notice given under sub-paragraph (1) must specify the date on which the termination is to take effect and the agreement terminates on the date so specified.

(3) Where the period of notice in relation to the termination (which must be a period of at least six months) has previously been agreed between the parties and provided for in the agreement, the date of termination specified in the notice must be calculated in accordance with the agreed period of notice.

(4) Where a period of notice in relation to the termination has not previously been agreed between the parties and provided for in the agreement, the period of notice required must be six months and the date of termination specified in the notice must be calculated accordingly and the agreement terminates on the date so calculated.

(5) This paragraph does not affect any other rights to terminate the agreement which the contractor and the Board may have.

Late payment notices

56.—(1) The contractor may give notice in writing (a "late payment notice") to the Board if the Board has failed to make any payments due to the contractor in accordance with a term of the agreement regarding prompt payments which has the effect specified in regulation 16(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 (4), the contractor may, at least 28 days after the date on which a late payment notice under sub-paragraph (1) was given, terminate the agreement 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—

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- (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 agreement in accordance with sub-paragraph (2) until—
- (a) there has been a final determination of the dispute under the NHS dispute resolution procedure and that determination permits the contractor to terminate the agreement; 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 agreement that the contractor may have.

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

- 57.—(1) Where sub-paragraph (2) applies, the Board may give notice in writing to the contractor terminating the agreement with immediate effect, or from such date as may be specified in the notice.
- (2) This sub-paragraph applies if, after the agreement was entered into, it comes to the Board’s attention that written information—
- (a) provided to the Board by the contractor before the agreement was entered into; or
 - (b) included in a notice given to the Board under paragraph 46(1)(a) or (b),
- relating to the conditions set out in regulation 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.

Other grounds for termination by the Board

- 58.—(1) The Board may give notice in writing to a contractor terminating the agreement with immediate effect, or from such date as may be specified in the notice, if sub-paragraph (4) applies to the contractor—
- (a) during the existence of the agreement; or
 - (b) if later, on or after the date on which a notice in respect of the contractor’s compliance with the conditions in regulation 5 was given under paragraph 46(1)(a) or (b).
- (2) Sub-paragraph (4) applies—
- (a) where a contractor who is an individual medical practitioner is a party to the agreement, to that medical practitioner; or
 - (b) where the agreement is with a contractor which is a qualifying body, to—
 - (i) the qualifying body,
 - (ii) any person both legally and beneficially owning a share in the qualifying body, or
 - (iii) any director or secretary of the qualifying body.
- (3) In the case of a person who is a party to an agreement made before 1st April 2004 which is deemed to be an agreement made under section 92 of the Act, the reference to “during the existence of the agreement” in sub-paragraph (1) is to be construed as excluding any period before 1st April 2004.
- (4) This sub-paragraph applies if—
- (a) the contractor is the subject of a national disqualification;

- (b) 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;
- (c) subject to sub-paragraph (6), the contractor has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless, before the Board has given notice to the contractor terminating the agreement under this paragraph, the contractor is employed by the health service body from which the contractor was dismissed or by another health service body;
- (d) 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⁽¹⁵⁹⁾ respectively) 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 and has been sentenced to a term of imprisonment of longer than six months;
- (g) subject to sub-paragraph (7), the contractor has been convicted elsewhere 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⁽¹⁶⁰⁾ (offences against children and young persons, with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1955⁽¹⁶¹⁾ (offences against children under the age of 17 years to which special provisions apply);
- (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⁽¹⁶²⁾ (barred lists), or
 - (ii) any barred list within the meaning of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007⁽¹⁶³⁾ (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 5 years before the signing of the agreement, been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission, the Charity Commission for Northern Ireland or the High Court, and that order was made on the grounds of misconduct or mismanagement in the administration of a charity for which the contractor was responsible or to which the contractor was privy, or which was contributed to, or facilitated by, the contractor's conduct;
- (k) the contractor has, within the period of five years before the signing of the agreement or the commencement of the agreement, whichever is the earlier, been removed from being concerned with the management or control of any body in any case where removal

⁽¹⁵⁹⁾Section 151 was amended by paragraph 79 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

⁽¹⁶⁰⁾1933 c.12. Schedule 1 was amended by section 51 of, and Schedule 4 to, the Sexual Offences Act 1956 (c.99); section 170 of, and Schedule 10 to, the Criminal Justice Act 1988 (c.33); section 139 of, and 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); and section 115(1) of, and Schedule 10 to, the Protection of Freedoms Act 2012 (c. 9).

⁽¹⁶¹⁾1995 c.46.

⁽¹⁶²⁾2006 c.47.

⁽¹⁶³⁾S.I. 2007/1351 (N.I.11)

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was by virtue of section 34(5)(e) of the Charities and Trustees Investment (Scotland) Act 2005**(164)** (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**(165)** (bankruptcy restrictions order and undertaking) or in Schedule 2A to the Insolvency (Northern Ireland) Order 1989**(166)** (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985**(167)** (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 a moratorium period under a debt relief order under Part VIIA of the Insolvency Act 1986**(168)** (debt relief orders) applies, or
 - (ii) is the subject of a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4ZB to that Act**(169)** (debt relief restrictions order and undertaking);
- (o) 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;
- (p) the contractor is a company which has been wound up under Part IV of the Insolvency Act 1986 **(170)**(winding up of companies registered under the Companies Acts);
- (q) an administrator, administrative receiver or receiver has been 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**(171)** (administration);
- (s) the contractor is subject to—
 - (i) a disqualification order under section 1 of the Company Directors Disqualification Act 1986**(172)** (disqualification orders: general) or a disqualification undertaking under Section 1A of that Act**(173)** (disqualification undertakings: general), or
 - (ii) a disqualification order or disqualification undertaking under article 3 (disqualification orders: general) or article 4 (disqualification undertakings: general)

(164) 2005 asp 10.

(165) 1986 c.45. Schedule 4A was inserted by section 257(2) of and Schedule 20 to the Enterprise Act 2002 (c.40).

(166) S.I.1989/2405 (N.I. 19). Schedule 2A was inserted by article 13(2) of, and Schedule 5 to, S.I. 2005/455 (N.I.10).

(167) 1985 c.66. Sections 56A to 56K were inserted by the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).

(168) 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).

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

(170) 1986 c.45. Part IV was substituted by S.I. 2009/1941.

(171) 1986 c.45. Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002 (c.40).

(172) 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 of, and paragraphs 1 and 2 of Schedule 7 to, the Small Business, Enterprise and Employment Act 2015 (c.26)

(173) 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.

of the Company Directors Disqualification (Northern Ireland) Order 2002(174) unless that order has ceased to have effect or has been annulled, or

(iii) a disqualification order under section 429(2) of the Insolvency Act 1986(175) (disabilities on revocation of an administration order against an individual); or

(t) the contractor has refused to comply with a request made 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 agreement.

(5) The Board may not terminate the agreement in accordance with sub-paragraph (4)(b) where the Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the contractor unsuitable to be—

(a) a party to the agreement; or

(b) in the case of an agreement with a qualifying body—

(i) a person both legally and beneficially owning a share in the qualifying body, or

(ii) a director or secretary of the qualifying body,

as the case may be.

(6) The Board may not terminate the agreement in accordance with sub-paragraph (4)(c)—

(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 dismissal, until proceedings before that tribunal or court are concluded,

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

(7) The Board must not terminate the agreement in accordance with sub-paragraph (4)(g) or, as the case may be (4)(h), where the Board is satisfied that the conviction does not make the person unsuitable to be—

(a) a party to the agreement; or

(b) in the case of a qualifying body—

(i) a person both legally and beneficially owning a share in the qualifying body, or

(ii) a director or secretary of the qualifying body,

as the case may be.

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

59. The Board may give notice in writing to the contractor terminating the agreement with immediate effect from such date as may be specified in the notice if—

(a) the contractor has breached a term of the agreement and, as a result of that breach, the safety of the contractor's patients is at serious risk if the agreement 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.

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

(175) 1986 c.45. Section 429 was amended by section 269 of, and Schedule 3 to, the Enterprise Act 2002, and section 106 of, and Schedule 16 to, the Tribunals, Courts and Enforcement Act 2007.

Termination by the Board for unlawful sub-contracting

60.—(1) This paragraph applies if the contractor breaches the condition specified in paragraph 43(5) relating to the sub-contracting of clinical services under the agreement and it comes to the attention of the Board that the contractor has done so.

- (2) Where this paragraph applies, the Board must give notice in writing to the contractor—
- (a) terminating the agreement 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 the instruction, the Board must give notice in writing to the contractor terminating the agreement with immediate effect.

Termination by the Board: remedial notices and breach notices

61.—(1) Where the contractor’s breach of the agreement is not one to which paragraphs 57 to 60 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 agreement, 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 agreement with effect from such date as the Board specifies in the notice.
- (5) Where the contractor’s breach of the agreement is not one to which any of paragraphs 57 to 60 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 agreement resulting in either a remedial notice or a further breach notice,

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

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

(8) If the contractor is in breach of any obligation under the agreement and a breach notice and a remedial notice in respect of that 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 agreement in respect of the obligation which is the subject matter of the default.

Termination by the Board: additional provisions specific to agreements with qualifying bodies

62. If the Board becomes aware that a contractor which is a qualifying body is carrying on any business which the Board considers to be detrimental to the contractor's performance of its obligations under the agreement—

- (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 not less than 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 agreement with immediate effect or from such date as is specified in the notice.

Agreement sanctions

63.—(1) In this paragraph and in paragraph 64, "agreement sanction" means—

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

(2) Where the Board is entitled to terminate the agreement in accordance with paragraph 57, 58, 59, 61(4) or (6) or 62, it may instead impose any of the agreement sanctions if the Board is reasonably satisfied that the agreement sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Board's entitlement to terminate the agreement.

(3) If the Board decides to impose an agreement sanction, the Board must—

- (a) give notice in writing to the contractor of the agreement 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.

(4) Subject to paragraph 64, the Board may not impose the agreement 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 to sub-paragraph (3) 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.

(5) Where the Board imposes an agreement 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 agreement sanction.

Agreement sanctions and the NHS dispute resolution procedure

64.—(1) If there is a dispute between the Board and the contractor in relation to an agreement sanction that the Board is proposing to impose, the Board may not, subject to sub-paragraph (4), impose the agreement 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 agreement sanction to the NHS dispute resolution procedure before the end of the period of 28 days beginning with the date on which the contractor was given notice by the Board in accordance with paragraph 60(4) (or such longer period as may be agreed in writing with the Board); and

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(b) gives notice in writing to the Board that it has done so.

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

(a) there has been a final determination of the dispute in accordance with regulation 77 (or by a court) and that determination permits the Board to impose the agreement 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 agreement sanction with immediate effect.

(5) If the Board is satisfied that it is necessary to impose the agreement 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 agreement sanction with immediate effect, pending the outcome of that procedure (or any court proceedings).

Termination and the NHS dispute resolution procedure

65.—(1) Where the Board is entitled to give notice in writing to the contractor terminating the agreement in accordance with paragraph 57, 58, 59, 61(4) or (6) or 62, the Board must, in the notice given to the contractor under those provisions, specify a date on which the agreement is to terminate 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 agreement 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 agreement 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 agreement; or

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

whichever is the sooner.

(5) If the Board is satisfied that it is necessary to terminate the agreement before the NHS dispute resolution procedure (or any court proceedings) is 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 agreement will nevertheless terminate at the end of the period of the notice given under paragraph 57, 58, 59, 61(4) or (6) or 62.

SCHEDULE 3

Regulation 89

Consequential amendments

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

1. In regulation 2 of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004(176) (interpretation), for the definition of “PMS Agreements Regulations” substitute—

““PMS Agreements Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2015;”.

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

2. In regulation 2 of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(177) (interpretation), for paragraph (b)(ii) of the definition of “relevant complaints procedure” substitute—

“(ii) regulation 76 of the National Health Service (Personal Medical Services Agreements) Regulations 2015;”.

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

3. In regulation 2 of the National Health Service (Functions of the First-tier Tribunal relating to Primary Medical, Dental and Ophthalmic Services) Regulations 2010(178) (interpretation), for the definition of “PMS Agreements Regulations” substitute—

““PMS Agreements Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2015;”.

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

4. In regulation 2 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(179) (interpretation), for the definition of “PMS Regulations” substitute—

““PMS Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2015;”.

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

(177) 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.

(178) 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.

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

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

5. In regulation 2 of the National Health Service (Clinical Commissioning Groups – Disapplication of Responsibility Regulations 2013(**180**) (persons for whom a CCG does not have responsibility in relation to its duty to commission services), in paragraph (4)(a), for “paragraph 15 of Schedule 5 to the National Health Service (Personal Medical Services Agreements) Regulations 2004” substitute “paragraph 19 of Schedule 2 to the National Health Service (Personal Medical Services Agreements) Regulations 2015”.

Amendment to the National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013

6. In regulation 11 of the National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013(**181**) (patient choice: primary medical services), for paragraph (2)(b) substitute—

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

Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2015

7. In regulation 2 of the National Health Service (Charges for Drugs and Appliances) Regulations 2015(**182**) (interpretation), for “the National Health Service (Personal Medical Services Agreements) Regulations 2004” in the definition of “PMS contractor” substitute “the National Health Service (Personal Medical Services Agreements) Regulations 2015”.

SCHEDULE 4

Regulation 90

Revocations

1. The enactments specified in column 1 of the Table to this Schedule 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 (Personal Medical Services Agreements) Regulations 2004 (S.I.2004/627) | The whole instrument |
| The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2005 (S.I.2005/893) | Regulations 6 to 9 and 15 |
| The National Health Service (Primary Medical Services) (Miscellaneous Amendments) (No.2) Regulations 2005 (S.I.2005/3315) | Regulations 8 to 13 |

(180)[S.I. 2013/350](#). There are no relevant amending instruments.

(181)[S.I. 2013/500](#). There are no relevant amending instruments.

(182)[S.I. 2015/570](#). There are no relevant amending instruments.

| <i>Title of instrument</i> | <i>Extent of revocation</i> |
|--|---|
| The National Health Service (Performers Lists) (Amendment) Regulations 2005 (S.I.2005/3491) | Regulation 12(9) |
| The Primary Medical Services and Pharmaceutical Services Miscellaneous Amendments Regulations 2006 (S.I. 2006/501) | Regulations 4 and 5 |
| The Local Involvement Networks (Miscellaneous Amendments) Regulations 2008 (S.I. 2008/1514) | Regulation 4 |
| The Primary Ophthalmic Services Amendment, Transitional and Consequential Provisions Regulations 2008 (S.I.2008/1700) | Schedule 1, paragraph 13 |
| The Local Authority Social Services and NHS (Complaints) (England) Regulations 2009 (S.I.2009/309) | Schedule, paragraph 4 |
| The National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing Regulations 2009 (S.I.2009/2205) | Regulation 36 |
| The National Health Service (Prescribing and Charging Amendments Relating to Pharmaceutical Services) Regulations 2009 (S.I.2009/2230) | Regulation 4 |
| The Value Added Tax Drugs and Medicines Order 2009 (S.I. 2009/2972) | Paragraph (4) of Note (2D) of the inserted text |
| The Transfer of Tribunal Functions Order 2010 (S.I.2010/22) | Schedule 3, paragraphs 59 to 61 |
| The Pharmacy Order 2010 (S.I.2010/231) | Schedule 4, paragraph 42 |
| The General Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I.2010/234) | Schedule 3, paragraph 13 |
| The Health and Social Care Act (Consequential Provisions – Social Workers) Order 2012 (S.I.2012/1479) | Schedule, paragraph 38 |
| The Human Medicines Regulations 2012 (S.I.2012/1916) | Schedule 34, paragraph 87 |
| The Tribunals, Courts and Enforcement Act 2007(Consequential Amendments) Order 2012 (S.I.2012/2404) | Schedule 3, paragraph 33 |
| The National Health Service (Primary Medical Services) (Miscellaneous Amendments and Transitional Provisions) Regulations 2013 (S.I.2013/363) | Parts 1 and 3 |

Status: This is the original version (as it was originally made).

| <i>Title of instrument</i> | <i>Extent of revocation</i> |
|--|-----------------------------|
| The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 (S.I. 2014/1887) | Schedule 2, paragraph 2 |
| The NHS (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015 (S.I. 2015/915) | Part 3 |

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate provision previously contained in the National Health Service (Personal Medical Services Agreements) Regulations 2004 (S.I. 2004/627) as amended which are revoked by regulation 90 and Schedule 4. They set out, in relation to England, the framework for personal medical services contracts made by virtue of provision in section 92 of the National Health Service Act 2006 (“the Act”) (arrangements by the National Health Service Commissioning Board for the provision of primary medical services).

Part 2 (agreements) prescribes the conditions which, in accordance with section 93 of the Act, must be met by a contractor before the relevant body may enter into a personal medical services agreement.

Part 3 (pre-agreement dispute resolution) prescribes the procedure for pre-agreement dispute resolution, in accordance with section 94(7) of the Act. Part 3 applies to cases where the contractor is not a health service body.

Part 4 (health service body status) provides for a contractor to be a health service body for the purposes of section 9 of the Act (NHS contracts) unless it objects to this by serving a notice on the relevant body before the agreement is made.

Part 5 (and Part 1 of Schedule 2) (agreements: required terms) prescribe the terms which, in accordance with section 94 of the Act, must be included in a personal medical services agreement.

The prescribed terms include terms relating to:

- the type of and general terms of an agreement (regulations 12 and 13);
- membership of a CCG (regulation 14);
- the issuing of medical certificates (regulation 15);
- finance, payments, fees and charges (regulations 16 to 19);
- the manner in which services general services are to be provided (Part 1 of Schedule 2) and out of hours services are to be provided (regulation 22);
- the conditions to be met by those who perform services or are employed or engaged by the contractor (regulations 33 to 47);
- procedures for variation and termination of agreements and consequences of termination of the agreement (regulations 24 to 26);
- other required general terms (regulation 27)

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

Part 7 (right to a general medical services contract) provides a right for a contractor to terminate its agreement and enter into a general medical services contract.

Part 8 (persons who perform services) prescribes the required qualifications, conditions, experience and professional verification required for persons who are employed or engaged by a contractor to perform services under the agreement.

Part 9 (prescribing and dispensing) prescribes the terms which, in accordance with regulations 48, 49 and 52 to 55, a person, prescriber or health care worker may prescribe and dispense with drugs, medicines or appliances.

Part 10 (prescribing and dispensing: out of hours services) prescribes terms additional to those in Part 9 in relation to contractors providing out of hours services.

Part 11 (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 12 (complaints) requires a contractor to establish and operate a complaints procedure to deal with any complaints in relation to any matter reasonably connected with the provision of services under the agreement. The complaints procedure must comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

Part 13 (dispute resolution) prescribes the procedure which is to apply in respect of the resolution of disputes.

Part 14 (miscellaneous) sets out miscellaneous provisions which a contractor must comply with in relation to a personal medical services agreement.

Part 15 (general transitional provision and saving and revocations) makes a general transitional provision and saving and 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.