SCOTTISH STATUTORY INSTRUMENTS

2018 No. 66

The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018

PART 1

GENERAL

Interpretation

3.—(1) In these Regulations—

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

"the 1998 Act" means the Data Protection Act 1998(1);

"the 2004 Act" means the Primary Medical Services (Scotland) Act 2004(2);

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

"the 2010 Order" means the Postgraduate Medical Education and Training Order of Council 2010(**3**);

"additional services" means one or more of-

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

"adjudicator" means the Scottish Ministers or a panel of 3 persons appointed by the Scottish Ministers (as the case may be) under paragraph 91 of schedule 6;

"advanced electronic signature" means an advanced electronic signature within the meaning given in Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23rd July 2014 on electronic identification and trust services for electronic transactions in the internal market(**4**) and repealing Directive 1993/93/EC;

⁽**1**) 1998 c.29.

⁽**2**) 2004 asp 1.

⁽³⁾ S.I. 2010/473

⁽⁴⁾ OJ L 257, 28.8.2014, p.73. Article 3(11) provides that an "advanced electronic signature" means an electronic signature which meets the requirements set out in Article 26 of that instrument. The requirements in Article 26 are that the electronic signature is (a) uniquely linked to the signatory; (b) capable of identifying the signatory; (c) created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and (d) linked to the data signed therewith in such a way that any subsequent change in the data is detectable.

"appliance" means an appliance which is included in a list for the time being approved by the Scottish Ministers for the purposes of section 27(1) of the Act(5);

"area medical committee" means the committee of that name recognised under section 9 of the Act(6) (local consultative committees) in the area of the Health Board;

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

"assessment panel" means a committee or subcommittee of a Health Board ("the first Health Board") (other than the Health Board ("the second Health Board") which is a party or prospective party to the contract in question) appointed by the first Health Board at the request of the second Health Board to exercise functions under paragraph 2 or 3 of schedule 2 or paragraph 28, 32, or 37 of schedule 6 and which must consist of—

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

"care home service" has the same meaning as in paragraph 2 of schedule 12 of the Public Services Reform (Scotland) Act 2010(7);

"CCT" means a Certificate of Completion of Training awarded under section 34L(1) of the Medical Act 1983(8), including any such certificate awarded in pursuance of the competent authority functions of the General Medical Council specified in section 49B and schedule 4A of that Act(9);

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

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

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

"child health surveillance services" means the services described in paragraph 6(2) of schedule 1;

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

"clinical commissioning group" means a body established under section 14D of the National Health Service Act 2006(10);

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

(7) 2010 asp 8.

⁽⁵⁾ Section 27(1) was amended by section 20 of the Health Services Act 1980, paragraph 19 of the National Health Service and Community Care Act 1990 ("the 1990 Act"), section 3 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), paragraph 44 of schedule 2 of the National Health Service (Primary Care) Act 1997 and section 44 of the Health and Social Care Act 2001 (c.15).

⁽⁶⁾ Section 9 was amended by section 29(5) of the 1990 Act and paragraph 43 of the Health Act 1999.

^{(8) 1983} c.54. Section 34 was inserted by S.I. 2010/234.

⁽⁹⁾ Section 49B was inserted by S.I. 2007/3101 and was amended by S.I. 2008/1774 and S.I. 2010/234. Schedule 4A was inserted by S.I. 2007/3101 and was amended by S.I. 2010/234 and S.I. 2016/1030.

^{(10) 2006} c.41. Section 14D was inserted by section 25(1) of the Health and Social Care Act 2012 (c.7).

"conditional disqualification" has the same meaning as in section 29C(1) of the Act(11) and includes a decision under provisions in force in England, Wales or Northern Ireland corresponding (whether or not exactly) to a conditional disqualification;

"contraceptive services" means the services described in paragraph 3(2) of schedule 1;

"contract" means, except where the context otherwise requires, a general medical services contract under section 17J of the Act(12) (Health Boards' power to enter into general medical services contracts);

"contractor" means a person with whom a Health Board enters into a contract;

"contractor's list of patients" means the list prepared and maintained by a Health Board under paragraph 11 of schedule 6;

"core hours" means the period beginning at 0800 hours and ending at 1830 hours on any working day;

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

"disqualified" means, unless the context otherwise requires, disqualified by the Tribunal (or a corresponding decision under provisions in force in England, Wales or Northern Ireland corresponding, whether or not exactly, to disqualified), but does not include conditional disqualification, and "disqualification" is to be construed accordingly;

"Drug Tariff" means the statement published under regulation 12 (payments to pharmacy contractors and standards of drugs and appliances) of the Pharmaceutical Regulations;

"electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000(13);

"electronic prescription form" means a prescription form as defined in paragraph (b) of the definition of "prescription form";

"electronic signature" has the meaning attributed to it in section 7(2)(14) of the Electronic Communications Act 2000;

"enhanced services" are-

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

"ePharmacy service" means the electronic system provided by the Agency by which electronic prescription forms are transmitted;

"essential services" means the services required to be provided in accordance with regulation 18;

"GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data(**15**), and repealing Directive 95/46/EC;

"general medical practitioner" means, unless the context otherwise requires, a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council;

⁽¹¹⁾ Section 29C(1) was inserted by section 58 of the Health Act 1999. There are amendments to section 29C not relevant to these Regulations.

⁽¹²⁾ Section 17J was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004.

^{(13) 2000} c.7. Section 15 was amended by paragraph 158 of schedule 17 of the Communications Act 2003 (c.21).

⁽¹⁴⁾ Section 7(2) was amended by S.I. 2016/696.

⁽**15**) OJ L 119, 4.5.2016, p.1–88.

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

"GMS Statement of Financial Entitlements" means the directions given by the Scottish Ministers under section 17M of the Act(16) (payments by Health Boards under general medical services contracts);

"GP Registrar" means a medical practitioner who is being trained in general practice by a general medical practitioner who is approved under section 34I(17) of the Medical Act 1983 for the purpose of providing training under that section, whether as part of training leading to a CCT or otherwise;

"Health and Social Care trust" means a Health and Social Care trust established under Article 10(1) of the Health and Personal Social Services (Northern Ireland) Order 1991(18) and renamed by section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(19);

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

"health care professional" has the same meaning as in section 17L(8) of the Act and "health care profession" is to be construed accordingly;

"health service body" means any person or body referred to in section 17A(2) of the Act (NHS contracts)(20) and includes, except where otherwise expressly provided, any person who is to be regarded as a health service body in accordance with regulation 13;

"immediate family member" means-

- a spouse or civil partner; (a)
- (b) a person whose relationship with the registered patient has the characteristics of the relationship between spouses or civil partners;
- (c) a parent or step-parent;
- (d) a son;
- a daughter; (e)
- (f) a child of whom the registered patient is
 - the guardian; or (i)
 - (ii) the carer duly authorised by the local authority to whose care the child has been committed under the Children (Scotland) Act 1995(21); or

(g) a grandparent;

"independent nurse prescriber" means a person-

- who is either engaged or employed by the contractor, or where the contractor is a (a) partnership, is a partner in that partnership; and
- who is registered in the Nursing and Midwifery Register; and (b)

⁽¹⁶⁾ Section 17M was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004. Directions are normally given before the beginning of the financial year to which they are to apply and will be available on http://www.show.scot.nhs.uk. (17) Section 34I was inserted by S.I. 2010/234.

⁽¹⁸⁾ S.I. 1991/194 (N.I.1). Article 10 was amended by S.I. 1994/429 (N.I. 2), sections 43 and 44 of the Health and Personal Services Act (Northern Ireland) 2001 (c.3) and paragraph 1 of schedule 6 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (c.1).

^{(19) 2009} c.1.

⁽²⁰⁾ Section 17A(2) was inserted by section 30 of the National Health Service and Community Care Act 1990 and was amended by paragraph 36 of schedule 2 of the National Health Service (Primary Care) Act 1997, paragraph 46 of schedule 4 and paragraph 1 of schedule 5 of the Health Act 1999, paragraph 1 of schedule 14 of the Health and Social Care (Community Health and Standards) Act 2003 (c.43), paragraph 8 of schedule 17 of the Public Services Reform (Scotland) Act 2010 and paragraph 2 of schedule 21 of the Health and Social Care Act 2012.

^{(21) 1995} c.36.

(c) against whose name is recorded in that register an annotation signifying that they are qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

"independent prescriber" means-

- (a) an independent nurse prescriber;
- (b) a pharmacist independent prescriber;
- (c) a physiotherapist independent prescriber;
- (d) a podiatrist or chiropodist prescriber;
- (e) a therapeutic radiographer independent prescriber; or
- (f) a paramedic independent prescriber;

"licensing authority" is to be construed in accordance with regulation 6(2) of the Human Medicines Regulations 2012(22);

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

"limited liability partnership" means a limited liability partnership incorporated in accordance with section 2 of the Limited Liability Partnerships Act 2000(23);

"limited partnership" means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907(24);

"list" has, unless the context otherwise requires, the meaning assigned to it in section 29(8) of the Act(25) and includes a list corresponding to such a list in England, Wales or Northern Ireland;

"local dispute resolution process" means the process for encouraging local resolution of disputes specified in paragraph 89 of schedule 6;

"Local Health Board" means a body established under section 11 of the National Health Service (Wales) Act 2006(**26**);

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

"Medical Register" means the registers kept under section 2 of the Medical Act 1983(27);

"NHS contract" means a contract—

- (a) which is a general medical services contract under section 17J of the Act; and
- (b) which is a NHS contract within the meaning of section 17A(3) of the Act(28) as a consequence of which the contractor is being regarded as a health service body pursuant to regulation 13(1) or (4);

"NHS dispute resolution procedure" means the procedure for the resolution of disputes specified in paragraphs 91 and 92 of schedule 6;

⁽**22**) S.I. 2012/1916.

^{(23) 2000} c.12. Section 2 was amended by S.I. 2009/1804 and S.I. 2016/340.

^{(24) 1907} c.24. Section 5 was amended by S.I. 2009/1940.

⁽²⁵⁾ Section 29 was substituted by section 58(1) of the Health Act 1999. Section 29 was further amended by paragraph 2(4) of schedule 2 of the Community Care and Health (Scotland) Act 2002 (asp 5), section 5(3) of the Primary Medical Services (Scotland) Act 2004 and section 26(2) and paragraph 2 of schedule 2 of the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13).

^{(26) 2006} c.42.

⁽²⁷⁾ Section 2 was amended by S.I. 2002/3135, S.I. 2006/1914, S.I. 2007/3103, S.I. 2008/1774 and S.I. 2014/1101.

⁽²⁸⁾ Section 17A(3) was inserted by section 30 of the National Health Service and Community Care Act 1990 and amended by paragraph 46 of schedule 4 and paragraph 1 of schedule 5 of the Health Act 1999.

"NHS foundation trust" has the same meaning as in section 30 of the National Health Service Act 2006(**29**);

"NHS trust" means a National Health Service trust established under section 25 of the National Health Service Act 2006;

"non-electronic prescription form" means a prescription form as defined in paragraph (a) of the definition of "prescription form";

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

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(**30**);

"open", in relation to the contractor's list of patients, means open to applications from patients in accordance with paragraph 12 of schedule 6;

"paramedic independent prescriber" means a person registered in Part 8 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(**31**) and against whose name in that register is recorded an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;

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

"patient" means-

- (a) a registered patient;
- (b) a temporary resident;
- (c) persons to whom the contractor is required to provide immediately necessary treatment under regulation 18(6) or (8) respectively; and
- (d) any other person to whom the contractor has agreed to provide services under the contract;

"the Pharmaceutical Regulations" means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(**32**);

"pharmacist" means a person who is registered as a pharmacist in-

- (a) Part 1 or Part 4 of the register maintained under article 19 of the Pharmacy Order 2010(33); or
- (b) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**34**);

"pharmacist independent prescriber" means a pharmacist against whose name in the relevant register is recorded an annotation signifying that the pharmacist is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"physiotherapist independent prescriber" means a physiotherapist who is registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001, and against whose name in that register is recorded an annotation signifying that the

(**32**) S.S.I. 2009/183.

⁽²⁹⁾ Section 30 was amended by section 159 of the Health and Social Care Act 2012.

⁽**30**) S.1. 2002/253.

⁽³¹⁾ S.I. 2002/254, as retitled by section 213(6) of the Health and Social Care Act 2012. Article 5 was amended by S.I. 2009/1182. The title of this Order is the Health and Social Work Professions Order 2002 but is cited as the Health and Social Work Professions Order 2001 in accordance with section 213(4) of the Health and Social Care Act 2012.

⁽³³⁾ S.I. 2010/231.

⁽³⁴⁾ S.I. 1976/1213 (N.I. 22), as relevantly amended by S.R. (NI) 2008 No 192.

physiotherapist is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"podiatrist or chiropodist independent prescriber" means a podiatrist or chiropodist who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001, and against whose name in that register is recorded an annotation signifying that the podiatrist or chiropodist is qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

"practice" means the business operated by the contractor for the purpose of delivering services under the contract;

"practice area" means the area referred to in regulation 21(1)(d);

"practice leaflet" means a leaflet drawn up in accordance with paragraph 74 of schedule 6;

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

"prescriber" means-

- (a) a medical practitioner;
- (b) an independent nurse prescriber;
- (c) a supplementary prescriber;
- (d) a pharmacist independent prescriber;
- (e) a physiotherapist independent prescriber;
- (f) a podiatrist or chiropodist independent prescriber;
- (g) a therapeutic radiographer independent prescriber; and
- (h) a paramedic independent prescriber,

who is either engaged or employed by the contractor or, where the contractor is a partnership, is a partner in that partnership;

"prescription form" means-

- (a) a form provided by the Health Board and issued by a prescriber; or
- (b) data that are created in an electronic form and which are signed with a prescriber's advanced electronic signature and transmitted as an electronic communication through the ePharmacy service,

to enable a person to obtain pharmaceutical services.

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

"primary medical services performers list" means the list of primary medical services performers prepared in accordance with regulations made under section 17P of the Act(**35**) (persons performing primary medical services);

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

"Regional Health and Social Care Board" means the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

"registered patient" means-

⁽³⁵⁾ Section 17P was inserted by section 5(2) of the Primary Medical Services (Scotland) Act 2004 ("the 2004 Act") (asp 1).

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

"relevant register" means-

- (a) in relation to a nurse, the Nursing and Midwifery Register;
- (b) in relation to a pharmacist—
 - (i) Part 1 of the register maintained under article 19 of the Pharmacy Order 2010; or
 - (ii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976; and
- (c) in relation to a chiropodist and podiatrist, a physiotherapist, paramedic and a therapeutic radiographer, the relevant part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health and Social Work Professions Order 2001;

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

"Scheduled drug" means-

- (a) a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act(36) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract; or
- (b) except where the conditions in paragraphs 40(2) and 41(2) of schedule 6 are satisfied, a drug, medicine or other substance which is specified in any directions given by the Scottish Ministers under section 17N(6) of the Act, as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes;

"section 17C provider" means a person or body who is providing primary medical services in accordance with an agreement pursuant to section 17C of the Act(**37**);

"supplementary prescriber" means a person who is either engaged or employed by the contractor, or where the contractor is a partnership, is a partner in that partnership, and whose name is registered in—

- (a) the Nursing and Midwifery Register;
- (b) Part 1 of the register maintained under article 19 of the Pharmacy Order 2010;
- (c) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;
- (d) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health and Social Work Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists;
 - (iii) diagnostic or therapeutic radiographers;
 - (iv) dietitians;
 - (v) paramedics; or

⁽³⁶⁾ Section 17N was inserted by section 4 of the 2004 Act.

⁽³⁷⁾ Section 17C was inserted by section 21(2) of the National Health Service (Primary Care) Act 1997 (c.46) and was amended by section 2(2) of the 2004 Act and paragraph 3 of schedule 21 of the Health and Social Care Act 2012 (c.7).

(e) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(**38**),

and against whose name is recorded in the relevant register an annotation signifying that they are 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 13 of schedule 6 and for whom the contractor's responsibility has not been terminated in accordance with that paragraph;

"therapeutic radiographer independent prescriber" means a person-

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

"the Tribunal" has the meaning indicated in section 29 of the Act (the NHS Tribunal);

"vaccinations and immunisations" means the services described in paragraph 4(2) of schedule 1;

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

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

- (2) In these Regulations, the use of the term "it" in relation to—
 - (a) the adjudicator is deemed to refer either to the Scottish Ministers or to the panel of 3 persons appointed by them, as the case may be; and
 - (b) a contractor is deemed to include a reference to a contractor who is an individual medical practitioner,

and related expressions are to be construed accordingly.

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