

# The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018

SCOTTISH STATUTORY INSTRUMENTS

**2018 No. 67**

NATIONAL HEALTH SERVICE

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**Prepared on behalf of GPDF**

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# The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018

S C O T T I S H   S T A T U T O R Y   I N S T R U M E N T S

**2018 No. 67**

NATIONAL HEALTH SERVICE

## The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018

*Made*

*15th February 2018*

*Laid before the Scottish Parliament*

*19th February 2018*

*Coming into force in accordance with regulation 1*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 9(6), 17A(6), 17CA, 17D(3), 17E, 28(1), 105(7) and 106(a) of the National Health Service (Scotland) Act 1978(1) and all other powers enabling them to do so.

### PART 1

#### GENERAL

##### **Citation and commencement**

1.—(1) These Regulations may be cited as the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018.

(2) Subject to paragraph (3), these Regulations come into force on 1st April 2018.

(3) Paragraph 34(2) of Schedule 1 comes into force on 25th May 2018.

##### **Application**

2. These Regulations apply to an agreement—

(a) to which the National Health (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004(2) National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 applied immediately before 1st April 2018; or

(b) which is entered into between a provider and the Health Board on or after 1st April 2018.

## 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(3);~~

“the 2004 Act” means the Primary Medical Services (Scotland) Act 2004(4);

“the 2004 Regulations” means the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004;

“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 58 of schedule 1;

“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 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market(5) and repealing Directive 1999/93/EC;

“agreement” means, unless the context otherwise requires, an agreement under section 17C of the Act(6) (personal medical or dental services) under which primary medical services are provided;

“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(7);

“area medical committee” means the committee of that name recognised under section 9(8) of the Act (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 sub-committee of a Health Board (“the first Health Board”) (other than the Health Board (“the second Health Board”) which is a party or a prospective party to the agreement in question) appointed by the first Health Board at the request of the second Health Board to exercise functions under paragraphs 21, 25 or 29 of schedule 2 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(9);...~~

“CCT” means a Certificate of Completion of Training awarded under section 34L(1) of the Medical Act 1983(10) 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;

“cervical screening services” means the services described in paragraph 2(2) of schedule 3;

“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 3;

~~“childhood vaccinations and immunisations” means the services described in paragraph 5(2) of schedule 3;~~

~~“clinical commissioning group” means a body established under section 14D of the National Health Service Act 2006(11);~~

“closed”, in relation to a provider’s list of patients, means closed to applications for inclusion in the list of patients other than from immediate family members of registered patients;

“community treatment and care” includes phlebotomy, chronic disease monitoring, the collection of biometric information, attending to minor injuries, changing dressings, suture removal and ear syringing;

“community treatment and care services” means the provisions of community treatment and care to the provider’s patients;

“conditional disqualification” has the same meaning as in section 29C(1) of the Act(12) 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 3;

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

“the data protection legislation” has the same meaning as in the Data Protection Act 2018 (see section 3 of that Act)

“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 pharmacists 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) of the Electronic Communications Act 2000(14);

“enhanced services” are—

(a)

services other than essential services, or additional services or vaccination services; or

(b)

in respect of essential services or additional services, or an element of such a service that a provider agrees in the agreement to provide in accordance with specifications set out in a plan, which requires of the provider an enhanced level of service provision compared to that which the provider 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 described in paragraphs 1(2), 1(4), 1(5) and 1(7) of schedule 2;...

“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;

“general medical services contract” means a general medical services contract under section 17J of the Act (Health Boards’ power to enter into general medical services contracts)(16);

“general medical services contractor” means a person who is providing primary medical services in accordance with a general medical services contract;

“GMS Contracts Regulations” means the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018(17);

“GP Registrar” means a medical practitioner who is being trained in general practice by a general medical practitioner who is approved under section 34I of the Medical Act 1983(18) 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(19) and renamed by section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(20);

“Health Board” means, unless the context otherwise requires, the Health Board which is a party, or prospective party, to an agreement and a reference to “the Board” is to be construed accordingly;

“health care professional” has the same meaning as in section 17D(2) of the Act(21) 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(22) and includes, except where otherwise expressly provided, any person who is to be treated as a health service body in accordance with regulation 10;

“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 or civil partners;

(c)

a parent or step-parent;

(d)

a son;

(e)

a daughter;

(f)

a child of whom the registered patient is—

(i)

the guardian; or

(ii)

the carer duly authorised by the local authority to whose care the child has been committed under the Children (Scotland) Act 1995(23); or

(g)

a grandparent;

"independent nurse prescriber" means a person—

(a)

who is either engaged or employed by the provider, is a party to the agreement or is a partner in a partnership that is a party to the agreement; and

(b)

who is registered in the Nursing and Midwifery Register; and

(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 independent prescriber;

(e)

a therapeutic radiographer independent prescriber; or

(f)

a paramedic independent prescriber;

"integrated care board" means an integrated care board established under Chapter A3 of Part 2 of the National Health Service Act 2006;

~~"licensing authority" is to be construed in accordance with regulation 6(2) of the Human Medicines Regulations 2012(24);...~~

"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 Partnerships Act 2000(25)~~ Limited Liability Partnerships Act 2000;

"limited partnership" means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907(26);

"list" has, unless the context otherwise requires, the meaning assigned to it in section 29(8) of the Act(27) 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 56 of schedule 1;

“Local Health Board” means a body established under section 11 of the National Health Service (Wales) Act 2006(28);

“maternity medical services” means the services described in paragraph 7(1) of schedule 3;

“Medical Register” means the registers kept under section 2 of the Medical Act 1983(29);

“NHS contract” means an agreement which is an NHS contract within the meaning of section 17A(3) of the Act(30) as a result of which the provider is being treated as a health service body pursuant to regulation 10(1) or (5);

“NHS dispute resolution procedure” means the procedure for the resolution of disputes specified in paragraphs 58 and 59 of schedule 1;

“NHS foundation trust” has the same meaning as in section 30 of the National Health Service Act 2006(31);

“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 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 the Nursing and Midwifery Order 2001(32);

“open”, in relation to a provider’s list of patients, means open to applications from patients in accordance with paragraph 7 of schedule 2;

“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(33)~~ Health Professions Order 2001 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 provider, is for the time being discharging in respect of that child the obligations normally attaching to a parent in respect of a child;

“party to the agreement” means where a Health Board makes an agreement with—

(a)

one person, the provider; and

(b)

more than one person, one of those persons;

“patient” means—

(a)

where the provider has a provider's list of patients—

(i)

a registered patient;

(ii)

a temporary resident; and

(iii)

persons to whom the provider is required to provide immediately necessary treatment under paragraph 1(5) or 1(7) of schedule 2 respectively; and

(b)

in all cases any person (or, where the provider has a provider's list of patients, any other person) to whom the provider has agreed to provide services under the agreement;

"Pharmaceutical Regulations" means the National Health Service (Pharmaceutical Services (Scotland) Regulations 2009<sup>(34)</sup>);

"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<sup>(35)</sup>; or

(b)

the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976<sup>(36)</sup>;

"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;

"pharmacotherapy" includes the management of acute and repeat prescriptions, medicines reconciliation, performing polypharmacy review and serial prescribing;

"pharmacotherapy services" means the provision of pharmacotherapy to the provider's patients;

"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~~ Health Professions Order 2001, and against whose name in that register is recorded an annotation signifying that the 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~~ Health 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 provider for the purpose of delivering services under the agreement;

"practice area" means the area referred to in regulation 13(1)(a);

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

“practice website” means a website published and maintained by the provider in accordance with paragraph 41A (practice website) of schedule 1;

“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 provider or is a party to the agreement or is a partner in a partnership that is a party to the agreement;

“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([37](#));

“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([38](#)) (persons performing primary medical services);

“provider”, means, unless the context otherwise requires, where the Health Board makes an agreement with—

(a)

one person, that person; and

(b)

more than one person, all those persons, but references to employment, engagement or sub-contracting by those persons must be deemed to include employment, or engagement or sub-contracting by any one of them;

"provider's list of patients" means the list prepared and maintained by the Health Board under paragraph 6 of schedule 2;

"public or local holiday" means any public or local holiday which is agreed in writing between the Health Board and the provider and which must, in aggregate, be no less than those available to NHS staff 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(2);

~~"Regional 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(39);~~

"registered patient" means—

(a)

a person who is recorded by the Health Board as being on the provider's list of patients; or

(b)

a person whom the provider has accepted for inclusion on the provider's 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; and

(b)

in relation to a pharmacist—

(i)

Part 1 of the register maintained under article 19 of the Pharmacy Order 2010(40); or

(ii)

the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(41); and

(c)

in relation to a chiropodist and podiatrist, a physiotherapist, a paramedic and a therapeutic radiographer, the relevant part of the register maintained by the ~~Health Professions Council~~Health and Care Professions Council in pursuance of article 5 of the ~~Health and Social Work Professions Order 2004~~Health 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(42) as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract; or

(b)

except where the conditions in paragraph 13 and 14 of schedule 1 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;

"Scottish SSP" has the meaning given in regulation 2(1) of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009;

"supplementary prescriber" means a person who is either engaged or employed by the provider or is a party to the agreement, or a partner in a partnership that is a party to the agreement, 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~~Health and Care Professions Council in pursuance of article 5 of the ~~Health and Social Work Professions Order 2001~~Health Professions Order 2001 relating to—

(i)

chiroprpodists and podiatrists;

(ii)

physiotherapists;

(iii)

diagnostic or therapeutic radiographers;

(iv)

dieticians;

(v)

paramedics; or

(e)

the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(43),

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 a provider as a temporary resident under paragraph 8 of schedule 2 and for whom the provider’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~~Health 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)(~~44~~);

“vaccination services” means one or more of the services described in schedule 3A;

~~“vaccinations and immunisations” means the services described in paragraph 4(2) of schedule 3;~~

“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) a provider, is deemed to include a reference to a provider who is

(i) comprised of more than one party to the agreement; or

(ii) an individual; and

(b) the adjudicator, is deemed to refer either to the Scottish Ministers or the panel of 3 persons appointed by them, as the case may be,

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.

## PART 2

### PROVIDERS

#### General conditions relating to providers

4.—(1) A Health Board may only enter into an agreement if the conditions set out in this regulation and regulation 5 are met.

(2) It is a condition in the case of an agreement to be entered into—

- (a) with a medical practitioner, that the medical practitioner;
- (b) with a health care professional (other than a medical practitioner), that the health care professional;
- (c) with a partnership, that any member of the partnership or the partnership;
- (d) with a limited liability partnership, that any member of the limited liability partnership or the limited liability partnership; and
- (e) with a company, that—
  - (i) the company;
  - (ii) any member of the company,
  - (iii) any director or secretary of the company,must not fall within paragraph (3).

(3) A person falls within this paragraph if—

- (a) the person has been disqualified or suspended by direction of the Tribunal made pursuant to section 32A(2) (applications for interim suspension)(~~45~~) or 32B(1) (suspension pending appeal)(~~46~~) of the Act, or under any provisions in force in England, Wales or Northern Ireland corresponding thereto;
- (b) subject to paragraph (4), the person is disqualified or suspended (otherwise than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
- (c) within the period of 5 years prior to the signing of the agreement or commencement of the agreement, whichever is the earlier, the person has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless—
  - (i) the person has subsequently been employed by that health service body or another health service body and, where the person has been employed as a member of a health care profession, any subsequent employment has also been as a member of that profession; or
  - (ii) that dismissal was the subject of a finding of unfair dismissal by any competently established tribunal or court;
- (d) within the period of 5 years prior to signing the agreement or commencement of the agreement, whichever is the earlier, the person has been disqualified from a list unless the person's name has subsequently been included in such a list;
- (e) the person has been convicted in the United Kingdom of murder;
- (f) the person has been convicted in the United Kingdom of a criminal offence, other than murder, and been sentenced to a term of imprisonment of over 6 months;

- (g)the person has been convicted elsewhere of an offence which would if committed in Scotland, constitute—
- (i)murder; or
- (ii)subject to paragraph (5), a criminal offence other than murder, and been sentenced to a term of imprisonment of over 6 months;
- (h)the person has been convicted of an offence referred to in schedule 1 of the Criminal Procedure (Scotland) Act 1995(47) or schedule 1 of the Children and Young Persons Act 1933(48);
- (i)the person has—
- (i)had sequestration of the person's estate awarded or been adjudged bankrupt unless (in either case) the person has been discharged or the bankruptcy order has been annulled;
- (ii)been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under—
- (aa)schedule 4A of the Insolvency Act 1986(49);
- (bb)schedule 2A of the Insolvency (Northern Ireland) Order 1989(50); or
- (cc)sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(51),
- unless that order has ceased to have effect or has been annulled; or
- (iii)made a composition or arrangement with, or granted a trust deed for, the person's creditors unless the person has been discharged in respect of it;
- (j)there is—
- (i)an administrator, administrative receiver or receiver appointed in respect of it; or
- (ii)an administration order made in respect of it under schedule B1 of the Insolvency Act 1986(52);
- (k)that person is a partnership or limited liability partnership and—
- (i)a dissolution of the partnership or limited liability partnership has been ordered by any competent court, tribunal or arbitrator; or
- (ii)an event has happened that makes it unlawful for the business of the partnership or limited liability partnership to continue, or for members of the partnership or limited liability partnership to carry on in partnership or limited liability partnership;
- (l)the person has been—
- (i)removed under section 34 of the Charities and Trustee Investment (Scotland) Act 2005 (powers of Court of Session)(53), from being concerned in the management or control of any body; or
- (ii)removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission for England and Wales or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person by that person's conduct contributed to or facilitated;

(m)the person is subject to a –

(i)disqualification order under section 1 of the Company Directors Disqualification Act 1986(54);

(ii)a disqualification undertaking under section 1A of that Act;

(iii)a disqualification order under article 3 of the Company Directors Disqualification (Northern Ireland) Order 2002(55);

(iv)a disqualification undertaking under article 4 of that Order; or

(v)a disqualification order under section 429(2)(b) of the Insolvency Act 1986(56); or

(n)the person falls within regulation 6(2)(d) (general conditions relating to all contracts) of the National Health Service (General Medical Services Contracts) Regulations 2015(57).

(4) A person will not fall within paragraph (3)(b) where the Health Board is satisfied that the disqualification or suspension from practising is imposed by a licensing body outside the United Kingdom and it does not make the person unsuitable to be—

(a)a party to the agreement;

(b)in the case where the person is a partner in a partnership that is a proposed party to the agreement, a partner in that partnership;

(c)in the case where the person is a member of a limited liability partnership that is a proposed party to the agreement, a member of that limited liability partnership;

(d)in the case where the person is—

(i)a member of a company that is a proposed party to the agreement; or

(ii)a director or secretary of a company that is a proposed party to the agreement, a member of that company, or a director or secretary of that company (as the case may be).

(5) A person will not fall within paragraph (3)(g) where the Health Board is satisfied that the conviction does not make the person unsuitable to be—

(a)a party to the agreement;

(b)in the case where the person is a partner in a partnership that is a proposed party to the agreement, a partner in that partnership;

(c)in the case where the person is a member of a limited liability partnership that is a proposed party to the agreement, a member of that limited liability partnership;

(d)in the case where the person is—

(i)a member of a company that is a proposed party to the agreement; or

(ii)a director or secretary of a company that is a proposed party to the agreement,

a member of that company, or a director or secretary of that company (as the case may be).

(6) In this regulation, "health service body" does not include any person who is to be treated as health service body in accordance with regulation 10.

#### **Further conditions relating to all agreements**

5.—(1) For the purposes of section 17CA(4) of the Act (primary medical services: persons with whom agreements can be made)(58), a person regularly performs or is engaged in the day to day provision of primary medical services where, subject to paragraphs (2) and (3), that person so performs or is so engaged, or will so perform or so engage, for no less than a total of 10 hours in each week for the duration of the agreement.

(2) For the purposes of section 17CA(5)(b) of the Act, references in section 17CA(4) to a person who is performing or is engaged in the provision of services, include a person who has performed or been engaged in providing the services within 6 months prior to the agreement being made.

(3) For the purposes of section 17CA(6) of the Act, the prescribed circumstances in which a period of time in which a person is not performing or is not engaged in the provision of primary medical services is to be disregarded for the purposes of determining whether the person regularly performs or is engaged in the day to day provision of those services are where the period of time is—

(a) a period of annual leave, as determined by the period of annual leave entitlement of the said person;

(b) a local or public holiday in Scotland;

(c) a period of—

(i) maternity leave;

(ii) paternity leave;

(iii) adoption leave;

(iv) parental leave;

(v) shared parental leave; or

(vi) neonatal care leave,

as determined by the period of entitlement of the said person;

(d) a period of time when a person has been incapable of work due to sickness, injury or pregnancy;

(e) a period of time up to a maximum of 12 months, when a person is undertaking approved study or training;

(f) a period of service as a medical practitioner employed under a contract of service by the Ministry of Defence, whether or not as a member of the armed forces of the Crown, provided that the medical practitioner is entered on the General Practitioner Register kept by virtue of section 34C of the Medical Act 1983(59);

(g) a period of whole time service in the armed forces of the Crown in a national emergency, as a volunteer or otherwise, or a compulsory whole time service in those forces, including any service resulting from any reserve liability, or any equivalent service by a person liable for compulsory whole-time service in those forces; or

(h) any period during which the person has been suspended by a professional regulatory body, a Health Board or the Tribunal where that person was suspended after the agreement with the Health Board was entered into.

(4) For the purposes of this regulation, “approved study or training” means study or training which is relevant for the purposes of the provider carrying out the obligations under the agreement effectively, and which has been approved by the appropriate partner, member or person responsible for training and development.

### **Reasons**

6.—(1) Where a Health Board is of the view that the conditions in regulations 4 or 5 for making an agreement are not met, it must notify in writing the person intending to make an agreement of the Health Board’s view and its reasons for that view and of that person’s right of appeal under regulation 7.

(2) The Health Board must also notify in writing of its view and its reasons for that view—

(a) any other persons intending to make the agreement;

(b) any partner in a partnership that is notified under paragraph (1);

(c) any member of a limited liability partnership that is notified under paragraph (1); and

(d) any member, or director or secretary of, a company that is notified under paragraph (1),

where its reasons for that view relates to that person or persons.

### **Appeal**

7. A person who has been served with a notice under regulation 6(1) may appeal to the Scottish Ministers against the decision of the Health Board by giving notice in writing to the Scottish Ministers within the period of 28 days beginning on the day that the Health Board served its notice.

### **Prescribed period under section 17D(3) of the Act**

8. The period prescribed for the purposes of section 17D(3) of the Act (persons with whom agreements may be made)(60) is 6 months.

### **Pre-agreement dispute resolution**

9.—(1) Except where the proposed provider is a health service body (in which case section 17A(5) of the Act(61) applies), if, in the course of negotiations intending to lead to any agreement, the proposed parties to that agreement are unable to agree on a particular term of the agreement, either the Health Board or the proposed provider may refer the terms of the proposed agreement to the Scottish Ministers to consider and determine the matter.

(2) Disputes as to the terms of any proposed agreement referred to the Scottish Ministers in accordance with paragraph (1) must be determined in accordance with—

(a) the NHS dispute resolution procedure, as if—

- (i) in paragraph 58(3)(b) of schedule 1, “agreement” read “terms of the proposed agreement”; and
- (ii) paragraphs 59(2) and (3) of schedule 1 were omitted; and
- (b) paragraph (3) of this regulation.

(3) In a dispute referred to the Scottish Ministers under paragraph (1), the determination of the adjudicator—

- (a) may specify terms to be included in the proposed agreement;
- (b) may require the Health Board to proceed with the proposed agreement, but may not require the proposed provider to proceed with the proposed agreement; and
- (c) is binding on the proposed parties to the agreement.

(4) In this regulation “health service body” does not include any provider who is to be treated as a health service body in accordance with regulation 10.

### **PART 3**

#### **HEALTH SERVICE BODY STATUS**

##### **Health service body status**

**10.**—(1) Where a proposed provider elects, in a written notice served on the Health Board at any time prior to the agreement being entered into, to be treated as a health service body for the purposes of section 17A of the Act (NHS contracts)(62), the proposed provider will be so treated from the date on which the agreement is made.

(2) If, pursuant to paragraph (1) or (5), a provider is to be treated as a health service body, it will not be treated as a health service body to the extent that—

- (a) the nature of, or any rights or liabilities arising under, any other arrangement or proposed arrangement with a health service body entered into or to be entered into by a provider is affected; and
- (b) a matter referred to the Scottish Ministers for the purposes of section 17A(4) of the Act must be determined under the provisions of section 17A.

(3) Where an agreement is made with a provider, and that provider is to be treated as a health service body in accordance with paragraph (1) or (5), the provider will, subject to paragraph (4) continue to be treated as a health service body for the purposes of section 17A of the Act, for as long as that agreement continues irrespective of any change in—

- (a) where a partnership is a party to the agreement, the membership of the partnership; and
- (b) the parties to the agreement comprising the provider.

(4) A provider may at any time request in writing to be treated or cease to be treated as a health service body for the purposes of section 17A of the Act, and if the provider does so—

- (a) the procedure in paragraph 61(1) of schedule 1 applies; and
- (b) the Health Board must agree to the variation.

(5) If the provider makes a request under paragraph (4), the provider must—

(a) be treated; or

(b) subject to paragraph (7) cease to be treated,

as a health service body for the purposes of section 17A of the Act from the date that variation is to take effect pursuant to paragraph 61(1) of schedule 1.

(6) Subject to paragraph (7), a provider ceases to be treated as a health service body for the purposes of section 17A of the Act if the agreement terminates.

(7) Where a provider ceases to be treated as a health service body pursuant to—

(a) paragraph (5), the provider will, if the provider or the Health Board has referred any matter to the Scottish Ministers for the purposes of section 17A(4) of the Act before the provider ceases to be a health service body, be bound by the determination of the adjudicator;

(b) paragraph (6), the provider will continue to be treated as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced—

(i) before the termination of the agreement; or

(ii) after the termination of the agreement, whether in connection with or arising out of the termination of the agreement or otherwise,

for which purpose the provider will cease to be treated as such a body on the conclusion of that procedure.

## **PART 4**

### **PROVISION OF PRIMARY MEDICAL SERVICES**

#### **Provision of primary medical services**

11. Whether or not the agreement includes arrangements for the provision of services which are not primary medical services, an agreement must include arrangements for the provision of one or more of the following primary medical services:—

(a) essential services;

(b) additional services; and

(c) enhanced services.

#### **Primary medical services and content of agreements**

12.—(1) An agreement must contain terms which have the same effect as those specified in schedule 1 (content of agreements), unless it is of a type or nature to which a particular provision does not apply, except paragraphs 5, 5A, 58(5) to (15), and 59.

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

#### **Essential services and content of agreements**

13.—(1) An agreement which includes the provision of essential services must specify—

(a) the area as respects which persons resident in it will, subject to any other terms of the agreement relating to patient registration, be entitled to—

(i) register with the provider; or

(ii) seek acceptance by the provider as a temporary resident; and

(b) whether, at the date on which the agreement comes into force, the provider's list of patients is open or closed.

(2) Where, in accordance with paragraph (1), the agreement specifies that the provider's list of patients is closed it must also specify in relation to that closure each of the items listed in paragraph 19(9)(a) to 19(9)(d) of schedule 2 (agreements to provide essential services).

(3) An agreement which includes the provision of essential services must, in addition to any other terms required by these Regulations, unless it is of a type or nature to which a particular provision does not apply contain terms with the same effect as those specified in schedule 2, except paragraphs 21(5) to 21(7), 25(5) to (9) and 26(3) of that schedule.

(4) The paragraphs specified in paragraph (3) will have effect in relation to matters set out in those paragraphs.

(5) An agreement which does not include the provision of essential services must not specify the matters referred to in paragraph (1) nor contain terms with the same effect as those specified in schedule 2.

#### **Additional services and content of agreements**

**14.** An agreement which includes the provision of additional services must, in addition to any other terms required by these Regulations—

(a) in relation to all such services included in the agreement, contain a provision which has the same effect as that specified in paragraph 1 of schedule 3;

(b) in relation to each such service included in the agreement, contain provisions which have the same effect as those specified in schedule 3, which are relevant to that service.

#### **Requirement to provide vaccination services**

**14A.—(1)** An agreement must include terms which have the same effect as paragraph 1 of schedule 3A.

(2) An agreement which includes the provision of any vaccination services must—

(a) in relation to all such services, contain a term which has the same effect as that specified in paragraph 2 of schedule 3A; and

(b) in relation to each such service which the provider is required to provide, contain terms which have the same effect as those specified in schedule 3A, which are relevant to that service.

## **PART 5**

### **CONTENT OF AGREEMENTS**

#### **Parties to the agreement**

**15.** An agreement must specify—

(a)the names of the parties;

(b)where a party to the agreement is a partnership—

(i)whether or not that partnership is a limited partnership; and

(ii)the names of the partners and, in the case of a limited partnership, their status as general or limited partner;  
and

(c)in the case of the Health Board and the provider and each party to the agreement comprising the provider, the address to which official correspondence and notices should be sent.

#### **NHS contracts**

16. If the provider is to be treated as a health service body the agreement must state that it is an NHS contract.

#### **Agreements with one or more partnerships**

17.—(1) Where a partnership is a party to the agreement, the agreement is to be treated as made with that partnership as it is from time to time constituted, and the agreement must make specific provision to this effect.

(2) Where a partnership is a party to the agreement, the provider must be required by the terms of the agreement to ensure that any person who becomes a member of the partnership after the agreement has been made is bound automatically by the agreement, whether by virtue of the partnership deed or otherwise.

(3) For the avoidance of doubt, in this regulation, a reference to a "partnership" does not include a reference to a limited liability partnership or any member of a limited liability partnership.

#### **Arrangements on termination**

18. An agreement must make suitable provision for arrangements on termination of an agreement, including the consequences (whether financial or otherwise) of the agreement ending.

#### **Services generally**

19.—(1) An agreement must specify—

(a)the services to be provided;

(b)subject to paragraph (2), the address of each of the premises to be used by the provider or any sub-contractor for the provision of such services;

(c)to whom such services are to be provided;

(d)the period (if any) for which the services are to be provided; and

(e)where the agreement does not include the provision of essential services, the area (if any) in which the provider agrees to attend on patients outside the practice premises.

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

(a)the homes of patients; or

(b)any other premises where services are provided on an emergency basis.

(3) Where on the date on which the agreement is to be made, the Health Board is not satisfied that all or any of the premises specified in accordance with sub-paragraph (1)(b) meet the requirements set out in paragraph 1 of schedule 1, the agreement may not be made unless it includes a plan, drawn up jointly by the Health Board and the provider, which specifies—

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

#### **Certificates**

**20.—**(1) An agreement must contain a term which has the effect of requiring the provider to issue free of charge to a patient or a patient's personal representatives any medical certificate of a description prescribed in column 1 of schedule 4 (list of prescribed medical certificates) of the GMS Contracts Regulations, which is reasonably required under or for the purposes of the enactments specified in relation to the certificate in column 2 of that schedule, except where, for the condition to which the certificate relates, the patient—

(a) is being attended by a medical practitioner or alternative provider for the relevant certificate who is not—

- (i) employed or engaged by the provider;
  - (ii) a party to the agreement;
  - (iii) in the case where a partnership is a party to the agreement, a partner in such a partnership;
  - (iv) in the case where a limited liability partnership is a party to the agreement, a member of the limited liability partnership; or
  - (v) in the case where a company is a party to the agreement, a member of the company; or
- (b) is not being treated by or under the supervision of a health care professional.

(2) The exception in paragraph (1)(a) must not apply where the certificate is a doctor's statement issued in accordance with regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976 (evidence of incapacity for work, limited capability for work and confinement)(63) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985 (medical information)(64).

(3) The agreement must contain a term which has the effect of permitting the provider's obligation to issue any medical certificate prescribed in column 1 of schedule 4 of the GMS Contracts Regulations to be discharged on behalf of the provider by an alternative provider for the relevant medical certificate.

(4) In this regulation, "alternative provider" means another health care professional(65) who falls within the description of alternative providers specified in column 3 of schedule 4 of the GMS Contracts Regulations in relation to the relevant medical certificate prescribed in column 1 of that schedule.

#### **Additional obligations in relation to practice premises**

**21.**—(1) A provider who receives financial assistance must comply with the obligations set out in schedule 4 throughout the period that the provider receives that assistance and a term to this effect must be included in the agreement.

(2) In this regulation, “financial assistance” means financial assistance from a Health Board or the Scottish Ministers in the form of—

(a) a recurring payment to the provider of—

- (i) the provider’s owner-occupier borrowing costs;
- (ii) notional rent payments as an owner-occupier; or
- (iii) reimbursement of the provider’s rent payments;

in accordance with directions under sections 2(5) and 17E(3A) of the Act(66); or

(b) a loan secured over the practice premises.

#### **Finance**

**22.**—(1) Subject to paragraph (2), the agreement must contain a term which has the effect of requiring the Health Board to make payments to the provider under the agreement promptly and in accordance with both the terms of the agreement and, as respects the provision or performance of primary medical services, any other conditions relating to the payment contained in directions by the Scottish Ministers under section 17E(3A) of the Act.

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

(a) that is owed by the provider to the Health Board under the agreement; or

(b) that the Health Board may withhold from the provider in accordance with the terms of the agreement or any other applicable provisions contained in directions given by the Scottish Ministers under section 17E(3A) of the Act.

#### **Finance**

**23.** An agreement must contain a term to the effect that where, pursuant to directions of the Scottish Ministers under section 2(5) or section 17E(3A) of the Act, a Health Board is required to make a payment to a provider under an agreement but subject to conditions, those conditions are to be a term of the agreement.

#### **Fees and charges**

**24.**—(1) An agreement must contain terms relating to fees and charges to the effect that, subject to the provisions of paragraph 5 of schedule 2, the provider must not, directly or indirectly, demand or accept a fee or other remuneration from any patient of the provider for—

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

(b) any prescription for any drug, medicine or appliance,

except in the circumstances set out in paragraph (1)(a) to (d) and paragraph (1)(f) to (j) of schedule 5 (Fees and Charges) of the GMS Contracts Regulations, subject to paragraph (2) of this regulation.

(2) The modifications, referred to in paragraph (1), of paragraph (1)(a) to (d) and paragraph (1)(f) to (j) of schedule 5 (Fees and Charges) of the GMS Contracts Regulations, are—

(a) for “contractor” read “provider” in each place where it occurs; and

(b) for “contract” read “agreement” in each place where it occurs.

#### **Implied agreement terms**

**25.—**(1) Where an agreement fails to include any required term, such a term is to be an implied term of the agreement.

(2) An agreement must contain terms which have the effect that—

(a) where, or to the extent that, a term is a required term and such a term is omitted, either in whole or in part, from the express terms of the agreement; and

(b) as a result, the agreement does not expressly include that required term in full,

that required term, to the extent that it was omitted from the express terms of the agreement, is to be an implied term of the agreement.

(3) In the event of, and only to the extent of, any conflict between any term that must be implied in accordance with this regulation, the clauses of the agreement and the schedules of the agreement, the following order of precedence applies:

(a) any required term that is implied in accordance with this regulation;

(b) the clauses of the agreement; and

(c) the schedules of the agreement.

(4) A “required term” is any term which is required to be included in the agreement by virtue of these Regulations, including any term which is required by an amendment, extension, re-enactment, or consolidation of these Regulations, whether before or after the commencement of the agreement.

## **PART 6**

### **FUNCTIONS OF AREA MEDICAL COMMITTEE**

#### **Functions of area medical committee**

**26.—**(1) The functions of an area medical committee which are prescribed for the purposes of section 9(6) of the Act (local consultative committees) are—

(a) the functions which are conferred upon it by these Regulations or by any order made under section 7 of the 2004 Act;

(b) the making of arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the provider or the Health Board is concerned that the medical practitioner is incapable of adequately

providing services under the agreement and the provider or the Health Board so requests with the agreement of the medical practitioner concerned;

(c)the consideration of the report of any medical examination arranged in accordance with sub-paragraph (b) and the making of a written report as to the capability of the medical practitioner of adequately providing services under the agreement to the medical practitioner concerned, the provider and the Health Board with whom the provider has the agreement;

(d)the making of all necessary arrangements and performance of all functions reasonably required to set up, support and facilitate any improvement or quality arrangement of a cluster or any other person as required by any directions given by Scottish Ministers under section 2(5) of the Act(67); and

(e)the making of all necessary arrangements and performance of all necessary functions reasonably required to support and facilitate local dispute resolution processes in its area, including any local dispute resolution process relating to remuneration and conditions of service.

(2) The medical practitioner referred to in paragraph (1)(b) is a medical practitioner who is—

(a)a party to the agreement;

(b)a partner in a partnership that is a party to the agreement;

(c)a member of a limited liability partnership that is a party to the agreement; or

(d)a member of a company that is a party to the agreement.

## PART 7

### RIGHT TO A GENERAL MEDICAL SERVICES CONTRACT

#### **Right to a general medical services contract**

**27.**—(1) A provider which is providing essential services under an agreement and which wishes a general medical services contract to be entered into pursuant to this regulation must notify the Health Board in writing at least three months before the date on which it wishes the general medical services contract to be entered into.

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

(a)state that the provider wishes to terminate the agreement and the date on which the provider wishes the agreement to terminate, which must be at least three months after the date of service of the notice;

(b)subject to paragraph (3), give the name of the person with whom the provider wishes the Health Board to enter into a general medical services contract; and

(c)confirm that the person so named meets the conditions set out in—

(i)section 17L of the Act (eligibility to be contractor under general medical services contract)(68); and

(ii)regulations 5 (conditions relating solely to medical practitioners) and 6 (general conditions relating to all contracts) and 7 (further conditions relating to all contracts) of the GMS Contracts Regulations,

where the provider is not able to confirm, the reason why it is not able to do so and confirmation that the person immediately prior to entering into the general medical services contract will 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 Health Board must acknowledge receipt of the notice served under paragraph (1) within the period of 7 days beginning on the day that it received the notice.

(5) Provided that the conditions set out in section 17L of the Act and regulations 4, 5 and 6 of the GMS Contracts Regulations are met, the Health Board must enter into a general medical services contract with the person named in the notice served under paragraph (1).

(6) In addition to the terms required by the Act and the GMS Contracts Regulations, a general medical services contract entered into pursuant to 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 provider'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 Health Board pursuant to paragraph 11 of schedule 6 of the GMS Contracts Regulations; and

(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.

(7) An agreement will terminate on the date stated in the notice given by the provider under paragraph (1) unless a different date is agreed by the provider and the Health Board or no general medical services contract is entered into by the Health Board pursuant to this regulation.

(8) Where the Health Board is of the view that the conditions in section 17L of the Act or regulations 4, 5 or 6 of the GMS Contracts Regulations are not met it must notify in writing the provider of its view, and its reasons for that view, and of the provider's right of appeal under sub-paragraph (9).

(9) The provider may appeal to the Scottish Ministers against the decision of the Health Board by giving notice in writing to the Scottish Ministers within the period of 28 days beginning on the day that the Health Board served its notice.

(10) Any other dispute relating to this regulation may be referred by the prospective party to the general medical services contract or the Health Board to the Scottish Ministers to consider and determine the matter in accordance with regulations 12(2) and (3) of the GMS Contracts Regulations.

## **PART 8**

### **TRANSITIONAL PROVISIONS**

#### **Out of Hours**

**28.—**(1) Where on 31st March 2018 an agreement included a requirement to provide out of hours services pursuant to regulation 13 of the 2004 Regulations—

(a)the agreement must continue to require the provider to provide out of hours services; and

(b)despite the revocation of the 2004 Regulations, the provisions of the 2004 Regulations referred to in paragraph (2) will continue to have effect in relation to that agreement on and after 1st April 2018 as they had effect immediately before that date,

until one of the end dates in paragraph (3) occurs.

(2) The provisions of the 2004 Regulations are—

(a)regulation 2, only in so far as that regulation relates to the definitions for “out of hours period” and “out of hours services”;

(b)regulations 9(d) and 13;

(c)paragraphs 6 and 7 of schedule 1;

(d)schedule 4; and

(e)paragraph 17 of schedule 6.

(3) The end dates referred to in paragraph (1) are—

(a)where on or after 1st April 2018, a provider serves on the Health Board a written notice stating that the provider wishes to terminate its obligation to provide out of hours services under its agreement, the end date is the date 9 months after the date of service of the notice or such earlier date as the Health Board and the provider agree; and

(b)where on or after 1st April 2018, the provider enters into an alternative arrangement with the Health Board to provide out of hours services, the end date is the date the provider commences providing out of hours services under the alternative arrangement, or such other date as the Health Board and the provider agree.

(4) The provider’s duty to provide out of hours services under the agreement will terminate with effect from 0800 hours on the end date specified in paragraph (3) unless the Health Board and the provider agree a different date or time.

(5) Nothing in -paragraphs (1) to (4) prevents the provider and the Health Board from agreeing a different date for the termination of the provider’s duty under the agreement to provide out of hours services and accordingly varying the agreement in accordance with paragraph 61(1) of schedule 1.

(6) Prior to the provider’s duty to provide out of hours services under the agreement ceasing, the Health Board and the provider must discuss how to inform patients of any change to the out of hours services which the provider provides.

(7) The provider must, if requested by the Health Board, inform the provider’s registered patients of the change in service by the provider and the arrangements made for them to receive out of hours services by—

(a)placing a notice in the practice’s waiting room; and

(b)including the information in the practice leaflet.

## **Transitional arrangements for vaccination and immunisation services**

**28A.—**(1) Where on 17 October 2021 an agreement included a requirement to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services in accordance with schedule 3—

(a) the Health Board may serve notice to the provider requiring the provider to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services for a period specified in the notice;

(b) despite the revocation of paragraphs 4 and 5 of schedule 3, where the Health Board has given notice under sub-paragraph (a), paragraphs 4 and 5 of schedule 3 continue to have effect in relation to that agreement on and after 18 October 2021 as they had effect immediately before that date, until the end of the period specified in the notice; ;

(c) where the Health Board has given notice under sub-paragraph (a), in relation to that agreement, the definition of “additional services” in regulation 3(1) is to be read as including “vaccinations and immunisations” and “childhood vaccinations and immunisations”.

(2) A notice served by the Health Board under paragraph (1)(a) must—

(a) be served no later than 1 December 2021; and

(b) specify a period which ends no later than 1 April 2022.

~~(3) A notice served by the Health Board under sub-paragraph (1)(a) must list all of the vaccinations and immunisations which the provider is required to provide as a consequence of the notice, as of the date of the notice.~~  
~~(4) A letter stating that the provider is to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services, for a period specified in the letter, which is sent by the Health Board to the provider’s official correspondence address (specified in accordance with regulation 15) before the coming into force of this regulation is deemed to have the same effect as a notice under paragraph (1)(a), if it complies with the requirements of this regulation.~~

(3) A notice served by the Health Board under sub-paragraph (1)(a) must list all of the vaccinations and immunisations which the provider is required to provide as a consequence of the notice, as of the date of the notice.

(4) A letter stating that the provider is to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services, for a period specified in the letter, which is sent by the Health Board to the provider’s official correspondence address (specified in accordance with regulation 15) before the coming into force of this regulation is deemed to have the same effect as a notice under sub-paragraph (1)(a), if it complies with the requirements of this regulation.

(5) The Health Board may reduce the duration of the period specified in a notice served under paragraph (1)(a) by serving the provider with a further notice.

(6) Where the provider is required to provide vaccination services in accordance with schedule 3A, the provider's obligation to provide services in accordance with a notice served under paragraph (1)(a) will end on the date on which the provider's obligation to provide vaccination services begins.

(7) Subject to paragraph (9), prior to the provider's duty to provide vaccination and immunisation services under this regulation ceasing, the Health Board and the provider must discuss how to inform patients of the change to how vaccinations and immunisations will be delivered.

(8) Subject to paragraph (9), if the Health Board requests it, the provider must inform the provider's patients of the change to how vaccinations and immunisations will be delivered to them by—

(a) placing a notice in the practice's waiting room;

(b) including the information in the practice leaflet.

(9) Paragraphs (7) and (8) do not apply where the provider is ceasing to provide vaccination and immunisation services under this regulation but will immediately begin providing vaccination services in accordance with schedule 3A.

#### **Revocations**

29. The enactments specified in column 1 of schedule 7 are hereby revoked to the extent specified in column 3 of that schedule.

#### **Consequential amendments**

30. Schedule 8 (consequential amendments) has effect.

*AILEEN CAMPBELL*

Authorised to sign by the Scottish Ministers

St Andrew's House,  
Edinburgh  
15th February 2018

Regulation 12

## **SCHEDULE 1**

### **CONTENT OF AGREEMENTS**

#### **PART 1**

#### **PROVISION OF SERVICES**

##### **Premises**

1. Subject to any plan which is included in the agreement pursuant to regulation 19(3), the provider 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 provider's patients.

##### **Telephone services**

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

(a) by patients to contact the practice for any purpose related to the agreement; or

(b) by any other person to contact the practice in relation to services provided as part of the health service, starts with the digits 087, or 09 or consists of a personal number, unless the service is provided free to the caller.

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

#### **Attendance outside practice premises**

3.—(1) In the case of a patient whose medical condition is such that in the reasonable opinion of the provider—

(a) attendance on the patient is required; and

(b) it would be inappropriate for the patient to attend at the practice premises,

the provider must provide services to that patient at whichever in the provider's judgement is the most appropriate of the places set out in sub-paragraph (2).

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

(a) the place recorded in the patient's medical records as being the patient's last home address or (where the patient's medical record is not immediately available) the place confirmed by the patient as being the patient's home address;

(b) such other place as the provider has informed the patient and the Health Board is the place where the provider has agreed to visit and treat the patient;

(c) where the provider has a list of patients, some other place in the provider's practice area; or

(d) where the provider has no list of patients, some other place within the area specified in the agreement pursuant to regulation 19(1)(e).

(3) Nothing in this paragraph prevents the provider from—

(a) arranging for the referral of the patient without first seeing the patient, in a case where the medical condition of that patient makes that course of action appropriate; or

(b) visiting the patient in circumstances where this paragraph does not place the provider under an obligation to do so.

#### **Clinical reports**

4.—(1) Where the provider provides any clinical services other than under a private arrangement, to a patient and either—

(a) the provider has no list of patients; or

(b) the patient is not on the provider's list of patients,

the provider must, as soon as reasonably practicable, provide a clinical report relating to the consultation and any treatment provided, to the Health Board.

(2) The Health Board must send any report received under sub-paragraph (1)—

(a) to the person with whom the patient is registered for the provision of essential services (or their equivalent); or

(b) if the person referred to in sub-paragraph (2)(a) is not known to it, to the Health Board in whose area the patient is resident.

### **Storage of vaccines**

5. The provider must ensure that—

(a) all vaccines are stored in a pharmaceutical refrigerator, designed for the purpose of storing vaccines or medicines, in accordance with the manufacturer's

instructions;

(b) all vaccine refrigerator is continually monitored and readings are taken on a calibrated maximum/minimum digital thermometer on all working days to ensure the temperature remains within the specified range of +2°C to +8°C; and

(c) it has regard to ~~Health Protection Scotland~~ Public Health Scotland Guidance on Vaccine Storage and Handling(69).

### **Anaphylaxis training**

5A. The provider must ensure that all registered medical practitioners and registered nurses routinely employed or engaged by the provider are trained in the recognition and initial treatment of anaphylaxis.

### **Infection control**

6. The provider must ensure that the provider has effective arrangements for infection control and decontamination.

### **Health Board support for providers**

6A.—(1) The Health Board must provide the provider with support by providing the community treatment and care services and pharmacotherapy services.

(2) The extent and manner of the community treatment and care services and the pharmacotherapy services which the Health Board must provide in terms of sub-paragraph (1) are to be determined in accordance with such directions as the Scottish Ministers may give.

(3) Any support which the provider receives from a pharmacist independent prescriber supplied by the Health Board in connection with dispensing services which the provider provides (under paragraph 16 of schedule 1) is not to be treated as the provision of pharmacotherapy services.

### **Duty of co-operation in relation to primary medical services**

7.—(1) A provider which does not provide to its patients—

- (a)essential services;
- (b)a particular additional service; or
- (c)a particular enhanced service; or
- (d)a particular vaccination service;

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

(2) The requirements referred to in sub-paragraph (1) are that the provider must—

- (a)co-operate, insofar as it is reasonable, with any person responsible for the provision of that service or those services; and
- (b)comply in core hours with any reasonable request for information from such a person or from the Health Board relating to the provision of that service or those services.

**Duty of co-operation in relation to primary medical services**

8. Where a provider will cease to be required to provide to its patients—

- (a)essential services;
- (b)a particular additional service; or
- (c)a particular enhanced service; or
- (d)a particular vaccination service;

the provider must comply with any reasonable request for information relating to the provision of that service or those services made by the Health Board or by any person with whom the Board intends to make arrangements for the provision of such services.

**Duty of co-operation with Health Board support for providers**

8A. Where a Health Board is providing support under paragraph 6A (Health Board support for providers), the provider must—

- (a)co-operate with the Health Board to allow the Health Board to provide pharmacotherapy services and community treatment and care services to the provider’s patients,
- (b)comply in core hours with any reasonable request for information from the Health Board to the provider in relation to such support,
- (c)provide to its patients any aspect of pharmacotherapy services and community treatment and care services which the Health Board is to provide under paragraph 6A(2) if the patient requires the services immediately to prevent injury or worsening of their clinical condition and Health Board provision is not immediately available.

**PART 2**

**PATIENTS**

**Patient preference of practitioner**

**9.—(1)** Where the provider has accepted a person as a patient the provider must—

(a) subject to sub-paragraph (3), notify the patient of the patient's rights to express a preference to receive services from a particular performer or class of performer either generally or in relation to any particular condition; and

(b) record in writing any such preference expressed by or on behalf of the patient.

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

(a) has reasonable grounds for refusing to provide services to the patient; or

(b) does not routinely perform the service in question within the practice.

(3) Where the patient is—

(a) a child, the provider may notify—

(i) a parent, guardian, or other adult person who has care of the child;

(ii) a person duly authorised by a local authority, where the child is in the care of the local authority under the Children (Scotland) Act 1995(70); or

(iii) a person duly authorised by a voluntary organisation, by which the child is being accommodated under the provisions of that Act;

(b) an adult person who is incapable of expressing such a preference or authorising such a preference to be made on their behalf, the provider may notify the primary carer of that person or a person authorised under the Adults with Incapacity (Scotland) Act 2000(71) to act on the patient's behalf,

of the right to express a preference for the patient to receive services from a particular performer or class of performer either generally or in relation to any particular condition.

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

**10.—(1)** Where the provider—

(a) has no provider's list of patients but is required in terms of the agreement to accept a person as a patient for the provision of an additional service or an enhanced service; or

(b) has a provider's list of patients and has received an application for the provision of clinical services other than essential services—

(i) from a person who is not included in the provider's list of patients;

(ii) from a person whom the provider has not accepted as a temporary resident; or

(iii) on behalf of a person mentioned in (i) or (ii) above, from one of the persons specified in paragraph 7(4) of schedule 2,

and has accepted that person as a patient for the provision of the service in question, the provider's responsibility for that patient may be terminated in one of the circumstances referred to in sub-paragraph (2).

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

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

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

(c) the patient has committed an act of violence against—

(i) an individual that is a party to the agreement;

(ii) a partner in a partnership that is a party to the agreement;

(iii) a member of a limited liability partnership that is a party to the agreement;

(iv) a member of a company that is a party to the agreement;

(v) a member of the provider's staff;

(vi) a person engaged by the provider to perform or assist in the performance of services under the agreement; or

(vii) any other person present—

(aa) on the practice premises; or

(bb) in the place where services were provided to the patient under the agreement,

or behaved in such a way that any such person has feared for that person's own safety and, in either case, the provider has reported that incident to the police or the Procurator Fiscal;

(d) it comes to the notice of the provider that the patient—

(i) no longer resides in the area for which the provider has agreed to provide the service; or

(ii) is no longer a person to which the provider has agreed to provide the service.

(3) A provider who wishes to terminate its responsibility for a patient under sub-paragraph (2) (b) or (c) must notify the patient of the termination and the reason for it.

(4) The provider must keep a written record of terminations under this paragraph and of the reason for them and must make this record available to the Health Board on request.

(5) A termination under—

(a) sub-paragraph (2)(b) will take effect 14 days from the date on which notice is given; and

(b) sub-paragraph (2)(c) will take effect from the date on which notice is given.

PART 3  
PRESCRIBING AND DISPENSING

**Prescribing**

11. The provider must ensure that any prescription form for drugs, medicines or appliances issued or created by a prescriber complies as appropriate with the requirements in paragraphs 12 to 14.

**Prescribing**

12.—(1) Subject to paragraphs 13 and 14, a prescriber must order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the agreement by—

(a) issuing to that patient a non-electronic prescription form; or

(b) creating and transmitting an electronic prescription form,

and such a non-electronic prescription form or electronic prescription form must not be used in any other circumstances.

(2) In issuing any non-electronic prescription form, the prescriber must sign the prescription form in ink with the prescriber's initials, or forenames, and surname in the prescriber's own handwriting and not by means of a stamp and must so sign only after particulars of the order have been inserted in the prescription form; ~~and~~.

(3) A prescription form must not refer to any previous prescription form.

(4) A separate prescription form must be used for each patient.

(5) In a case of urgency a prescriber may request a pharmacist to dispense a drug or medicine before a prescription form is issued or created, only if—

(a) that drug or medicine is not a Scheduled drug;

(b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(72) other than a drug which is for the time being specified in schedules 4 or 5 of the Misuse of Drugs Regulations 2001(73); and

(c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2) or with an electronic prescription form.

(6) In a case of urgency a prescriber may request a pharmacist to dispense an appliance before a prescription form is issued or created only if—

(a) that appliance does not contain a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in schedule 5 of the Misuse of Drugs Regulations 2001;

(b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and

(c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2) or with an electronic prescription form.

(7) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription form if the prescription is not for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in schedule 4 or 5 of the Misuse of Drugs Regulations 2001.

(8) A prescriber who orders drugs, medicines or appliances by means of an electronic prescription form must issue the patient with a written record of the prescription which has been created.

#### **Restrictions on prescribing by medical practitioners**

**13.—**(1) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner must not order on a prescription form a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act(74) as being drugs, medicines or other substances which may not be ordered for patients in the provision of primary medical services under a general medical services contract but may, subject to regulation 24(1)(b), prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(2) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner must not order on a prescription form or repeatable prescription a drug, medicine or other substance 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 may only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract unless:

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

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

(c) the practitioner includes on the prescription form the reference "SLS",

but may, subject to regulation 24(1)(b), prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner must not order on a prescription form a restricted availability appliance unless—

(a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and

(b) the practitioner includes on the prescription form the reference "SLS",

but may, subject to regulation 24(1)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

#### **Restrictions on prescribing by supplementary prescribers**

**14.—**(1) The provider must have arrangements in place to secure that a supplementary prescriber will—

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

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

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

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

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

(a) the supplementary prescriber satisfies the applicable conditions set out in regulation 215 of the Human Medicines Regulations 2012(75) (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 drug, medicine or other substance is not 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 may not be ordered for patients in the provision of primary medical services under a general medical services contract;

(c) the drug, medicine or other substance is not 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 in the provision of primary medical services under a general medical services contract unless—

(i) the patient is a person of the specified description;

(ii) the medicine is prescribed for that patient only for the specified purposes; and

(iii) if the supplementary prescriber is issuing or creating the prescription, the supplementary prescriber includes on the prescription form the reference "SLS".

(3) Where the functions of a supplementary prescriber include prescribing, the provider must have arrangements in place to secure that that person will only issue or create a prescription for—

(a) an appliance; or

(b) a medicine which is not a prescription only medicine,

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

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

(a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time the supplementary 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 notification of—

(aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan; and

(bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient; and

(viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;

(b) 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 drug, medicine or other substance, that drug, medicine or other substance is not 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 may not be ordered for patients in the provision of primary medical services under a general medical services contract;

(d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the 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 in the provision of primary medical services under a general medical services contract unless—

(i) the patient is a person of the specified description;

(ii) the medicine is prescribed for that patient only for the specified purposes; and

(iii) when issuing or creating the prescription, the supplementary prescriber includes on the prescription form the reference SLS;

(e) if it is a prescription for an appliance, the appliance is listed in Parts 2 to 6 or 8 to 10 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 3 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 sub-paragraph (4)(a), "clinical management plan" means a 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.

### **Excessive prescribing**

**15.—**(1) The provider must not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.

(2) In considering whether a provider has breached its obligations under sub-paragraph (1), the Health Board must seek the views of the area medical committee for its area.

### **Provision of dispensing services**

**16.—**(1) A provider may secure the provision of dispensing services to its patients under the agreement only if it is authorised or required to do so by the Health Board in accordance with the following provisions of this paragraph.

(2) Where the Health Board is satisfied, after consultation with the area pharmaceutical committee that a person, by reason of—

(a) distance;

(b) inadequacy of means of communication; or

(c) other exceptional circumstances,

will have serious difficulty in obtaining from a pharmacist any drugs, medicines or appliances, other than Scheduled drugs, required for that person's treatment, the Health Board must require or authorise the provider with whom the person is a registered patient to supply such drugs, medicines and appliances to that person until further notice.

(3) Notwithstanding anything in sub-paragraph (2)—

(a) a provider will not be required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) if the provider satisfies the Health Board that the provider is not in the habit of dispensing drugs, medicines and appliances for the provider's patients;

(b) a provider will be entitled to receive reasonable notice from the Health Board that the provider is required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) or that such supply is to be discontinued.

(4) A provider must receive the support of an appropriately qualified pharmacist independent prescriber provided by the Health Board, where the Health Board considers that the health outcomes of patients are likely to be improved by the provider and pharmacist independent prescriber working together with the aim of ensuring that the patient gets the best clinical benefit from their prescribed medicines.

(5) Subject to sub paragraph (7), a provider, who is required by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) to a patient, in the course of treating that patient under these Regulations—

(a) must, subject to sub-paragraph (8), record on a prescription form completed in accordance with paragraph 12, an order for supply of any drugs, medicines or appliances which are needed for the treatment of that patient, but will not be required to issue that form to that patient;

(b) must supply those drugs, medicines or appliances for that patient under sub paragraph (2) but—

(i) must not supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract, except that, where the provider has ordered a drug which has an appropriate non proprietary name either by that name or by its formula, the provider may supply a drug which has the same specification notwithstanding that it is such a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non proprietary name);

(ii) must supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may only be ordered for specific patients and purposes in the provision of primary medical services under a general medical services contract, only where—

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

(bb) that drug, medicine or other substance is supplied to that patient only for the specified purpose;

(iii) must supply under sub paragraph (2) for that patient a restricted availability appliance only if it is for a patient in a category of person or a purpose specified in the Drug Tariff;

(c) may supply for that patient with the provider's consent, in respect of that treatment but otherwise than under sub paragraph (2), any Scheduled drug.

(6) A provider must comply with any arrangements made by the Scottish Ministers, or made by the Health Board after consultation with the area medical committee and the area pharmaceutical committee and approved by the Scottish Ministers, under which the provider may obtain and have available any drugs, medicines or appliances which the provider is required or entitled to supply in terms of this paragraph.

(7) Sub-paragraph (5) does not apply to drugs, medicines or appliances ordered on a prescription form by a supplementary prescriber, or an independent prescriber.

(8) Where a patient presents an order on a non-electronic prescription form for listed drugs or medicines, or appliances, signed by a supplementary prescriber, or an independent prescriber, to a provider who is required

under sub-paragraph (2) to provide drugs or appliances to that patient, or a provider who is required under sub-paragraph (2) to provide drugs or appliances to a patient receives from the ePharmacy service an electronic prescription form which contains an order for listed drugs or medicines, or appliances in respect of that patient, signed by a supplementary prescriber, or an independent prescriber, the provider may provide to the patient such drugs, medicines or appliances so ordered as the provider supplies in the normal course of the provider's practice.

(9) A drug supplied by a provider unless administered in person must be supplied in a suitable container.

(10) Nothing in this paragraph must prevent a provider providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(11) A provider who is required or authorised by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) may do so in accordance with a Scottish SSP.

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

**17.**—(1) Subject to sub-paragraph (2), a provider—

(a) must provide to a patient any drug, medicine or appliance, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and

(b) may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which the provider personally administers or applies to that patient,

but may, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff.

(2) Nothing in sub-paragraph (1) authorises a person to supply any drug or medicine to a patient otherwise than in accordance with Part 3 of the Medicines Act 1968(76) or any regulations or orders made thereunder.

## **PART 4**

### **PERSONS WHO PERFORM SERVICES**

#### **Qualifications of performers**

**18.**—(1) Subject to sub-paragraph (2), no medical practitioner may perform medical services under the agreement unless the practitioner is—

(a) included in the primary medical services performers list for the Health Board which is under a duty to provide or secure the provision of the service to be performed;

(b) not suspended from that list or from the Medical Register; and

(c) not subject to interim suspension under section 41A of the Medical Act 1983 (interim orders)(77).

(2) Sub-paragraph (1)(a) will not apply in the case of—

(a) a medical practitioner employed in Scotland by a Health Board, in England and Wales by an NHS trust, or in Northern Ireland by a Health and Social Care trust who is providing services other than primary medical services at the practice premises;

(b) a person who is provisionally registered under section 15 (provisional registration), 15A (provisional registration for EEA nationals) or 21 (provisional registration) of EEA nationals with certain overseas qualifications of the Medical Act 1983(78) acting in the course of the person's employment in a resident medical capacity in an approved medical practice within the meaning of section 44D of the Medical Act 1983 (approved practice settings)(79); or

(c) a GP Registrar who has applied to the Health Board to have the GP Registrar's name included in the primary medical services performers list of the Health Board, until the first of the following events arises:—

(i) the Health Board notifies the GP Registrar of the Board's decision on that application;

(ii) the end of a period of 2 months, starting with the date on which the GP Registrar's vocational training scheme begins.

(2A) Sub-paragraph (1)(a) does not apply in the case of a person who is performing primary medical services by virtue of regulation 3A of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004 (S.S.I. 2004/114).

(3) In this paragraph, "vocational training scheme" has the meaning given in regulation 2 (interpretation) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(80).

#### **Qualifications of performers**

19. No health care professional other than one to whom paragraph 18 applies may perform clinical services under the agreement unless the health care professional is appropriately registered with the health care professional's relevant professional body and the health care professional's registration is not currently suspended.

#### **Qualifications of performers**

20. Where the registration of a health care professional or, in the case of a medical practitioner, the practitioner's inclusion in a list, is subject to conditions, the provider must ensure compliance with those conditions insofar as they are relevant to the agreement.

#### **Qualifications of performers**

21. No health care professional may perform any clinical services unless the health care professional has such clinical experience and training as are necessary to enable the health care professional properly to perform such services.

#### **Conditions for employment and engagement**

22.—(1) Subject to sub-paragraphs (2) and (3), a provider must not employ or engage a medical practitioner (other than one falling within paragraph 18(2)) unless—

(a) that practitioner has provided the provider with the name and address of the Health Boards on whose primary medical services performers lists the practitioner appears; and

(b) the provider has checked that the practitioner meets the requirements in paragraph 18.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible for the provider to check the matters referred to in paragraph 18 in accordance with sub-paragraph (1)(b) before employing or engaging that practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) Where the prospective employee is a GP Registrar, the requirements set out in sub-paragraph (1) must apply with the modifications that—

(a) the name and address provided under sub-paragraph (1) may be the name and address of the Health Boards on whose primary medical services performers lists the GP Registrar Scheme Guidance has applied for inclusion; and

(b) confirmation that the GP Registrar's name appears on those lists will not be required until the end of the first two months of the GP Registrar's training period.

(4) The provider may only offer employment to a general medical practitioner on terms and conditions which are no less favourable than those contained in the "Model terms and conditions of service for a salaried general practitioner employed by a GMS practice" published by the British Medical Association and the NHS Confederation as item 1.2 of the supplementary documents to the GMS contract 2003(81).

(5) This paragraph does not apply in the case of a person who is performing primary medical services by virtue of regulation 3A of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004 (S.S.I. 2004/114).

#### **Conditions for employment and engagement**

**23.—**(1) A provider must not employ or engage—

(a) a health care professional (other than one to whom paragraph 18 applies) unless the provider has checked that the health care professional meets the requirements in paragraph 19;

(b) a health care professional to perform clinical services unless the provider has taken reasonable steps to satisfy the provider that the health care professional meets the requirements in paragraph 21.

(2) Where the employment or engagement of a health care professional is urgently needed and it is not possible to check the matters referred to in paragraph 19 in accordance with sub-paragraph (1) before employing or engaging the health care professional, the health care professional may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) When considering a health care professional's experience and training for the purposes of sub-paragraph (1)(b) the provider must have regard in particular to—

(a) any post-graduate or post-registration qualification held by the health care professional; and

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

#### **Conditions for employment and engagement**

**24.—**(1) A provider must not employ or engage a health care professional to perform medical services under the agreement unless—

(a) that person has provided two clinical references, relating to two recent posts (which may include any current post) as a health care professional which lasted for three months without a significant break, or where this is not possible, a full explanation and alternative referees; and

(b) the provider has checked and is satisfied with the references.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible to obtain and check the references in accordance with sub-paragraph (1)(b) before employing or engaging the practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 14 days whilst the practitioner's references are checked and considered, and for an additional single period of a further 7 days if the provider believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the provider employs or engages the same person on more than one occasion within a period of three months, it may rely on the references provided on the first occasion, provided that those references are not more than twelve months old.

(4) This paragraph does not apply in the case of a person who is performing primary medical services by virtue of regulation 3A of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004 (S.S.I. 2004/114).

#### **Conditions for employment and engagement**

**25.—**(1) Before employing or engaging any person to assist the provider in the provision of services under the agreement, the provider must take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which the person is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 22 to 24.

(3) When considering the competence and suitability of any person for the purpose of sub-paragraph (1), the provider must have regard, in particular, to—

(a) that person's academic and vocational qualifications;

(b) the person's education and training; and

(c) the person's previous employment or work experience.

#### **Training**

**26. (1)** Subject to sub-paragraph (2) the provider 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 health care professional's skills and knowledge in relation to the services which the health care professional is performing or assisting in performing.

(2) Sub-paragraph (1) does not apply in respect of a health care professional who is—

(a) employed by the Health Board, and

(b) performing clinical services under the agreement solely as part of the support which the Health Board is required to provide under paragraph 6A (Health Board support for providers).

### **Training**

27. The provider must afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

### **Arrangements for GP registrars**

28.—(1) The provider may only employ or engage a GP Registrar subject to the conditions in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that the provider must not, by reason only of having employed or engaged a GP Registrar, reduce the total number of hours for which other medical practitioners perform primary medical services under the agreement or for which other staff assist them in the performance of those services.

(3) A provider which employs or engages a GP Registrar must—

(a) offer the GP Registrar terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Scottish Ministers to NHS Education for Scotland (**82**) concerning the grants, fees travelling and other allowances payable to GP Registrars; and

(b) take into account any guidance issued by the Scottish Ministers in relation to the GP Registrar Scheme (**83**).

### **Independent prescribers and supplementary prescribers**

29.—(1) Where—

(a) a provider employs or engages a person who is an independent prescriber or a supplementary prescriber whose functions will include prescribing;

(b) a party to the agreement is an independent prescriber or a supplementary prescriber whose functions will include prescribing;

(c) a partner or member as the case may be of a partnership or limited liability partnership that is a party to the agreement, is an independent prescriber or a supplementary prescriber whose functions will include prescribing;

(d) the member of a company that is a party to the agreement is an independent prescriber or a supplementary prescriber whose functions will include prescribing; or

(e) the functions of a person who is an independent prescriber or a supplementary prescriber whom it already employs or has already engaged are extended to include prescribing,

it must notify the Health Board in writing within the period of seven days beginning with the date on which the provider employed or engaged the person, the person became a party to the agreement, the person became a partner or member as the case may be of the partnership, limited liability partnership or company that is a party to the agreement (unless, immediately before becoming such a party, or partner or member of that partnership, limited liability partnership or company that is such a party, the person fell under sub-paragraph (1)(a)) or the person's functions were extended as the case may be.

(2) Where—

(a) the provider ceases to employ or engage a person who is an independent prescriber or a supplementary prescriber, whose functions included prescribing in the provider's practice;

(b) the party to the agreement, who is an independent prescriber or a supplementary prescriber, whose functions include prescribing, ceases to be a party to the agreement;

(c) the partner or member, as the case may be in a partnership or limited liability partnership who is an independent prescriber or a supplementary prescriber, whose functions include prescribing, ceases to be a partner or member of the partnership or limited liability partnership;

(d) the member of a company that is a party to the agreement, who is an independent prescriber or a supplementary prescriber whose functions include prescribing, ceases to be a member of the company;

(e) the functions of a person who is an independent prescriber or a supplementary prescriber whom the provider employs or engages in its practice are changed so that they no longer include prescribing in its practice; or

(f) the provider becomes aware that a person who is an independent prescriber or a supplementary prescriber whom the provider employs or engages has been removed or suspended from the relevant register,

it must notify the Health Board in writing by the end of the second day after the day when the event occurred.

(3) The provider must provide the following information when it notifies the Health Board in accordance with sub-paragraph (1).

(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;

(iii) the person became a partner or member, as the case may be in the partnership or limited liability partnership that is a party to the agreement, if applicable;

- (iv) the person became a member of a company that is a party to the agreement, if applicable; or
- (v) one of the person's functions became to prescribe in its practice.

(4) The provider must provide the following information when it notifies the Health Board in accordance with sub-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—
  - (i) the person ceased to be employed or engaged in its practice;
  - (ii) the person ceased to be a party to the agreement;
  - (iii) the person ceased to be a partner or member, as the case may be, in a partnership or limited liability partnership that is a party to the agreement;
  - (iv) the person ceased to be a member of a company that is a party to the agreement;
  - (v) the person's functions changed so as no longer to include prescribing; or
  - (vi) on which the person was removed or suspended from the relevant register.

#### **Signing of documents**

30.—(1) In addition to any other requirements relating to such documents whether in these regulations or otherwise, the provider must ensure that the documents specified in sub-paragraph (2) include—

- (a) the clinical profession of the health care professional who signed the document; and
- (b) the name of the provider on whose behalf it is signed.

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

- (a) certificates issued in accordance with regulation 20, unless regulations relating to particular certificates provide otherwise;
- (b) prescription forms; and
- (c) any other clinical documents.

#### **Level of skill**

31. The provider must carry out its obligations under the agreement with reasonable skill and care.

#### **Appraisal and assessment**

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

- (a) participates in the appraisal system provided by the Health Board unless the practitioner participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and

(b)co-operates with any assessment process which the Health Board operates in relation to poorly performing doctors, as set out in NHS circular PCA(M) (2001)17(84).

(2) The Health Board must provide an appraisal system for the purposes of sub-paragraph (1)(a) after consultation with the area medical committee and such other persons as appear to it to be appropriate.

(3) In sub-paragraph (1)—

“armed forces GP” means a medical practitioner who is employed on a contract of service by the Ministry of Defence, whether or not as a member of the United Kingdom Armed Forces of Her Majesty; and

“health service body” does not include any provider who is to be treated as a health service body in accordance with regulation 10.

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

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

(a)in all cases, it has taken reasonable steps to satisfy itself that—

(i)it is reasonable in all the circumstances; and

(ii)that person is qualified and competent to provide the service; and

(b)it has notified the Health Board of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into force.

(2) Sub-paragraph (1)(b) must not apply to an agreement for services with a health care professional for the provision by that person of clinical services.

(3) The notification referred to in sub-paragraph (1)(b) must include—

(a)the name and address of the proposed sub-contractor;

(b)the duration of the proposed sub-contract;

(c)the services to be covered;

(d)the address of any premises to be used for the provision of services; and

(e)in the case of an agreement entered into on or after 22nd December 2010, whether the sub-contractor, if that sub-contractor were a provider, would have sufficient involvement in patient care in terms of section 17CA(3) and

(4) of the Act(85).

(4) Following receipt of a notice in accordance with sub-paragraph (1)(b), the Health Board may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the provider must supply such information promptly.

(5) The provider must not proceed with the sub-contract or, if it has already taken effect, must take appropriate steps to terminate it, where, within 28 days of receipt of the notice referred to in sub-paragraph (1)(b), the Health Board has served notice of objection to the sub-contract on the grounds that—

(a) the sub-contract would—

(i) put at serious risk the safety of the provider's patients; or

(ii) put the Board at risk of material financial loss;

(b) the sub-contractor would be unable to meet the provider's obligations under the agreement; or

(c) in the case of an agreement entered into on or after 22nd December 2010, if the sub-contractor were a provider, that sub-contractor would not have sufficient involvement in patient care in terms of section 17CA(3) and (4) of the Act.

(6) Where the Health Board objects to a proposed sub-contract in accordance with sub-paragraph (5), it must include with the notice of objection a statement in writing of the reasons for its objection.

(7) Sub-paragraphs (1) and (3) to (6) must also apply in relation to any renewal or material variation of a sub-contract in relation to clinical matters.

(8) Where a Health Board does not object to a proposed sub-contract under sub-paragraph (5), the parties to the agreement will be deemed to have consented to a variation of the agreement which has the effect of adding to the list of practice premises any premises whose address was notified to it under sub-paragraph (3)(d) and paragraph 61 must not apply.

(9) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the clinical services it has agreed with the provider to provide.

(10) The provider, if it has a provider's list of patients, must not sub-contract any of its rights or duties under the agreement in relation to the provision of essential services to a company, partnership or limited liability partnership—

(a) owned wholly or partly by the provider or a party to the agreement, or by any former or current employee of the provider, or any partner or member of a party to the agreement;

(b) formed by or on behalf of the provider or a party to the agreement, or from which the provider or a party to the agreement derives or may derive a pecuniary benefit; or

(c) formed by or on behalf of a former or current employee of the provider, or a partner or member of a party to the agreement, or from which such a person derives or may derive a pecuniary benefit,

where that company, partnership or limited liability partnership 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 35 of the Act(86) or any regulations made wholly or partly under that section.

## PART 5

### DATA PROTECTION, RECORDS, INFORMATION, NOTIFICATIONS AND RIGHTS OF ENTRY

## Interpretation

~~34.—(1) Subject to sub-paragraph (3),...~~ for the purposes of this Part—

(za) “controller” has the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(6) and (14) of that Act);

(zb) “data protection officer” means a person designated as a data protection officer under the data protection legislation;

(a) “electronic patient records” means records of the provider’s attendance on its patients created by way of data entries on a computer and electronically held and controlled by the provider;

(b) “patient records” means records of the provider’s attendance on and treatment of its patients by way of electronic patient records or on forms supplied by the Health Board to the provider;

(c) “practice data” means data about a provider’s practice and which may include any information or data about employees, sub-contractors, remuneration, finances, workloads, and contracts other than personal data within patient records; and

(d) the meaning of “data controller”, “personal data”, “processing” and “supervisory authority” is to be construed in accordance with the 1998 Act.

(e) “personal data” and “processing” have the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(2), (4) and (14) of that Act).

~~(2) The meaning of “data controller”, “data protection officer”, “personal data”, “processing” and “supervisory authority” is to be construed in accordance with the GDPR.~~

~~(3) Sub-paragraph (1)(d) ceases to have effect on 25th May 2018.~~

~~(4) No provision of this Part is to be construed as creating a duty, obligation or right which is contrary to any duty, obligation or right created by the 1998 Act and any directly applicable EU instrument relating to data protection. —~~

~~(a) the data protection legislation, or~~

~~(b) any directly applicable EU legislation which is not part of the data protection legislation but which relates to data protection.~~

~~(5) The Health Board and the provider, when processing any data under this Part, must comply with any relevant direction, or guidance issued by the Scottish Ministers.~~

~~(6) The Health Board and the provider must include within the agreement—~~

~~(a) terms which have the effect of the obligations mentioned in paragraph 35; and~~

~~(b) a term that requires the Health Board and the provider to act jointly as data controllers in relation to the processing of patient records.~~

## Provider and Health Board Obligations

**35.—(1)** The provider must—

- (a) take all reasonable steps to ensure the accuracy of patient records;
- (b) verify the accuracy of any templates and notices provided to it by the Health Board in accordance with sub-paragraph (2)(b), and once verified, use such templates and notices;
- (c) comply with the Health Board's current policies concerning data security, personal data or IT security notified by the Health Board to the provider under sub-paragraph (2)(c);
- (d) maintain a record of all of the provider's processing activities carried out in performance of the agreement and make the records available to the Health Board on request;
- (e) where the Health Board and the provider have not appointed a jointly designated data protection officer; the provider must nominate a person with responsibility for working together with the Health Board's data protection officer in matters relating to the protection of personal data and the implementation of the Health Board's guidance, templates and policies on such matters set out under paragraph (2)(b); and
- (f) ensure that any person under its direction who has access to patient records has undergone adequate data protection training.

**(2)** The Health Board must—

- (a) take all reasonable steps to confirm the accuracy of patient records provided to or accessed by it;
- (b) provide to the provider, guidance, templates, and privacy notices, relating to the provider's processing of personal data and the provider's maintenance of a record in accordance with sub-paragraph (1)(d);
- (c) notify the provider timeously of its current policies regarding data security, personal data security and IT security processes;
- (d) maintain a record of its processing activities carried out in relation to a provider's patient records;
- (e) where the Health Board and provider agree, appoint a jointly designated data protection officer;
- (f) ensure that any of its employees who have access to the provider's patient records and practice data has undergone adequate data protection training; and
- (g) make available appropriate data protection training to the provider and its employees.

### **Records**

**36.—(1)** The provider must keep adequate patient records of its attendance on and treatment of its patients and must do so—

- (a) on forms to be supplied to it for ~~the purpose~~ that purpose by the Health Board; or
- (b) with the written consent of the Health Board, by way of electronic patient records; or
- (c) in a combination of those two ways.

(2) The provider must include in patient records referred to in sub-paragraph (1), clinical reports sent in accordance with paragraph 6 of schedule 1 or from any other health care professional who has provided clinical services to a person on its list of patients.

(3) The consent of the Health Board required by sub-paragraph (1)(b) must not be withheld or withdrawn provided the Health Board is satisfied, and continues to be satisfied, that—

(a) the provider ensures that the computer system upon which the provider proposes to keep the electronic patient records is accredited by the Scottish Ministers or another person on their behalf as suitable for that purpose in accordance with a relevant standard issued by the Scottish Ministers;

(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 agreement signed by the provider contains an obligation requiring the provider to have regard to any guidelines issued by the Scottish Ministers and notified in writing, to the provider by the Health Board concerning good practice in the keeping of electronic patient records.

(4) Where a patient's records are electronic patient records, the provider must, as soon as possible following a request from the Health Board, allow the Health Board to access the information recorded on the provider's computer system by means of the audit function referred to in sub-paragraph (3)(b) to the extent necessary for the Health Board to confirm that the audit function is enabled and functioning correctly.

(5) The provider must send the complete patient record relating to a person mentioned in sub-paragraph 5(a) or (b) to the Health Board—

(a) where a person on its list dies, before the end of the period of 14 days beginning with the date on which it was informed by the Health Board of the death, or (in any other case) before the end of the period of one month beginning with the date on which it learned of the death; or

(b) in any other case where the person is no longer registered with the provider, as soon as possible, at the request of the Health Board.

(6) To the extent that a patient's records are electronic patient records, the provider complies with sub-paragraph (5) if it sends to the Health Board a copy of those records—

(a) in written form; or

(b) with the written consent of the Health Board, in any other form.

(7) The consent of the Health Board to the transmission of information other than in written form for the purposes of sub-paragraph (6)(b) must not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with—

(a) the provider's proposals as to how the record will be transmitted;

(b) the provider's proposals as to the format of the transmitted record;

- (c) how the provider will ensure that the record received by the Health Board is identical to that transmitted; and
- (d) how a written copy of the record can be produced by the Health Board.

(8) A provider with electronic patient records must not disable, or attempt to disable, either the security measures or the audit and system management functions referred to in sub-paragraph (3)(b).

### **Processing and access of data**

**37.**—(1) Subject to paragraphs (2) and (4), the provider must on the request of the Health Board—

- (a) allow the Health Board to access practice data and patient records;
- (b) produce or disclose practice data and data within patient records to the Health Board or to any person authorised in writing by the Health Board; and
- (c) produce or disclose any other information to the Health Board which is reasonably required in connection with the Health Board's functions.

(2) A request under sub-paragraph (1) must be made—

- (a) after consideration of whether the relevant information could be so provided in compliance with the ~~1998 Act~~, and any directly applicable EU instrument relating to data protection;—
  - (i) the data protection legislation, and
  - (ii) any directly applicable EU legislation which is not part of the data protection legislation but which relates to data protection;
- (b) in accordance with directions given to the Health Board by the Scottish Ministers under section 2(5) of the Act that have been consulted upon by a body representative of general medical practitioners providing primary medical services in accordance with a general medical services contract or a section 17C arrangement; and
- (c) for a purpose mentioned in sub-paragraph (3).

(3) The purposes mentioned in sub-paragraph (2)(c) are—

- (a) medical diagnosis of or provision of healthcare to patients;
- (b) the planning, including workforce planning, and management of health and social care services; or
- (c) where information is reasonably required in connection with the agreement.

(4) The provider must produce any information relating to a request made in accordance with sub-paragraph (1)(b)—

- (a) by such date as has been agreed as reasonable between the provider and the Health Board; or
- (b) in the absence of such agreement, within 28 days of the request being made.

(5) In this paragraph—

(a)“access” includes access by way of any computerised system, information management & technology system or software; and

(b)“disclose” includes the provision of information by electronic means.

### **Confidentiality of personal data**

38. The provider must nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it and also data protection generally.

### **GP IT Services**

39.—(1) The Health Board will provide, maintain and where necessary, upgrade any integrated information management and technology systems used by the provider for provision of services under the agreement and any telecommunication links between these systems and the systems used by the Health Board, a Special Health Board, the Agency, or Healthcare Improvement Scotland, in accordance with any relevant guidance (including standards) issued from time to time by the Scottish Ministers.

(2) The Health Board and provider must take into account any relevant guidance issued by the Scottish Ministers for the purposes of this paragraph and this Part.

(3) On the expiry or termination of the agreement, the provider must immediately return to the Health Board any integrated information management and technology systems and telecommunication links purchased or provided by the Health Board for the purposes of this paragraph in its possession unless otherwise agreed between the Health Board and provider.

### **Patient online appointment services**

40.—(1) A provider must provide its registered patients with—

(a)an optional-online appointment service; and

(b)an optional-online repeat prescription service; and

(c)an optional-online repeat prescription information service,

in a manner which is capable of being electronically integrated with the computer systems of the provider’s practice and using appropriate systems authorised by the Health Board .

(2) ~~The requirements in sub-paragraph (1) do not apply where the provider does not have access to computer systems and software which would enable it to provide the services listed in that sub-paragraph.~~

(3) ~~If~~The provider provides an optional online appointment service, the provider must regularly consider whether it is desirable, in order to meet the reasonable needs of its registered patients, to increase the proportion of appointments which are made available to registered patients through that service and if it is so desirable, to increase the proportion of appointments accordingly.

(4) ~~If a provider provides any of the services referred to in sub-paragraph (1), the provider must promote that service to its registered patients—~~

~~(a) in practice leaflets in accordance with paragraph 11 of schedule 6; and~~

~~(b) if the provider has a website, on that website.~~

(4) The provider must promote the services referred to in sub-paragraph (1) to its registered patients—

(a) in practice leaflets in accordance with paragraph 11 of schedule 6; and

(b) on the practice website.

(5) In this paragraph—

(a) "online appointment service" means a facility which allows patients to book, view, amend and cancel appointments online;

(b) "repeat prescription service" means a facility which allows patients to order repeat prescriptions for drugs, medicines or appliances online; and

(c) "online repeat prescription information service" means a facility which allows patients to view online, and print, a list of any drugs, medicines or appliances in respect of which the patient has a repeat prescription.

#### **Practice leaflet**

**41.** The provider must—

(a) compile a document (in this paragraph called a practice leaflet) which includes the information specified in schedule 6;

(b) review its practice leaflet at least once in every period of twelve months and make any amendments necessary to maintain its accuracy; and

(c) make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

#### **Practice website**

**41A.—(1)** The provider is required to publish a website for its practice which—

(a) displays the information specified in schedule 6,

(b) is capable of providing the online services described by paragraph 40 (patient online appointment services) of schedule 1.

(2) The provider must make reasonable efforts to maintain the accuracy of the information on the website.

(3) Where the website is not operational, the provider must inform the Health Board.

#### **Inquiries about prescriptions and referrals**

**42.—(1)** The provider must, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the Health Board concerning—

(a) any prescription form issued by a prescriber;

(b) the considerations by reference to which prescribers issue such forms;

(c)the referral, by or on behalf of the provider, of any patient to any other services provided under the Act; or

(d)the considerations by which the provider makes such referrals or provides for them to be made on its behalf.

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist the Health Board to discharge its functions or of assisting the provider in the discharge of its obligations under the agreement.

(3) The provider will not be obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made—

(a)in the case of sub-paragraph (1)(a) or (1)(b), by an appropriately qualified health care professional;

(b)in the case of sub-paragraph (1)(c) or (1)(d), by an appropriately qualified medical practitioner,

appointed in either case by the Health Board to assist the Board in the exercise of its functions under this paragraph and that person produces, on request, written evidence that the person is authorised by the Health Board to make such an inquiry on its behalf.

**Provision of information to a medical officer etc.**

**43.**—(1) The provider must, if satisfied that the patient has given explicit consents—

(a)supply in writing to any person specified in sub-paragraph (3), within such reasonable period as that person may specify, such clinical information as any of the persons mentioned in sub-paragraph (3)(a) to (d) considers relevant about a patient to whom the provider or a person acting on behalf of the provider has issued or has refused to issue a medical certificate; and

(b)answer any inquiries by any person mentioned in sub-paragraph (3) about—

(i)a prescription form or medical certificate issued or created by, or on behalf of, the provider; or

(ii)any statement which the provider or a person acting on behalf of that provider has made in a report.

(2) For the purposes of being satisfied that a patient has given explicit consent, a provider may rely on an assurance in writing from any person mentioned in sub-paragraph (3) that the explicit consent of the patient has been obtained, unless the provider has reason to believe that the patient does not consent.

(3) For the purposes of sub-paragraph (1) and (2), the persons are—

(a)a medical officer;

(b)a nursing officer;

(c)an occupational therapist;

(d)a physiotherapist; or

(e)an officer of the Department for Work and Pensions who is acting on behalf of, and at the direction of, any person specified in sub-paragraphs (a) to (d).

(4) In this paragraph—

(a)“medical officer” means a medical practitioner who is—

(i)employed or engaged by the Department for Work and Pensions; or

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

(b)“nursing officer” means a health care professional who is registered on the Nursing and Midwifery Register and—

(i)employed or engaged by the Department for Work and Pensions; or

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

(c)“occupational therapist” means a health care professional who is registered in the part of the register maintained by the ~~Health Professions Council~~Health and Care Professions Council under article 5 of the ~~Health and Social Work Professions Order 2001~~(87)Health Professions Order 2001 relating to occupational therapists and—

(i)employed or engaged by the Department for Work and Pensions; or

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

(d)“physiotherapist” means a health care professional who is registered in the part of the register maintained by the ~~Health Professions Council~~Health and Care Professions Council under article 5 of the ~~Health and Social Work Professions Order 2001~~Health Professions Order 2001 relating to physiotherapists and—

(i)employed or engaged by the Department for Work and Pensions; or

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

#### **Annual return and review**

**44.**—(1) The provider must submit an annual return relating to the agreement to the Health Board.

(2) One such return may be requested by the Health Board 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 provider must submit the completed return to the Health Board—

(a)by such date as has been agreed as reasonable between the provider and the Health Board; or

(b)in the absence of such agreement, within 28 days of the request being made.

(4) Without prejudice to the generality of sub-paragraph (1)—

(a)in the case of agreements entered into on or after 22nd December 2010, the provider must include in the annual return a statement confirming that the provider meets the conditions of section 17CA(3) and (4) of the Act(88); and

(b)in all cases the provider must include in the annual return a statement confirming that any sub-contractor satisfies the requirements of paragraph 33(3)(e), and such details as the Health Board considers appropriate.

(5) Following receipt of the return referred to in sub-paragraph (1), the Health Board must arrange with the provider an annual review of its performance in relation to the agreement.

(6) Either the provider or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Health Board to participate in the annual review.

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

(8) A copy of the final record referred to in sub-paragraph (7) must be sent to the provider.

(9) In this paragraph, "financial year" means a period of twelve months ending with 31st March.

#### **Notifications to the Health Board**

**45.** In addition to any requirements of notification elsewhere in these Regulations, the provider must notify the Health Board in writing, as soon as reasonably practicable, of—

(a) any serious incident that in the reasonable opinion of the provider affects or is likely to affect the provider's performance of its obligations under the agreement;

(b) any circumstances which give rise to the Health Board's right to terminate the agreement under paragraph 68, 69 and 70;

(c) any appointments system which it proposes to operate and the proposed discontinuance of any such system;

(d) where the provider has a provider's list of patients, any change of which it is aware in the address of a registered patient; and

(e) the death of any patient of which it is aware.

#### **Notifications to the Health Board**

**46.** The provider must, unless it is impracticable for it to do so, notify the Health Board in writing within 28 days of any occurrence requiring a change in the information about it published by the Health Board in accordance with regulations made under section 2C(3) of the Act (functions of Health Boards: primary medical services)(**89**).

#### **Notice provisions specific to agreements with one or more companies limited by shares**

**47.—**(1) This paragraph applies to agreements entered into prior to 22nd December 2010.

(2) Where a company limited by shares is a party to the agreement, the provider must give notice to the Health Board forthwith when—

(a) any share in the company is transmitted or transferred (whether legally or beneficially) to another person on a date after the agreement has come into force;

(b) a new director or secretary is appointed;

(c) the company passes a resolution or a court of competent jurisdiction makes an order that one or more of those companies be wound up;

(d) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the company;

(e) circumstances arise which would enable the court to make a winding up order in respect of the company; or

(f) the company is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986(90).

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

(a) where the company is a qualifying body, within the meaning of section 17D(2)(91) of the Act, is a person falling within section 17D(1)(a) to (d) of the Act as in force at 21st December 2010 (persons with whom agreements may be made); and

(b) satisfies the condition imposed on shareholders by virtue of regulation 4 (general conditions relating to providers).

(4) A notice under sub-paragraph (1)(b) must confirm that the new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 4.

#### **Notice provisions specific to an agreement with one or more companies**

**48.—**(1) This paragraph applies to agreements entered into on or after 22nd December 2010.

(2) Where a company is a party to the agreement, the provider must give notice in writing to the Health Board forthwith when—

(a) a member, director or secretary of the company ceases to be a member, director or secretary of the company or informs the other members of the company that that person intends to cease to be a member, director or secretary of the company, and the date upon which he or she ceased, or will cease, to be a member, director or secretary of the company;

(b) a new member, director or secretary becomes a member, director or secretary of the company;

(c) the company passes a resolution or a court of competent jurisdiction makes an order that the company be wound up;

(d) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the company;

(e) circumstances arise which would enable the court to make a winding up order in respect of the company; or

(f) the company is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986.

(3) A notice under sub-paragraph (2)(b) must—

(a) state the date the new member, director or secretary became a member, director or secretary of the company;

(b) confirm that the new member is an individual who satisfies the conditions imposed on members by virtue of section 17CA(3) and (4) of the Act(92) and the conditions imposed by regulations 4 and 5; and

(c) confirm that the new director or, as the case may be, secretary satisfies the conditions imposed on directors and secretaries by virtue of regulation 4.

**Notice provisions specific to an agreement with one or more partnerships**

**49.**—(1) Where a partnership is party to the agreement, the provider must give notice to the Health Board without delay—

(a) when a partner leaves or informs the other members of the partnership of which they are a member, that the partner intends to leave the partnership, and the notice must state the date upon which the partner left or will leave the partnership;

(b) when a new partner joins a partnership.

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

(a) state the date that the new partner joined the partnership;

(b) in the case of an agreement entered into prior to 22nd December 2010—

(i) confirm that the new partner satisfies the conditions imposed by regulation 3 of the 2004 Regulations (general conditions relating to providers) as in force at 21st December 2010; and

(ii) state whether the new partner is a general or a limited partner;

(c) in the case of an agreement entered into on or after 22nd December 2010—

(i) confirm that the new partner is an individual who satisfies the conditions imposed on members by virtue of section 17CA(3) and (4) of the Act; and

(ii) satisfies the conditions imposed by regulations 4 and 5; and

(d) state whether the new partner is a general or a limited partner.

**Notice provisions specific to an agreement with persons practising with one or more limited liability partnership**

**50.**—(1) Where a limited liability partnership is party to the agreement, the provider must give notice to the Health Board without delay—

(a) when a member ceases to be a member, or informs the other members of the limited liability partnership that the member intends to cease to be a member, of the limited liability partnership, and the notice must state the date upon which the member ceased, or will cease, to be a member of the limited liability partnership;

(b) when a new member joins the limited liability partnership.

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

(a) state the date that the new member joined the limited liability partnership; and

(b) confirm that the new member is an individual who satisfies the conditions imposed on members by virtue of section 17CA(3) and (4) of the Act and the conditions imposed by regulations 4 and 5.

### **Notification of deaths**

**51.**—(1) The provider must report, in writing, to the Health Board, the death on the provider's practice premises of any patient no later than the end of the first working day after the date on which the death occurred.

(2) The report must include—

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

(3) The provider must send a copy of the report referred to in sub-paragraph (1) to any other Health Board in whose area the deceased was resident at the time of the patient's death.

### **Notifications to patients following variation of the agreement**

**52.** Where the agreement is varied in accordance with Part 8 of this schedule and, as a result of that variation—

- (a) there is to be a change in the range of services provided to the provider's patients; or
- (b) where the provider has a provider's list of patients, patients who are on that list are to be removed from that list,

the Health Board must notify those patients in writing of the variation and its effect and inform them of the steps they can take to obtain elsewhere the services in question or, as the case may be, register elsewhere for the provision of essential services (or their equivalent).

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

**53.**—(1) Subject to the conditions in sub-paragraph (2), the provider must allow persons authorised in writing by the Health Board to enter and inspect the practice premises at any reasonable time.

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

- (a) reasonable notice of the intended entry has been given;
- (b) written evidence of the authority of the person seeking entry is produced to the provider on request; and
- (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) Either the provider or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Board to be present at an inspection of the practice premises which takes place under this paragraph.

## **PART 6**

### **COMPLAINTS**

## **Complaints procedure**

**54.** The provider must have arrangements in place which operate in accordance with section 15 of the Patient Rights (Scotland) Act 2011(93), and any regulations or directions made under that Act.

## **Co-operation with investigations**

**55.**—(1) The provider must co-operate with—

(a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the agreement undertaken by—

(i) the Health Board; and

(ii) the Scottish Public Services Ombudsman; and

(b) any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the provider.

(2) In sub-paragraph (1)—

“NHS body” means in Scotland a Health Board or Special Health Board or the Agency, in England and Wales, ~~clinical-commissioning group~~integrated care board, a NHS trust, a NHS foundation trust, [ NHS England ], a Local Health Board and in Northern Ireland, Health and Social Care trust or Regional Health and Social Care Board; and

“local authority” means—

(a)

a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 (constitution of councils)(95);

(b)

any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities)(96);

(c)

the Council of the Isles of Scilly; or

(d)

a council of county or county borough in Wales.

(3) The co-operation required by sub-paragraph (1) includes—

(a) answering questions reasonably put to the provider by the NHS body, local authority or Scottish Public Services Ombudsman;

(b) providing any information relating to the complaint reasonably required by the NHS body, local authority or Scottish Public Services Ombudsman; and

(c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given) if the provider’s presence at the meeting is reasonably required by the NHS body, local authority or Scottish Public Services Ombudsman.

## **PART 7**

## DISPUTE RESOLUTION

### Local resolution of contract disputes – Local Dispute Resolution Process

56.—(1) For the purposes of this paragraph—

“local medical committee” means a local representative committee which represents the interests of general medical practitioners providing primary medical services in its locality and which is identified and recognised by the British Medical Association as a local medical committee on the British Medical Association’s website<sup>(97)</sup> as updated or replaced from time to time;

“local resolution approved mediator” means a mediator who is on the list of trained mediators kept in accordance with sub-paragraph (2) by the Health Board (“the first Health Board”)(other than the Health Board who is a party to the agreement (“the Second Health Board”)) which is requested by the Second Health Board to appoint a local resolution panel and which mediator is chosen by the local resolution panel in accordance with sub-paragraph (6);

“local resolution approved mediator functions” means the functions of—

(a)

facilitating, co-ordinating and mediating communication between the parties to a dispute arising out of or in connection with an agreement with a view to helping the parties to reach a voluntary resolution to their dispute;

(b)

assisting the parties to explore options for negotiating a resolution to the dispute; and

(c)

providing recommendations to facilitate resolution of the dispute arising out of or in connection with an agreement and reporting to the area medical committee, the local resolution panel and the parties to the dispute in accordance with sub-paragraph (9)(9);.

“local resolution panel” means a committee or a subcommittee of the first Health Board appointed by the first Health Board at the request of the second Health Board which must consist of—

(a)

a person representative of patients in the area of the second Health Board;

(b)

a person representative of the local medical committee, in the area of the second Health Board;

(c)

a person who is an employee of the first Health Board;

“local resolution report” means the written report provided by a local resolution approved mediator in accordance with sub-paragraph (9).

(2) Every Health Board will keep a list of local resolution approved mediators who are also employees of the Health Board or available to be engaged by the Health Board and who the Health Board is satisfied are capable of performing the local resolution approved mediator functions.

(3) In the case of any dispute arising out of or in connection with the agreement—

(a) the provider and the first Health Board must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute in accordance with the local dispute resolution process, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings);

(b) neither the provider nor the first Health Board may refer the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings) until the local dispute resolution process has been completed.

(4) Either party to the agreement may commence the local dispute resolution process by serving written notice on—

(a) the other party to the agreement; and

(b) the area medical committee for the second Health Board's area.

(5) The written notice referred to out in sub-paragraph (4) must set out—

(a) the issue in dispute which must arise out of or be in connection with the agreement;

(b) contact details for the parties to the agreement; and

(c) any background information which may be reasonably required by a local resolution approved mediator to perform their functions.

(6) Upon receipt of the notice referred to in sub-paragraph (4)—

(a) the Second Health Board must request that the First Health Board convene a local resolution panel; and

(b) that local resolution panel must choose from the list of local resolution approved mediators a local resolution approved mediator whom the panel considers capable of performing the local resolution approved mediator functions in relation to the dispute.

(7) The parties must provide the local resolution approved mediator and each other with any information which may reasonably be required to facilitate the resolution of the dispute and to enable the local resolution approved mediator to perform their local resolution approved mediator functions.

(8) The local resolution approved mediator must complete their local resolution approved mediator functions within three months from service of the notice referred to in sub-paragraph (4).

(9) Within the period specified in sub-paragraph (8), the local resolution approved mediator must provide a written report to the parties, the area medical committee and the local resolution panel referred to in sub-paragraph (4)(6) which sets out the following—

(a) any agreement reached between the parties;

(b) the local resolution approved mediator's recommendation on how to resolve any issues still in dispute; and

(c) confirmation that the local dispute resolution process has been completed.

(10) The local resolution report may be considered by the Scottish Ministers in the event that either party wishes to refer the dispute to the Scottish Ministers for determination in accordance with paragraphs 57 or 58.

#### **Dispute resolution: non-NHS agreements**

**57.**—(1) In the case of an agreement which is not an NHS agreement or an NHS contract, any dispute arising out of or in connection with the agreement, except matters dealt with under the complaints procedure pursuant to Part 6 of this schedule, may be referred for consideration and determination to the Scottish Ministers, if—

- (a) the Health Board so wishes and the provider has agreed in writing; or
- (b) the provider so wishes (even if the Health Board does not agree).

(2) In the case of a dispute referred to the Scottish Ministers under sub-paragraph (1)—

- (a) the procedure to be followed is the NHS dispute resolution procedure; and
- (b) the parties agree to be bound by any determination made by the adjudicator.

#### **NHS dispute resolution procedure**

**58.**—(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 59 applies in the case of any dispute arising out of or in connection with the agreement, which is referred to the Scottish Ministers—

- (a) in accordance with section 17A(4) of the Act (98) (where the agreement is an NHS contract); or
- (b) in accordance with paragraph 57(1) (where the agreement is not an NHS contract).

(2) In the case where—

- (a) a dispute is referred to the Scottish Ministers in accordance with regulation 9(1) (pre agreement disputes); or
- (b) a provider (or providers) refers a matter for determination in accordance with paragraph 26(1) or (2) of schedule 2,

the procedure specified in the following sub paragraphs and paragraph 59 is modified as mentioned in regulation 9 or, as the case may be, paragraph 26 of schedule 2.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1), must send to the Scottish Ministers 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 describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (3) within a period of three years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(5) The Scottish Ministers may determine the dispute themselves or, if they consider it appropriate, appoint a panel consisting of three persons (referred to as "the panel") to consider and determine the dispute.

(6) Before reaching a decision as to who should determine the dispute under sub paragraph (5), the Scottish Ministers must, within the period of 7 days beginning with the date on which the dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter under dispute.

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

(8) The Scottish Ministers must give a copy of any representations received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(9) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (6) or (8), the Scottish Ministers must, if they decide to appoint a panel to hear the dispute—

- (a) inform the parties in writing of the names of the persons whom they have appointed on the panel; and
- (b) pass to the panel any documents received from the parties under or pursuant to sub-paragraph (3), (6) or (8).

(10) For the purpose of assisting it in its consideration of the matter, the adjudicator may—

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which it wishes them to give special consideration; or
- (b) consult other persons whose expertise the adjudicator considers will assist the adjudicator in the adjudicator's consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), the adjudicator must notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator must give to the parties such opportunity as it considers reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the adjudicator must consider—

- (a) any written representations made in response to a request under sub-paragraph (6), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (10)(a);

(d)the results of any consultation under sub-paragraph (10)(b); and

(e)any observations made in accordance with an opportunity given under sub-paragraph (11).

(13) In this paragraph, “specified period” means such period as the Scottish Ministers must specify in the request under sub-paragraph (6) or (8), being not less than 2, nor more than 4, weeks beginning with the date on which the request is sent, but the adjudicator may, if the adjudicator considers that there is good reason for doing so, extend any such period (even after it has expired) and, where it does so, a reference in this paragraph to the specified period is to the period as so extended.

(14) Subject to the other provisions of this paragraph and paragraph 59 and to any agreement by the parties, the adjudicator must have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(15) Where the adjudicator is a panel, any decision or determination by the panel for the purposes of this paragraph and paragraph 59 may be by a majority.

#### **Determination of dispute**

**59.**—(1) The adjudicator must record the determination, and the reasons for it, in writing and must give notice of the determination (including the record of the reasons) to the parties and, in the case where the adjudicator is a panel, to the Scottish Ministers.

(2) A determination of a reference to the Scottish Ministers for the purposes of section 17A(4) of the Act or in accordance with paragraph 57(1) may contain such directions (including directions as to payment) as the adjudicator considers appropriate to resolve the matter in the dispute, and it is the duty of the provider and the Health Board to comply with such directions.

(3) Without prejudice to the generality of the adjudicator’s powers on a reference to the Scottish Ministers for the purposes of section 17A(4) or referred in accordance with paragraph 57(1), the adjudicator may, by the adjudicator’s determination, in relation to an agreement vary the terms of the agreement or bring it to an end; and where the agreement is so varied or brought to an end—

(a)subject to paragraph (b), the variation or termination will be treated as being effected by agreement between the Health Board and the provider; and

(b)directions included in the determination by virtue of sub-paragraph (2) may contain such provisions as the adjudicator considers appropriate in order satisfactorily to give effect to the variation or to bring the agreement to an end.

#### **Interpretation of Part 7**

**60.**—(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) Any term of the agreement that makes provision in respect of the requirements in this Part will survive even where the agreement has terminated.

PART 8  
VARIATION AND TERMINATION OF AGREEMENTS

**Variation of an agreement: general**

**61.**—(1) Subject to ~~regulation 25~~ regulations 25 and 28A, paragraphs 33(8), 65 and 75 of this schedule, paragraph 1 of schedule 3A and sub-paragraph (2), no amendment or variation will have effect unless it is in writing and signed by or on behalf of the Health Board and the provider.

(2) In addition to the specific provision made in paragraph 75 the Health Board may vary the agreement without the provider's consent where it—

(a) is reasonably satisfied that it is necessary to vary the agreement so as to comply with the relevant legislation; and

(b) notifies the provider in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect will not be less than 14 days after the date on which the notice under sub-paragraph (b) is served on the provider.

(3) In this paragraph "relevant legislation" means—

(a) the Act;

(b) ~~the 1998 Act or any directly applicable EU instrument relating to data protection;~~

(c) the Patient Rights (Scotland) Act 2011<sup>(99)</sup>;

(d) the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016<sup>(100)</sup>;

(da) the data protection legislation;

(db) any directly applicable EU legislation which is not part of the data protection legislation but which relates to data protection; and

(e) any regulations or direction given by the Scottish Ministers pursuant to the Acts referred to at sub-paragraphs

(a), (c) and (d).

**Variation of an agreement: execution**

**62.**—(1) If the agreement or any amendment or variation to the agreement under paragraph 61(1) is executed in counterpart, each counterpart when executed and delivered is to constitute an original of the agreement or amendment or variation to the agreement; but both of the counterparts will together constitute the same agreed agreement, amendment or variation and no counterpart is to be effective until each party has executed and delivered an executed counterpart to the other party.

(2) A counterpart of an agreement or an amendment or variation to the agreement may be delivered by a party ("the executing party") to the other party by:

- (a) the executing party printing out and signing the signature pages of the agreement or amendment or variation (both the signature page following the last clause and the signature page following any schedule);
- (b) the executing party scanning those signed signature pages to an electronic file; and
- (c) the executing party (or its legal representative) emailing the files of the scanned signature pages together with a copy of the agreement, amendment or variation to the other party.

#### **Termination by agreement**

63. The Health Board and the provider may agree in writing to terminate the agreement, and if the parties so agree, they must agree the date upon which that termination should take effect and any further terms upon which the agreement should be terminated.

#### **Termination by the provider**

64.—(1) A provider may terminate the agreement by serving notice in writing on the Health Board at any time.

(2) Where a provider serves notice pursuant to sub-paragraph (1), the agreement will, subject to sub-paragraph (3), terminate 6 months after the date on which the notice is served (“the termination date”), save that if the termination date is not the last calendar day of a month, the agreement will instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the provider is an individual, sub-paragraph (2) will apply to the provider, save that the reference to “6 months” will instead be to “3 months”.

(4) This paragraph and paragraph 66 are without prejudice to any other rights to terminate the agreement that the provider may have.

#### **Withdrawal by parties to an agreement other than Health Boards**

65.—(1) Where the provider comprises more than one party to the agreement, a party to the agreement may withdraw from the agreement by serving notice in writing on the Health Board and the other parties to the agreement at any time.

(2) Where a party serves notice pursuant to sub-paragraph (1), the agreement will, subject to sub-paragraph (3), be varied to the extent that that party is no longer a party to the agreement 6 months after the date on which the notice is served (“the variation date”), save that if the variation date is not the last calendar day of a month, the agreement will instead vary on the last calendar day of the month in which the variation date falls.

(3) Where a party to the agreement is an individual, sub-paragraph (2) will apply to that party, save that the reference to “6 months” will instead be to “3 months”.

(4) This paragraph is without prejudice to the right of the Health Board to terminate an agreement in accordance with paragraph 74.

#### **Late payment notices**

66.—(1) The provider may give notice in writing (a “late payment notice”) to the Health Board if the Board has failed to make any payments due to the provider in accordance with a term of the agreement that has the effect

specified in regulation 22 and the provider must specify in the late payment notice the payments that the Board has failed to make in accordance with that regulation.

(2) (Subject to sub-paragraph (3), the provider may, at least 28 days after having served a late payment notice, terminate the agreement by a further written notice if the Health Board has still failed to make the payments due to the provider, and that were specified in the late payment notice served on the Health Board pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Health Board refers the matter to the NHS dispute resolution procedure within 28 days of the date upon which it is served with the late payment notice, and it notifies the provider in writing that it has done so within that period of time, the provider may not terminate the agreement pursuant to sub-paragraph (2) until whichever is the earlier of the following dates—

(a) there has been a determination of the dispute pursuant to paragraph 59 and that determination permits the provider to terminate the agreement; or

(b) the Health Board ceases to pursue the NHS dispute resolution procedure.

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

**67.—**(1) The Health Board may only terminate the agreement with the provider or a party to the agreement in accordance with the provisions in this Part.

(2) The Health Board may serve notice in writing on a party to the agreement terminating the agreement with that party with immediate effect, or from such date as may be specified in the notice if—

(a) in the case of an agreement entered into prior to 22nd December 2010, after the agreement has been made, it comes to the attention of the Health Board that written information provided to the Health Board by that party to the agreement—

(i) before the agreement was entered into; or

(ii) pursuant to paragraphs 42(2) or (3) or 43(2) of schedule 1 of the 2004 Regulations as in force at 21st December 2010, in relation to the conditions set out in regulation 3 of the 2004 Regulations as in force at 21st December 2010 (and compliance with those conditions),

was, when given, untrue or inaccurate in a material respect; or

(b) in the case of an agreement entered into on or after 22nd December 2010, after the agreement has been made, it comes to the attention of the Health Board that written information provided to the Health Board by that party to the agreement—

(i) before the agreement was entered into; or

(ii) pursuant to paragraphs 48(2) or (3), 49(2) or 50(2),

in relation to the conditions set out in regulations 3 and 3A of the 2004 Regulations or regulations 4 and 5 of these Regulations (and compliance with those conditions), was, when given, untrue or inaccurate in a material respect.

### **Other grounds for termination by the Health Board**

68.—(1) In the case of agreements entered into prior to 22nd December 2010, the Health Board may serve notice in writing on a party to the agreement terminating the agreement with that party with immediate effect, or from such date as may be specified in the notice, if—

- (a) where an individual is a party to the agreement, that individual;
- (b) where a partnership is a party to the agreement, any partner or the partnership; and
- (c) where a company limited by shares is a party to the agreement—
  - (i) the company;
  - (ii) any person legally or beneficially owning a share in the company; or
  - (iii) any director or secretary of the company,

falls within sub-paragraph (3) during the existence of the agreement.

(2) Where the provider comprises more than one party to the agreement, a Health Board that serves notice pursuant to sub-paragraph (1) must send a copy of that notice to any other party to the agreement whose agreement is not being terminated.

(3) A person falls within this sub-paragraph if—

- (a) the person has been disqualified;
- (b) subject to sub-paragraph (4), the person is disqualified or suspended from practising by any licensing body anywhere in the world (other than by—
  - (i) a direction under section 32A(2) (applications for interim suspension) or 32B(1) (suspension pending appeal) of the Act(101);
  - (ii) a Health Board in terms of regulation 8A of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(102); or
  - (iii) any provision in force in England, Wales or Northern Ireland corresponding to the provisions referred to in sub-heads (i) and (ii));
- (c) subject to sub-paragraph (5), the person has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Health Board has served a notice terminating the agreement pursuant to this paragraph, the person is employed by the health service body that dismissed the person or by another health service body;
- (d) the person is disqualified from a list unless the person's name has subsequently been included in such a list;
- (e) the person has been convicted in the United Kingdom of murder;
- (f) the person has been convicted in the United Kingdom of a criminal offence other than murder, and has been sentenced to a term of imprisonment of over 6 months;

- (g) the person has been convicted elsewhere of an offence which would, if committed in Scotland, constitute—
- (i) murder; or
- (ii) subject to sub-paragraph (6), a criminal offence other than murder, and been sentenced to a term of imprisonment of over 6 months;
- (h) the person has been convicted of an offence referred to in schedule 1 of the Criminal Procedure (Scotland) Act 1995(103) or schedule 1 of the Children and Young Persons Act 1933(104);
- (i) the person has—
- (i) had sequestration of the person's estate awarded or been adjudged bankrupt unless (in either case) the person has been discharged or the bankruptcy order has been annulled;
- (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under schedule 4A of the Insolvency Act 1986(105) or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(106) or sections 155 to 160 of the Bankruptcy (Scotland) Act 2016(107), unless that order has ceased to have effect or has been annulled;
- (iii) made a composition or arrangement with, or granted a trust deed for, the person's creditors unless the person has been discharged in respect of it; or
- (iv) been wound up under Part IV of the Insolvency Act 1986;
- (j) there is—
- (i) an administrator, administrative receiver or receiver appointed in respect of it; or
- (ii) an administration order made in respect of it under schedule B1 of the Insolvency Act 1986(108);
- (k) that person is a partnership or limited liability partnership and—
- (i) a dissolution of the partnership or limited liability partnership is ordered by any competent court, tribunal or arbitrator; or
- (ii) an event happens that makes it unlawful for the business of the partnership or limited liability partnership to continue, or for members of the partnership to carry on in partnership or limited liability partnership;
- (l) the person has been—
- (i) removed under section 34 of the Charities and Trustee Investment (Scotland) Act 2005(109) (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of ~~anybody~~; or any body; or
- (ii) removed from the office of charity trustee or a charity by an order made by the Charity Commission for England and Wales or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person by the person's conduct contributed to or facilitated; or

(m)the person is subject to—

(i)disqualification order under section 1 of the Company Directors Disqualification Act 1986(110);

(ii)a disqualification undertaking under section 1A of that Act;

(iii)a disqualification order under article 3 of the Company Directors Disqualification (Northern Ireland) Order 2002(111);

(iv)a disqualification undertaking under article 4 of that Order; or

(v)a disqualification order under section 429(2)(b) of the Insolvency Act 1986(112); or

(n)the person has refused to comply with a request by the Health Board for that person to be medically examined on the grounds that the Health Board is concerned that the person is incapable of adequately providing services under the agreement and, in a case where that person is a partner in a partnership, or a legal and beneficial owner of shares in a company, that is a party to the agreement, the Health Board is not satisfied that the partnership or company is taking adequate steps to deal with the matter; or

(o)that person would otherwise fall within paragraph 67(3)(e) of schedule 3 of the National Health Service (General Medical Services Contracts) Regulations 2015(113).

(4) A Health Board may not terminate the agreement pursuant to sub-paragraph (3)(b) where the Health Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—

(a)a party to the agreement;

(b)in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership; or

(c)in the case where the person is—

(i)a person legally or beneficially holding a share in a company limited by shares that is a party to the agreement; or

(ii)a director or secretary of a company limited by shares that is a party to the agreement,

a person legally or beneficially holding share in that company or a director or secretary of that company, as the case may be.

(5) A Health Board may not terminate the agreement pursuant to sub-paragraph (3)(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 of time specified in sub-paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

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

(6) A Health Board may not terminate the agreement pursuant to sub-paragraph (3)(g) where the Health Board is satisfied that the conviction does not make the person unsuitable to be—

(a) a party to the agreement;

(b) in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership;

(c) in the case where the person is—

(i) a person legally and beneficially holding a share in a company limited by shares that is a party to the agreement; or

(ii) a director or secretary of a company limited by shares that is a party to the agreement.

(7) In this paragraph “health service body” does not include any provider who is to be treated as a health service body in accordance with regulation 10.

**Other grounds for termination by the Health Board for agreements entered into on or after 22nd December 2010**

**69.**—(1) In the case of agreements entered into on or after 22nd December 2010, the Health Board may serve notice in writing on a party to the agreement terminating the agreement with the party with immediate effect, or from such date as may be specified in the notice, if—

(a) in the case of an agreement with an individual, that individual;

(b) in the case of an agreement with a partnership, any partner or the partnership;

(c) in the case of an agreement with a limited liability partnership, any member or the limited liability partnership; and

(d) in the case of an agreement with a company—

(i) the company;

(ii) any member of the company; or

(iii) any director or secretary of the company,

falls within sub-paragraph (2) during the existence of the agreement.

(2) A person falls within this sub-paragraph if—

(a) subject to sub-paragraph (3), the person does not satisfy the requirements of section 17CA(1), (2) or (3) of the Act(114);

(b) the person has been disqualified;

- (c)subject to sub-paragraph (5), the person is disqualified or suspended from practising by any licensing body anywhere in the world (other than by—
- (i)a direction under section 32A(2) (applications for interim suspension) or 32B(1) (suspension pending appeal) of the Act;
- (ii)a Health Board in terms of regulation 8A of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004; or
- (iii)any provision in force in England, Wales or Northern Ireland corresponding to the provisions referred to in sub-heads (i) and (ii));
- (d)subject to sub-paragraph (6), the person has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Health Board has served a notice terminating the agreement pursuant to this paragraph, the person is employed by the health service body that dismissed the person or by another health service body;
- (e)the person is disqualified from a list unless the person's name has subsequently been included in such a list;
- (f)the person has been convicted in the United Kingdom of murder;
- (g)the person has been convicted in the United Kingdom of a criminal offence, other than of murder, and has been sentenced to a term of imprisonment of over six months;
- (h)subject to sub-paragraph (7), the person has been convicted elsewhere of an offence—
- (i)which would, if committed in Scotland, constitute murder; or
- (ii)constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
- (i)the person has been convicted of an offence referred to in schedule 1 of the Criminal Procedure (Scotland) Act 1995 (offences against children under the age of 17 to which special provisions apply) or schedule 1 of the Children and Young Persons Act 1933 (offences against children and young persons with respect to which special provisions apply);
- (j)the person has—
- (i)had sequestration of the person's estate awarded or been adjudged bankrupt unless (in either case) the person has been discharged or the bankruptcy order has been annulled,
- (ii)been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under schedule 4A of the Insolvency Act 1986 or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985, or sections 155 to 160 of the Bankruptcy (Scotland) Act 2016, unless that order has ceased to have effect or has been annulled,
- (iii)made a composition or arrangement with, or granted a trust deed for, the person's creditors unless the person has been discharged in respect of it, or

(iv) been wound up under Part IV of the Insolvency Act 1986;

(k) there is—

(i) an administrator, administrative receiver or receiver appointed in respect of it; or

(ii) an administration order made in respect of it under schedule B1 of the Insolvency Act 1986;

(l) that person is a partnership or limited liability partnership and—

(i) a dissolution of the partnership or limited liability partnership is ordered by any competent court, tribunal or arbitrator; or

(ii) an event happens that makes it unlawful for the business of the partnership or limited liability partnership to continue, or for members of the partnership or limited liability partnership to carry on in partnership or limited liability partnership;

(m) the person has been—

(i) removed under section 34 of the Charities and Trustee Investment (Scotland) Act 2005 (powers of the Court of Session), from being concerned in the management or control of any body; or

(ii) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission for England and Wales or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person by the person's conduct contributed to or facilitated;

(n) the person is subject to a disqualification order under the company Directors Disqualification Act 1986, the Company Directors Disqualification (Northern Ireland) Order 2002 or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or

(o) the person has refused to comply with a request by the Health Board for that person to be medically examined on the grounds that the Health Board is concerned that the person is incapable of adequately providing services under the agreement and, in a case where the agreement is with a partnership, limited liability partnership or a company, the Health Board is not satisfied that the partnership, limited liability partnership or company is taking adequate steps to deal with the matter; or

(p) the person would otherwise fall within paragraph 67(3)(e) of schedule 3 of the National Health Service (General Medical Services Contracts) Regulations 2015.

(3) Subject to sub-paragraph (4), a Health Board may not terminate the agreement pursuant to sub-paragraph (2)(a) where—

(a) a party to the agreement who is an individual;

(b) in the case of a party to an agreement which is a partnership, a partner;

(c) in the case of a party to an agreement which is a limited liability partnership, a member; or

(d) in the case of a party to an agreement which is a company, a member of the company,

after having entered into an agreement (“the relevant agreement”), retires and is therefore not performing or is not engaged in the provision of primary medical services, in accordance with regulation 5.

(4) Sub-paragraph (3) only applies for the period of time following the date of retirement, which is the equivalent to the length of time that the relevant person referred to in sub-paragraph (3)(a), (b), (c) or (d) has performed or been engaged in the provision of primary medical services for the purposes of the relevant agreement, up to a maximum period of 2 years following the date of retirement.

(5) A Health Board may not terminate the agreement pursuant to sub-paragraph (2)(c) where the Health Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—

(a) a party to the agreement;

(b) in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership;

(c) in the case where the person is a member of a limited liability partnership that is a party to the agreement, a member of that partnership; or

(d) in the case where the person is a member, director or secretary of a company that is a party to the agreement—

(i) a member of the company; or

(ii) a director or secretary of the company,

as the case may be.

(6) A Health Board may not terminate the agreement pursuant to sub-paragraph (2)(d)—

(a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or

(b) if, during the period of time specified in sub-paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

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

(7) A Health Board may not terminate the agreement pursuant to sub-paragraph (2)(h) where the Health Board is satisfied that the conviction does not make the person unsuitable to be—

(a) a party to the agreement;

(b) in the case where the person is a partner in a partnership that is a party to the agreement, a partner in that partnership;

(c) in the case where the person is a member of a limited liability partnership that is a party to the agreement, a member of that limited liability partnership; or

(d)in the case where the person is a member, director or secretary of a company that is a party to the agreement—

(i)a member of the company; or

(ii)a director or secretary of the company,

as the case may be.

(8) In this paragraph, "health service body" does not include any person who is to be regarded as a health service body in accordance with regulation 10.

#### **Other grounds for termination by the Health Board**

**70.** The Health Board may serve notice in writing on the provider terminating the agreement with the provider with immediate effect or with effect from such date as may be specified in the notice if—

(a)the provider has breached the agreement and, as a result of that breach, the safety of the provider's patients is at serious risk if the agreement is not terminated; or

(b)the provider's financial situation is such that the Health Board considers that the Health Board is at risk of material financial loss.

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

**71.** If the provider breaches the condition specified in paragraph 33(10) and it comes to the Health Board's attention that the provider has done so, the Health Board must serve notice in writing on the provider—

(a)terminating the agreement with immediate effect; or

(b)instructing the provider to terminate the sub contracting arrangements that give rise to the breach with immediate effect, and if it fails to comply with the instruction, the Health Board must serve a notice in writing on the provider terminating the agreement with immediate effect.

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

**72.—(1)** Where a provider has breached the agreement other than as specified in paragraphs 67(2) to 71 and the breach is capable of remedy, the Health Board must, before taking any action it is otherwise entitled to take by virtue of the agreement, serve a notice on the provider requiring it to remedy the breach ("a remedial notice").

(2) A remedial notice must specify—

(a)details of the breach;

(b)the steps the provider must take to the satisfaction of the Health Board in order to remedy the breach; and

(c)the period during which the steps must be taken ("the notice period").

(3) The notice period shall, unless the Health Board is satisfied that a shorter period is necessary to—

(a)protect the safety of the provider's patients; or

(b)protect itself from material financial loss,

be no less than 28 days from the date that notice is given.

(4) Where a Health Board is satisfied that the provider has not taken the required steps to remedy the breach by the end of the notice period, the Health Board may terminate the agreement with the provider with effect from such date as the Health Board may specify in a further notice to the provider.

(5) Where a provider has breached the agreement other than as specified in paragraphs 67(2) to 71 and the breach is not capable of remedy, the Health Board may serve notice on the provider requiring the provider not to repeat the breach ("breach notice").

(6) If, following a breach notice or a remedial notice, the provider—

(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 Health Board may serve notice on the provider terminating the agreement with effect from such date as may be specified in that notice.

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

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

**Termination by the Health Board: additional provisions specific to agreements with one or more companies limited by shares/bodies corporate**

**73.—**(1) Where a company, partnership or limited liability partnership is a party to the agreement, if the Health Board becomes aware that the company, partnership or limited liability partnership, is carrying on any business which the Health Board considers to be detrimental to the provider's performance of its obligations under the agreement—

(a) the Health Board will be entitled to give notice to the company, partnership or limited liability partnership requiring that the company, partnership or limited liability partnership ceases carrying on that business before the end of a period of not less than 28 days beginning on the day on which the notice is given ("the notice period"); and

(b) if the company, partnership or limited liability partnership has not satisfied the Health Board that the company, partnership or limited liability partnership has ceased carrying on that business by the end of the notice period, the Health Board may, by a further written notice, terminate the agreement with that company, partnership or limited liability partnership with immediate effect or from such date as may be specified in the notice.

(2) Where the provider comprises more than one party to the agreement, a Health Board that serves notice pursuant to sub-paragraph (1)(a) or (b) must send a copy of that notice to any other party to the agreement.

### **Termination by the Health Board: changes in the provider**

**74.—(1)** The Health Board may be entitled to terminate the agreement with the provider by notice in writing on such date as may be specified in that notice where, during the existence of the agreement—

- (a) one or more parties to the agreement have withdrawn from or ceased to be parties to the agreement;
- (b) where one or more partnerships are parties to the agreement, one or more partners have left that partnership or those partnerships;
- (c) where one or more limited liability partnerships are parties to the agreement, one or more members have left that limited liability partnership or those limited liability partnerships; or
- (d) where one or more companies are parties to the agreement, one or more members have left that company or those companies,

if in its reasonable opinion, the Health Board considers that the change in the parties to the agreement or membership of the partnership, limited liability partnership or company (as the case may be) is likely to have a serious adverse impact on the ability of the provider or the Health Board to perform its obligations under the agreement.

(2) A notice given to the provider pursuant to sub-paragraph (1) must specify—

- (a) the date upon which the agreement is to be terminated; and
- (b) the Health Board's reasons for considering that the change in the parties to the agreement or the membership of the partnership, limited liability partnership or company (as the case may be) is likely to have a serious adverse impact on the ability of the provider or the Health Board to perform its obligations under the agreement.

### **Agreement sanctions**

**75.—(1)** In this paragraph and paragraphs 76 and 78, "agreement sanction" means—

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

(2) Where the Health Board is entitled to terminate the agreement with the provider or with a party to the agreement pursuant to paragraph 69(2), 70, 71, 72(4) or (6), 73, 74 it may instead impose any of the agreement sanctions if the Health Board is reasonably satisfied that the agreement sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Health Board's entitlement to terminate the agreement.

(3) Where the agreement includes the provision of essential services, the Health Board must not, under sub-paragraph (2), be entitled to impose any agreement sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

(4) If the Health Board decides to impose an agreement sanction, it must notify the provider of the agreement sanction that it proposes to impose, the date upon which that sanction will be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(5) Subject to paragraph 76 the Health Board must not impose the agreement sanction until at least 28 days after it has served notice on the provider pursuant to sub-paragraph (4) unless the Health Board is satisfied that it is necessary to do so in order to—

(a) protect the safety of the provider's patients; or

(b) protect itself from material financial loss.

(6) Where the Health Board imposes an agreement sanction, the Health Board must be entitled to charge the provider the reasonable costs of additional administration that the Health Board has incurred in order to impose, or as a result of imposing, the agreement sanction.

#### **Agreement sanctions and the dispute resolution procedure**

**76.**—(1) If there is a dispute between the Health Board and the provider in relation to an agreement sanction that the Health Board is proposing to impose, the Health Board must not, subject to sub-paragraph (4), impose the proposed agreement sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the provider refers the dispute relating to the agreement sanction to the local dispute resolution process within 28 days beginning on the date on which the Health Board served notice on the provider in accordance with paragraph 75(4) (or such longer period as may be agreed in writing with the Health Board), and notifies the Health Board in writing that it has done so, the Health Board must not impose the agreement sanctions unless—

(a) there has been a resolution of the dispute between the parties which allows the Health Board to impose the agreement sanction;

(b) there has been no resolution of the dispute between the parties as a result of the local dispute resolution process and the provider does not refer the matter to the Scottish Ministers under paragraph 57 or 58 within 28 days of the end of the period specified in—

(i) paragraph 56(8); or

(ii) the date on which the local dispute resolution process was completed,

whichever is the earlier;

(c) either party refers the matter to the Scottish Ministers under paragraph 57 or 58 within the period specified in sub-paragraph (b) and either —

(i) there has been a determination of the dispute pursuant to paragraph 59 and that determination permits the Health Board to impose the agreement sanction; or

(ii) the provider ceases to pursue the NHS dispute resolution procedure.

(3) If the provider does not invoke the local dispute resolution process within the time specified in sub-paragraph (2), the Health Board must be entitled to impose the agreement sanction with immediate effect.

(4) If the Health Board is satisfied that it is necessary to impose the agreement sanction before the local dispute resolution process or the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the provider's patients; or

(b) protect itself from material financial loss,

the Health Board is entitled to impose the agreement sanction with immediate effect, pending the outcome of that procedure.

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

77.—(1) Where the Health Board is entitled to serve written notice on the provider or a party to the agreement terminating the agreement with the provider or a party to the agreement pursuant to paragraphs 67 to 74, the Health Board must, in the notice served on the provider or the party to the agreement pursuant to those provisions, specify a date on which the agreement with the provider or a party to the agreement terminates that is not less than 28 days after the date on which the Health Board has served that notice on the provider or the party to the agreement unless sub-paragraph (2) applies.

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

(a) protect the safety of the provider's patients; or

(b) protect itself from material financial loss.

(3) In a case falling with sub-paragraph (1), where the exceptions in sub-paragraph (2) do not apply, where the provider invokes the local dispute resolution process before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Health Board in writing that it has done so, the agreement must not terminate at the end of the notice period but instead must only terminate in the circumstances specified in sub-paragraph (4).

(4) The agreement must only terminate if and when—

(a) there has been a resolution of the dispute between the parties which allows the Health Board to terminate the agreement with the provider or the party to the agreement;

(b) there has been no resolution of the dispute between the parties as a result of the local dispute resolution process and the provider does not refer the matter to the Scottish Ministers under paragraph 57 or 58 within 28 days of the end of the period specified in—

(i) paragraph 56(8); or

(ii) the date on which the local dispute resolution process was completed,

whichever is the earlier;

(c) either party refers the matter to the Scottish Ministers under paragraph 57 or 58 within the period specified in sub-paragraph (b); and either

(i) there has been a determination of the dispute pursuant to paragraph 59 and that determination permits the Health Board to terminate the agreement with the provider or the party to the agreement; or

(ii) the provider ceases to pursue the NHS dispute resolution procedure

whichever is earlier.

(5) If the Health Board is satisfied that it is necessary to terminate the agreement before the local dispute resolution process or the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the provider's patients; or

(b) protect itself from material financial loss,

sub-paragraphs (3) and (4) must not apply and the Health Board must be entitled to confirm, by written notice to be served on the provider, that the agreement with the provider or a party to the agreement will nevertheless terminate at the end of the period of the notice it served pursuant to paragraphs 67 to 74.

#### **Consultation with the area medical committee**

**78.**—(1) Whenever the Health Board is considering—

(a) terminating the agreement with the provider or with a party to the agreement pursuant to paragraph 67 to 74; or

(b) imposing an agreement sanction,

it must, whenever it is reasonably practicable to do so, consult the area medical committee for its area before it terminates the agreement with the provider or with a party to the agreement or imposes an agreement sanction.

(2) Whether or not the area medical committee has been consulted pursuant to sub-paragraph (1), whenever the Health Board imposes an agreement sanction on the provider or terminates an agreement with the provider or a party to the agreement pursuant to this Part, it must, as soon as reasonably practicable, notify the area medical committee in writing of the agreement sanction imposed or of the termination of the agreement (as the case may be).

## **PART 9**

### **MISCELLANEOUS**

#### **Clinical governance**

**79.**—(1) The provider must have an effective system of clinical governance.

(2) The provider must nominate a person who will have responsibility for ensuring the effective operation of a system of clinical governance.

(3) The person nominated under sub-paragraph (2) must be a person who performs or manages services under the agreement.

(3A) Where a health care professional employed by the Health Board performs clinical services from the provider's practice premises—

(a) the provider must provide the Health Board with information about its system of clinical governance which is sufficient to allow that health care professional to effectively co-operate with that system of clinical governance, and

(b) the Health Board must ensure that any such health care professional employed by the Health Board is aware of the provider's system of clinical governance.

(3B) Where the Health Board provides clinical services from the provider's practice premises, the Health Board must have regard to the provider's system of clinical governance.

(4) In this paragraph "system of clinical governance" means a framework through which the provider endeavours continuously to improve the quality of its services and safeguard high standards of care by creating an environment in which clinical excellence can flourish.

### **Medical Indemnity Insurance**

**80.**—(1) The provider must at all times have in force in relation to it an indemnity arrangement which provides appropriate cover under the agreement.

(2) The provider must not sub-contract its obligations to provide clinical services under the agreement unless it has satisfied itself that the sub-provider has in force in relation to it an indemnity arrangement which provides appropriate cover.

(3) In this paragraph—

(a) "indemnity arrangement" means a contract of insurance or other arrangement made for the purpose of indemnifying the provider;

(b) "appropriate cover" means cover against liabilities that may be incurred by the provider 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; and

(c) a provider must be regarded as having in force in relation to it an indemnity arrangement if there is an indemnity arrangement in force in relation to a person employed or engaged by that provider in connection with clinical services which that person provides under the agreement or, as the case may be, sub-contract.

### **Public Liability Insurance**

**81.** The provider 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 an indemnity arrangement referred to in paragraph 80.

### **Gifts**

**82.**—(1) The provider must keep a register of gifts which—

(a) are given to any of the persons specified in sub-paragraph (2) by or on behalf of—

- (i) a patient;
  - (ii) a relative of a patient; or
  - (iii) any person who provides or wishes to provide services to the provider or its patients in connection with the agreement; and
- (b) have, in its reasonable opinion, an individual value of more than £100.00.

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

- (a) the provider;
- (b) where a partnership is a party to the agreement, any partner in the partnership;
- (c) where a limited liability partnership is a party to the agreement, any member of the limited liability partnership;
- (d) where a company is a party to the agreement—
  - (i) any member of the company; or
  - (ii) a director or secretary of the company;
- (e) any person employed by the provider for the purposes of the agreement;
- (f) any general medical practitioner engaged by the provider for the purposes of the agreement;
- (g) any spouse or civil partner of an individual (where an individual is a party to the agreement) or of a person specified in paragraphs (b) to (f); or
- (h) any person whose relationship with any individual (where an individual is a party to the agreement) or with a person specified in paragraphs (b) to (f) has the characteristics of the relationship between spouses or civil partners.

(3) Sub-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 provider;
- (b) the provider is not aware of the gift; or
- (c) the provider is not aware that the donor wishes to provide services to the provider.

(4) The provider must take reasonable steps to ensure that it is informed of gifts which fall within sub-paragraph (1) and which are given to the persons specified in sub-paragraph (2)(b) to (h).

(5) The register referred to in sub-paragraph (1) must include the following information:—

- (a) the name of the donor;
- (b) in a case where the donor is a patient, the patient's National Health Service number or, if the number is not known, the patient's address;
- (c) in any other case, the address of the donor;

- (d)the nature of the gift;
- (e)the estimated value of the gift; and
- (f)the name of the person or persons who received the gift.

(6) The provider must make the register available to the Health Board on request.

#### **Compliance with legislation and guidance**

83. The provider must—

- (a)comply with all relevant legislation; and
- (b)have regard to all relevant guidance issued by the Health Board and the Scottish Ministers.

#### **Third party rights**

84. The agreement will not create any right enforceable by any person not a party to it.

#### **Duty of candour**

85. The provider must have arrangements in place which operate in accordance with Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016(115), and any regulations or directions made under that part of that Act(116).

### **PART 10**

### **QUALITY**

#### **Duty to participate in quality arrangements**

86.—(1) Subject to paragraph 87, the provider must meaningfully participate in quality arrangements.

(2) The provider must nominate a person who will be a Practice Quality Lead for the purpose of—

- (a)their cluster membership; and
- (b)attending meetings of the provider's cluster.

(3) The person nominated under sub-paragraph (2) must be a general medical practitioner who performs services under the agreement.

(4) In this paragraph and paragraph 87—

"cluster" means a group of practices where each practice is represented by a Practice Quality Lead;

"Cluster Quality Lead" means a person who is a member of a cluster that is appointed by a Health Board to represent that cluster to the Health Board;

"meaningfully participate" means, as a minimum—

- (a)ensuring that all members of the provider's practice supply the Practice Quality Lead with any requested information;
- (b)considering practice quality data with the support and direction of the Practice Quality Lead; and

(c)

having regard to any quality improvement measures proposed by the provider's cluster; and

"Practice Quality Lead" means a medical practitioner nominated by a provider to represent the provider's practice to the cluster; and

"quality arrangements" means the proceedings and arrangements specified in directions by the Scottish Ministers made under section 2(5) of the Act.

### **Quality arrangements**

**87.**—(1) The provider and the provider's practice must comply with the quality arrangements as determined by and with the support of the Practice Quality Lead and with any further conditions relating to quality set out in directions given by Scottish Ministers under section 2(5) of the Act.

(2) The Practice Quality Lead must spend a minimum of two sessions a month in pursuance of their role and regularly attend meetings of the provider's cluster.

(3) Where a Health Board is considering appointing a Cluster Quality Lead, that Health Board must consult a Practice Quality Lead who is a member of that cluster prior to offering an appointment.

(4) Where a cluster determines that a provider is failing to meaningfully participate in quality arrangements it must arrange for the provider to receive supportive measures that enable the provider to meet their duties under this paragraph and paragraph 88.

Regulation 13

## SCHEDULE 2

### AGREEMENTS TO PROVIDE ESSENTIAL SERVICES

#### PART 1

#### PROVISION OF ESSENTIAL SERVICES

##### **Essential services**

**1.**—(1) Subject to paragraph 2, the provider must provide the services described in sub-paragraphs (2), (4), (5) and (7) throughout the core hours.

(2) The services described in this paragraph are services required for the management of the provider's registered patients and temporary residents who are, or believe themselves to be—

(a) ill, with conditions from which recovery is generally expected;

(b) terminally ill; or

(c) suffering from chronic disease,

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

(3) For the purpose of sub-paragraph (2)—

(a) "disease" means a disease included in the list of three-character categories contained in the tenth revision of the International Statistical Classification of Diseases and Related Health Problems(117);

(b) "management" includes—

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

(ii) the making available of such treatment or further investigation as is necessary and appropriate, including, where appropriate, the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care.

(4) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all registered patients and temporary residents taking account of their specific needs including—

(a) the provision of advice in connection with the patient's health, including relevant health promotion advice; and

(b) the referral of the patient for other services under the Act.

(5) A provider must provide primary medical services required in core hours, taking into account the provider's safety and the availability of other options for care, for the immediately necessary treatment of any person to whom the provider has been requested to provide treatment owing to an accident or emergency at any place in the provider's practice area.

(6) In sub-paragraph (5), "emergency" includes any medical emergency whether or not related to services provided under the agreement.

(7) A provider must provide primary medical services required in core hours for the immediately necessary treatment of any person falling within sub-paragraph (8) who requests such treatment, for the period specified in sub-paragraph (9).

(8) A person falls within this sub-paragraph if the person is one—

(a) whose application for inclusion in the provider's list of patients has been refused in accordance with paragraph 9 and who is not registered with another provider (by any arrangement) of essential services (or their equivalent) in the area of the Health Board;

(b) whose application for acceptance as a temporary resident has been refused under paragraph 9; or

(c) who is present in the provider's practice area for less than 24 hours.

(9) The period referred to in sub-paragraph (7) is—

(a) in the case of sub-paragraph (8)(a), 14 days beginning with the date on which that person's application was refused, or until that person has been subsequently registered elsewhere for the provision of essential services (or their equivalent), whichever occurs first;

(b)in the case of sub-paragraph (8)(b), 14 days beginning with the date on which that person's application was rejected, or until that person has been accepted as a temporary resident elsewhere as a temporary resident, whichever occurs first; and

(c)in the case of sub-paragraph (8)(c), 24 hours or such shorter period as the person is present in the provider's practice area.

### **Essential services**

2. The provider must—

(a)provide essential services, at such times, within core hours, as are appropriate to meet the reasonable needs of the provider's patients; and

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

### **Attendance at practice premises**

3.—(1) The provider must take steps to ensure that any patient who—

(a)has not previously made an appointment; and

(b)attends at the practice premises during the normal hours for essential services,

is provided with such services by an appropriate health care professional during that surgery period except in the circumstances specified in sub-paragraph (2).

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

(a)it is more appropriate for the patient to be referred elsewhere for services under the Act; or

(b)the patient is offered an appointment to attend again within a time which is appropriate and reasonable having regard to all the circumstances and the patient's health would not thereby be jeopardised.

### **Newly registered patients**

4.—(1) Where a patient has been—

(a)accepted on a provider's list of patients under paragraph 7; or

(b)assigned to that list by the Health Board,

the provider must, in addition to and without prejudice to its other obligations in respect of that patient under the agreement, invite the patient to participate in a consultation either at the provider's practice premises or, if a medical condition of the patient so warrants, at one of the places referred to in paragraph 3(2) of schedule 1.

(2) An invitation under sub-paragraph (1) must be issued within 6 months of the date of acceptance of the patient on, or their assignment to, the provider's list and may offer the patient a consultation with—

(a)the provider;

(b)a medical practitioner employed or engaged by the provider; or

(c) a healthcare professional employed or engaged by the provider.

(3) Where a patient (or, where appropriate, in the case of a patient who is a child, the child's parent) agrees to participate in a consultation mentioned in sub-paragraph (1), with a person mentioned in sub-paragraph (2), that person must, in the course of that consultation make such inquiries and undertake such examinations as appear to them to be appropriate in all the circumstances.

#### **Fees and charges for essential services**

5.—(1) Where a person applies to the provider for the provision of essential services and claims to be on that provider's list of patients, and the provider has reasonable doubts about that person's claim, the provider must provide any necessary treatment and will be entitled to demand and accept a reasonable fee in accordance with sub-paragraph (2) subject to the provision for repayment contained in paragraph (3).

(2) The provider may demand and accept a reasonable fee when the provider treats a patient under sub-paragraph (1) for any treatment given, if the provider gives the patient a receipt.

(3) Where a person from whom a provider received a fee under sub-paragraph (1) applies to the Health Board for a refund within 14 days of payment of the fee (or such longer period not exceeding one month as the Health Board may allow, if it is satisfied that the failure to apply within 14 days was reasonable) and the Health Board is satisfied that the person was on the provider's list of patients when the treatment was given, the Health Board may recover the amount of the fee from the provider, by deduction from the provider's remuneration or otherwise, and must pay that amount to the person who paid the fee.

## **PART 2**

### **LIST OF PATIENTS**

#### **List of patients**

6. The Health Board must prepare and keep up to date a provider's list of patients—

(a) who have been accepted by the provider for inclusion in the provider's list of patients under paragraph 7 and who have not subsequently been removed from that list under paragraphs 10 to 18; and

(b) who have been assigned to the provider under paragraph 22 or 23 and whose assignment has not subsequently been rescinded.

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

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

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

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

(4) An application may be made—

(a) on behalf of any child—

(i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child;

(ii) by a person duly authorised by a local authority, where the child is in the care of the local authority under the Children (Scotland) Act 1995(118); or

(iii) by a person authorised by a voluntary organisation, by which the child is being accommodated under the provisions of that Act; or

(b) on behalf of any adult person who is incapable of making such an application, or authorising such an application to be made on their behalf, by the primary carer of that person or by a person authorised under the Adults with Incapacity (Scotland) Act 2000(119) to act on the patient's behalf.

(5) A provider which accepts an application for inclusion in the provider's list of patients must notify the Health Board in writing as soon as possible.

(6) On receipt of a notice under sub-paragraph (5), the Health Board must—

(a) include that person in the provider's list of patients from the date on which the notice is received; and

(b) notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) of the acceptance.

### **Temporary residents**

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

(a) temporarily resident away from 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 the 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 the person arrives in that place, the person intends to stay there for more than 24 hours but not more than 3 months.

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

(a) 3 months; or

(b) such shorter period for which the provider agreed to accept the person as a patient,

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

(4) At the end of 3 months, or on such earlier date as the provider's responsibility for the temporary resident has come to an end, the provider must notify the Health Board in writing of any person whom it accepted as a temporary resident.

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

9.—(1) The provider may only refuse an application made under paragraph 7 or 8 if the provider has reasonable grounds for doing so which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition.

(2) [ Subject to sub-paragraph (5), the ] reasonable grounds referred to in sub-paragraph (1) may, in the case of applications made under paragraph 7, include the ground that the applicant does not live in the provider's practice area.

(3) A provider which refuses an application made under paragraph 7 or 8 must, within 14 days of its decision notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) in writing of the refusal and the reasons for it.

(4) The provider must keep a written record of refusals of applications made under paragraph 7 and of the reasons for them and must make this record available to the Health Board on request.

[ (5) For the purpose of sub-paragraph (2), "reasonable grounds" do not include refusal of an application from a person who—

(a) at the time of making the application, is detained in a prison, a young offenders institution or the state hospital, and

(c) will live after their release from detention, in the provider's practice area.

(6) For the purpose of sub-paragraph (5)—

"young offenders institution" has the meaning given in section 19(1)(b) of the Prisons (Scotland) Act 1989<sup>3</sup>, and

"state hospital" has the meaning given in section 102 of the National Health Service (Scotland) Act 1978<sup>4</sup>.

]

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

10.—(1) The provider must notify the Health Board of any request for removal from its list of patients received from a registered patient.

(2) Where the Health Board—

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

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

the Health Board must remove that person from the provider's list of patients.

(3) A removal in accordance with sub-paragraph (2) will take effect on whichever is the earlier of the following dates—

(a) on the date on which the Health Board receives notification of the registration of the person with another provider (by any arrangement) of essential services (or their equivalent); or

(b) 14 days after the date on which the notification or request made under sub-paragraph (1) or (2) respectively is received by the Health Board.

(4) The Health Board must, as soon as is practicable, notify in writing—

(a) the patient; and

(b) the provider,

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

(5) In this paragraph and in paragraphs 11(1) and 11(10), 12(6) and 12(7), 14 and 17, a reference to a request received from or advice, information or notification required to be given to a patient includes a request from or advice, information or notification ~~required~~ required to be given to—

(a) in the case of a patient who is a child, a parent or other person referred to in paragraph 7(4)(a); or

(b) in the case of an adult patient who is incapable of making the relevant request or receiving the relevant advice, information or notification, a relative or the primary carer of the patient.

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

**11.—**(1) Subject to paragraph 18, a provider which has reasonable grounds for wishing a patient to be removed from its list of patients which do not relate to the ~~applicant's~~ patient's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition must—

(a) notify the Health Board in writing that it wishes to have the patient removed; and

(b) subject to sub-paragraph (2), notify the patient of its specific reasons for requesting removal.

(2) Where, in the reasonable opinion of the provider—

(a) the circumstances of the removal are such that it is not appropriate for a more specific reason to be given; and

(b) there has been an irrevocable breakdown in the relationship between the patient and the provider,

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

(3) Except in the circumstances described in sub-paragraph (4), a provider may only request a removal under sub-paragraph (1) if, within the period of 12 months prior to the date of the provider's request to the Health Board, the provider ~~has~~ has warned the patient that the patient is at risk of removal and explained to the patient the reasons for this.

(a) ~~warned the patient that the patient is at risk of removal and explained to the patient the reasons for this;~~ and

~~(b) confirmed that the Health Board has agreed to the removal grounds mentioned in sub-paragraph (1).~~

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

(a) the reason for the removal relates to a change of address;

(b) the provider has reasonable grounds for believing that the issue of such a warning would—

(i) be harmful to the physical or mental health of the patient; or

(ii) put at risk the safety of a person specified in sub-paragraph (5); or

(c) it is, in the opinion of the provider, not otherwise reasonably practicable for a warning to be given.

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

(a) an individual that is a party to the agreement;

(b) a partner in a partnership that is a party to the agreement;

(c) a member of a limited liability partnership that is a party to the agreement;

(d) a member of a company that is a party to the agreement;

(e) a member of the provider's staff;

(f) a person engaged by the provider to perform or assist in the performance of services under the agreement; or

(g) any other person present—

(i) on the practice premises; or

(ii) in the place where services are being provided to the patient under the agreement.

(6) The provider must record in writing—

(a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the patient; or

(b) the reason why no such warning was given.

(7) The provider must keep a written record of refusals under this paragraph which is to include—

(a) the reason for removal given to the patient;

(b) the circumstances of the removal; and

(c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate,

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

(8) A removal requested in accordance with sub-paragraph (1) will, subject to sub-paragraph (9) take effect from whichever is the earlier of the following dates—

(a) the date on which the Health Board receives notification of the registration of the person with another provider (by any arrangement) of essential services (or their equivalent); or

(b)the eighth day after the Health Board receives the notice referred to in sub-paragraph (1)(a).

(9) Where, on the date on which the removal would take effect under sub-paragraph (8), the provider is treating the patient at intervals of less than 7 days, the provider must notify the Health Board in writing of the fact and the removal will take effect on whichever is the earlier of the following dates—

(a)the eighth day after the Health Board receives notification from the provider that the person no longer needs such treatment; or

(b)the date on which the Health Board receives notification of the registration of the person with another provider (by any arrangement) of essential services or their equivalent.

(10) The Health Board must notify in writing—

(a)the patient; and

(b)the provider,

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

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

12.—(1) A provider which wishes a patient to be removed from its list of patients with immediate effect on the grounds that—

(a)the patient has committed an act of violence against any of the persons specified in sub-paragraph (2) or behaved in such a way that any such person has feared for that person's own safety; and

(b)the provider has reported the incident to the police or the Procurator Fiscal,

must notify the Health Board in accordance with sub-paragraph (3).

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

(a)an individual that is a party to the agreement;

(b)a partner in a partnership that is a party to the agreement;

(c)a member of a limited liability partnership that is a party to the agreement;

(d)a member of a company that is a party to the agreement;

(e)a member of the provider's staff;

(f)a person engaged by the provider to perform or assist in the performance of services under the agreement; or

(g)any other person present—

(i)on the practice premises; or

(ii)in the place where services were provided to the patient under the agreement.

(3) Notification under sub-paragraph (1) may be given by any means including telephone and must be confirmed in writing within 7 days (and for this purpose notification or transmission by electronic means is not a written one).

(4) The Health Board must acknowledge in writing receipt of a request from the provider under sub-paragraph (1).

(5) A removal requested in accordance with sub-paragraph (1) will take effect at the time that the provider—  
(a) makes the telephone call to the Health Board; or  
(b) sends or delivers the notification to the Health Board.

(6) Where, pursuant to this paragraph, the provider has notified the Health Board that it wishes to have a patient removed from the provider's list of patients, it must inform the patient concerned unless—

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

(7) Where the Health Board has removed a patient from the provider's list of patients in accordance with sub-paragraph (5) it must give written notice of the removal to that patient.

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

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

**13.—**(1) The Health Board must remove a patient from the provider's list of patients if—

(a) the patient has subsequently been registered with another provider (by any arrangement) of essential services (or their equivalent) in the area of the Health Board; or  
(b) it has received notice from another Health Board, Local Health Board, [ NHS England ] (120) or the Regional Health and Social Care Board that the patient has subsequently been registered with a provider (by any arrangement) of essential services (or their equivalent) outside the area of the Health Board.

(2) A removal in accordance with sub-paragraph (1) will take effect—  
(a) on the date on which the Health Board receives notification of the registration of the person with the new provider (by any arrangement); or  
(b) with the consent of the Health Board, on such other date as has been agreed between the provider and the new provider (by any arrangement).

(3) The Health Board must notify the provider in writing of persons removed from the provider's list of patients under sub-paragraph (1).

#### **Removals from list of patients who have moved**

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

(a) inform that patient and the provider that the provider is no longer obliged to visit and treat the person;

(b) advise the patient either to obtain the provider's agreement to the continued inclusion of the person on the provider's list of patients or to apply for registration with another provider (by any arrangement) of essential services (or their equivalent); and

(c) inform the patient that if, after the expiry of 30 days from the date of the letter of advice mentioned in paragraph (b), the patient has not acted in accordance with the advice and informed the Board accordingly, the Health Board will remove the patient from the provider's list of patients.

(2) If, at the expiry of the period of 30 days referred to in sub-paragraph (1)(c), the Health Board has not been notified of the action taken, it must remove the patient from the provider's list of patients and inform the patient and the provider accordingly.

#### **Removals from list of patients who have moved**

**15.** Where the address of a patient who is on the provider's list of patients is no longer known to the Health Board, the Health Board must—

(a) give the provider notice in writing that it intends, at the end of the period of 6 months commencing with the date of the notice, to remove the patient from the provider's list of patients; and

(b) at the end of that period, remove the patient from the provider's list of patients unless, within that period, the provider satisfies the Health Board that the provider is still responsible for providing essential services to that patient.

#### **Removals from the list of patients absent from the United Kingdom etc.**

**16.**—(1) The Health Board must remove a patient from the provider's list of patients where it receives notification that that patient—

(a) intends to be away from the United Kingdom for a period of at least three months;

(b) is in Her Majesty's Forces;

(c) has been absent from the United Kingdom for a period of more than three months; or

(d) has died.

(2) A removal in accordance with sub-paragraph (1) will take effect—

(a) in the cases referred to in sub-paragraphs (1)(a) and (1)(b) from the date of the departure or enlistment or the date on which the Health Board first receives notification of the departure or enlistment, whichever is the later; or

(b) in the cases referred to in sub-paragraphs (1)(c) and (1)(d) from the date on which the Health Board first receives notification of the absence or death.

(3) The Health Board must notify the provider in writing of patients removed from its list of patients under sub-paragraph (1).

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

**17.—**(1) The Health Board must remove from the provider's list of patients a patient who has been accepted as a temporary resident by another provider (by any arrangement) of essential services (or their equivalent) where it is satisfied, after due inquiry—

(a) that the person's stay in the place of temporary residence has exceeded 3 months; and

(b) that the patient has not returned to the patient's normal place of residence or any other place within the provider's practice area.

(2) The Health Board must notify in writing of a removal under sub-paragraph (1)—

(a) the provider; and

(b) where practicable, the patient.

(3) A notification to the patient under sub-paragraph (2)(b) must inform the patient of—

(a) the patient's entitlement to make arrangements for the provision to the patient of essential services (or their equivalent), including by the provider (by any arrangement) by which the patient has been treated as a temporary resident; and

(b) the name and address of the Health Board in whose area the patient is resident.

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

**18.—**(1) Where the provider provides essential services under the agreement to persons on the ground that they are pupils at or staff or residents of a school, the Health Board must remove from the provider's list of patients any such patients who do not appear on particulars of persons who are pupils at or staff or residents of that school provided by that school.

(2) Where the Health Board has made a request to a school to provide the particulars mentioned in sub-paragraph (1) and has not received them, it must consult the provider as to whether it should remove from its list of patients any persons appearing on that list as pupils at, or staff or residents of, that school.

(3) The Health Board must notify the provider in writing of patients removed from its list of patients under sub-paragraph (1).

#### **Closure of lists of patients**

**19.—**(1) A provider which wishes to close its list of patients must notify the Health Board in writing to that effect.

(2) Within a period of 28 days beginning with the date of receipt of the notification referred to in sub-paragraph (1), the Health Board must enter into discussions with the provider concerning the support which the Health Board may give the provider, or other changes which the Health Board or the provider may make, which would enable the provider to keep its list of patients open.

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

(4) The discussions mentioned in sub-paragraph (2) must be completed within a period of 3 months beginning with the date of the Health Board's receipt of the notification referred to in ~~sub-paragraph (1)~~ sub-paragraph (1), or within such longer period as the parties may agree.

(5) Notwithstanding the requirements mentioned in sub-paragraphs (2) and (4), the provider may issue a closure notice to the Health Board which the Health Board must approve in accordance with sub-paragraph (13)—

(a) if the period of 28 days mentioned in sub-paragraph (2) has expired and the Health Board has not begun discussions with the provider in accordance with sub-paragraph (2);

(b) if the 3 month period or such longer period as has been agreed in accordance with sub-paragraph (4) has expired and the Health Board has failed to complete the discussions mentioned in sub-paragraph (2).

(6) If, following the discussions mentioned in sub-paragraph (2), the Health Board and the provider reach agreement that the provider's list of patients should remain open, the Health Board must send full details of the agreement in writing to the provider within a period of 2 weeks from the date the agreement was reached.

(7) The Health Board and the provider must comply with the terms of an agreement reached as mentioned in sub-paragraph (6).

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

(a) the Health Board and the provider reach agreement that the provider's list of patients should close; or

(b) the Health Board and the provider fail to reach agreement and the provider still wishes to close the provider's list of patients,

the provider must send a closure notice to the Health Board.

(9) A closure notice mentioned in sub-paragraph (5) or sub-paragraph (8) must be submitted in the form specified in schedule 5, and must include the following details which (in a case falling within sub-paragraph (8)(a)) have been agreed between the parties or (in a case falling within sub-paragraph (8)(b)) are proposed by the provider:—

(a) the period of time (which may not exceed 12 months) for which the provider's list of patients will be closed;

(b) the current number of the provider's registered patients;

(c) the number of registered patients (lower than the current number of such patients, and expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-opening of the provider's list of patients;

(d) the number of registered patients (expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-closure of the provider's list of patients; and

(e) any withdrawal or reduction in provision of any additional or enhanced services which had previously been provided under the agreement.

(10) The Health Board must forthwith acknowledge receipt of the closure notice mentioned in sub-paragraph (5) or sub-paragraph (8) in writing to the provider.

(11) Before the Health Board reaches a decision as to whether to approve or reject the closure notice mentioned in sub-paragraph (8) under sub-paragraph (14), the Health Board and the provider may enter into further discussions concerning the details of the closure notice as specified in sub-paragraph (9), with a view to reaching agreement; and, in particular, if the parties are unable to reach agreement regarding the period of time for which the provider's list of patients will be closed, that period must be 12 months.

(12) A provider may not withdraw a closure notice mentioned in sub-paragraph (5) or sub-paragraph (8) for a period of 3 months beginning with the date on which the Health Board has received the notice, unless the Health Board has agreed otherwise in writing.

(13) Within a period of 14 days beginning with the date of the receipt of the closure notice mentioned in sub-paragraph (5), the Health Board must approve the closure notice and notify the provider in writing as soon as possible.

(14) Within a period of 14 days beginning with the date of receipt of the closure notice mentioned in sub-paragraph (8), the Health Board must—

(a) approve the closure notice; or

(b) reject the closure notice,

and must notify the provider of its decision in writing as soon as possible.

(15) Approval of a closure notice includes—

(a) where it is a closure notice mentioned in sub-paragraph (5), approval of the details in sub-paragraph (9); or

(b) where it is a closure notice mentioned in sub-paragraph (8) and approved under sub-paragraph 14(a), approval of the details specified in sub-paragraph (9) (or, where those details are revised following discussions under sub-paragraph (11) approval of those details as so revised).

#### **Approval of closure notice by the Health Board**

**20.—**(1) If the Health Board approves the closure notice in accordance with paragraph 19(13) or 19(14), the provider must close the provider's list of patients—

(a) with effect from a date agreed between the Health Board and the provider; or

(b) if no such agreement has been reached, with effect from that date on which the provider receives notification of the Health Board's decision to approve the closure notice.

(2) Subject to sub-paragraph (3), the provider's list of patients is to remain closed for the period specified in the closure notice in accordance with paragraph 19(9)(a) (or, where a period of 12 months has been fixed in accordance with paragraph 19(11), for that period).

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

(a) the number of the provider's registered patients falls to the number specified in the closure notice in accordance with paragraph 19(9)(c); or

(b) the Health Board and the provider agree that the list of patients should re-open.

(4) If the provider's list of patients has re-opened pursuant to sub-paragraph (3)(a) it will nevertheless close again if, during the period specified in the closure notice in accordance with paragraph 19(9)(a) or where the period of 12 months specified in paragraph 19(11) applies, during that period, the number of the provider's registered patients rises to the number specified in the closure notice in accordance with paragraph 19(9)(d).

(5) Except in cases where the provider's list of patients is already open pursuant to sub-paragraph (3), the Health Board must notify the provider in writing between 7 and 14 days before the expiry of the period of closure specified in sub-paragraph (2), confirming the date on which the provider's list of patients will re-open.

(6) Where the details specified in the closure notice mentioned in paragraph 19(8), in accordance with paragraph 19(9), have been revised following discussions under paragraph 19(11), references in this paragraph to details specified in the closure notice are references to those details as so revised.

#### **Rejection of closure notice by the Health Board**

**21.—**(1) This regulation applies where the Health Board rejects the closure notice in accordance with paragraph 19(14)(b).

(2) The provider and the Health Board may not refer the matter for determination in accordance with the NHS dispute resolution procedure (or, where applicable, in the case of a non-NHS contract, commence court proceedings) until the assessment panel has given its determination in accordance with the following sub-paragraphs.

(3) The Health Board must ensure that the assessment panel is appointed by another Health Board as soon as is practicable to consider and determine whether the provider should be permitted to close its list of patients, and if so, the terms on which the provider should be permitted to do so.

(4) The Health Board must provide the assessment panel with such information as the assessment panel may reasonably require to enable the panel to reach a determination and must include in such information any written observations received from the provider.

(5) At least one member of the assessment panel must visit the provider before reaching a determination under sub-paragraph (6).

(6) Within the period of 28 days beginning with the date on which the Health Board rejected the closure notice, the assessment panel must—

(a) approve the list closure; or

(b) reject the list closure,

and must notify the Health Board and the provider of its determination in writing as soon as possible.

(7) Where the assessment panel determines, in accordance with sub-paragraph 21(6)(a), that the provider's list of patients should close, it must specify—

(a) a date from which the closure is to take effect, which must be within a period of 7 days beginning with the date of the assessment panel's determination; and

(b) those details specified in paragraph 19(9).

(8) Subject to sub-paragraph (9), the provider's list of patients must remain closed for the period specified by the assessment panel in accordance with sub-paragraph (7)(b).

(9) The provider's list of patients must re-open before the expiry of the period mentioned in sub-paragraph (8) if—

(a) the number of the provider's registered patients falls to the number specified by the assessment panel in accordance with sub-paragraph (7)(b) as the number of registered patients which, if that number were reached, would trigger the re-opening of the provider's list of patients; or

(b) the Health Board and the provider agree that the list of patients should re-open.

(10) If the provider's list of patients has re-opened pursuant to sub-paragraph (9)(a), it must nevertheless close again if, during the period specified by the assessment panel as the period for which the list should remain closed, the number of the provider's registered patients rise to the number specified by the assessment panel in accordance with sub-paragraph (7)(b) as the number of registered patients which, if that number were reached, would trigger the re-closure of the provider's list of patients.

(11) Except in cases where the provider's list of patients is already open pursuant to sub-paragraph (9), the Health Board must notify the provider in writing between 7 and 14 days before the expiry of the closure period specified in sub-paragraph (8), confirming the date on which the provider's list of patients will re-open.

(12) Where the assessment panel rejects the list closure in accordance with sub-paragraph (6)(b) that list must remain open, and the Health Board and the provider must enter into discussions with a view to ensuring that the provider receives support from the Health Board which will enable the provider to continue to provide services safely and effectively.

(13) An assessment panel which rejects the list closure in accordance with sub-paragraph (6)(b) must specify the number of registered patients (expressed either in absolute terms or as a percentage of the number of such patients specified as the current number of the provider's registered patients), which if that number were reached, would trigger the closure of the provider's list of patients.

(14) Where a list closure is triggered in accordance with sub-paragraph (13), a provider must notify the Health Board to confirm and the details specified in sub-paragraph (6).

(15) Where the assessment panel rejects the list closure in accordance with sub-paragraph (6)(b) the provider may not submit a further closure notice as described in paragraph 19 until—

(a) the expiry of a period of six months beginning with the date of the assessment panel's determination; or

(b) (if applicable) the final determination of the NHS dispute resolution procedure (or any court proceedings),

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

(16) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

#### **Assignment of patients to lists: open lists**

**22.—**(1) A Health Board may, subject to paragraph 24, assign a new patient to a provider whose list of patients is open.

(2) In this paragraph and in paragraphs 23 and 25 to 27, a "new" patient means a person who—

(a) is resident (whether or not temporarily) within the area of the Health Board;

(b) has been refused inclusion in a list of patients of, or has not been accepted as a temporary resident by, a provider (by any arrangement) of essential services (or their equivalent) whose premises are within such an area; and

(c) wishes to be included in the list of patients of a provider (by any arrangement) of essential services (or their equivalent) whose practice premises are within that area.

#### **Assignment of patients to lists: closed lists**

**23.—**(1) A Health Board may not assign a patient to a provider which has closed the provider's list of patients except in the circumstances specified in sub-paragraph (2).

(2) A Health Board may, subject to paragraph 24 assign a new patient to a provider whose practice premises are within the Health Board's area and which has closed the provider's list of patients, if—

(a) most or all of the providers (by any arrangement) of essential services (or their equivalent) whose practice premises are within the Health Board's area have closed their lists of patients;

(b) the assessment panel has determined under paragraph 25(7) that patients may be assigned to the provider in question, and that determination has not been overturned either by a determination of the Scottish Ministers or the adjudicator under the NHS dispute resolution procedure as modified by paragraph 26(3) or (where applicable) by a court; and

(c) the Health Board has entered into discussions with the provider in question regarding the assignment of a patient if such discussions are required under paragraph 30.

### **Factors relevant to assignments**

24. In making an assignment to a provider under paragraph 22 or 23, the Health Board is to have regard to—
- (a) the wishes and circumstances of the patient to be assigned;
  - (b) the distance between the patient's place of residence and the provider's practice premises;
  - (c) whether during the 6 months ending on the date on which the application for assignments is received by the Health Board, the patient's name has been removed from the list of patients of a provider in the area of the Health Board under paragraph 11 or its equivalent provision in relation to a general medical services contractor in the area of the Health Board;
  - (d) whether the patient's name has been removed from the list of patients of a provider in the area of the Health Board under paragraph 12 or its equivalent provision in relation to a general medical services contractor in the area of the Health Board and, if so, whether the provider has appropriate facilities to deal with such a patient; and
  - (e) such other matters as the Health Board considers to be relevant.

### **Assignments to closed lists: determination of the assessment panel**

25.—(1) This paragraph applies where most or all of the providers (by any arrangement) of essential services (or their equivalent) whose practice premises are within the area of a Health Board have closed their lists of patients.

(2) If the Health Board wishes to assign new patients to providers which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel, and the proposal must include details of those providers to which the Health Board wishes to assign patients.

(3) The Health Board must ensure that the assessment panel is appointed to consider and determine its proposal made under sub-paragraph (2).

(4) The Health Board must notify in writing—

(a) providers or general medical services contractors whose practice premises are within the Health Board's area which—

(i) have closed their list of patients; and

(ii) may, in the opinion of the Health Board, be affected by the determination of the assessment panel; and

(b) the area medical committee, for the area of the Health Board,

that it has referred the matter to the assessment panel.

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

(a) whether the Health Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of their assignment to providers with closed lists of patients; and

(b)the workload of those providers likely to be affected by any decision to assign such patients to their list of patients.

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

(7) The assessment panel must determine whether the Health Board may assign patients to providers which have closed their lists of patients; and if it determines that the Health Board may make such assignments, it must also determine those providers to which patients may be assigned.

(8) The assessment panel may determine that the Health Board may assign patients to providers other than those providers specified by the Health Board in its proposal under sub-paragraph (2), as long as the providers were notified under sub-paragraph (4)(a).

(9) The assessment panel's determination must include its comments on the matters specified in sub-paragraph (5), and must be notified in writing to those providers which were notified under sub-paragraph (4)(a).

(10) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

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

**26.**—(1) Where an assessment panel makes a determination under paragraph 25(7) that the Health Board may assign new patients to providers which have closed their lists of patients, any provider specified in that determination may refer the matter in dispute to the Scottish Ministers to review the determination of the assessment panel.

(2) Where more than one provider specified in the determination in accordance with paragraph 25(7) wishes to refer the matter for dispute resolution, those providers may, if they all agreed, refer the matter jointly, and in that case the Scottish Ministers must review the matter in relation to those providers together.

(3) Where a matter is referred to the Scottish Ministers under sub-paragraph (1) or (2), it will be determined in accordance with the NHS dispute resolution procedure as modified as follows—

(a)in paragraph 58(3) of schedule 1, for "a dispute as mentioned in sub-paragraph (1)" substitute "the matter as mentioned in paragraph 28(1) paragraphs 26(1) and (2) of schedule 2";

(b)for paragraph 58(4) of schedule 1, substitute—

"(4) The provider (or providers) wishing to refer the matter as mentioned in paragraph 26(1) or (2) of schedule 2 must send the request to the Scottish Ministers within the period of 7 days beginning with the date of the determination by the assessment panel in accordance with paragraph 25(7) of schedule 2";

(c)for paragraph 58(13) of schedule 1, substitute—

"(13) In this paragraph, "specified period" means such period as the Scottish Ministers specify in the request sent under sub-paragraphs (6) or (8), being not less than one, nor more than two, weeks beginning

with the date on which the request is given, but the adjudicator may, if the period for determination of the dispute has been extended in accordance with sub-paragraph (19), extend any such period (even after it has expired) and, where the adjudicator does so, a reference in this paragraph to the specified period is to the period as so extended.”;

(d) after paragraph 58(15) of schedule 1, there must be inserted the following sub-paragraphs—

“(16) Subject to sub-paragraph (19), within the period of 21 days beginning with the date on which the matter was referred to the Scottish Ministers, the adjudicator must determine whether the Health Board may assign patients to providers which have closed their lists of patients; and if the adjudicator determines that the Health Board may make such assignments, the adjudicator must also determine those providers to which patients may be assigned.

(17) The adjudicator may not determine that patients may be assigned to a provider which was not specified in the determination of the assessment panel under paragraph 25(7) of schedule 2.

(18) In the case of a matter referred jointly by providers in accordance with paragraph 26(2) of schedule 2, the adjudicator may determine that patients may be assigned to one, some or all of the providers which referred the matter.

(19) The period of 21 days referred to in sub-paragraph (16) 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 adjudicator;

(b) the Health Board; and

(c) the provider (or providers) which referred the matter to dispute resolution; and”resolution.”; and

(d) paragraph 59(2) and (3) of schedule 1 do not apply.”.

(e) paragraph 59(2) and (3) of schedule 1 do not apply.

#### **Assignments of patients to lists at request of provider**

27.—(1) A Health Board may, subject to sub-paragraph (3), at the request of a provider, assign a patient on the provider's list of patients to a receiving provider's list of patients.

(2) A request under sub-paragraph (1) must be notified in writing to the Health Board and confirm that—

(a) the patient has given written consent to the assignment; and

(b) the requesting and receiving provider have agreed to the assignment.

(3) An assignment under this paragraph may only be made where either the requesting provider or receiving provider have varied their practice area in accordance with paragraph 28.

(4) In this paragraph, “a receiving provider” may include a provider who has closed its list of patients.

#### **Application for variation of a practice area**

**28.**—(1) A provider may request a variation of their practice area by notifying the Health Board in writing of its variation request.

(2) The Health Board must—

(a) enter into discussions with the provider regarding the variation request mentioned in sub-paragraph (1), within a period of 1 month beginning with the date of receipt of the notification referred to in that sub-paragraph; and

(b) have concluded such discussions within a period of 3 months beginning with the date of the receipt of the notification mentioned in sub-paragraph (1).

(3) Following the discussions mentioned in sub-paragraph (2), the Health Board must—

(a) consult with the Area Medical Committee regarding the provider's variation request;

(b) consider the effect of the variation request mentioned in sub-paragraph (1) on the practice areas of other providers within its Health Board area; and

(c) taking account of the discussions mentioned in sub-paragraph (2) and the factors at sub-head (a) and (b), approve or reject the provider's variation request.

(4) The Health Board must notify the provider in writing as soon as possible of its decision to approve or reject the variation request in accordance with sub-paragraph (3).

(5) A notification of approval mentioned in sub-paragraph (4) must confirm the date the variation is to take effect.

#### **Rejection of a practice area variation request**

**29.**—(1) This paragraph applies where the Health Board rejects the variation request in accordance with paragraph 28(3).

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

(3) The Health Board must ensure that an assessment panel is appointed by another Health Board as soon as is practicable to consider and determine whether the provider should be permitted to vary its practice area.

(4) The Health Board must provide the assessment panel with such information as the assessment panel may reasonably require to enable the panel to reach a determination and must include in such information any written observations received from the provider.

(5) Within the period of three months beginning with the date on which the Health Board rejected the variation request, the assessment panel must—

(a) approve the variation request; or

(b) reject the variation request,

and must notify the Health Board and the provider of its determination in writing as soon as possible.

(6) Where the assessment panel approves a variation request in accordance with sub-paragraph (5)(a), it must specify the date from which the variation of the practice area takes effect.

(7) Where the assessment panel rejects the variation request in accordance with sub-paragraph (5)(b), the provider may not request a further practice area variation under paragraph 28 until whichever is the later of the following dates—

(a) the expiry of a period of one year beginning with the date of the assessment panel's determination; or

(b) (if applicable) the final determination of the NHS dispute resolution procedure (or any court proceedings).

(8) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

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

**30.**—(1) Before the Health Board may assign a new patient to a provider, it must, subject to sub-paragraph (3), enter into discussions with that provider regarding additional support that the Health Board can offer the provider, and the Health Board must use its best endeavours to provide appropriate support.

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

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

(a) to the first assignment of a patient to a particular provider; and

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

### **PART 3**

#### **NOTICES**

##### **Notifications to the Health Board**

**31.** The provider must notify the Health Board in writing of any person, other than a registered patient or a person whom it has accepted as a temporary resident, to whom it has provided the essential services described in paragraph 1(5) or 1(7) within the period of 28 days beginning on the day that the services were provided.

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### **SCHEDULE 3**

#### **AGREEMENTS TO PROVIDE ADDITIONAL SERVICES**

##### **Additional services generally**

**1.** The provider must—

(a) provide in relation to each additional service, such facilities and equipment as are necessary to enable the provider properly to perform that service;

(b) provide each additional service, within core hours, as is appropriate to meet the reasonable needs of its patients; and

(c) have in place arrangements for its patients to access each additional service throughout the core hours in case of emergency.

### **Cervical screening**

2.—(1) A provider whose agreement includes the provision of cervical screening services must—

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

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

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

(a) the provision of any necessary information and advice to assist women identified by the Health Board as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Scotland Cervical Screening Programme;

(b) the performance of cervical screening tests on women who have agreed to participate in that Programme;

(c) arranging for women to be informed of the results of the test; and

(d) ensuring that test results are followed up appropriately.

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

### **Contraceptive services**

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

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

(a) the giving of advice about the full range of contraceptive methods;

(b) where appropriate, the medical examination of patients seeking such advice;

(c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);

(d) the giving of advice about emergency contraception and, where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the provider has a conscientious objection to emergency contraception, a prompt referral to another provider (by any arrangement) of primary medical services who does not have such conscientious objections;

(e) the provision of advice and referral in cases of unplanned or unwanted pregnancy, including advice about the availability of free pregnancy testing in the practice area and, where appropriate, where the provider has a

conscientious objection to the termination of pregnancy, a prompt referral to another provider (by any arrangement) of primary medical services who does not have such conscientious objections;

(f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and

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

(3) An agreement which includes the provision of contraceptive services must provide that, for the purposes of paragraphs 11 to 14 of schedule 1, drugs includes contraceptive substances and appliances includes contraceptive appliances.

### **Vaccinations and immunisations**

~~4.—(1) A provider whose agreement includes the provision of vaccinations and immunisations must comply with the requirements in sub-paragraphs (2) and (3).~~

~~(2) The provider must—~~

~~(a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act(121) other than influenza and pneumococcal vaccinations;~~

~~(b) provide appropriate information and advice to patients about such vaccinations and immunisations;~~

~~(c) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offer referred to in sub-paragraph (2)(a);~~

~~(d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—~~

~~(i) the patient's consent to the vaccination or immunisation or the name of the person who gave consent to the vaccination or immunisation and the person's relationship to the patient;~~

~~(ii) the batch numbers, expiry date and title of the vaccine;~~

~~(iii) the date of administration;~~

~~(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;~~

~~(v) any contraindications to the vaccination or immunisation; and~~

~~(vi) any adverse reactions to the vaccination or immunisation.~~

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

### **Childhood vaccinations and immunisations**

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

(2) The provider must—

(a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;

(b) provide appropriate information and advice to patients and, where appropriate, their parents about such vaccinations and immunisations;

(c) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offer referred to in sub-paragraph (2)(a);

(d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—

(i) the patient's consent to the vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and the person's relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

(v) any contraindications to the vaccination or immunisation; and

(vi) any adverse reactions to the vaccination or immunisation.

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

### **Child health surveillance**

6.—(1) A provider whose agreement includes the provision of child health surveillance services must, in respect of any child under the age of 5 for whom the provider has responsibility under the agreement—

(a) provide all the services described in sub-paragraph (2), other than any examination so described which the parent refuses to allow the child to undergo, until the date upon which the child attains the age of 5 years; and

(b) maintain such records as are specified in sub-paragraph (3).

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

(a) the monitoring—

(i) by the consideration of any information concerning the child received by or on behalf of the provider; and

(ii) on any occasion when the child is examined or observed by or on behalf of the provider (whether pursuant to sub-paragraph (2)(b), or otherwise),

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

(b) the examination of the child at a frequency that has been agreed with the Health Board in accordance with the nationally agreed evidence based programme set out in the fourth edition of “Health for all Children”(122).

(3) The records mentioned in sub-paragraph (1)(b) are an accurate record of—

(a) the development of the child while under the age of 5 years, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination mentioned in that sub paragraph; and

(b) the responses (if any) to offers made to the child’s parent for the child to undergo any examination referred to in sub-paragraph (2)(b).

### **Maternity medical services**

7.—(1) A provider whose agreement includes the provision of maternity medical services must provide—

(a) to female patients who have been diagnosed as pregnant all necessary maternity medical services throughout the ante-natal period;

(b) to female patients and their babies all necessary maternity medical services throughout the postnatal period other than neonatal checks;

(c) all necessary maternity medical services to female patients whose pregnancy has terminated as a result of miscarriage or abortion or, where the provider has a conscientious objection to the termination of pregnancy, prompt referral to another provider (by any arrangement) of primary medical services who does not have such conscientious objections.

(2) In this paragraph—

“ante-natal period” means the period from the start of the pregnancy to the onset of labour;

“maternity medical services” means—

(a)

in relation to female patients (other than babies) all primary medical services relating to pregnancy, excluding intra partum care; and

(b)

in relation to babies, any primary medical services necessary in their first 14 days of life; and

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

## **SCHEDULE 3A**

### **VACCINATION SERVICES**

### **Requirement to provide vaccination services**

1.—(1) Subject to the provisions of this paragraph, where the Health Board is satisfied that by reason of distance, inadequacy of means of communication, or other exceptional circumstances, the Health Board will have serious difficulties in delivering any vaccination service to the provider's patients, the Health Board may require the provider to provide those services to the provider's patients until further notice.

(2) The Health Board may not require a provider to deliver services in accordance with sub-paragraph (1) unless it has first consulted the area medical committee regarding the matter.

(3) The Health Board may not require a provider to provide a vaccination service in accordance with sub-paragraph (1) unless the provider was, immediately prior to the Health Board notifying the provider of the requirement, offering that particular vaccination service to the provider's patients as part of an additional service, an enhanced service or as part of a transitional arrangement under regulation 28A.

(4) Nothing in sub-paragraph (3) prevents the provider and the Health Board from agreeing that the provider will deliver a vaccination service in accordance with this schedule.

(5) The Health Board must give a provider reasonable notice that the provider is required to provide a vaccination service and must, if the provider is no longer required to provide a service, give reasonable notice that the requirement to provide the service is to be discontinued.

(6) A notice served by the Health Board under sub-paragraph (1) must list all of the vaccinations and immunisations which the provider is required to provide as a consequence of the notice, as of the date of the notice.

(7) A provider which is required to provide a vaccination service may request that the Health Board reviews that requirement.

(8) A review request under sub-paragraph (7) may not be made by the provider—

(a) unless the provider has been providing the vaccination service for a period of not less than 6 months; and

(b) the provider has not made a review request in respect of the service in the 6 months prior to its present review request.

(9) Where it receives a review request, the Health Board must—

(a) acknowledge the review request within 30 days;

(b) consider any comments which the provider has provided to accompany the review request;

(c) within 3 months of receiving the review request, provide the provider with either—

(i) a written statement of reasons as to why the provider is required to continue to provide the vaccination service;

or

(ii) a written plan for the discontinuation of the requirement that the provider provide the vaccination service which includes the date on which the requirement will end.

(10) When considering whether it will have serious difficulty in delivering a vaccination service or serving notice under sub-paragraph (1), or when considering a review request submitted under sub-paragraph (7), the Health Board must comply with any directions given by the Scottish Ministers in relation to these matters.

(11) For the purposes of this paragraph a "vaccination service" comprises—

- (a) offering and administering to patients all doses necessary to complete the recommended course of vaccination for a single disease, or in the case of a combination vaccine which protects the patient against multiple diseases, all doses necessary to complete the recommended course of vaccination for all of the diseases for which that combination vaccine provides protection; and
- (b) providing appropriate information and advice to patients regarding the course of vaccination offered.

#### **Conditions which apply to all vaccination services**

2. The provider must—

- (a) in relation to each vaccination service which they provide, provide such facilities and equipment as are necessary to enable the provider to properly perform that service; and
- (b) provide each vaccination service which they provide, within core hours as is appropriate to meet the reasonable needs of their patients.

#### **Vaccinations and immunisations**

3.—(1) A provider who is required in accordance with paragraph 1 to provide vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

(2) The provider must—

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (b) where a patient has informed the provider that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (c) provide appropriate information and advice to patients about such vaccinations and immunisations;
- (d) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offers referred to in sub-paragraphs (a) and (b);
- (e) where an offer referred to in sub-paragraphs (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—
  - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
  - (ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

(v) any contraindications to the vaccination or immunisation; and

(vi) any adverse reactions to the vaccination or immunisation.

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

#### **Childhood vaccinations and immunisations**

4.—(1) A provider who is required in accordance with paragraph 1 to provide childhood vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

(2) The provider must—

(a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;

(b) where a patient has informed the provider that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;

(c) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;

(d) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offers referred to in sub-paragraph (a) and (b);

(e) where an offer referred to in sub-paragraph (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—

(i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to vaccination or immunisation and that person's relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

(v) any contraindications to the vaccination or immunisation; and

(vi) any adverse reactions to the vaccination or immunisation.

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

## **Supplementary vaccinations and immunisations**

5.—(1) Where directions given under section 17M of the Act have provided for a fee to be payable for the provision of a vaccination or immunisation of a specified type in specified circumstances, but those directions have not specified that the vaccination or immunisation is to form part of the vaccinations and immunisations described by paragraph 3 or the childhood vaccinations and immunisations described by paragraph 4, the vaccination or immunisation is to be considered a “supplementary vaccination and immunisation”.

(2) Subject to paragraph 1, a Health Board may require a provider to provide to their patients any of the supplementary vaccinations and immunisations.

(3) A provider who is required to provide any supplementary vaccination and immunisation to their patients must comply with the requirements in sub-paragraph (4) and (5).

(4) The provider must—

(a) offer to provide to patients all such vaccinations and immunisations which the Health Board may specify;

(b) provide appropriate information and advice to patients about such vaccinations and immunisations or, where appropriate, if the patient is a child, provide this information and advice to their parents;

(c) record in the patient’s record kept in accordance with paragraph 36 of schedule 1 any refusal of the offered offer referred to in sub-paragraph (a);

(d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient’s record kept in accordance with paragraph 36 of schedule 1—

(i) the patient’s consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person’s relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

(v) any contraindications to the vaccination or immunisation; and

(vi) any adverse reactions to the vaccination or immunisation.

(5) The provider must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Regulation 21

## **SCHEDULE 4**

### **MINIMUM STANDARDS FOR PRACTICE PREMISES**

The provider must ensure that it meets minimum standards for its practice premises which are that—

1. the provider complies with any obligations under the Health and Safety at Work etc. Act 1974(123) (and provision made under that Act) and the Equality Act 2010(124) in relation to—

(1) the design or construction of the practice premises; and

(2) the approach or access to the practice premises,

which the provider has to its own members (where applicable), staff, providers and to persons to whom it provides primary medical services, including taking such steps as are reasonable to—

(a) provide for ease of access to the practice premises and ease of movement within the practice premises for all users of the practice premises (including wheelchair users);

(b) provide adequate sound and visual systems for the hearing and visually impaired; and

(c) remove barriers to the employment of disabled people;

2. there are adequate facilities for the elderly and young children, including nappy-changing and feeding facilities;

3. there are adequate lavatory and hand hygiene facilities for all persons on the practice premises which meet current infection control standards;

4. there is such equipment as is necessary to enable the provider to properly perform appropriate clinical services in the consultation rooms and treatment areas;

5. the practice has arrangements for instrument decontamination that comply with any national guidelines for instrument decontamination published by the Scottish Ministers from time to time which apply to primary care in accordance with paragraph 83 of schedule 1;

6. Subject to sub-paragraph (7), consulting rooms and treatment areas are properly equipped for use by practitioners working in the practice, including—

(1) adequate arrangements to ensure the privacy of consultations; and

(2) patients have personal privacy when dressing or undressing, either in a separate examination room or in a screened-off area around an examination couch within the relevant consulting rooms and treatment areas;

7. in the case of branch surgeries where the provider provides outlying consultation facilities in premises usually used for other purposes, and these outlying consultation facilities meet with the approval of the Health Board, the standards set out in paragraph 6 do not apply in relation to the outlying consultation facilities;

8. the access arrangements for the practice premises are convenient for all users;

9. there are washbasins connected to running hot and cold water (ideally distributed through elbow, knee or sensor operated taps) in all consulting rooms and treatment areas, or, if this is not possible, then in immediately adjacent rooms;

**10.** there are adequate internal waiting areas with—

(1) enough seating to meet all normal requirements, either in the reception area or elsewhere; and

(2) a facility for patients to communicate confidentially with reception staff, including by telephone;

**11.** there are adequate standards of lighting, heating and ventilation;

**12.** the premises, fittings and furniture of the practice premises are in good repair and (when being used for the provision of primary medical services) clean and hygienic;

**13.** there are arrangements for the storage and disposal of clinical waste and that these arrangements comply with the legislative requirements and national guidance in place from time to time in accordance with paragraph 8583 of schedule 1;

**14.** there are, in the practice premises, arrangements for adequate fire precautions designed in accordance with the Building Regulations 2004(125) and agreed with the local fire authority, including provision for safe exit from the practice premises;

**15.** there is adequate security for drugs, records, prescription pads and pads of doctors' statements; and

**16.** If the practice premises are to be used for minor surgery or the treatment of minor injuries, there are necessary facilities and equipment to enable the proper performance of these procedures in the practice premises.

schedule 2, paragraph 19(9)

## SCHEDULE 5

### CLOSURE NOTICE

### Application for list Closure

**From: Name(s) of Provider**

**To: Name of Health Board**

Date:

In accordance with paragraph 19 of schedule 2 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018, on behalf of the above named provider I/we wish to make a formal application for our list to be closed to new patients and assignments, as follows:

|   |
|---|
| (1) Length of period of closure (which may not exceed 12 months and, in the absence of any agreement, must be 12 months)  |
| (2) Date from which closure will take effect  |
| (3) Date from which closure will cease to have effect   |
| (4) Current number of registered patients   |
| (5) The number of registered patients which would trigger re-opening (or suspension of list closure) of the provider's list of patients, expressed either as a number of registered patients or as a percentage of the number indicated in (4)                |
| (6) the number of registered patients which would trigger a reclosure (or lifting of the suspension of list closure) of the provider's list of patients expressed either as a number of registered patients or as a percentage of the number indicated in (4) |
| (7) Any withdrawal or reduction of additional or enhanced services  |

Signed

For Name(s) of provider

schedule 1, paragraph 41

## SCHEDULE 6

### PRACTICE INFORMATION

#### INFORMATION TO BE INCLUDED IN PRACTICE LEAFLETS...

A practice leaflet must include—

1. The name(s) of the provider.
2. In the case where a partnership is a party to the agreement—

(a) whether or not it is a limited partnership; and

(b) the names of all the partners and, in the case of a limited partnership, their status as a general or limited partner.

3. In the case where a company is a party to the agreement—

(a) the names of the directors, the company secretary and the members

(b) of that company; and

~~the address of the company's registered office.~~(c) the address of the company's registered office.

4. In the case where a limited liability partnership is a party to the agreement—

(a) the names of all the members of that limited liability partnership; and

(b) the address of the registered office of the limited liability partnership.

5. The full name of each person performing services under the agreement.

6. In the case of each health care professional performing services under the agreement the health care professional's professional qualifications.

7. Whether the provider undertakes the teaching or training of health care professionals or persons intending to become health care professionals.

8. The provider's practice area, by reference to a map, plan or postcode.

9. The address of each of the practice premises.

10. The provider's telephone number and the address of the provider's website (if any).

11. Where the provider offers its registered patients an online service in accordance with paragraph 40 of schedule 1, the website address where such patients can access and use the service and guidance on how such patients can access and use that service.

12. Whether the practice premises have suitable access for all disabled patients and, if not, the alternative arrangements for providing services to such patients.

13. Where the provider provides essential services, how to register a patient.

14. The right of patients to express a preference of practitioner in accordance with paragraph 9 of schedule 1 and the means of expressing such a preference.

15. The services available under the agreement.

16. The opening hours of the practice premises and the method of obtaining access to services throughout the core hours. Information on access to services should include any usual periods of consultation time provided during the opening hours.

17. The criteria for home visits and the method of obtaining such a visit.

**18.** Where the provider provides essential services, the consultations available to patients under paragraphs 1 and 2 of schedule 2.

**19.** Where the provider provides essential services, the details of—

- (a) the out of hours period as set out in paragraph (20);
- (b) arrangements for services in the out of hours period; and
- (c) ~~and how the patient may contact such services.~~

**20.** The out of hours period is:

- (i) the period beginning at 1830 hours on any day from Monday to Thursday and ending at 0800 hours on the following day;
- (ii) the period beginning 1830 hours on Friday and ending at 0800 hours on the following Monday; and
- (iii) Christmas Day, New Year's Day and any other public or local holiday.

**21.** If the services in paragraph (19) are not provided by the provider, the fact that the Health Board referred to in paragraph 29 is responsible for commissioning the services.

**21A.** The details of the arrangements for the delivery of vaccinations and immunisations (and childhood vaccinations and immunisations) to the provider's patients.

**22.** The telephone number of NHS 24 and details of the NHS 24 website.

**23.** The method by which patients are to obtain repeat prescriptions.

**24.** If the provider is a dispensing provider the arrangements for dispensing prescriptions.

**25.** How patients may make a complaint or comment on the provision of service.

**26.** The rights and responsibilities of the patient, including keeping appointments.

**27.** The action that may be taken where a patient is violent or abusive to the provider or the provider's staff, persons present on the practice premises, or in the place where treatment is provided under the agreement, or other persons specified in paragraph 10(2)(c) of schedule 1 or paragraph 12(2) of schedule 2.

**28.** Details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information.

**29.** The name, address and telephone number of the Health Board which is a party to the agreement and from whom details of primary medical services in the area may be obtained.

Regulation 29

## SCHEDULE 7

### REVOCATIONS

| Column 1  | Column 2                        | Column 3      |
|---|---------------------------------|---------------|
| Secondary legislation revoked   | Reference                       | Extent        |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004   | <a href="#">S.S.I. 2004/116</a> | The v         |
|   |                                 | regul         |
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| The Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) (Scotland) Regulations 2004   | <a href="#">S.S.I. 2004/162</a> | Regu          |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2004   | <a href="#">S.S.I. 2004/217</a> | The v         |
| National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2005   | <a href="#">S.S.I. 2005/336</a> | The v         |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2006   | <a href="#">S.S.I. 2006/248</a> | The v         |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2007   | <a href="#">S.S.I. 2007/205</a> | The v         |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment (No. 2) Regulations 2007   | <a href="#">S.S.I. 2007/393</a> | The v         |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment (No. 3) Regulations 2005   | <a href="#">S.S.I. 2007/502</a> | The v         |
| The National Health Service (Pharmaceutical Services)(Scotland) Regulations 2009  | <a href="#">S.S.I. 2009/183</a> | Sche          |
| The National Health Service (General Medical Services Contracts, Primary Medical Services Section 17C Agreements and Primary Medical Services Performers Lists) (Scotland) Amendment Regulations 2010 | <a href="#">S.S.I. 2010/93</a>  | Regu          |
| National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2010   | <a href="#">S.S.I. 2010/395</a> | The v         |

| Column 1  | Column 2                        | Column 3     |
|---|---------------------------------|--------------|
| Secondary legislation revoked   | Reference                       | Extent       |
| The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Scotland) Regulations 2011   | <a href="#">S.S.I. 2011/55</a>  | Sche         |
| The Public Services Reform (Scotland) Act 2010 (Consequential Modifications) Order 2011   | <a href="#">S.S.I. 2011/211</a> | Sche<br>para |
| The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2012   | <a href="#">S.S.I. 2012/10</a>  | The v        |
| The Patient Rights (Complaints Procedure and Consequential Provisions) (Scotland) Regulations 2012  | <a href="#">S.S.I. 2012/36</a>  | Sche         |
| The National Health Service (Physiotherapist, Podiatrist or Chiropodist Independent Prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2014                       | <a href="#">S.S.I. 2014/73</a>  | Regu         |
| The National Health Service (Pharmaceutical Services)(Scotland) (Miscellaneous Amendments) Regulations 2014   | <a href="#">S.S.I. 2014/148</a> | Regu         |
| The National Health Service (Dietitian Supplementary Prescribers and Therapeutic Radiographer Independent Prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2016 | <a href="#">S.S.I. 2016/393</a> | Regu         |

Regulation 30

## SCHEDULE 8

### CONSEQUENTIAL AMENDMENTS

#### **The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013**

1.—(1) The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013([126](#)) is amended as follows.

(2) In schedule 3—

(a) In paragraph 8(c), for “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”; and

(b) In paragraph 11 for “The amendment made by paragraph 71(1) and (3) of Schedule 2 does not affect the duty of a provider under paragraph 52 of schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 to co-operate with any investigation of a complaint which is begun by a Primary Care Trust and which continues to be investigated after 31st March 2013.” substitute “The absence of reference to ‘Primary Care Trusts’ from the definition of “NHS Body” in paragraph 55 of schedule 1 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018 does not affect the duty of a provider under that paragraph to co-operate with any investigation of a complaint begun by a Primary Care Trust and which continues to be investigated after 31st March 2013”.

#### **The National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004**

2.—(1) The National Health Service (Primary Medical Services Performers Lists (Scotland) Regulations 2004(127) are amended as follows.

(2) In regulation 2 (interpretation), in the definition of “Section 17C Agreements Regulations”, for “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “the National Health Service (Primary Medical Services Section 17C Agreement) (Scotland) Regulations 2018”.

(3) In schedule 1—

(a) in paragraph 3(c) for the words “paragraph 78 (gifts) of Schedule 1 (content of agreements)” substitute “paragraph 82 of schedule 1”; and

(b) in paragraph 3(d), for the words “paragraph 78 (gifts) of Schedule 1 (content of agreements)” substitute “paragraph 82 of schedule 1”.

**The General Medical Services and Section 17C Agreements (Transitional and other Ancillary Provisions) (Scotland) Order 2004**

3.—(1) The General Medical Services and Section 17C Agreements (Transitional and other Ancillary Provisions) (Scotland) Order 2004(128) is amended as follows.

(2) In article 1(2) (citation, commencement and interpretation) in the definition of “the Section 17C Agreement Regulations” for “the National Health Service (Primary Medical Services Section 17C Agreements)(Scotland) Regulations 2004” substitute “the National Health Service (Primary Medical Services Section 17C Agreements)(Scotland) Regulations 2018”.

(3) In article 51 (4) (Interpretation of transitional agreements):

(a) for the words “paragraph 66 of Schedule 1” substitute “paragraph 68 of schedule 1”; and

(b) for the words substitute “paragraph 66(3)” to paragraph 68(3).

(4) In article 55 (2)(c) (Assignment of patients: transitional provisions) for the words “paragraph 13 of Schedule 2” substitute to “paragraph 11 of schedule 2”.

(5) In article 55 (5)(c) (Assignment of patients: transitional provisions) for the words “paragraph 14 of Schedule 2” substitute “paragraph 12 of schedule 2”.

(6) In article 57(3) (Variation and termination of transitional agreements):

(a) for the words “paragraph 66 of Schedule 1” substitute “paragraph 68 of Schedule 1”; and

(b) for the words “paragraph 66(3)” substitute “paragraph 68(3).

(7) In article 58 (1) (Health body status) for the words “regulation 8” substitute “regulation 10”.

**The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009**

4.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(129) are amended as follows.

(2) In ~~Regulation 2 (Interpretation and application)~~—

(a) in the definition of “dispensing doctor” for the words “under the terms of a section 17C agreement which gives effect to paragraph 15 of Schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “under the terms of a section 17C agreement which gives effect to paragraph 16 of schedule 1 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”. In regulation 2(1) (interpretation and application) in paragraph (b) of the definition of “dispensing doctor”, for “paragraph 15 of Schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “paragraph 16 of schedule 1 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”.

(3) In paragraph 4(2)(b)(ii) of schedule 1, for the words “regulation 2 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “regulation 3 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”.

### **The Patient Rights (Complaints Procedure and Consequential Provisions) (Scotland) Regulations 2012**

5.—(1) The Patient Rights (Complaints Procedure and Consequential Provisions) (Scotland) Regulations 2012(**130**) are amended as follows.

(2) In regulation 1(2) for “ part 6 of Schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “part 6 of schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”.

### **The Public Bodies (Joint Working) (Prescribed Health Board Functions) (Scotland) Regulations 2014**

6.—(1) The Public Bodies (Joint Working)(Prescribed Health Board Functions) (Scotland) Regulations 2014(**131**) are amended as follows.

(2) In schedule 1 (Functions prescribed for the purposes of section 1(6) of the Act), in column B for “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”.

(3) In schedule 2 (Functions prescribed for the purposes of section 1(8) of the Act), in column B of the table for the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004” substitute “the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018”.

## **EXPLANATORY NOTE**

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

These Regulations consolidate the National Health Service (Primary Medical Services Section 17C Agreements)(Scotland) Regulations 2004 and set out, for Scotland, the framework for section 17C agreements for primary medical services under section 17C of the National Health Service (Scotland) Act 1978 (“the Act”).

Part 2 of the Regulations prescribes the conditions which, in accordance with section 17D of the Act, must be satisfied by a medical practitioner, health care professional or any of the other persons listed in 17D(1)(b)(iii) to (ix),

(d) or (e) of the Act for a Health Board to be able to make an agreement under section 17C under which primary medical services are provided.

Part 3 of the Regulations sets out the circumstances and the extent to which the provider under an agreement may be treated as a health service body.

Part 4 of the Regulations (and schedules 1 to 3) prescribe the categories of primary medical services that may be provided in accordance with section 17C arrangements, and make provision with respect to the provision of those services. The regulations require agreements which include the provision of any primary medical services to contain the terms in schedule 1, agreements which include the provision of essential services to include the terms in schedule 2, and agreements which include the provision of additional services to include terms set out in schedule 3.

Part 5 makes additional provision with respect to such agreements and their content, including provision as to the effect on an agreement of a change in the membership of a partnership that is party to it (regulation 17), provision for termination of the agreement (regulation 18), services generally (regulation 19), certificates (regulation 20), the terms applicable to agreements which provide for a payment in respect of premises costs (regulation 21), finance and payments for the provision of services to be made in accordance with the directions of the Scottish Ministers (regulation 22 and 23), fees and charges (regulation 24) and terms to be implied if omitted from the express terms of an agreement (regulation 25).

Part 6 sets out the functions of the Area Medical Committee in relation to the operation of section 17C agreements.

Part 7 of the Regulations makes provision requiring a Health Board in certain circumstances and subject to certain conditions, to enter into a general medical services contract with a person providing services under section 17C arrangements.

Part 8 of the Regulations makes transitional provision for persons continuing to provide out of hours services, notwithstanding the repeal of the National Health Service (Primary Medical Services Section 17C Agreements)(Scotland) Regulations 2004.

Schedule 1 sets out terms that must be contained in all section 17C agreements for primary medical services. These include terms relating to—

(a) the provision of services (Part 1);

(b) the right of patients to choose the persons from whom they are to receive primary medical services, and the circumstances in which providers may decline responsibility for patients not registered with them (Part 2);

(c) the prescribing and dispensing of drugs, medicines and appliances (Part 3);

(d) the conditions (including conditions as to qualifications and experience) to be satisfied by persons performing primary medical services in accordance with section 17C arrangements (Part 4);

(e) patient records, the provision of information and rights of entry (Part 5);

(f) complaints (Part 6);

(g) procedures for the determination of disputes where the provider is to be treated as a health service body, or where the provider elects (Part 7); and

(h) the variation and termination of section 17C arrangements by either the Health Board or another participant (Part 8);

(i) clinical governance, medical indemnity insurance, public liability, the requirement to keep a register of gifts, compliance by providers with legislation and guidance, third party rights and the duty of candour (Part 9); and

(j) quality arrangements (Part 10).

Schedule 2 sets out the terms that must be contained in all section 17C agreements which include the provision of essential services. These include terms relating to—

(a) the provision of essential services; and

(b) lists of patients, and the circumstances in which the provider must or may accept or may decline to accept a person as a patient and may terminate responsibility a patient.

Schedule 3 sets out the terms relating to the provision of additional services that must be included in all agreements for the provision of those services.

Schedule 4 sets out the minimum standards to which a practice premises must adhere, if the provider receives financial assistance with their premises costs.

Schedule 5 sets out the closure notice with which a provider may notify the Health Board that the provider wishes to close its list to new patients.

Schedule 6 sets out the information to be included in a provider's practice leaflet.

Schedule 7 revokes provisions which are re-enacted or replaced by the making of these Regulations.

Schedule 8 makes amendments to existing legislation consequential to making of these Regulations and the revocation of the National Health Service (Primary Medical Services Section 17C Agreements)(Scotland) Regulations 2004.

(1)

1978 c.29. Section 17A was inserted by section 30 of the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"). Section 17A was moved under a new heading entitled "NHS Contracts" by section 31 of the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"). Section 17CA was inserted by section 38 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3). Section 17D was inserted by section 21(2) of the 1997 Act and section 17D(3) was amended by section 2(3) of the Primary Medical Services (Scotland) Act 2004 (asp 1) ("the 2004 Act"). Section 17E was inserted by section 22(2) of the 1997 Act and amended by paragraph 47 of schedule 4, and paragraph 1 of schedule 5 of the Health Act 1999 (c.8) ("the 1999 Act"), and section 2(4) of the 2004 Act. Section 28 was relevantly amended by section 3(4) of the National Health Service (Amendment) Act 1986 (c.66), paragraph 19(8) of schedule 9 of the 1990 Act, and paragraph 1(8) of schedule 1 of the 2004 Act. Section 105(7) was amended by paragraph 5 of schedule 6, and schedule 7, of the Health Services

Act 1980 (c.53), and paragraph 24 of schedule 9 of the Health and Social Services and Social Security Adjudications Act 1983 (c.41), and paragraph 60 of schedule 4 of the 1999 Act. Section 108(1) contains a definition of "prescribed" and "regulations" relevant to the statutory powers under which these Regulations are made. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

(2)

S.S.I. 2004/116, as amended by paragraph 19 of schedule 4 of the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), and by S.S.I. 2004/162, S.S.I. 2004/217, S.S.I. 2005/336, S.S.I. 2006/248, S.S.I. 2007/205, S.S.I. 2007/393, S.S.I. 2007/502, S.S.I. 2009/183, S.S.I. 2010/93, S.S.I./2010/395, S.I. 2010/231, S.I. 2010/234, S.S.I. 2011/55, S.S.I. 2011/211, S.I. 2012/1479, S.I. 2012/1916, S.S.I. 2012/10, S.S.I. 2012/36, S.I. 2013/235, S.I. 2014/1887, S.S.I. 2014/73, S.S.I. 2014/148, S.S.I. 2016/393 and S.S.I. 2016/696.

(3)

1998 c.29.

(4)

2004 asp 1.

(5)

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.

(6)

Section 17C was inserted by section 21(2) of the National Health Service (Primary Care) Act 1997 (c.46), and amended by section 2(2) of the Primary Medical Services (Scotland) Act 2004 (asp 1), and paragraph 3 of schedule 21 of the Health and Social Care Act 2012 (c.7).

(7)

Section 27(1) was amended by section 20 of the Health Services Act 1980 (c.53), paragraph 19 of schedule 9 of the National Health Service and Community Care Act 1990 ("the 1990 Act"), section 3 of the Medicine Products: Prescription by Nurses etc. Act 1992 (c.28), paragraph 44 of schedule 2 of the National Health Service (Primary Medical Services Act 1997, and section 44 of the Health and Social Care Act 2001 (c.15).

(8)

Section 9 was amended by section 29(5) of the 1990 Act, and paragraph 43 of schedule 4 of the Health Act 1999.

(9)

2010 asp 8.

(10)

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

(11)

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

(12)

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

(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.

(16)

Section 17J was inserted into the Act by section 4 of the 2004 Act.

(17)

S.S.I. 2018/66.

(18)

1983 c.54. Section 34I was inserted into the Act by S.I. 2010/234.

(19)

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).

(20)

2009 c.1.

(21)

Section 17D(2) was inserted into the Act by section 21(2) of the National Health Service (Primary Care) Act 1997, and was amended by section 2(3) of the 2004 Act.

(22)

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, and 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 2003 (c.43) and paragraph 2 of schedule 21 of the Health and Social Care Act 2012.

(23)

1995 c.36.

(24)

S.I. 2012/1916.

(25)

2000 c.12. Section 2 was amended by S.I. 2009/1804 and S.I. 2016/340.

(26)

1907 c.24. Section 5 was amended by S.I. 2009/1940.

(27)

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](#)).

(28)

[2006 c.42](#).

(29)

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](#).

(30)

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

(31)

Section 30 was amended by section 159 of the Health and Social Care Act 2012 ([c.7](#)).

(32)

[S.I. 2002/253](#).

(33)

[S.I. 2002/254](#), as retitled by the Health and Social Care Act 2012 ([c.7](#)), section 213(6). Article 5 was amended by [S.I. 2009/1182](#).

(34)

[S.S.I. 2009/183](#).

(35)

[S.I. 2010/231](#).

(36)

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

(37)

[S.I. 2012/1916](#).

(38)

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

(39)

[2009 c.1](#).

(40)

[S.I. 2010/231](#).

(41)

[S.I. 1976/1213 \(N.I. 22\)](#) as relevantly amended by [S.R. 2008/192](#), regulations 5 and 9.

(42)

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

(43)

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

(44)

Section 29 was substituted by the Health Act 1999 (c.8) section 58(1) and amended by the Community Care and Health (Scotland) Act 2002 (asp 5), schedule 1, paragraph 2(4), the 2004 Act, section 5, and the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) section 26(2) and schedule 2, paragraph 2.

(45)

Section 32A was inserted into the Act by section 8 of the National Health Service (Amendment) Act 1995 (c.31) ("the 1995 Act"), and amended by paragraph 51 of schedule 4 of the Health Act 1999 (c.8) ("the 1999 Act"), and section 26(7) of the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) ("the 2005 Act").

(46)

Section 32B was inserted into the Act by section 8 of the 1995 Act, and substituted by paragraph 52 of schedule 4 of the 1999 Act, and amended by paragraph 1 of schedule 3 of the 2005 Act.

(47)

1995 c.46.

(48)

1933 c.12. Schedule 1 was amended by paragraph 52 of schedule 4 of the Sexual Offences Act 1956 (c.69), paragraph 170(2) of schedule 16 of the Criminal Justice Act 1988 (c.33), paragraph 7 of schedule 6 of the Sexual Offences Act 2003 (c.42) and paragraph 1 of schedule 5 of the Modern Slavery Act 2015 (c.3).

(49)

1986 c.45. Schedule 4A was inserted by section 257 and paragraph 1 of schedule 20 of the Enterprise Act 2002 (c.40) ("the 2002 Act") and was amended by paragraph 63 of the Enterprise and Regulatory Reform Act 2013 (c.24).

(50)

S.I. 1989/2405 (N.I. 19). Schedule 2A was inserted by S.I. 2005/1455.

(51)

1985 c.66. Sections 56A to 56 K were inserted by section 2(1) of the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3), amended by the Bankruptcy and Debt Advice (Scotland) Act 2014 (asp 11) and repealed by Part 1 of schedule 9 of the Bankruptcy (Scotland) Act 2016 (asp 21).

(52)

Schedule B1 was inserted by paragraph 1 of schedule 16 of the 2002 Act.

(53)

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

(54)

1986 c.46, as relevantly amended by section 5 and paragraph 2 of schedule 4 of the Insolvency Act 2000 (c.39), section 204 of the Enterprise Act 2002 ("the 2002 Act") and paragraph 2 of schedule 7 of the Small Business, Enterprise and Employment Act 2015 (c.26) ("the 2015 Act").

(55)

S.I. 2002/3150 (N.I. 4), as relevantly amended by paragraph 9 of schedule 8 of the 2015 Act.

(56)

Section 429(2) was amended by paragraph 15 of schedule 23 of the 2002 Act.

(57)

S.I. 2015/1862.

**(58)**

Section 17CA was inserted into the Act by section 38 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3).

**(59)**

1983 c.54. Section 34C was inserted by S.I. 2010/234.

**(60)**

Section 17D was inserted by section 21(2) of the National Health Service (Primary Care) Act 1997 (c.46) and amended by section 2(3) of the Primary Medical Services (Scotland) Act 2004 (asp 1).

**(61)**

Section 17A was inserted into the Act by section 30 of the National Health Service and Community Care Act 1990 (c.19). Section 17A was moved under a new heading entitled "NHS Contracts" by section 31 of the National Health Service (Primary Care) Act 1997 (c.46).

**(62)**

Section 17A was inserted into the Act by section 30 of the National Health Service and Community Care Act 1990 and amended by paragraph 102 of schedule 1 of the Health Authorities Act 1995 (c.17), paragraph 36 of schedule 2 of the National Health Service (Primary Care) Act 1997 (c.46), paragraph 46 of schedule 4 and paragraph 1 of schedule 5 of the Health Act 1999 (c.8), 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 (asp 8), and paragraph 2 of schedule 21 of the Health and Social Care Act 2012 (c.7).

**(63)**

S.I. 1976/615. Regulation 2(1) was substituted by S.I. 2010/137.

**(64)**

S.I. 1985/1604. Regulation 2(1) was substituted by S.I. 2010/137.

**(65)**

"Health care professional" includes nurses and midwives registered with the Nursing and Midwifery Council.

**(66)**

Section 2(5) was amended by paragraph 19 of schedule 9 of the National Health Service and Community Care Act 1990 (c.19). Section 17E(3A) was inserted by section 2(4) of the Primary Medical Services (Scotland) Act 2004.

**(67)**

Section 2(5) was amended by paragraph 19 of schedule 9 of the National Health Service and Community Care Act 1990.

**(68)**

Section 17L was inserted by section 4 of the Primary Medical Services (Scotland) Act 2004 (asp 1) and substituted by section 39 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3).

**(69)**

The current version of the guidance is version 3.0, December 2017, and is available at <http://www.hps.scot.nhs.uk/resourcedocument.aspx?id=6330>.

**(70)**

1995 c.36.

**(71)**

2000 asp 4.

**(72)**

1971 c.38. Section 2 (Controlled drugs and their classification for purposes of this Act.) was relevantly amended by paragraph 2(a) of schedule 17 of the Police Reform and Social Responsibility Act 2011 (c.13).

**(73)**

S.I. 2001/3998. Schedule 4 was amended by S.I. 2009/3136 and S.I. 2013/625. Schedule 5 was amended by S.I. 2005/2864.

**(74)**

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

**(75)**

S.I. 2012/1916.

**(76)**

1968 c.67. Part 3 was amended by section 1(1) to (3) of the Medicinal Products: Prescription by Nurses etc Act 1992 (c.28), section 63 of the Health and Care Social Care Act 2001 (c.5), section 220 of the Health and Social Care Act 2012 (c.7), S.I. 1984/187, S.I. 1993/2538, 1994/105, 1994/3142, 1994/3144, 1997/322, 1998/108, S.I. 2002/236, 2002/253, 2003/1590, 2004/1771, 2005/2789, 2006/1916, 2006/2407 and S.I. 2012/1916.

**(77)**

1983 c.54. Section 41A was inserted by S.I. 2000/1803 and amended by S.I. 2002/3135, 2006/1914 and 2015/794.

**(78)**

Section 15 was substituted by S.I. 2006/1914; section 15A was inserted by S.I. 2000/3041 and amended by S.I. 2006/1914, 2007/3101 and 2011/1043; section 21 was amended by S.I. 2002/3135, 2006/1914 and 2007/3103.

**(79)**

Section 44D was inserted by S.I. 2006/1914.

**(80)**

S.S.I. 2004/114 as relevantly amended by S.I. 2010/234.

**(81)**

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**(82)**

NHS Education for Scotland was constituted by S.S.I. 2002/103, as relevantly amended by S.S.I. 2006/79, which applies section 2(5) of the National Health Service (Scotland) Act 1978 to NHS Education for Scotland as it applies to Health Boards.

**(83)**

The current guidance is PCS(GPR) 2009/1 which is available at [http://www.sehd.scot.nhs.uk/pcs/PCS2009\(GPR\)01.pdf](http://www.sehd.scot.nhs.uk/pcs/PCS2009(GPR)01.pdf) as amended by PCS(GPR) 2011/1, which is available

at [http://www.sehd.scot.nhs.uk/pcs/PCS2011\(GPR\)01.pdf](http://www.sehd.scot.nhs.uk/pcs/PCS2011(GPR)01.pdf) as amended by PCS (GPR) 2015/1 which is available at [http://www.sehd.scot.nhs.uk/pcs/PCS2015\(GPR\)01.pdf](http://www.sehd.scot.nhs.uk/pcs/PCS2015(GPR)01.pdf).

(84)

Published by the then Scottish Executive as NHS Circular PCA(M)(2001)(17), copies available at [http://www.sehd.scot.nhs.uk/pca/pca2001\(m\)17.htm](http://www.sehd.scot.nhs.uk/pca/pca2001(m)17.htm).

(85)

Section 17CA was inserted by section 38 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3).

(86)

Section 35 was substituted by section 34(2) of the National Health Service (Primary Care) Act 1997 (c.46) and amended by paragraph 1 of schedule 1 of the 2004 Act.

(87)

S.I. 2002/254 which was relevantly amended by S.I. 2009/1182. The title of this Order is the Health and Social Work Professions Order 2001 in accordance with section 213(4) of the Health and Social Care Act 2012 c.7.

(88)

Section 17CA(3) and (4) were inserted by section 38 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3).

(89)

Section 2C was inserted into the Act by section 1(2) of the 2004 Act.

(90)

1986 c.45.

(91)

Section 17D was inserted by section 21 of the National Health Service (Primary Care) Act 1997 (c.46), and relevantly amended by section 2(3) of the 2004 Act, paragraph 6 of schedule 2(2) of the Tobacco and Primary Care Act 2010 (asp 3) and S.S.I. 2006/30.

(92)

Section 17CA was inserted into the Act by section 38 of the Tobacco and Medical Services (Scotland) Act 2010 (asp 3).

(93)

2011 asp 5.

(94)

Established under section 1H of the National Health Service Act 2006 (c.41). Section 1H was inserted by section 9(1) of the Health and Social Care Act 2012 (c.7), and was amended by S.I. 2012/1831.

(95)

1994 c.39.

(96)

1970 c.42. Section 1 was amended by section 195 of the Local Government Act 1972 (c.70), and by paragraph 7 of schedule 10 of the Local Government (Wales) Act 1994 (c.19).

(97)

<https://www.bma.org.uk/about-us/how-we-work/local-representation/local-medical-committees>.

**(98)**

Section 17A was inserted by section 30 of the National Health Service and Community Care Act (c.19), and moved under a new heading entitled "NHS Contracts" by section 31(2) of the National Health Service (Primary Care) Act 1997 (c.46).

**(99)**

2011 asp 5.

**(100)**

2016 asp 14.

**(101)**

Sections 32A(2) and 32B(1) were inserted into the Act by section 8 of the National Health Service (Amendment) Act 1995 (c.31). Section 32A was amended by paragraph 51 of schedule 4 of the Health Act 1999 (c.8) ("the 1999 Act"), and section 26(7) of the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) ("the 2005 Act"). Section 32B(1) was amended by paragraph 52 of schedule 4 of the 1999 Act and paragraph 1 of schedule 3 of the 2005 Act.

**(102)**

S.S.I. 2004/114. Regulation 8A was inserted by S.S.I. 2011/392.

**(103)**

1995 c.46. Schedule 4A was added by section 257 and schedule 20 of the Enterprise Act 2002 (c.40) ("the 2002 Act").

**(104)**

1933 c.12 as amended by section 170 and paragraph 8 of schedule 15 and schedule 16 of the Criminal Justice Act 1988 (c.33); schedules 3 and 4 of the Sexual Offences Act 1956 (c.69); paragraph 7 of schedule 6 of the Sexual Offences Act 2003 (c.42); paragraph 2 of schedule 10 of the Domestic Violence, Crime and Victims Act 2004 (c.28); paragraph 53 of schedule 21 of the Coroners and Justice Act 2009 (c.25) and paragraph 1 of schedule 5 of the Modern Slavery Act 2015 (c.30).

**(105)**

1986 c.45 was inserted by section 257 and schedule 20 of the 2002 Act.

**(106)**

1985 c.66. Sections 56A to 56K were substituted by section 33 of the Bankruptcy and Debt Advice (Scotland) Act 2014 (asp 11) and repealed by the Bankruptcy (Scotland) Act 2016 (asp 21).

**(107)**

2016 asp 21.

**(108)**

1986 c.45. Schedule B1 was inserted by paragraph 1 of schedule 16 of the 2002 Act.

**(109)**

2005 asp 10.

**(110)**

1986 c.46, as relevantly amended by section 5 and paragraph 2 of schedule 4 of the Insolvency Act 2000 (c.39), section 204 of the 2002 Act and paragraph 2 of schedule 7 of the Small Business, Enterprise and Employment Act 2015 (c.26).

**(111)**

S.I. 2002/3150 (N.I. 4), as relevantly amended by paragraph 9 of schedule 8 of the Small Business, Enterprise and Employment Act 2015.

**(112)**

Section 429(2) was amended by paragraph 15 of schedule 23 of the Enterprise Act 2002.

**(113)**

S.I. 2015/1862.

**(114)**

Section 17CA was inserted by section 38 of the Tobacco and Primary Medical Services (Scotland) Act 2010 (asp 3).

**(115)**

2016 asp 14.

**(116)**

S.S.I. 20185/57 are made under section 22 of the 2016 Act.

**(117)**

World Health Organisation, 2010 ISBN 9789241548342.

**(118)**

1995 c.36.

**(119)**

2000 asp 4.

**(120)**

Established under section 1H of the National Health Service Act 2006 (c.41). Section 1H was inserted by section 9(1) of the Health and Social Care Act 2012 (c.7) and was amended by S.I. 2012/1831.

**(121)**

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

**(122)**

David Hall and David Elliman, January 2003, Oxford University Press, ISBN 10: 01985188X, ISBN 13: 9780198515883.

**(123)**

1974 c.37.

**(124)**

2010 c.15.

**(125)**

S.S.I. 2004/406 as amended by S.S.I. 2006/534, S.S.I. 2008/310, S.S.I. 2009/119, S.S.I. 2010/32, S.S.I. 2011/120, 2011/211, S.S.I. 2012/209, S.S.I. 2013/143, S.S.I. 2014/219, S.I. 2014/1638, S.S.I. 2015/218, S.S.I. 2016/70, S.S.I. 2016/71 and S.S.I. 2017/188.

**(126)**

S.I. 2013/235.

**(127)**

S.S.I. 2004/114.

**(128)**

S.S.I. 2004/163.

**(129)**

S.S.I. 2009/183.

**(130)**

S.S.I. 2012/36.

**(131)**

S.S.I. 2014/344.