

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

2023 No. 953 (W. 155)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (General Medical Services
Contracts) (Wales) Regulations 2023

(as in force at 01.10.24)

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The Welsh Ministers make the following Regulations in exercise of the powers conferred on them by sections 7(8), 41(3), (5) and (6), 43, 44, 47, 48(1) and (3), 54(6) and (7), 135 and 203(9) and (10) of the National Health Service (Wales) Act 2006(1).

PART 1 General

Title and commencement

1.—(1) The title of these Regulations is the National Health Service (General Medical Services Contracts) (Wales) Regulations 2023.

(2) These Regulations come into force on 1 October 2023.

Application

2. These Regulations apply in relation to Wales and to a contract—

(a) to which the 2004 Regulations(2) applied immediately before the date on which these Regulations come into force, or

(b) which is entered into between a contractor and a Local Health Board on or after that date.

Interpretation

3.—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the National Health Service (Wales) Act 2006;

“the 2004 Regulations” (“*Rheoliadau 2004*”) means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004;

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

“accredited course” (“*cwrs a achredwyd*”) means a course accredited by the Nursing and Midwifery Council;

“adjudicator” (“*dyfarnwr*”) means the Welsh Ministers or a person appointed by the Welsh Ministers under section 7(8) of the Act (NHS contracts) or paragraph 106(5) of Schedule 3;

“advanced electronic signature” (“*llofnod electronig uwch*”) means an electronic signature which meets the following requirements—

(a) it is uniquely linked to the signatory,

(b) it is capable of identifying the signatory,

(c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under the signatory’s sole control, and

(d) it is linked to the data signed in such a way that any subsequent change in the data is detectable;

“APMS contract” (“*contract GMDdA*”) means an arrangement to provide primary medical services made with a Local Health Board under section 41(2)(b) of the Act (primary medical services);

“APMS contractor” (“*contractwr GMDdA*”) means a party to an APMS contract, other than the Local Health Board;

“appliance” (“*cyfarpar*”) means an appliance which is included in a list approved by the Welsh Ministers for the purposes of section 80 of the Act (arrangements for pharmaceutical services);

“armed forces of the Crown” (“*lluoeedd arfog y Goron*”) means the forces that are “the regular forces” or “the reserve forces” within the meaning given to those terms in section 374 of the Armed Forces Act 2006(5) (definitions applying for the purposes of the whole Act);

“assessment panel” (“*panel asesu*”) means a committee or sub-committee of a Local Health Board (other than the Local Health Board which is a party to the contract in question) for the purpose of making determinations under paragraph 45(7) of Schedule 3;

“Assurance Framework” (“*Fframwaith Sicwydd*”) means the national approach, using national datasets and processes, specified in guidance issued from time to time by the Welsh Ministers for Local Health Boards to use for contract governance and management;

“authorised person” (“*person awdurdodedig*”) means, in relation to a patient, a person who is entitled to make an application for pharmaceutical services on behalf of the patient by virtue of regulation 62(a) to (d) of the Pharmaceutical Regulations (exercise of choice in certain cases);

“batch issue” (“*swpddyroddiad*”) means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable an NHS pharmacist or NHS appliance contractor to receive payment for the provision of repeat dispensing services which is in the required format, and which—

(a)

is generated by a computer and not signed by a repeatable prescriber,

(b)

relates to a particular non-electronic repeatable prescription and contains the same date as that prescription,

(c)

is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided, and

(d)

specifies a number denoting its place in the sequence referred to in paragraph (c);

“care home” (“*cartref gofal*”) means a place in Wales at which accommodation, together with nursing or care, is provided to persons because of their vulnerability or need but excludes a place mentioned in paragraph 1(2) of Schedule 1 to the Regulation and Inspection of Social Care (Wales) Act 2016(6);

“CCT” (“*TCH*”) means Certificate of Completion of Training awarded under section 34L(1) of the Medical Act 1983(7) (award and withdrawal of a Certificate of Completion of Training);

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

"child" (*"plentyn"*) means a person who has not attained the age of 16;

"child health surveillance services" (*"gwasanaethau gwyliadwriaeth iechyd plant"*) means the services described in paragraph 2 of Schedule 2;

"childhood vaccinations and immunisations services" (*"gwasanaethau brechu ac imiwneiddio i blant"*) means the services described in paragraph 3 of Schedule 2;

"clinical services" (*"gwasanaethau clinigol"*) means medical services under the contract which relate to the actual observation and treatment of patients;

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

"cluster" (*"clwstwr"*) means a group of local service providers involved in health and care who have agreed to collaboratively work together to deliver primary medical services across a specified geographical area;

"contraceptive services" (*"gwasanaethau atal cenhedlu"*) means the services described in paragraph 4 of Schedule 2;

"contract" (*"contract"*) except in regulation 31 (general transitional provision and saving) means a general medical services contract made under section 42 of the Act (general medical services contracts: introductory);

"contractor" (*"contractwr"*), except in regulation 6 (general condition relating to all contracts), has the meaning given in section 42(5) of the Act (general medical services contracts: introductory);

"contractor's list of patients" (*"rhestr contractwr o gleifion"*) means the list prepared and maintained by the Local Health Board under paragraph 22 of Schedule 3;

"core hours" (*"oriau craidd"*) means the period beginning with 8.00am and ending with 6.30pm on a working day;

"dentist" (*"deintydd"*) means a dental practitioner registered in the dentists register under section 14 of the Dentists Act 1984(8);

"Digital Health and Care Wales" (*"Iechyd a Gofal Digidol Cymru"*) means the organisation established under the Digital Health and Care Wales (Establishment and Membership) Order 2020(9);

"dispenser" (*"gweinyddydd"*) means an NHS pharmacist, medical practitioner or contractor whom a patient wishes to dispense the patient's electronic prescriptions;

"dispensing doctor" (*"meddyg fferyllol"*) has the same meaning given to it by regulation 2(1) of the Pharmaceutical Regulations (interpretation);

“dispensing services” (*“gwasanaethau gweinyddu”*) means the provision of drugs, medicines or appliances that may be provided as pharmaceutical services by a medical practitioner in accordance with arrangements under section 80 (arrangements for pharmaceutical services) and section 86 (persons authorised to provide pharmaceutical services) of the Act;

“Drug Tariff” (*“Tariff Cyffuriau”*) means the publication known as the Drug Tariff which is referred to in section 81(4) of the Act (arrangements for additional pharmaceutical services);

“electronic communication” (*“cyfathrebiad electronig”*) has the meaning given by section 15(1) of the Electronic Communications Act 2000(**10**) (general interpretation);

“electronic prescription” (*“presgripsiwn electronig”*) means an electronic prescription form or an electronic repeatable prescription;

“electronic prescription form” (*“ffurflen bresgripsiwn electronig”*) means data created in an electronic form for the purpose of ordering a drug or appliance which—

(a)

is signed, or is to be signed, with a prescriber’s advanced electronic signature,

(b)

is transmitted, or is to be transmitted, as an electronic communication to a nominated dispenser by the ETP service, or via an information hub by the Electronic Prescription Service, and

(c)

does not indicate that the drug or appliance ordered may be provided more than once;

“Electronic Prescription Service” (*“Gwasanaeth Presgripsiynau Electronig”*) means the service of that name which is managed by NHS England;

“electronic repeatable prescription” (*“presgripsiwn amlroddadwy electronig”*) means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription”;

“electronic signature” (*“llofnod electronig”*) means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;

“electronic signature creation data” (*“data creu llofnod electronig”*) means unique data which is used by the signatory to create an electronic signature;

“EPS token” (*“tocyn GPE”*) means a form (which may be an electronic form), approved by the Secretary of State, which—

(a)

may be issued by a prescriber at the same time as an electronic prescription is created, and

(b)

has a barcode or unique identifier that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispenser;

“ETP service” (“*gwasanaeth TPE*”) means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;

“general medical practitioner” (“*ymarferydd meddygol cyffredinol*”) means a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council under section 2 of the Medical Act 1983(11) (registration of medical practitioners);

“the General Pharmaceutical Council” (“*y Cyngor FferylloI Cyffredinol*”) means the body established under article 4(1) of the Pharmacy Order 2010 (the Council and its committees);

“the General Pharmaceutical Council Register” (“*Cofrestr y Cyngor FferylloI Cyffredinol*”) means the register established and maintained under article 19 of the Pharmacy Order 2010 (establishment, maintenance of and access to the Register);

“General Practice Escalation Tool” (“*Offeryn Uwchgyfeirio Ymarfer Cyffredinol*”) means the tool agreed by Welsh Ministers, Local Health Boards and the Welsh General Practitioners Committee containing a framework for reporting pressures on service delivery within practices;

“global sum” (“*swm craidd*”) is to be interpreted in accordance with Part 2 of the GMS Statement of Financial Entitlements;

“GMS contract” (“*contract GMC*”) means a general medical services contract under section 42 of the Act (general medical services contracts: introductory);

“GMS contractor” (“*contractwr GMC*”) means a party to a GMS contract, other than the Local Health Board;

“GMS Statement of Financial Entitlements” (“*Datganiad ar Hawlogaethau Ariannol yr GMC*”) means the Directions to Local Health Boards as to the Statement of Financial Entitlements given by Welsh Ministers under section 45 of the Act (GMS contracts: payments);

“GP Collaborative” (“*Cydweithredfa Ymarfer Cyffredinol*”) means a group of primary medical service providers working together, within the area in which the registered patients of those primary medical service providers reside, to deliver co-ordinated primary medical services in that area, and to promote the wellbeing of patients across the area in which the registered patients of those primary medical service providers reside;

“GP Specialty Registrar” (“*Cofrestrydd Arbenigol Ymarfer Cyffredinol*”) 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(12) for the purpose of providing training under that section, whether as part of training leading to the award of a CCT or otherwise;

“the Health and Care Professions Council” (“*y Cyngor Proffesiynau Iechyd a Gofal*”) is the body established under article 3(1) of the Health Professions Order 2001 (the Health and Care Professions Council and its committees);

“the Health and Care Professions Council Register” (“*Cofrestr y Cyngor Proffesiynau Iechyd a Gofal*”) is the register established and maintained under article 5(1) of the Health Professions Order 2001 (registration);

“Health and Social Care Trust” (“*Ymddiriedolaeth Iechyd a Gofal Cymdeithasol*”) means a Health and Social Care Trust established under article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991(**13**) (Health and Social Care trusts);

“Health Board” (“*Bwrdd Iechyd*”) means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(**14**) (Health Boards);

“health care professional” (“*proffesiynolyn gofal iechyd*”) means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**15**);

“health service body” (“*corff gwasanaeth iechyd*”) has the meaning given in section 7(4)(**16**) of the Act (NHS contracts);

“home oxygen order form” (“*ffurflen archebu ocsigen cartref*”) means a form provided by a Local Health Board and issued by a health care professional to authorise a person to supply home oxygen services to a patient requiring oxygen therapy at home;

“home oxygen services” (“*gwasanaethau ocsigen cartref*”) means any of the following forms of oxygen therapy or supply—

- (a) ambulatory oxygen supply,
- (b) urgent supply,
- (c) hospital discharge supply,
- (d) long term oxygen therapy, and
- (e) short burst oxygen therapy;

“immediate family member” (“*aelod o deulu agos*”) means—

- (a) a spouse or civil partner,
- (b) a person (whether or not of the opposite sex) whose relationship with the registered patient has the characteristics of the relationship between husband and wife,
- (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 a local authority to whose care the child has been committed under the Children Act 1989(**17**), or
 - (iii) a grandparent;

“independent nurse prescriber” (“*nyrs sy'n rhagnodi'n annibynnol*”) means a person—

- (a) who is registered in the Nursing and Midwifery Register, and

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

“LHBMS practice” (“*practis GMBILl*”) means a practice providing Local Health Board Medical Services;

“licensing body” (“*corff trwyddedu*”) means a body that licenses or regulates a profession;

“limited partnership” (“*partneriaeth gyfyngedig*”) means a partnership registered in accordance with section 5 of the Limited Partnerships Act 1907(19) (registration of limited partnerships required);

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means the Local Health Board which is a party, or prospective party, to a contract;

“Local Health Board Medical Services” (“*Gwasanaethau Meddygol Bwrdd Iechyd Lleol*”) means primary medical services provided by a Local Health Board under section 41(2)(a) of the Act (primary medical services);

“Local Medical Committee” (“*Pwyllgor Meddygol Lleol*”) means a committee recognised under section 54 of the Act (Local Medical Committees);

“local pharmaceutical services” (“*gwasanaethau fferyllol lleol*”) has the meaning given by regulation 2(1) of the Pharmaceutical Regulations;

“maternity medical services” (“*gwasanaethau meddygol mamolaeth*”) means the services described in paragraph 5 of Schedule 2;

“medical performers list” (“*rhestr cyflawnwyr meddygol*”) means a list of medical practitioners prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004(20);

“medical practitioner” (“*ymarferydd meddygol*”) has the meaning given by section 206(1) of the Act;

“Medical Register” (“*Cofrestr Feddygol*”) means the register kept under section 2 of the Medical Act 1983(21) (registration of medical practitioners);

“minor surgery” (“*mân lawdriniaeth*”) means the services described in paragraph 6 of Schedule 2;

“national disqualification” (“*anghymhwysiad cenedlaethol*”) means—

(a) a decision made by the First Tier Tribunal under section 115 of the Act (national disqualification) or under regulations corresponding to that section made under—

(i) section 49 of the Act (persons performing primary medical services),

(ii) section 63 of the Act (persons performing primary dental services),

(iii) section 72 of the Act (regulations as to general ophthalmic services), and

(iv) section 83 (regulations as to pharmaceutical services, 86 (persons authorised to provide pharmaceutical services), 103 (application of enactments) or 105 (supplementary lists) of the Act, or

(b) any decision in England, Scotland or Northern Ireland corresponding to a national disqualification under section 115(2) and (3) of the Act;

"NHS appliance contractor" (*"contractwr cyfarpar GIG"*) means a person who is included in a pharmaceutical list under regulation 10 of the Pharmaceutical Regulations (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;

"NHS contract" (*"contract GIG"*) has the meaning given to it by section 7 of the Act;

"NHS dispute resolution procedure" (*"gweithdrefn datrys anghydfodau'r GIG"*) means the procedure for resolution of disputes specified—

- (a) in paragraphs 106 and 107 of Schedule 3, or
- (b) in a case to which paragraph 46 of Schedule 3 applies, in that paragraph;

"NHS pharmacist" (*"fferyllydd GIG"*) means—

- (a) a registered pharmacist, or
- (b) person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(22),

whose name is included in a pharmaceutical list under regulation 10 of the Pharmaceutical Regulations (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;

"nominated dispenser" (*"gweinyddydd enwebedig"*) means an NHS pharmacist, medical practitioner or contractor who has been nominated in respect of a patient where the details of that nomination are held in respect of that patient in the Personal Demographic Service which is managed by NHS England;

"non-electronic prescription form" (*"ffurflen bresgripsiwn anelectronig"*) means a prescription form which falls within paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" (*"presgripsiwn amlroddadwy anelectronig"*) means a prescription which falls within paragraph (a)(i) of the definition of "repeatable prescription";

"nurse independent prescriber" (*"nyrs-ragnodydd annibynnol"*) means a person—

- (a) who is either engaged or employed by a contractor or is a party to a contract,
- (b) whose name is registered in the Nursing and Midwifery Register,
- (c) against whose name in that register is recorded an annotation or entry signifying that they are qualified to order drugs, medicines and appliances as—
 - (i) a nurse independent prescriber, or
 - (ii) a nurse independent/supplementary prescriber, and

who, in respect of a person practising in Wales on or after 19 July 2010, has passed an accredited course to practise as a nurse independent prescriber;

"Nursing and Midwifery Register" (*"Cofrestr Nyrsio a Bydwreigiaeth"*) means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(23) (establishment and maintenance of register);

"online practice profile" (*"proffil practis ar-lein"*) means a profile—

- (a) which is on a website (other than an NHS website), or online platform, provided by another person for use by the contractor, and
- (b) through which the contractor advertises the primary medical services it provides;

“online resource” (*“adnodd ar-lein”*) means a practice website or online practice profile;

“open” (*“agored”*), in relation to a contractor's list of patients, means open to applications from patients in accordance with paragraphs 23, 24 and 25 of Schedule 3;

“optometrist independent prescriber” (*“optometrydd-ragnodydd annibynnol”*) means a person—

- (a) who is an optometrist registered in the register of optometrists maintained under section 7 of the Opticians Act 1989(24) (which relates to the register of optometrists and the register of dispensing opticians) or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a)(83) of that Act, and
- (b) against whose name is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

“out of hours period” (*“cyfnod y tu allan i oriau”*) means any days or times outside of the core hours;

“out of hours services” (*“gwasanaethau y tu allan i oriau”*) means services provided in all or part of an out of hours period which would be unified services if provided by a contractor to its registered patients in core hours;

“paramedic independent prescriber” (*“parafeddyg-ragnodydd annibynnol”*) means a person—

- (a) who is either engaged or employed by a contractor or who is a party to a contract,
- (b) who is registered as a paramedic in Part 8 of the Health and Care Professions Council register, and
- (c) against whose name is recorded in Part 8 of that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;

“parent” (*“rhiant”*) includes, in relation to any child, any adult who, in the opinion of the contractor, is for the time being discharging in respect of that child the obligations normally attaching to a parent in respect of their child;

“patient” (*“claf”*) means—

- (a) a registered patient,
- (b) a temporary resident,
- (c) persons to whom the contractor is required to provide immediately necessary treatment under regulation 17(7) or (9), and
- (d) any other person to whom the contractor has agreed to provide services under the contract;

“performer” (*“cyflawnydd”*) means a performer of medical services under the contract to whom the provisions of Part 6 of Schedule 3 apply;

“Pharmaceutical Regulations” (*“Rheoliadau Fferyllol”*) means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(25);

"pharmaceutical services" (*"gwasanaethau fferyllol"*) means pharmaceutical services that fall within sections 80 and 81 of the Act and includes services which have been arranged as a result of a direction from the Welsh Ministers under the Act;

"pharmacist independent prescriber" (*"fferyllydd-ragnodydd annibynnol"*) means a registered pharmacist—

- (a) who is either engaged or employed by the contractor or is a party to the contract, and
- (b) against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**26**) (which relates to registers and the registrar) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"physiotherapist independent prescriber" (*"ffisiotherapydd-ragnodydd annibynnol"*) means a person—

- (a) who is either engaged or employed by the contractor or is a party to the contract, and
- (b) against whose name in Part 9 of the register maintained under article 5 of the Health Professions Order 2001(**27**) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"podiatrist or chiropodist independent prescriber" (*"podiatrydd-ragnodydd neu giropodydd-ragnodydd annibynnol"*) means a person—

- (a) who is engaged or employed by the contractor or is a party to the contract,
- (b) who is registered in Part 2 of the register maintained under article 5 of the Health Professions Order 2001(**28**) (establishment and maintenance of register), and
- (c) against whose name in Part 2 of that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

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

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

"practice area" (*"ardal practis"*) means the area referred to in regulation [18\(1\)\(d\)](#);

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

"practice website" (*"gwefan practis"*) means a website through which the contractor advertises the primary medical services it provides;

"Pre-employment Checks Standards" (*"Safonau Gwirio Cyn Cyflogaeth"*) means the pre-appointment checks that an employer must undertake as part of their recruitment process before recruiting staff which must at least include the following elements of the NHS Employment Checks Standards published by the NHS Confederation—

- (a) identity checks standard,

- (b) right to work checks standard,
- (c) professional registration and qualification checks standard,
- (d) reference checks standard, and
- (e) criminal record checks standard;

"prescriber" (*"rhagnodydd"*) means a—

- (a) dentist,
- (b) independent nurse prescriber,
- (c) medical practitioner,
- (d) nurse independent prescriber,
- (e) optometrist independent prescriber,
- (f) paramedic independent prescriber,
- (g) pharmacist independent prescriber,
- (h) physiotherapist independent prescriber,
- (i) podiatrist or chiropodist independent prescriber,
- (j) supplementary prescriber, or
- (k) therapeutic radiographer independent prescriber,

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

"prescription form" (*"ffurflen bresgripsiwn"*) means—

- (a) a form provided by a Local Health Board, an NHS Trust, an NHS Foundation Trust or an equivalent body and issued by a prescriber, or
- (b) an electronic prescription form,

that enables a person to obtain pharmaceutical services and does not include a repeatable prescription;

"prescription only medicine" (*"meddyginiaeth a roddir ar bresgripsiwn yn unig"*) means a medicine referred to in regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012;

"primary care list" (*"rhestr gofal sylfaenol"*) means—

- (a) a list of persons performing primary medical or dental services prepared in accordance with regulations made under section 49 or section 63 of the Act,
- (b) a list of persons undertaking to provide or assist in primary medical services, primary dental services, general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under Part 4, Part 5, Part 6, Part 7 or Part 8 of the Act, or
- (c) a list corresponding to any of the above in England, Scotland or Northern Ireland;

"primary carer" (*"prif ofalwr"*) means, in relation to an adult, the adult or organisation primarily caring for that adult;

"primary medical services" (*"gwasanaethau meddygol sylfaenol"*) means medical services provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the Act applies;

“private services” (“*gwasanaethau preifat*”) means the provision of any paid treatment of a type which would usually amount to primary medical services if it were provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the Act apply;

“prohibited act” (“*gweithred waharddedig*”) means committing an offence under the Bribery Act 2010;

“Public Health Wales” (“*Iechyd Cyhoeddus Cymru*”) means the Public Health Wales Trust as established by the Public Health Wales National Health Service Trust (Establishment) Order 2009(**29**);

“registered paramedic” (“*parafeddyg cofrestredig*”) means a person registered in Part 8 of the Health and Care Professions Council register;

“registered patient” (“*claf cofrestredig*”) means—

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

“registered pharmacist” (“*fferyllydd cofrestredig*”) means a person who is registered in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

“registered radiographer” (“*radiograffydd cofrestredig*”) means a person registered in Part 11 of the Health and Care Professions Council register;

“regulatory or supervisory body” (“*corff rheoleiddio neu oruchwylio*”) means any statutory or other body having authority to issue guidance, standards or recommendations with which the contractor, or those persons employed or engaged by it, must comply or have regard, including—

- (a) the Welsh Ministers,
- (b) the Department of Health and Social Care,
- (c) NICE,
- (d) Healthwatch England and Local Healthwatch,
- (e) the UK Health Security Agency,
- (f) the General Pharmaceutical Council,
- (g) the Health Services Safety Investigation Body,
- (h) the Information Commissioner, and
- (i) any other body listed in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002;

“relevant register” (“*cofrestr berthnasol*”) means—

- (a) in relation to a nurse, the Nursing and Midwifery Register,
- (b) in relation to a pharmacist, Part 1 of the register maintained under article 19 (establishment, maintenance of and access to the register) of the Pharmacy Order 2010(**30**) or the register maintained under Article 6 (the Register) and Article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976(**31**),

(c) in relation to an optometrist, the register maintained by the General Optical Council in pursuance of section 7(a) of the Opticians Act 1989 (register of opticians)(**32**), and

(d) the part of the register maintained by the Health and Care Professions Council under article 5 of the Health Professions Order 2001(**33**) (establishment and maintenance of register) relating to—

- (i) chiropodists and podiatrists,
- (ii) paramedics,
- (iii) physiotherapists, or
- (iv) radiographers;

“repeat dispensing services” (*“gwasanaethau amlweinyddu”*) means pharmaceutical services or local pharmaceutical services which involve the provision of drugs, medicines or appliances by an NHS pharmacist or an NHS appliance contractor in accordance with a repeatable prescription;

“repeatable prescribing services” (*“gwasanaethau amlragnod”*) means services which involve the prescribing of drugs, medicines or appliances on a repeatable prescription;

“repeatable prescriber” (*“rhagnodydd amlroddadwy”*) means a person who is—

(a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 52 (repeatable prescribing services) of Schedule 3,

(b) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the Act in relation to APMS contracts which is the equivalent provision to paragraph 52 of Schedule 3, or

(c) employed or engaged by—

(i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 52 of Schedule 3,

(ii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the Act in relation to APMS contracts which is the equivalent provision to paragraph 52 of Schedule 3, or

(iii) a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing services in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the Act in relation to Local Health Board Medical Services which is the equivalent provision to paragraph 52 of Schedule 3;

“repeatable prescription” (*“presgripsiwn amlroddadwy”*) means a prescription contained in a form provided by a Local Health Board for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS Business Services Authority and which—

(a) is either—

(i) generated by computer but signed by a repeatable prescriber, or

(ii) a form created in an electronic format, identified using a repeatable prescriber’s code, transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service and is signed with a repeatable prescriber’s advanced electronic signature,

(b) is issued or created to enable a person to obtain pharmaceutical services, and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

"restricted availability appliance" ("*cyfarpar argaeledd cyfyngedig*") means an appliance which is approved for particular categories of persons or particular purposes only;

"Scheduled drug" ("*cyffur Atodlen*") means a drug or other substance specified in Schedule 1 or 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(34) (which relate to drugs, medicines and other substances not to be ordered under a general medical services contract or that may be ordered only in certain circumstances);

"service provider" ("*darparwr gwasanaeth*") has the meaning given by section 3(1)(c) of the Regulation and Inspection of Social Care (Wales) Act 2016(35);

"signatory" ("*llofnodwr*") means a natural person who creates an electronic signature;

"supplementary prescriber" ("*rhagnodydd atodol*") means—

(a) a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber,

(b) a person whose name is registered in the Nursing and Midwifery Register and against whose name in that Register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a nurse independent/supplementary prescriber,

(c) a person—

(i) who is registered in a part of the register maintained under article 5 of the Health Professions Order 2001 (establishment and maintenance of register) which relates to chiropodists and podiatrists, dieticians, paramedics, physiotherapists or radiographers, and

(ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber, or

(d) an optometrist against whose name in the register of optometrists maintained under section 7 or 8B(1)(a) of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as a supplementary prescriber;

"supplementary services" ("*gwasanaethau atodol*") are—

(a) services other than unified services or out of hours services, or

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

"temporary resident" ("*preswilydd dros dro*") means a person accepted by the contractor as a temporary resident under paragraph 25 of Schedule 3 and for whom the contractor's responsibility has not been terminated in accordance with that paragraph;

“therapeutic radiographer independent prescriber” (*“radiograffydd therapiwtig-ragnodydd annibynnol”*) means a radiographer—

- (a) who is a registered radiographer, and
 - (b) against whose name is recorded in Part 11 of the Health and Care Professions Council register—
 - (i) an entitlement to use the title “therapeutic radiographer” or “radiograffydd therapiwtig”, and
 - (ii) an annotation signifying that they are qualified to order drugs, medicines and appliances
- as a therapeutic radiographer independent prescriber;

“unified services” (*“gwasanaethau unedig”*) means the services required to be provided in accordance with regulation 17;

“vaccine and immunisation services” (*“gwasanaethau brechu ac imiwneiddio”*) means the services described in paragraph 7 of Schedule 2;

“working day” (*“diwrnod gwaith”*) means any day apart from Saturday, Sunday, Christmas Day, Good Friday or a bank holiday;

“writing” (*“ysgrifennu”*), except in paragraph 109(1) of Schedule 3 and unless the context otherwise requires, includes electronic mail and “written” is to be construed accordingly.

(2) In these Regulations, the use of the term “it” in relation to the contractor is to be deemed to include a reference to a contractor that is an individual medical practitioner, two or more individuals practising in partnership or a company limited by shares and related expressions are to be construed accordingly.

(3) Expressions used in these Regulations and in the Act have the same meaning as in that Act.

PART 2 Contractors: conditions and eligibility

Conditions: general

4. The Local Health Board may only enter into a contract if the conditions specified in regulations 5 and 6 are met.

Conditions relating solely to medical practitioners

5.—(1) Where the Local Health Board enters, or is proposing to enter into a contract with—

- (a) a medical practitioner, that medical practitioner must be a general medical practitioner;
- (b) two or more persons practising in a partnership—
 - (i) at least one partner (who must not be a limited partner) must be a general medical practitioner, and
 - (ii) any other partner who is a medical practitioner must be—
 - (aa) a general medical practitioner, or
 - (bb) employed by a Local Health Board, (in England and Wales and Scotland) an NHS Trust, an NHS foundation trust, (in Scotland) a Health Board, or (in Northern Ireland) a Health and Social Care Trust; or
 - (c) a company limited by shares—

(i) at least one share in the company must be both legally and beneficially owned by a general medical practitioner, and

(ii) any other share or shares in the company that are legally and beneficially owned by a medical practitioner must be so owned by—

(aa) a general medical practitioner, or

(bb) a medical practitioner who is employed by a Local Health Board, (in England and Wales and Scotland) an NHS Trust, an NHS foundation trust, (in Scotland) a Health Board or, (in Northern Ireland) a Health and Social Care Trust.

(2) In paragraph (1)(a), (b)(i) and (c)(i) "general medical practitioner" does not include a medical practitioner whose name is included in the General Practitioner Register by virtue of being a medical practitioner to whom paragraph (3), (4) or (5) applies.

(3) This paragraph applies to a medical practitioner referred to in article 4(3) of the 2010 Order (general practitioners eligible for entry in the General Practitioner Register) who was exempt from the requirement to have the prescribed experience under—

(a) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) Regulations 1997(36),

(b) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998(37), or

(c) regulation 5(1)(d) of the Medical Practitioners (Vocational Training) Regulations (Northern Ireland) 1998(38).

(4) This paragraph applies to a medical practitioner who has an acquired right for the purposes of article 6(2) of the 2010 Order (persons with acquired rights) by virtue of—

(a) having been a restricted services principal, and

(b) that medical practitioner's name being included, as at 31 December 1994, in—

(i) a medical list which was, at that date, kept by a Family Health Services Authority(39), or

(ii) any corresponding list which was, at that date, kept by a Health Board or by the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland.

(5) This paragraph applies to a medical practitioner who has an acquired right for the purposes of article 6(6) of the 2010 Order (which relates to persons engaged or provided as a deputy or employed as an assistant) because, on at least 10 days in the 4 years ending with 31 December 1994, or on at least 40 days in the 10 years ending with that date, that medical practitioner was—

(a) engaged as a deputy by, or provided as a deputy to, a medical practitioner whose name was included in—

- (i) the medical list which was, at that date, kept by a Family Health Services Authority, or
 - (ii) any corresponding list kept, at that date, by a Health Board or by the Northern Ireland Central Services Agency for the Health and Social Services in Northern Ireland, or
- (b) employed as an assistant (other than as a trainee general practitioner) by such a medical practitioner.

(6) In paragraph (4)(a), "restricted services principal" means a medical practitioner who provided general medical services limited to child health surveillance, contraceptive services, maternity medical services or minor surgery.

General condition relating to all contracts

6.—(1) The Local Health Board must not enter into a contract with—

- (a) a medical practitioner to whom paragraph (2) applies,
- (b) two or more persons practising in partnership, where paragraph (2) applies to any person who is a partner in the partnership, or
- (c) a company limited by shares where paragraph (2) applies to—
 - (i) the company,
 - (ii) any person legally or beneficially owning a share in the company, or
 - (iii) any director or secretary of the company.

(2) This paragraph applies if—

- (a) the person is the subject of a national disqualification;
- (b) subject to paragraph (3), the person is disqualified or suspended (other than by interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
- (c) the person has, within the 5 years before either the signing of the contract or commencement of the contract (whichever is the earlier), been dismissed (otherwise than by reason of redundancy) from any employment by a health service body, unless—
 - (i) if the person was employed as a member of a health care profession at the time of the dismissal, the person has subsequently been employed by that health service body or by another health service body, and
 - (ii) the dismissal was the subject of a finding of unfair dismissal by any competent tribunal or a court;
- (d) the person has, within the 5 years before either the signing of the contract or commencement of the contract (whichever is the earlier), been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 107(2), (3) or (4) of the Act (disqualification of practitioners)), or a performers list held by the Local Health Board by virtue of regulation

made under section 49(3) (persons performing primary medical services) of the Act, unless the person's name has been 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 committed on or after 14 December 2001 and has been sentenced to a term of imprisonment of longer than 6 months;

(g) subject to paragraph (3), the person has been convicted outside the United Kingdom of an offence which would, if committed in England and Wales, constitute murder and—

(i) the offence was committed on or after 26 August 2002, and

(ii) the person was sentenced to a term of imprisonment of longer than 6 months;

(h) the person has been convicted of an offence, referred to in Schedule 1 to the Children and Young Persons Act 1933(40) (offences against children and young persons, with respect to which special provisions of this Act apply), or in Schedule 1 to the Criminal Procedure (Scotland) Act 1995(41) (offences against children under the age of 17 years of to which special provisions apply), committed on or after 1 March 2004;

(i) the person has at any time been included in—

(i) any barred list within the meaning of section 2 of the Safeguarding Vulnerable Groups Act 2006(42) (barred lists), or

(ii) any barred list within the meaning of Article 6 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007(43) (barred lists),

unless the person was removed from the list either on the grounds that it was not appropriate for the person to have been included in it or as the result of a successful appeal;

(j) the person has, within the period of 5 years before either the signing of the contract or commencement of the contract (whichever is the earlier), been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission, the Charity Commission for Northern Ireland or the High Court, and that order was made on the grounds of misconduct or mismanagement in the administration of a charity for which the person was responsible or to which the person was privy, or which was contributed to, or facilitated by, the person's conduct;

(k) the person has, within the 5 years before either the date of the signing of the contract or the commencement of the contract (whichever is the earlier), been removed from being concerned with the management or control of any body in a case where the removal was by virtue of section 34(5)(e) of the Charities and Trustee Investment (Scotland) Act 2005(44) (powers of Court of Session);

(l) the person—

(i) has been made bankrupt and has not been discharged from the bankruptcy or the bankruptcy order has not been annulled, or

(ii) has had sequestration of the person's estate awarded and has not been discharged from the sequestration;

(m) the person is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(45) (bankruptcy restrictions order and undertaking), Schedule 2A to the Insolvency (Northern Ireland) Order 1989(46) (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(47) (bankruptcy restrictions order, interim bankruptcy restrictions order and bankruptcy restrictions undertaking), unless the person has been discharged from that order or that order has been annulled;

(n) the person—

(i) is subject to moratorium period under a debt relief order under Part 7A of the Insolvency Act 1986(48) (debt relief orders), or

(ii) is the subject of a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4ZB to the Insolvency Act 1986(49) (debt relief restrictions orders and undertakings);

(o) the person has made a composition agreement or arrangement with, or granted a trust deed for, the person's creditors and the person has not been discharged in respect of it;

(p) the person is subject to—

(i) a disqualification order under section 1 of the Company Directors Disqualification Act 1986(50) (disqualification orders: general) or a disqualification undertaking under section 1A of that Act(51) (disqualification undertakings: general),

(ii) a disqualification order or disqualification undertaking under article 3 (disqualification orders: general) or Article 4 (disqualification undertakings: general) of the Company Directors Disqualification (Northern Ireland) Order 2002(52), or

(iii) a disqualification order under section 429(2) of the Insolvency Act 1986(53) (disabilities on revocation of an administration order against an individual);

(q) the person has had an administrator, administrative receiver or receiver appointed in respect of them;

(r) the person has had an administration order made in respect of the contractor under Schedule B1 to the Insolvency Act 1986(54) (administration); or

(s) the contractor is a partnership and—

(i) a dissolution of the partnership is ordered by any competent court, tribunal or arbitrator, or

(ii) an event happens that makes it unlawful for the business of the partnership to continue, or for members of the partnership to carry on in partnership.

(3) Paragraph (2)(b) or, as the case may be, paragraph (2)(g), does not apply to a person where—

(a) that person—

(i) has been disqualified or suspended from practising by a licensing body outside of the United Kingdom, or

(ii) has been convicted of a criminal offence outside of the United Kingdom, and

(b) the Local Health Board is satisfied that the disqualification, suspension or, as the case may be, the conviction does not make that person unsuitable to be—

(i) a contractor,

(ii) a partner, in the case of a contract with two or more persons practising in partnership, or

(iii) in the case of a company limited by shares—

(aa) a person who legally or beneficially owns a share in the company, or

(bb) a director or secretary of the company.

(4) For the purposes of paragraph (2)(c), where a person has been employed as a member of a health care profession, any subsequent employment must also be as a member of that profession.

(5) In this regulation, “contractor” includes a person with whom the Local Health Board is proposing to enter into a contract with.

Notice of conditions not being met and reasons

7.—(1) Where the Local Health Board considers that the conditions specified in regulations 5 and 6 for entering into a contract are not met, it must give notice in writing to the person or persons intending to enter into the contract of—

(a) its view and the reasons for that view, and

(b) the right of appeal under regulation 8.

(2) The Local Health Board must also give notice in writing of its view and the reasons for that view to any person who both legally and beneficially owns a share in, or who is a director or secretary of, a company that is given notice under paragraph (1) in any case where its reason for the decision relates to such a person.

Right of appeal

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

PART 3 Pre-contract dispute resolution

Pre-contract disputes

9.—(1) Except where both parties to the prospective contract are health service bodies (in which case section 7 of the Act (NHS contracts) applies) if, in the course of negotiations intending to lead to a contract, the prospective parties to that contract are unable to agree on a particular term of the contract, either party may refer the dispute to the Welsh Ministers to consider and determine the matter.

(2) Disputes referred to the Welsh Ministers in accordance with paragraph (1) or section 7 of the Act must be considered and determined in accordance with the provisions of paragraphs 106(3) to (14) and 107(1) of Schedule 3, and paragraph (3) (where it applies) of this regulation.

(3) In the case of dispute referred to the Welsh Ministers under paragraph (1), the determination—

(a) may specify the terms to be included in the proposed contract,

(b) may require the Local Health Board to proceed with the proposed contract, but may not require the proposed contractor to proceed with the proposed contract, and

(c) is binding upon the prospective parties to the contract.

PART 4 Health service body status

Health service body status: election

10.—(1) A person who proposes to enter into a contract with a Local Health Board (“a proposed contractor”) may elect, by giving notice in writing to the Local Health Board prior to entering into the contract, to be regarded as a health service body for the purposes of section 7 of the Act.

(2) An election made by a proposed contractor under paragraph (1) has effect beginning with the date on which the contract is entered into.

(3) If, by virtue of paragraph (1) a proposed contractor elects to be regarded as a health service body, the nature of, or any rights or liabilities arising under, any other contract previously entered into by that proposed contractor with a health service body before the date of that election remains unaffected.

(4) Paragraph (5) applies where—

(a) a contractor who is an individual medical practitioner enters, or two or more persons practising in a partnership enter, into a contract with the Local Health Board, and

(b) that contractor is to be regarded as a health service body in accordance with paragraph (1).

(5) Subject to regulation 11, the contractor is to be regarded as a health service body for the purposes of section 7 of the Act (NHS contracts) for as long as that contract continues irrespective of any change in—

(a) the partners comprising the partnership,

(b) the status of the contractor from that of an individual medical practitioner to that of a partnership, or

(c) the status of the contractor from that of a partnership to that of an individual medical practitioner.

Health service body status: variation of contracts

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

(a) the Local Health Board must agree to the variation, and

(b) the procedure specified in regulation 27 and Part 11 of Schedule 3 for the variation of contracts applies.

(2) If, by virtue of a request under paragraph (1), the contractor is to be regarded as a health service body any rights or liabilities under any other contract with a health service body entered into by the contractor before the date on which the contractor is so regarded remain unaffected.

(3) Where the Local Health Board agrees to the variation to the contract, the contractor must—

(a) be regarded, or

(b) subject to regulation 12, cease to be regarded,

as a health service body for the purposes of section 7 of the Act beginning with the date that the variation is to take effect pursuant to regulation 27 and Part 11 of Schedule 3.

Cessation of health service body status

12.—(1) A contractor ceases to be a health service body for the purposes of section 7 of the Act (NHS contracts) if the contract terminates.

(2) Where, by virtue of paragraph (1), a contractor ceases to be a health service body in relation to a contract (“the relevant contract”), the contractor is to continue to be regarded as a health service body for the purposes of any other NHS contract to which it became a party between the date on which it became a health service body in relation to the relevant contract and the date on which it ceased to be regarded as a health service body for the purposes of that contract (but it ceases to be a health service body for the purposes of such other NHS contract on the termination of that contract).

(3) Where—

(a) a contractor ceases to be regarded as a health service body in relation to a contract by reason of either paragraph (1) or a variation of the contract by virtue of regulation 11(1), and

(b) the contractor or the Local Health Board—

(i) has referred any matter to the NHS dispute resolution procedure before the contractor ceases to be a health service body, or

(ii) refers any matter that occurred during the period when the contractor was regarded as a health service body to the NHS dispute resolution procedure, in accordance with paragraph 106 of Schedule 3, after it ceases to be a health service body,

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

(4) Where a contractor continues to be regarded as a health service body by virtue of paragraph 3 for the purposes of the NHS dispute resolution procedure, the contractor ceases to be regarded as a health service body for those purposes on the conclusion of that procedure.

PART 5 Contracts: required terms

Parties to the contract

13. A contract must specify—

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

Health service contract

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

Contracts with individuals practising in partnership

15. Where a contract is with two or more individuals practising in partnership—

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

Duration

16.—(1) Except in the circumstances specified in paragraph (2), a contract must provide for it to subsist until it is terminated in accordance with the terms of the contract or by virtue of the operation of any other legal provision.

(2) The circumstances referred to in paragraph (1) are that the Local Health Board wishes to enter into a temporary contract for a period not exceeding 24 months for the provision of services to former patients of a contractor, following the termination of that contractor's contract.

(3) Either party to a prospective contract to which paragraph (2) applies may, if it wishes to do so, invite the Local Medical Committee for the area of the Local Health Board to participate in the negotiations intending to lead to such a contract.

Unified services

17.—(1) For the purposes of section 43(1) of the Act (requirement to provide certain primary medical services), the services which must, except in circumstances where regulation 18(7) or paragraph 124 of Schedule 3 applies, be provided under a GMS contract ("unified services") are the services described in paragraphs (3), (5), (6), (7) and (9), and Schedule 2, during the period specified in paragraph (2).

(2) The period specified in this paragraph is, in the case of—

(a) paragraphs 3, 5 and 6 at all times within core hours as is appropriate to meet the reasonable needs of the contractor's patients, and

(b) paragraphs 7 and 9 at all times within core hours.

(3) The services described in this paragraph are services required for the management of a contractor's registered patients and temporary residents who are or believe themselves to be—

(a) ill, with conditions from which recovery is generally expected,

(b) terminally ill, or

(c) suffering from chronic disease,

delivered in the manner determined by the contractor's practice after consideration of relevant nationally agreed clinical guidance or pathways and in discussion with the patient.

(4) For the purposes of paragraph (3)—

"disease" (*"clefyd"*) means a disease included in the list of three-character categories contained in the latest publication of the International Statistical Classification of Diseases and Related Health Problems, and

"management" (*"rheoli"*) includes—

(a) offering consultation and, where appropriate, physical examination for the purpose of identifying the need, if any, for treatment or further investigation, and

(b) the making available of such treatment or further investigation as is necessary and appropriate, including the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care.

(5) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all of the contractor's registered patients and temporary residents taking into account their specific needs including—

(a) advice in connection with the patient's health and relevant health promotion advice, and

(b) the referral of a patient for services under the Act,

together with the provision of the services specified in paragraph (6).

(6) The services specified in paragraph (5) are—

(a) cervical screening services,

(b) child health surveillance services,

(c) childhood vaccinations and immunisation services,

(d) contraceptive services,

(e) maternity medical services,

(f) minor surgery services, and

(g) vaccine and immunisation services.

(7) The services described in this paragraph are primary medical services required for the immediately necessary treatment of any person to whom the contractor has been requested to provide treatment owing to an accident or emergency at any place in its practice area.

(8) In paragraph (7), “emergency” includes any medical emergency whether or not related to services provided under the contract.

(9) The services described in this paragraph are primary medical services required for the immediately necessary treatment of any person falling within paragraph (10) who requests such treatment for the period specified in paragraph (11).

(10) This paragraph applies to a person if—

(a) that person’s application for inclusion in the contractor’s list of patients has been refused in accordance with paragraph 26 of Schedule 3 and that person is not registered with another provider of unified services (or their equivalent) in the area of the Local Health Board,

(b) that person’s application for acceptance as a temporary resident has been rejected in accordance with paragraph 26 of Schedule 3, or

(c) that person is present in the contractor’s practice area for less than 24 hours.

(11) The period specified in this paragraph is, in the case of a person to whom—

(a) paragraph (10)(a) applies, 14 days beginning with the date on which that person’s application was refused or until that person has been subsequently registered elsewhere for the provision of unified services (or their equivalent), whichever occurs first,

(b) paragraph (10)(b) applies, 14 days beginning with the date on which that person’s application was rejected or until that person has been subsequently accepted elsewhere as a temporary resident, whichever occurs first, and

(c) paragraph (10)(c) applies, 24 hours or such shorter period as the person is present in the contractor’s practice area.

Services: general

18.—(1) A contract must specify—

(a) the services to be provided,

(b) subject to paragraph (4), the address of each of the premises to be used by the contractor or any sub-contractor for the provision of such services,

(c) the persons to whom such services are to be provided,

(d)the area (the contractor's "practice area") as respects which persons resident in it are, subject to any other terms of the contract relating to patient registration, entitled to—

(i)register with the contractor, or

(ii)seek acceptance by the contractor as a temporary resident, and

(e)whether, beginning with the date on which the contract comes into force, the contractor's list of patients is open or closed.

(2) A contract must also—

(a)contain a term which requires the contractor to—

(i)make appointments for unified services available to its patients for such proportion of the core hours on each working day as is appropriate to meet the reasonable needs of those patients,

(ii)have in place arrangements for its patients to access unified services throughout the core hours in case of emergency,

(iii)ensure that all practice premises, other than any practice premises specified in paragraph (3), are open and physically accessible to patients—

(aa)at all times between 8.30am and 6.00pm on each working day, and

(bb)for such other periods in core hours as may be required to enable the contractor to comply with the requirements in regulation 17, regulation 18 and Schedule 3, and

(b)state the period (if any) for which any services, other than unified services, are to be provided.

(3) The practice premises specified in this paragraph are those for which the Local Health Board has agreed, in writing with the contractor, more limited opening hours because the practice premises are not one of the contractor's main sites.

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

(a)the homes of patients, or

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

(5) Where, on the date on which the contract is signed, the Local Health Board is not satisfied that all or any of the premises specified in accordance with paragraph (1)(b) meet the requirements set out in paragraph 1 of Schedule 3, the contract must include a plan, drawn up jointly by the Local Health Board and the contractor, which specifies—

(a)the steps taken by the contractor to bring the premises up to the relevant standard,

(b)any financial support that may be available from the Local Health Board, and

(c)the timescale in which the steps referred to in sub-paragraph (a) are to be taken.

(6) Where, in accordance with paragraph (1)(e), the contract specifies that the contractor's list of patients is closed the contract must also specify in relation to that closure each of the items listed in paragraph 39(2) of Schedule 3.

(7) The Local Health Board may, in exceptional circumstances or for protected learning time, give prior written agreement for contractors to temporarily reduce the hours during which they provide unified services on a working day, subject to the contractor having in place arrangements for its patients to maintain access to unified services throughout the core hours on that working day in case of emergency.

Certificates

19.—(1) A contract must contain a term which has the effect of requiring the contractor to issue, free of charge to a patient or patient's representative, any medical certificate of a description prescribed in column 1 of Schedule 1, which is reasonably required under, or for the purposes of, the enactments specified in relation to the certificate in column 2 of that Schedule, subject to paragraph (2).

(2) A certificate must not be issued where, for the condition to which the certificate relates, the patient is—

(a) being attended to by a medical practitioner who is not—

(i) employed or engaged by the contractor,

(ii) in the case of a contract with two or more persons practising in a partnership, one of those persons, or

(iii) in the case of a contract with a company limited by shares, one of the persons legally or beneficially owning shares in that company, or

(b) not being treated by or under the supervision of a health care professional.

(3) The exception in paragraph (2)(a) does not apply where the certificate is issued in accordance with—

(a) regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976(55) (evidence of incapacity for work, limited capability for work and confinement), or

(b) regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985(56) (medical information).

Finance

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

(a) the terms of the contract, and

(b) any other conditions relating to payment contained in directions given by the Welsh Ministers under section 12 (exercise of functions) or section 45 of the Act (GMS contracts: payments).

(2) The contract must contain a term to the effect that where, in accordance with directions given by the Welsh Ministers under section 12 (exercise of functions) or section 45 (GMS contracts: payments) of the Act, the Local Health Board is required to make a payment to a contractor under a contract but subject to conditions, those conditions must be a term of the contract.

(3) The obligation referred to in paragraph (1) is subject to any right the Local Health Board may have to set off against any amount payable to the contractor under the contract any amount—

(a) that is owed by the contractor to the Local Health Board under the contract; or

(b) that the Local Health Board may withhold from the contractor in accordance with the terms of the contract or any applicable provisions contained in directions given by the Welsh Ministers under section 45 of the Act.

Fees, charges and financial interests

21.—(1) The contract must contain terms relating to fees, charges and financial interests which have the same effect as those set out in paragraphs (2) to (9).

(2) The contractor must not, either for itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person in respect of—

(a) the provision of any treatment whether under the contract or otherwise, or

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

except in the circumstances set out in regulation 22.

(3) The contractor must not, either for itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person, for the completion, in relation to the patient's mental health, of—

(a) the debt and mental health evidence form, or

(b) any examination of the patient or of the patient's medical record in order to complete the form, the purpose of which is to assist creditors in deciding what action to take where the debtor has a mental health problem.

(4) The contractor must not, either for itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person, for the preparation or provision of—

(a) evidence that the individual is, or is at risk of being, a victim of domestic abuse which is intended to support an application by the individual for civil legal services, or

(b) any other evidence that the individual is, or is at risk of being, a victim of domestic abuse which is of a description specified in regulations made by the Welsh Ministers or Secretary of State.

(5) Subject to paragraph (6), where—

(a) a person—

(i) applies to a contractor for the provision of unified services, and

(ii) claims to be on that contractor's list of patients, and

(b) the contractor has reasonable doubts about that person's claim,

the contractor must give any necessary treatment to that person and may demand and accept from that person a reasonable fee in accordance with regulation 22(e).

(6) Where—

(a) a person from whom the contractor has received a fee under regulation 22(e) applies to the Local Health Board for a refund within 14 days beginning with the date of the payment of the fee (or within such longer period not exceeding 4 weeks as the Local Health Board may allow if it is satisfied that the failure to apply within 14 days was reasonable); and

(b) the Local Health Board is satisfied that that person was on the contractor's list of patients when the treatment was given,

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

(7) The contractor must in the provision of services to patients under the contract—

(a) provide information regarding services it provides otherwise than under the contract only where appropriate and in accordance with the restriction on advertising private services in paragraph 134 of Schedule 3,

(b) where it does provide such information, ensure that the information provided is fair and accurate, and

(c) where the other services are available to the patient as part of the health service established under section 1(1) of the Act (Welsh Ministers' duty to promote health service), to inform the patient—

(i) that the services are so available,

(ii) of any charge that applies to that health service and, if no such charge applies, that the service is free, and

(iii) how to access that health service.

(8) The contractor must in making a decision—

(a) to refer a patient for other services under the Act, or

(b) to prescribe any drug, medicine or appliance to a patient,

make that decision without regard to its own financial interests.

(9) The contractor must not inform patients that any prescription for any drug, medicine or appliance must be dispensed only by the contractor or by a person with whom the contractor is associated.

Circumstances in which fees and charges may be made

22. The contractor may demand or accept (directly or indirectly) a fee or other remuneration—

(a) from any statutory body for services rendered for the purposes of that body's statutory functions;

(b) from any body, employer or school for—

(i) a routine medical examination of persons for whose welfare the body, employer or school is responsible,
or

(ii) examination of such persons for the purpose of advising the body, employer or school of any
administrative action they might take;

(c) for treatment which is not primary medical services or otherwise required under the contract and which is
given—

(i) at accommodation made available in accordance with the provisions of paragraph 11 of Schedule 5 to
the Act (accommodation and services for private patients), or

(ii) in a registered nursing home which is not providing services under the Act,

if, in either case, the person administering the treatment is serving on the staff of a hospital providing services
under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving
the treatment, the contractor or the person providing the treatment supplies the Local Health Board, on a
form provided by the Local Health Board for that purpose, with such information as the Local Health Board
may require;

(d) under section 158 of the Road Traffic Act 1988 (payment for emergency treatment of traffic casualties);

(e) when the contractor treats a patient under regulation 21(5), in which case the contractor is entitled to
demand and accept a reasonable fee (recoverable in certain circumstances under regulation 21(6)) for any
treatment given, if the contractor gives the patient a receipt;

(f) for attending and examining (but not otherwise treating) a patient—

(i) at a police station, at the patient's request, in connection with possible criminal proceedings against the
patient;

(ii) for the purpose of creating a medical report or certificate, at the request of a commercial, educational or
not-for-profit organisation;

(iii) for the purpose of creating a medical report required in connection with an actual or potential claim for
compensation by the patient;

(g) for treatment consisting of an immunisation for which no remuneration is payable by the Local Health
Board and which is requested in connection with travel abroad;

(h) for a medical examination—

(i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear
a seat belt, or

(ii) for the purpose of creating a report—

(aa) relating to a road traffic accident or criminal assault, or

(bb)that offers an opinion as to whether a patient is fit to travel;

(i)for testing the sight of a person to whom none of paragraphs (a), (b) or (c) of section 71(2) of the Act (arrangements for general ophthalmic services) applies (including by reason of regulations under section 71(8) and (9) of the Act).

Activity and Appointment Data

23.—(1) A contract must contain a term requiring contractors to—

- (a)maintain their mapped appointments in the relevant section of the Primary Care Information Portal;
- (b)review their submission data at least once a month;
- (c)ensure the mapped categories are up-to-date; and
- (d)ensure their server is at all times switched on, maintained and available to enable the relevant software to extract the data.

(2) The activity and appointment data across the GP Collaborative must be discussed at GP Collaborative meetings by the authorised representatives from the member practices comprising the GP Collaborative, with the aim of developing measures across those member practices to manage demand and standardise good practice and, where applicable, data quality.

Dataset and business rules

24. A contract must contain a term requiring contractors to provide data, where applicable, in accordance with the business rules utilised within the Assurance Framework.

Contract assurance

25.—(1) A contract must contain, in addition to the requirements in Schedule 3, a term requiring contractors to engage with the Local Health Board in the processes outlined in the latest published Assurance Framework by—

- (a)providing returns and data, or facilitating the supply of data, as required for management of the contract and to satisfy contract assurance requirements,
- (b)as required by the Assurance Framework, engaging with the Local Health Board in formal contract and governance practice review processes,
- (c)following each formal contract and governance practice review, producing a Practice Contract and Governance Framework Response Plan to address within an agreed period any concerns raised by the Local Health Board, and
- (d)if concerns need to be addressed through the escalation ladder levels of the Assurance Framework, working positively with the Local Health Board to resolve concerns.

(2) A contract must contain a term requiring the Local Health Board to follow the processes and take account of the principles outlined in the latest published Assurance Framework by—

- (a) using the Assurance Framework's nationally agreed indicators together with the self-reported assessment from the contractor, to identify the priorities in the contract assurance and governance process,
- (b) determining the nature and depth of the formal contract and governance practice review taking account of the priorities identified in the contract assurance and governance process,
- (c) engaging and working positively with the contractor to resolve concerns,
- (d) giving verbal feedback to the contractor during the visit, including any requirements for the contractor to address any immediate concerns,
- (e) sending written feedback in a Contract and Governance Visit Report to the contractor within 20 working days of the visit,
- (f) evaluating a Practice Contract and Governance Framework Response Plan within 20 working days of receipt,
- (g) agreeing any date for follow up with the contractor, including to review whether any immediate concerns had been addressed satisfactorily, and
- (h) notifying the contractor if concerns need to be addressed through use of the escalation ladder levels of the Assurance Framework.

Sub-contracting

26. A contract must contain terms which prevent a contractor from sub-contracting any of its obligations under the contract in relation to clinical matters, or non-clinical matters directly affecting patients, except in the circumstances provided for by paragraph 76 of Schedule 3.

Variation of contracts

27.—(1) Subject to paragraph (2), a variation of, or amendment to, the contract may only be made in the circumstances provided for in Part 11 of Schedule 3.

(2) Paragraph (1) does not prevent a variation of, or amendment to, a contract in the circumstances provided for in paragraphs 76(8), 109, 110, 111 and 124 of Schedule 3.

Termination of a contract

28.—(1) A contract may only be terminated as provided for by Part 11 of Schedule 3.

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

(3) The provisions dealing with the financial consequences of termination must include at least provisions having the effect specified in paragraphs (4) to (8) and must provide for those provisions to survive the termination of the contract.

(4) Subject to paragraphs (5) to (8), the Local Health Board's obligation to make payments to the contractor in accordance with the contract ceases on the date of termination of the contract.

(5) On termination of the contract or termination for any reason, the Local Health Board must perform a reconciliation of the payments made by the Local Health Board to the contractor and the extent to which the contractor has performed the obligations under the contract to which those payments relate. The Local Health Board must also, in the event that the contractor has terminated the contract pursuant to paragraph 114 of Part 11 of Schedule 3 but has not performed its obligations under the contract for the duration of the notice period (or such shorter period as the Local Health Board and contractor have agreed in writing), be entitled to reflect in the reconciliation any additional costs that the Local Health Board has incurred in securing alternative services for the duration of that notice period.

(6) The Local Health Board must serve the contractor with written details of the reconciliation as soon as reasonably practicable, and in any event no later than 28 days after the termination of the contract.

(7) If the contractor disputes the accuracy of the reconciliation, the contractor may refer the dispute to the NHS dispute resolution procedure within 28 days beginning on the date on which the Local Health Board served the contractor with written details of the reconciliation. That determination of the dispute is binding on the parties.

(8) Each party must pay the other any monies due within 3 months of the date on which the Local Health Board served the contractor with written details of the reconciliation, or the conclusion of the NHS dispute resolution procedure, as the case may be.

(9) The provisions dealing with the non-financial consequences of termination must include at least the provisions in paragraphs (10) and (11) and must provide for those provisions to survive the termination of the contract.

(10) The contract must provide that the termination of the contract, for whatever reason, is without prejudice to the accrued rights of either party under the contract.

(11) The contract must provide that on termination of the contract for any reason, the contractor must—

(a) subject to the requirements of this paragraph (11), cease performing any work or carrying out any obligations under the contract,

(b) co-operate with the Local Health Board to enable any outstanding matters under the contract to be dealt with or concluded in a satisfactory manner,

(c) co-operate with the Local Health Board to enable the contractor's patients to be transferred to one or more other contractors or providers of unified services (or their equivalent), which must include—

(i) providing reasonable information about individual patients, and

(ii) delivering patient records

to such other appropriate person or persons as the Local Health Board specifies, and

(d) deliver up to the Local Health Board all property belonging to the Local Health Board including all documents, forms, computer hardware and software, drugs, appliances or medical equipment which may be in the contractor's possession or control.

Other contractual terms

29.—(1) A contract must, unless it is of a type or nature to which a particular provision does not apply, contain, other terms which have, the same effect as those specified in Schedule 3 except paragraphs 45(5) to (9), 46(5) to (17), 106(5) to (14), and 107.

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

PART 6 Functions of Local Medical Committees

30.—(1) The functions of a Local Medical Committee which are prescribed for the purposes of section 54(7) of the Act (Local Medical Committees) are—

(a) the consideration of any complaint made to it by any medical practitioner against a medical practitioner specified in paragraph (2) providing services under a contract in the relevant area involving any question of the efficiency of those services,

(b) the reporting of the outcome of the consideration of any such complaint to the Local Health Board with whom the contract is held in cases where that consideration gives rise to any concerns relating to the efficiency of services provided under a contract,

(c) the making of arrangements for the medical examination of a medical practitioner specified in paragraph (2), where the contractor or the Local Health Board is concerned that the medical practitioner is incapable of adequately providing services under the contract and it so requests with the agreement of the medical practitioner concerned, and

(d) the consideration of the report of any medical examination arranged in accordance with sub-paragraph (c) and the making of a written report as to the capability of the medical practitioner of adequately providing services under the contract to the medical practitioner concerned, the contractor and the Local Health Board with whom the contractor holds a contract.

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

(a) a contractor,

(b) one of two or more persons practising in partnership which holds a contract, or

(c) both a legal and beneficial shareholder in a company limited by shares which holds a contract.

(3) In this regulation, "the relevant area" means the area for which the Local Medical Committee is formed.

PART 7 General transitional provision and saving, consequential amendments and revocations

General transitional provision and saving

31.—(1) This regulation applies to—

(a) the exercise by the Local Health Board of any of its functions under the 2004 Regulations before the commencement date, and

(b) any rights or liabilities of the Local Health Board in respect of the exercise of any of its functions under the 2004 Regulations.

(2) Subject to paragraph (4), any act or omission concerning a contract to which the 2004 Regulations applied immediately before the commencement date in respect of any of the matters specified in paragraph (1), is to be treated as an act or omission concerning a contract to which these Regulations apply.

(3) Subject to paragraph (4), anything which, before the commencement date, is done or is in the process of being done under the 2004 Regulations concerning a contract to which the 2004 Regulations applied immediately before that date in respect of any of the matters specified in paragraph (1), is to be treated as if done or in the process of being done under these Regulations.

(4) Notwithstanding paragraphs (2) and (3) and the revocations provided for in Schedule 6, where the 2004 Regulations contain a provision for which there is no equivalent provision in these Regulations (“the relevant provision”), the 2004 Regulations, as they were in force immediately before the commencement date, are to continue to apply to the extent necessary for the purposes of—

(a) preserving any rights conferred or liabilities accrued by or under the relevant provision, or

(b) the assessment or determination of any rights or liabilities arising under or in accordance with the relevant provision.

(5) In this regulation—

“the commencement date” (“*y dyddiad cychwyn*”) means the date on which these Regulations come into force;

“contract” (“*contract*”) includes any contract to which the 2004 Regulations applied immediately before the commencement date under which medical services were provided before the commencement date (whether or not such services continued to be provided after that date).

Consequential amendments

32. Schedule 5 makes provision in respect of the amendments to secondary legislation which are consequential upon the coming into force of these Regulations.

Revocations

33. Schedule 6 makes provision in respect of the revocation of the enactments specified.

Eluned Morgan

Minister for Health and Social Services, one of the Welsh Ministers

1 September 2023

Regulation 19

List of Prescribed Medical Certificates

Table

<i>Description of medical certificate</i>	<i>Enactment under or for the purposes of which certificate required</i>
1. To support a claim or to obtain payment either personally or by proxy; to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc.	Naval and Marine Pay and Pensions Act 1865 (c. 73) Air Force (Constitution) Act 1917 (c. 51) Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939 (c. 83) Personal Injuries (Emergency Provisions) Act 1939 (c. 82) Social Security Administration Act 1992 (c. 5) Social Security Contributions and Benefits Act 1992 (c. 4) Social Security Act 1998 (c. 14)
2. To establish pregnancy for the purpose of obtaining welfare foods	Section 13 of the Social Security Act 1998 (c. 14) (benefits under schemes for improving nutrition: pregnant women, mothers and children)
3. To secure registration of still-birth	Section 11 of the Births and Deaths Registration Act 1953 (c. 20) (special provision as to registration of still-birth)
4. To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment public funds	Section 142 of the Mental Health Act 1983 (c. 20) (pay, pensions, et., of mentally disordered persons)
5. To establish unfitness for jury service	Juries Act 1974 (c. 23)
6. To support late application for reinstatement in civil employment or notification of non-availability to take up employment owing to sickness	Reserve Forces (Safeguard of Employment Act 1985 (c. 22)
7. To enable a person to be registered as an absent voter on grounds of physical incapacity	Representation of the People Act 1983 (c. 2)

8. To support applications for certificates conferring exemption from charges in respect of drugs National Health Service Act 2006 (c. 41)

9. To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable Local Government Finance Act 1992 (c. 28)

Regulation 17

SCHEDULE 2 Further details about specific Unified Services

Cervical screening

1.—(1) A contractor must—

(a) provide all the services described in sub-paragraph (2), and

(b) make the records specified in sub-paragraph (4) within the patient's record kept in accordance with paragraph 78 of Schedule 3.

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

(a) the provision of any necessary information and advice to assist relevant patients in making an informed decision as to participation in the Cervical Screening Wales Programme undertaken by Public Health Wales (the "Programme"),

(b) performing cervical screening tests on people who have agreed to participate in that Programme,

(c) arranging for people to be informed of the results of their test, and

(d) ensuring that test results are followed up as clinically appropriate.

(3) For the purposes of sub-paragraph (2)(a) "relevant patients" means patients on the contractor's patient list who have been identified by Public Health Wales as suitable candidates for a cervical screening test.

(4) The records referred to in sub-paragraph (1)(b) are—

(a) an accurate record of the cervical screening test undertaken, and

(b) the result of any test undertaken, and

(c) any clinical follow up requirements.

Child health surveillance

2.—(1) A contractor must in respect of any child under the age of 5 for whom it has responsibility under the contract—

- (a) provide all the services described in sub-paragraph (2), other than any examination so described which a parent refuses to allow their child to undergo, until the date on which the child attains 5 years of age, and
- (b) maintain the records specified in sub-paragraph (3).

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

(a) the monitoring of the health, well-being and physical, mental and social development (which together are referred to in this paragraph as "development") of a child under 5 years of age with a view to detecting any deviations from normal development—

(i) by the consideration of any information concerning the child received by or on behalf of the contractor, and

(ii) on any occasion when the child is examined or observed by or on behalf of the contractor (whether pursuant to paragraph (b) or otherwise);

(b) the examination of a child at a frequency that has been agreed with the Local Health Board in accordance with the nationally agreed evidence based programme set out in the latest clinical guidance in relation to the Newborn and Infant Physical Examination Cymru, and the Local Health Board or the contractor may seek the views of the relevant Local Medical Committee prior to reaching agreement on the appropriate frequency of such examinations.

(3) The records specified for the purposes of sub-paragraph (1)(b) must be an accurate record of—

(a) the development of the child while under 5 years of age, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination, and

(b) the responses (if any) to offers made to the child's parent for the child to undergo any examination referred to in sub-paragraph (2)(b).

Childhood vaccinations and immunisations

3.—(1) A contractor must comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor must—

(a) offer to provide to children for whom the contractor has responsibility under the contract all vaccinations and immunisations of a type and in the circumstances specified in the relevant Annex of the GMS Statement of Financial Entitlements;

(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 78 of Schedule 3 any refusal of the offer referred to in 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 78 of Schedule 3—

(i) 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 contra-indications to the vaccination or immunisation, and

(vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor must ensure that all staff involved in administering vaccines are trained and their knowledge kept up to date in the recognition and initial treatment of anaphylaxis.

Contraceptive services

4. A contractor must make available to all its patients who so request them, those services described in sub-paragraphs (a) to (g)—

(a) the giving of advice about the full range of contraceptive methods,

(b) where appropriate, the medical examination of patients seeking such advice,

(c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants),

(d) the giving of advice about emergency contraception and where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the contractor has a conscientious objection to emergency contraception, prompt referral to another provider of primary medical services who does not have such 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 contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider 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 home testing or self-testing kits for sexually transmitted infections.

Maternity medical services

5.—(1) A contractor must provide all the necessary maternity medical services to—

- (a) patients who have been diagnosed as pregnant throughout the antenatal period;
- (b) patients and their babies throughout the postnatal period, other than neonatal checks;
- (c) patients whose pregnancy has terminated as a result of miscarriage or abortion or, where the contractor has a conscientious objection to the termination of pregnancy, the contractor must promptly refer the patient to another provider of primary medical services who does not have such conscientious objections.

(2) In this paragraph—

“antenatal period” (“*cyfnod cynnedigol*”) means the period from the start of the pregnancy to the onset of labour;

“maternity medical services” (“*gwasanaethau meddygol mamolaeth*”) means—

- (a) in relation to 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 to their first 14 days of life;

“neonatal check” (“*gwiriad newydd-anedig*”) means the examination of the baby in the first month after birth;

“postnatal period” (“*cyfnod ôl-enedigol*”) means the period beginning with the conclusion of delivery of the baby or the patient’s discharge from secondary care services, whichever is the later, and ending with the 14th day after the birth.

Minor surgery

6. A contractor must—

- (a) make available to patients, cryocautery, curettage and cautery of warts, verrucae and other skin lesions where clinically appropriate, and
- (b) ensure that its record of any treatment provided under this paragraph includes—
 - (i) details of the minor surgery provided to the patient, and
 - (ii) the consent of the patient to that treatment.

Vaccinations and immunisations

7.—(1) A contractor must—

- (a) offer to administer or provide to patients all vaccinations and immunisations of a type and in the circumstances specified in the relevant Annex to the GMS Statement of Financial Entitlements and that are funded under the global sum;
- (b) provide appropriate information and advice to patients and, where appropriate, to the parents of patients, about such vaccinations and immunisations;
- (c) in relation to patients other than children and taking into account the individual circumstances of the patient, consider whether—

(i) immunisation ought to be administered by the contractor or by a health care professional employed or engaged by the contractor, or

(ii) a prescription form ought to be provided for the purpose of self-administration by the patient of the immunisation;

(d) record in the patient's record any refusal of the offer mentioned in paragraph (a);

(e) where—

(i) the offer mentioned in paragraph (a) is accepted, and

(ii) in case of a patient who is not a child, the immunisation is to be administered by the contractor or another health care professional,

administer the immunisations and record the immunisation information in the patient's record, using codes agreed by the Local Health Board for this purpose;

(f) where—

(i) the offer mentioned in paragraph (a) is accepted, and

(ii) in the case of a patient who is not a child, the immunisation is not to be administered by the contractor or another health care professional,

issue a prescription form for the purposes of self-administration by the patient.

(2) For the purposes of this paragraph—

"immunisation information" means—

(a) either—

(i) the patient's consent to immunisation, or

(ii) where another person consents to immunisation on behalf of the patient, the name of the

person who gave that consent and their relationship to the patient;

(b) the batch number, expiry date and title of the vaccine,

(c) the date of administration of the vaccine,

(d) where two vaccines are administered by injections, in close succession, the route of administration and the injection site of each vaccine,

(e) any contraindications to the vaccine, and

(f) any adverse reactions to the vaccine.

(3) The contractor must ensure that all staff involved in administering vaccines are trained and their knowledge kept up to date in the recognition and initial treatment of anaphylaxis.

8. For the purposes of paragraphs 1 to 7 "a patient's record" means the record which is kept in relation to a patient in accordance with paragraph 78 of Schedule 3.

PART 1 Provision of services

Premises, facilities and equipment

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

(a) are suitable for the delivery of those services,

(b) are sufficient to meet the reasonable needs of the contractor's patients, and

(c) meet or exceed the minimum standards set out in directions issued by the Welsh Ministers under the Act.

(2) The requirement in sub-paragraph (1) is subject to any plan included in the contract in accordance with regulation 18(5) which sets out steps to be taken by the contractor to bring the premises up to the required standard.

(3) In relation to each service it provides, the contractor must provide such facilities and equipment as are necessary to enable it properly to perform that service.

Telephone services

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

(a) by patients to contact the practice for any purpose related to the contract, 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 084, 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller.

(2) The contractor must ensure their telephone lines are staffed—

(a) for the duration of core hours, unless any agreement has been reached between the Local Health Board and the contractor pursuant to regulation 18(7) which allows the use of an answer phone message for temporary periods, and

(b) answered by appropriately qualified members of the contractor's staff that are located within the United Kingdom.

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

Cost of relevant calls

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

(2) In this paragraph—

“geographical number” (“*rhif daearyddol*”) means a number which has a geographical area code as its prefix;

“relevant calls” (“*galwadau perthnasol*”) means—

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

Access

4.—(1) The contractor must—

- (a) have a telephone system with a recording function for incoming and outgoing lines, that stacks calls and allows for the analysis of call data,
- (b) have a telephone introduction message recorded bilingually in Welsh and English that in total lasts no longer than 2 minutes,
- (c) ensure that patients and care homes can order repeatable prescriptions digitally,
- (d) for the duration of core hours, ensure that patients can digitally request a non-urgent appointment or a call back, and that the necessary governance arrangements are in place for this process,
- (e) publicise information via the practice’s online resource on—
 - (i) the access requirements specified in this paragraph 4, and
 - (ii) how patients can—
 - (aa) access the contractor’s services, and
 - (bb) request an urgent, routine and advanced consultation,
 - (f) offer a same day consultation for—
 - (i) children under 16 with acute presentations, and
 - (ii) patients clinically triaged as requiring an urgent assessment,
 - (g) offer pre-bookable appointments to take place during core hours; and
 - (h) actively signpost patients to appropriate services—
 - (i) available from the members of the contractor’s cluster,
 - (ii) provided or commissioned by the Local Health Board, or
 - (iii) available locally or nationally.

(2) The contractor must self-declare quarterly that the requirements in sub-paragraph (1) have been met and if requested be prepared to provide the evidence to the Local Health Board as required.

Attendance at practice premises

5.—(1) The contractor must take steps to ensure that any patient who—

- (a) has not previously made an appointment, and
 - (b) attends at the practice premises for unified services between 8.30am and 6.00pm on a working day,
- is provided with such services by an appropriate health care professional on that day.

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

- (a) it is more appropriate for the patient to be referred elsewhere for services under the Act, or
- (b) the patient is then 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.

Attendance outside practice premises

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

- (a) attendance on the patient is required, and
 - (b) it would be inappropriate for the patient to attend at the practice premises,
- the contractor must provide services to that patient at whichever of the places described in sub-paragraph (2) is in the contractor's judgement the most appropriate.

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

- (a) the place recorded in the patient's medical records as being the patient's last home address,
- (b) such other place as the contractor has informed the patient and the Local Health Board is the place where the contractor has agreed to visit and treat the patient, or
- (c) another place in the contractor's practice area.

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

- (a) arranging for the referral of the patient without first seeing the patient, in any case where the patient's medical condition makes that course of action appropriate, or
- (b) visiting the patient in circumstances where this paragraph does not place the contractor under an obligation to do so.

Newly registered patients

7.—(1) Where a patient has been—

- (a) accepted on a contractor's list of patients, or
- (b) assigned to that list by the Local Health Board,

the contractor must invite the patient to participate in a consultation either at the contractor's practice premises or, if the patient's medical condition so warrants, at one of the places referred to in paragraph 6(2).

(2) An invitation under sub-paragraph (1) must be issued by the contractor before the end of the period of 6 months beginning with the date of the acceptance of the patient on, or assignment of the patient to, the contractor's list of patients.

(3) Where a patient (or, where appropriate, in the case of a patient who is a child, the child's parent) agrees to participate in a consultation mentioned in sub-paragraph (1) the contractor must during the course of that consultation—

(a) make such inquiries and undertake such examinations as appear to the contractor to be appropriate in all the circumstances, and

(b) for all newly registered patients who have attained the age of 16 years, with the co-operation of the patient, complete the latest version of the national minimum dataset questionnaire issued by the Welsh Ministers in order to secure health screening information.

(4) Nothing in this paragraph affects the contractor's other obligations under the contract in respect of the patient.

Patients not seen within 3 years

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

(a) requests a consultation with the contractor, and

(b) has not attended either a consultation with, or a clinic provided by, the contractor within the period of 3 years prior to the date of the request.

(2) The contractor must—

(a) provide the patient with a consultation, and

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

(3) Nothing in this paragraph affects the contractor's other obligations under the contract in respect of the patient.

Patients aged 75 years and over

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

(a) has attained the age of 75 years, and

(b) has not participated in a consultation within the year prior to the date of the request,

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

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

(3) Nothing in this paragraph affects the contractor's other obligations under the contract in respect of the patient.

Clinical reports

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

(2) The Local 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 unified services or their equivalent, or

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

Storage of vaccines

11. The contractor must ensure that—

(a) all vaccines are stored in accordance with the manufacturer's instructions, and

(b) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that temperature readings are taken on all working days.

Infection control

12. The contractor must ensure that it has appropriate arrangements for infection control and decontamination.

Duty of co-operation in relation to supplementary services

13.—(1) Where a contractor does not provide to its registered patients or to persons whom it has accepted as temporary residents a particular supplementary service it must comply with the requirements specified in sub-paragraph (2).

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

(a) co-operate, insofar as is reasonable, with any person responsible for the provision of that service or those services, and

(b) comply with any reasonable request for information from such a person or from the Local Health Board relating to the provision of that service or those services.

Duty of co-operation in relation to out of hours services

14. The contractor must—

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

Membership of a cluster

15. A contract must contain a term which requires the contractor to be a member of a cluster.

Duty of co-operation: cluster working

16.—(1) A contractor must comply with the requirements in sub-paragraph (2) where registered patients or temporary residents are provided with services by the contractor's cluster.

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

- (a) co-operate, in so far as is reasonable, with any person responsible for the provision of the services,
- (b) comply in core hours with any reasonable request for information from such a person or from the Local Health Board relating to the provision of the services,
- (c) agree the mandate for the GP Collaborative representative at cluster meetings and take account of feedback from those cluster meetings,
- (d) take reasonable steps to provide information to its registered patients about the services, including information on how to access the services and any changes to them, and
- (e) ensure engagement in the planning and delivery of local services, as agreed within the cluster action plan, which includes suitable arrangements to enable the sharing of data, where appropriate safeguards are met, to support the delivery of the services and discussion of cluster funding and budgets.

(3) In this paragraph, and in paragraphs 18 and 19 "services" means primary medical services.

Membership of a GP Collaborative

17.—(1) A contract must contain a term which has the effect of requiring the contractor to be a member of a GP Collaborative.

(2) A contractor must—

(a) appoint at least 1 health care professional with authority to act on the contractor's behalf in the dealings between the contractor and the GP Collaborative to which the contractor belongs, and

(b) attend at least 4 meetings of the GP Collaborative to which the contractor belongs in each financial year (unless agreed otherwise in writing by the Local Health Board), or appoint a senior practice clinician, or where appropriate a senior administrator, employed by the practice to attend those meetings and to act on the contractor's behalf in those meetings.

Contribution to clusters and GP Collaboratives

18. A contractor must—

(a) contribute relevant information, including demand and capacity planning, to the cluster Integrated Medium Term Plan via the GP Collaborative, and the contribution must include information on demand and capacity planning,

(b) demonstrate how they have engaged in planning and delivery of local services agreed within the GP Collaborative's contribution to the cluster plan, including evidence of wide partnership, multi-professional/multi-agency working, and development of integrated services, and

(c) contribute to delivering specific cluster-determined outcomes, including engagement in planning of local initiatives through engagement with the cluster via the GP Collaborative lead.

Demand and capacity

19. A contractor is required to engage with a GP Collaborative to assist the collaborative in—

(a) undertaking a population needs assessment of its patients,

(b) analysing the current services available to the GP Collaborative population, identifying any gaps in provision,

(c) analysing the current numbers and skills of the workforce and its development needs,

(d) undertaking a measurement of local health needs as determined by the GP Collaborative, and

(e) providing evidence of the demand and capacity assessment undertaken which is to be evidenced in the GP Collaborative Integrated Medium-Term Plan.

Cessation of service provision: information requests

20. Where a contractor ceases to provide a supplementary service to its patients the contractor must comply with any reasonable request for information relating to the provision of that service, or those services, made by the Local Health Board or by any person with whom the Local Health Board intends to enter into a contract for the provision of such services.

Welsh Language

21.—(1) Where the contractor provides medical services under the contract through the medium of Welsh, it must notify the Local Health Board in writing.

(2) The contractor must make available a Welsh language version of any document or form for use by patients and/or members of the public, provided by the Local Health Board.

(3) Where the contractor displays a new sign or notice in connection with medical services provided under the contract, the text on the sign or notice must be in English and Welsh, and the contractor may utilise the translation service offered by the Local Health Board for this purpose.

(4) The contractor must encourage the wearing of a badge, provided by the Local Health Board, by those delivering medical services under the contract who are Welsh speaking, to convey that they are able to speak Welsh.

(5) The contractor must encourage those delivering medical services under the contract to utilise information and/or attend training courses and events provided by the Local Health Board, so that they can develop—

(a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and

(b) an understanding of how the Welsh language can be used when delivering medical services under the contract.

(6) The contractor must encourage those delivering medical services under the contract to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

PART 2 Patients

List of patients

22.—(1) The Local Health Board must prepare and keep up to date a list of the patients who have been—

(a) accepted by the contractor for inclusion in the contractor's list of patients under paragraphs 22 to 25 and who have not been subsequently removed from that list under paragraphs 28 to 36, and

(b) assigned by the Local Health Board to the contractor's list of patients under—

(i) paragraph 43(1)(a), or

(ii) paragraph 43(1)(b) (by virtue of a determination of the assessment panel under paragraph 45(7) which has not subsequently been overturned by a determination by the Welsh Ministers under paragraph 46 or by a court).

(2) The contractor must, upon receipt of a reasonable written request from the Local Health Board—

(a) take appropriate steps (including contacting patients where reasonably necessary to confirm that their patient data is correct) as soon as is reasonably practicable, to correct and update patient data held on the

practice's computerised clinical systems, and where necessary register or deregister patients to ensure that the patient list is accurate, and

(b) provide information relating to its list of patients to the Local Health Board as soon as is reasonably practicable and, in any event, no later than 30 days from the date on which the request was received by the contractor, in order to assist the Local Health Board in the exercise of its duties under sub-paragraph (1).

Application for inclusion in a list of patients

23.—(1) Unless paragraph 26(1) applies, the contractor must, if the contractor's list of patients is open, accept an application for inclusion in that 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 that application, in the list of patients of another contractor or provider of primary medical services.

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

(3) Subject to sub-paragraph (4), an application for inclusion in a contractor's list of patients must be made by the applicant, or a person authorised by the applicant, submitting to the contractor an application form (including an electronic application form). The contractor must not make proof of identification or address a prerequisite for an applicant to be included in the contractor's list of patients (or make an application conditional upon the production of such proof of identification or address).

(4) An application may be made—

(a) where the patient is a child, on behalf of the patient by—

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

(ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989(57), or

(iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of the Children Act 1989, or

(b) where the patient is an adult who lacks capacity to make the application, or to authorise the application to be made on their behalf, by—

(i) a relative of that person,

(ii) the primary carer of that person,

(iii) a donee of a lasting power of attorney granted by that person, or

(iv) a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005(58).

(5) Where a contractor accepts an application for inclusion in the contractor's list of patients, the contractor must give notice in writing to the Local Health Board of that acceptance as soon as practicable.

(6) The Local Health Board must, on receipt of a notice given under sub-paragraph (5)—

(a) include the applicant in the contractor's list of patients from the date on which the notice is received, and

(b) if it is the first time the applicant has been accepted as a registered patient by (or assigned by a Local Health Board to) a contractor or APMS contractor, give notice in writing of that acceptance to the applicant (or, in the case of a child or an adult who lacks capacity, the person making the application on their behalf).

Inclusion in list of patients: armed forces personnel

24.—(1) Unless paragraph 26(1) applies, the contractor must, if its list of patients is open, include a person to whom sub-paragraph (2) applies in that list for a period of up to 2 years and paragraph 34(1)(b) does not apply in respect of any person who is included in the contractor's list of patients by virtue of this paragraph.

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

(a) a serving member of the armed forces of the Crown who has received written authorisation from Defence Medical Services to receive primary medical services from the contractor's practice, and

(b) living or working within the contractor's practice area during the period in respect of which that written authorisation is given.

(3) Where the contractor has accepted a person to whom sub-paragraph (2) applies onto its list of patients, the contractor must—

(a) obtain a copy of the patient's medical record, or a summary of that record, from Defence Medical Services, and

(b) provide regular updates to Defence Medical Services, at such intervals as are agreed with Defence Medical Services, about any care and treatment which the contractor has provided to the patient.

(4) At the end of the period of 2 years, or on such earlier date as the contractor's responsibility for the patient has come to an end, the contractor must—

(a) notify Defence Medical Services in writing that the contractor's responsibility for the patient has come to an end, and

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

Temporary residents

25.—(1) Unless paragraph 26(1) applies, the contractor must, if its list of patients is open, accept a person as a temporary resident if that the person is—

(a) temporarily resident away from their normal place of residence and is not being provided with unified services (or their equivalent) under any other arrangement in the locality where that person is temporarily residing, or

(b) moving from place to place and not for the time being resident in any place.

(2) For the purposes of sub-paragraph (1), a person is to be regarded as temporarily resident in a place if, when that person arrives in that place, they intend to stay there for more than 24 hours but not more than 12 weeks.

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

(a) 12 weeks, or

(b) such shorter period for which the contractor agreed to accept that person as a temporary resident, the contractor must give notice of that fact to the person either orally or in writing and the contractor's responsibility for that person ceases 7 days after the date on which notice is given.

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

(a) at the end of the period of 12 weeks beginning with the date on which the contractor accepted that person as a temporary resident, or

(b) if the contractor's responsibility for that person as a temporary resident came to an end earlier than at the end of the 12 week period referred to in paragraph (a), at the end of that period.

Refusal of applications for inclusion in the list of patients or early termination of responsibility for temporary residents

26.—(1) The contractor may only refuse an application made under paragraphs 23, 24 or 25 or terminate its responsibility for a person accepted by it as a temporary resident under paragraph 25(3) if it has reasonable grounds for doing so which do not relate to the applicant's race, social class, age, religion or belief, sexual orientation, appearance, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, disability or medical condition.

(2) The reasonable grounds referred to in sub-paragraph (1) may, in the case of applications made under paragraph 23, include the ground that the applicant does not live in the contractor's practice area.

(3) Where a contractor refuses an application made under paragraphs 23, 24 or 25 or terminates its responsibility for a person accepted by it as a temporary resident under paragraph 25(3), the contractor must give notice in writing of that refusal or termination and the reasons for it to the applicant (or, in the case of a child or an adult who lacks capacity, to the person who made the application on their behalf) before the end of the period of 14 days beginning with the date of its decision.

(4) The contractor must—

(a) keep a written record of—

(i) the refusal of any application made under paragraphs 23, 24 or 25 or termination its responsibility for a person accepted by it as a temporary resident under paragraph 25(3), and

(ii) the reasons for that refusal or termination, and

(b) make such records available to the Local Health Board on request.

Patient preference of practitioner

27.—(1) Where the contractor has accepted an application made under paragraphs 23, 24 or 25 for inclusion in its list of patients, the contractor must record in writing any preference expressed by that person (or, in the case of a child or an adult who lacks capacity, the person who made the application on the applicant's behalf) to receive services from a particular performer, either generally or in relation to a specific condition.

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

(a) has reasonable grounds for refusing to provide services to the person who expressed the preference, or

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

Removal from the list at the request of the patient

28.—(1) The contractor must notify the Local Health Board in writing of any request made by any person who is a registered patient to be removed from the contractor's list of patients.

(2) Where the Local Health Board—

(a) receives notification from the contractor under sub-paragraph (1), or

(b) receives directly a request from the person to be removed from the contractor's list of patients,

the Local Health Board must remove that person from the contractor's list of patients.

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

(a) the date on which the Local Health Board is given notice of the registration of that person with another provider of unified services (or their equivalent), or

(b) 14 days after the date on which the notice given under sub-paragraph (1) or the request made under sub-paragraph (2) is received by the Local Health Board.

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

(a) the person who requested the removal, and

(b) the contractor,

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

(5) In this paragraph and in paragraphs 29(1)(b) and (10), 30(5) and (6), 32 and 35, a reference to a request received from or advice, information or notice required to be given to, a person must include a request received from or advice, information or notice required to be given to—

(a) in the case of a child—

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

(ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989, or

(iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the Children Act 1989, or

(b) in the case of an adult patient who lacks capacity to make the relevant request or receive the relevant advice, information or notice—

(i) a relative of that person,

(ii) the primary carer of that person,

(iii) a donee of a lasting power of attorney granted by that person, or

(iv) a deputy appointed for that person by the court under the Mental Capacity Act 2005.

Removal from the list at the request of the contractor

29.—(1) Subject to paragraph 30, a contractor who has reasonable grounds for wanting a person to be removed from its list of patients which do not relate to the person's race, social class, age, religion or belief, sexual orientation, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, appearance, disability or medical condition must—

(a) give notice in writing to the Local Health Board that it wants to have the person removed and provide within the notice an explanation of the grounds for the requested removal and why the removal would be reasonable, and

(b) subject to sub-paragraph (2), give notice in writing to the person of its specific reasons for requesting the removal of that person.

(2) Where in the reasonable opinion of the contractor—

(a) the circumstances of the person's removal are such that it is not appropriate for a more specific reason to be given, and

(b) there has been an irrevocable breakdown in the relationship between the relevant person and the contractor,

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

(3) Except in the circumstances specified in sub-paragraph (4) a contractor may only request the removal of a person from its list of patients under sub-paragraph (1), if, during the period of 1 year ending with the date of the contractor's request to the Local Health Board, the contractor has—

- (a) warned that person of the risk of being removed from that list; and
- (b) explained to that person the reasons for this.

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

- (a) the reason for removal relates to a change of address,
- (b) the contractor has reasonable grounds for believing that the giving of a warning under sub-paragraph (3)(a) would—
 - (i) be harmful to the person's physical or mental health, or
 - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (5), or
- (c) the contractor considers that it is not otherwise reasonable or practicable for a warning to be given.

(5) The persons referred to in sub-paragraph (4) are—

- (a) the contractor, where the contractor is an individual medical practitioner,
- (b) in the case of a contract with two or more persons practising in partnership, a partner in that partnership,
- (c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company,
- (d) a member of the contractor's staff,
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract, or
- (f) any other person present—
 - (i) on the practice premises, or
 - (ii) in the place where services are being provided to the patient under the contract.

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

- (a) the date of any warning given in accordance with sub-paragraph (3)(a) and the reasons for giving such a warning as explained to the person concerned, or
- (b) the reason why no such warning was given.

(7) The contractor must keep a written record of removal of any person from its list of patients under this paragraph which includes—

(a) the reason for removal,

(b) the circumstances of the removal, and

(c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate, and the contractor must make this record available to the Local Health Board on request.

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

(a) the date on which the Local Health Board is given notice of the registration of that person with another provider of unified services (or their equivalent),

(b) the eighth day after the Local Health Board gives notice to the contractor of its approval of the removal, or

(c) the twenty-eighth day after the date on which the Local Health Board receives the notice from the contractor, if the Local Health Board has neither approved nor rejected the notice during that period.

(9) Where, on the date on which the removal would take effect under sub-paragraph (8), the contractor is treating that person at intervals of less than 7 days, the contractor must give notice in writing to the Local Health Board of that fact and the removal takes effect on whichever is the earlier of—

(a) the eighth day after the Local Health Board is given notice by the contractor that the person no longer needs such treatment, or

(b) the date on which the Local Health Board is given notice of the registration of the person with another provider of unified services (or their equivalent).

(10) If a person is to be removed from the contractor's list of patients pursuant to sub-paragraph (8) or (9), the Local Health Board must give notice in writing to—

(a) the person in respect of whom the removal is approved, and

(b) the contractor,

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

Removals from the list of patients who are violent

30.—(1) Where a contractor wants a person to be removed from its list of patients on the grounds that—

(a) the person has committed an act of violence against any of the persons specified in sub-paragraph (2) or has behaved in such a way that any of those persons has feared for their safety, and

(b) the contractor has reported the incident to the police,

the contractor must give notice to the Local Health Board in accordance with sub-paragraph (3) requesting that the person be removed from its list of patients.

(2) The persons specified in this sub-paragraph are—

- (a) the contractor, where the contractor is an individual medical practitioner,
- (b) in the case of a contract with two or more persons practising in partnership, a partner in the partnership,
- (c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company,
- (d) a member of the contractor's staff,
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract, or
- (f) any other person present—
 - (i) on the contractor's practice premises, or
 - (ii) in the place where services were provided to the person under the contract.

(3) Notification under sub-paragraph (1) must be in writing and include the crime reference number allocated to the incident by the police.

(4) A removal requested in accordance with sub-paragraph (1) takes effect from whichever is the earlier of—

- (a) the date on which the Local Health Board is given notice of the registration of that person with another provider of unified services (or their equivalent),
- (b) the day after the day on which the Local Health Board gives notice to the contractor of its approval of the removal, or
- (c) the seventh day after the date on which the Local Health Board receives the notice from the contractor, if the Local Health Board has neither approved nor rejected the notice within that period.

(5) Where, pursuant to this paragraph, the contractor has given notice to the Local Health Board that it wants to have a patient removed from its list of patients and that request has taken effect under sub-paragraph (4), the contractor must inform that person of that fact unless—

- (a) it is not reasonably practicable for the contractor to do so, or
- (b) the contractor has reasonable grounds for believing that to do so would—
 - (i) be harmful to that person's physical or mental health, or
 - (ii) put the safety of any person specified in sub-paragraph (2) at risk.

(6) Where a person is removed from the contractor's list of patients under this paragraph, the Local Health Board must give that person notice in writing of that removal.

(7) The contractor must record the removal of any person from its list of patients under this paragraph and the circumstances leading to that removal in the medical records of the person removed.

Removal from list if patient registered elsewhere

31.—(1) The Local Health Board must remove a person from the contractor's list of patients if—

- (a) the person has subsequently been registered with another provider of unified services (or their equivalent) in the area of the Local Health Board, or
- (b) it has received notice from another Local Health Board, NHS England, a Health Board or a Health and Social Care Trust that the patient has subsequently been registered with a provider of unified services (or their equivalent) outside the area of the Local Health Board.

(2) A removal in accordance with sub-paragraph (1) is to take effect—

- (a) on the date on which the Local Health Board is given notice of the person's registration with the new provider, or
- (b) with the consent of the Local Health Board, on such other date as has been agreed between the contractor and the new provider.

(3) The Local Health Board must give notice in writing to the contractor of any person removed from its list of patients under sub-paragraph (1).

Removal from the list of patients who have moved

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

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

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

Removal from the list of patients whose address is unknown

33. Where the address of a person who is on the contractor's list of patients is no longer known to the Local Health Board and the Local Health Board reasonably believes this is not due to the patient being unable to provide proof of their address the Local Health Board may—

(a) give notice in writing to the contractor that it intends, at the end of the period of 6 months beginning with the date on which the notice was given, to remove the person from the contractor's list of patients, and

(b) at the end of the period referred to in sub-paragraph (a), remove the person from the contractor's list of patients unless, before the end of that period, the contractor satisfies the Local Health Board that the person is a patient to whom it is still responsible for providing unified services.

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

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

(a) intends to be away from the United Kingdom for a period of at least 12 weeks,

(b) is in the armed forces of the Crown (except in the case of a patient to which paragraph 24 applies),

(c) is serving a term of imprisonment of more than 2 years or more than one term of imprisonment totalling, in the aggregate more than 2 years,

(d) has been absent from the United Kingdom for a period of more than 12 weeks, or

(e) has died.

(2) The removal of a person from a contractor's list of patients under this paragraph takes effect from—

(a) where sub-paragraph (1)(a) to (c) applies, whichever is the latest of—

(i) the date of the person's departure, enlistment or imprisonment, or

(ii) the date on which the Local Health Board first receives notice of the person's departure, enlistment or imprisonment, or

(b) where sub-paragraph (1)(d) and (e) applies, the date on which the Local Health Board is given notice of the person's absence or death.

(3) The Local Health Board must give notice in writing to the contractor of the removal of any person from the contractor's list of patients under this paragraph.

Removal from the list of patients accepted elsewhere as temporary residents

35.—(1) The Local Health Board must remove a person from the contractor's list of patients where the person has been accepted as a temporary resident by another contractor or other provider of unified services (or their equivalent) where the Local Health Board is satisfied, after due inquiry that—

(a) the person's stay in the place of temporary residence has exceeded 12 weeks, and

(b) the person has not returned to their normal place of residence or to any other place within the contractor's practice area.

(2) The Local Health Board must give notice in writing of the removal of a person from a contractor's list of patients under this paragraph—

(a) to the contractor, and

(b) where practicable, to that person.

(3) A notice given under sub-paragraph (2)(b) must inform the person of—

(a) that person's entitlement to make arrangements for the provision to that person of unified services (or their equivalent), including by the contractor by which that person has been treated as a temporary resident; and

(b) the name, postal and electronic mail address and telephone number of the Local Health Board.

Removal from the list of pupils etc. of a school

36.—(1) Where the contractor provides unified services under the contract to persons on the grounds that they are pupils at, or staff or residents of, a school, the Local Health Board must remove any person from a contractor's list of patients who does not appear on the particulars provided by that school of persons who are pupils at, or staff or residents of, that school.

(2) Where the Local Health Board has requested a school to provide the particulars referred to in sub-paragraph (1) and has not received those particulars, the Local Health Board must consult the contractor as to whether it should remove from the contractor's list of patients any persons appearing in that list as pupils at, or staff or residents of, that school.

(3) The Local Health Board must give notice in writing to the contractor of the removal of any person from the contractor's list of patients under this paragraph.

Termination of responsibility for patients not registered with the contractor

37.—(1) Where the contractor has—

(a) received an application for the provision of medical services other than unified services—

(i) from a person who is not included (and who is not applying to be included) in the contractor's list of patients,

(ii) from a person that the contractor has not accepted as a temporary resident, or

(iii) made on behalf of a person referred to in sub-paragraph (i) or (ii), by a person specified in paragraph 23(4), and

(b) accepted the person making the application or on whose behalf the application is made as a patient for the provision of the service in question,

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

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

(a) the contractor is informed that the person no longer wishes the contractor to be responsible for the provision of the service in question, or

(b)it comes to the contractor's attention that the person—

(i)no longer resides in the area for which the contractor has agreed to provide the service in question, or

(ii)is no longer included in the list of patients of another contractor to whose registered patients the contractor has agreed to provide that service.

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

PART 3List of patients: closure, etc.

Application for closure of list of patients

38.—(1) Where a contractor wants to close its list of patients, the contractor must send a written application to that effect ("the application") to the Local Health Board.

(2) The application must include the following information—

(a)the period of time, being a period of not less than 12 weeks and not more than 1 year, during which the contractor proposes its list of patients is to be closed,

(b)the current number of the contractor'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 contractor'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 contractor's list of patients,

(e)any withdrawal from or reduction in provision of any supplementary services which had previously been provided under the contract, and

(f)any other information which the contractor considers ought to be drawn to the attention of the Local Health Board.

(3) The Local Health Board must acknowledge receipt of the application before the end of the period of 7 days beginning with the date on which the Local Health Board received the application.

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

(5) The Local Health Board must enter into discussions with the contractor concerning—

(a)the support which the Local Health Board may give to the contractor, or

(b)any changes which the Local Health Board or the contractor may make,

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

(6) The Local Health Board and the contractor must, throughout the period of the discussions referred to in sub-paragraph (5), use reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.

(7) The Local Health Board or the contractor may, at any stage during the discussions, invite the Local Medical Committee (if there is one) for the area in which the contractor provides services under the contract to attend any meetings arranged between the Local Health Board and the contractor to discuss the application.

(8) The Local Health Board may consult such persons as it appears to the Local Health Board may be affected by the closure of the contractor's list of patients and, if the Local Health Board does so, it must provide to the contractor a summary of the views expressed by those persons consulted in respect of the application.

(9) The Local Health Board must enable the contractor to consider and comment on all the information before the Local Health Board makes a decision in respect of the application.

(10) A contractor may withdraw the application at any time before the Local Health Board makes a decision in respect of that application.

(11) The Local Health Board must, before the end of the period of 21 days beginning with the date on which the application was received by the Local Health Board (or within such longer period as the parties may agree), make a decision to—

(a) approve the application and determine the date from which the closure of the contractor's list is to take effect, or

(b) reject the application.

(12) The Local Health Board must give notice in writing to the contractor of its decision to—

(a) approve the application in accordance with paragraph 39, or

(b) reject the application in accordance with paragraph 40.

(13) A contractor may not submit more than one application to close its list of patients in any period of 1 year beginning with the date on which the Local Health Board makes its decision on the application unless—

(a) paragraph 40(3) applies, or

(b) there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

Approval of an application to close a list of patients

39.—(1) Where the Local Health Board approves an application to close a contractor's list of patients, the Local Health Board must—

(a) give notice in writing to the contractor of its decision as soon as possible and the notice (“the closure notice”) must include the details specified in sub-paragraph (2), and

(b) at the same time as the Local Health Board gives notice to the contractor, send a copy of the closure notice to—

(i) the Local Medical Committee (if any) for the area in which the contractor provides services under the contract, and

(ii) any person who the Local Health Board consulted in accordance with paragraph 38(8).

(2) The closure notice must include—

(a) the period of time for which the contractor’s list of patients is to be closed which must be—

(i) the period specified in the application, or

(ii) where the Local Health Board and the contractor have agreed in writing to a different period, that different period, and

in either case, the period must not be less than 12 weeks and not more than 1 year,

(b) the date on which the closure of the list of patients is to take effect (“the closure date”), and

(c) the date on which the list of patients is to re-open.

(3) Subject to paragraph 41, a contractor must close its list of patients with effect from the closure date and the list of patients must remain closed for the duration of the closure period as specified in the closure notice.

Rejection of an application to close a list of patients

40.—(1) Where the Local Health Board rejects an application to close a contractor’s list of patients it must—

(a) give notice in writing to the contractor of its decision as soon as possible, including the Local Health Board’s reasons for rejecting the application, and

(b) at the same time as it gives notice to the contractor, send a copy of the notice to—

(i) the Local Medical Committee (if any) for the area in which the contractor provides services under the contract, and

(ii) any person who the Local Health Board consulted in accordance with paragraph 38(8).

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

(a) the end of the period of 12 weeks beginning with the date on which the Local Health Board’s decision to reject the application was made, or

(b) in a case where a dispute arising from the Local Health Board's decision to reject the application has been referred to the NHS dispute resolution procedure, the end of the period of 12 weeks beginning with the date on which a final determination to reject the application was made in accordance with that procedure (or any court proceedings).

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

Re-opening of list of patients

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

PART 4 Assignment of patients to lists

42.—(1) This Part applies in respect of the assignment by the Local Health Board of—

(a) a person as a new patient to a contractor's list of patients where that person—

(i) has been refused inclusion in a contractor's list of patients or has not been accepted as a temporary resident by a contractor, and

(ii) would like to be included in the list of patients of a contractor within the area of the Local Health Board in which that person resides, or

(b) any person who is part of a list dispersal resulting from the closure of a practice where that person—

(i) has not registered with another contractor, and

(ii) would like to be included in the list of patients of a contractor within the area of the Local Health Board in which that person resides; or

(c) any person who is part of a list dispersal resulting from the closure of a practice where that person has not registered with another contractor and the Local Health Board has been unable to contact that person.

(2) In this paragraph, "list dispersal" means the allocation of patients from a contractor's list of patients by the Local Health Board following termination of the contract or during the period set out in the notice of termination or agreement to terminate.

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

43.—(1) Subject to paragraph 44, the Local Health Board may—

(a) assign a new patient to a contractor whose list of patients is open, and

(b) only assign a new patient to a contractor whose list of patients is closed in the circumstances specified in sub-paragraph (2).

(2) The circumstances specified in this sub-paragraph are where—

(a) the assessment panel has determined under paragraph 45(7) that new patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Welsh Ministers under paragraph 46(13) or (where applicable) by a court, and

(b) the Local Health Board has entered into discussions with the contractor in question regarding the assignment of new patients if such discussions are required under paragraph 47.

Factors relevant to assignments

44. When assigning a person as a new patient to a contractor's list of patients under paragraph 43(1)(a) or (b), the Local Health Board must have regard to—

(a) the preferences and circumstances of the person,

(b) the distance between the person's place of residence and the contractor's practice premises,

(c) any request made by a contractor to remove the person from its list of patients within the preceding period of 6 months beginning with the date on which the application for assignment is received by the Local Health Board,

(d) whether, during the preceding period of 6 months beginning with the date on which the application for assignment is received by the Local Health Board, the person has been removed from a list of patients on the grounds referred to in—

(i) paragraph 29 (relating to the circumstances in which a person may be removed from a contractor's list of patients at the request of the contractor),

(ii) paragraph 30 (relating to the removal from the contractor's list of patients of persons who are violent), or

(iii) the equivalent provisions to those paragraphs in relation to arrangements made under section 41(2) of the Act (which relate to arrangements for the provision of primary medical services),

(e) in a case to which sub-paragraph (d)(ii) applies (or equivalent provisions as mentioned in sub-paragraph (d)(iii) apply), whether the contractor has appropriate facilities to deal with such patients, and

(f) such other matters as the Local Health Board considers relevant.

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

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

(2) The Local Health Board must give notice in writing that it has referred the matter to the assessment panel to—

(a) contractors, including those contractors who provide primary medical services under arrangements made under section 41(2) of the Act (which relate to arrangements for the provision of primary medical services) which—

(i) have closed their lists of patients, and

(ii) may, in the opinion of the Local Health Board, be affected by the determination of the assessment panel, and

(b) the Local Medical Committee (if any) for the area in which the contractors referred to in paragraph (a) provide unified services (or their equivalent).

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

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

(a) the Chief Executive of the Local Health Board of which the assessment panel is a committee or sub-committee,

(b) a person representative of patients in an area other than that of the Local Health Board which is a party to the contract, and

(c) a person representative of a Local Medical Committee which does not represent practitioners in the area of the Local Health Board which is a party to the contract.

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

(a) whether the Local Health Board has attempted to secure the provision of unified services (or their equivalent) for new patients other than by means of assignment to a contractor with a closed list; and

(b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.

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

(7) The assessment panel must—

(a) determine whether the Local Health Board may assign new patients to a contractor which has a closed list of patients, and

(b) if it determines that the Local Health Board may make such an assignment, determine, where there is more than one contractor, the contractors to which patients may be assigned.

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

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

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

46.—(1) Where an assessment panel makes a determination under paragraph 45(7) that the Local Health Board may assign new patients to contractors who have closed their lists of patients, any contractor specified in the determination may refer the matter to the Welsh Ministers to review that determination.

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

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

(4) The contractor (or contractors) must send to the Welsh Ministers, before the end of the period of 7 days beginning with the date of the determination of the assessment panel in accordance with paragraph 45(7), a written request for dispute resolution which must include or be accompanied by—

- (a) the names and addresses of the parties to the dispute,
- (b) a copy of the contract (or contracts), and
- (c) a brief statement describing the nature of and circumstances giving rise to the dispute.

(5) The Welsh Ministers must, before the end of the period of 7 days beginning with the date on which the matter was referred to the Welsh Ministers—

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

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

(7) The Welsh Ministers must, upon receiving any representations from a party—

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

(8) The Welsh Ministers may—

- (a) invite representatives of the parties to appear before, and make oral representations to, the Welsh Ministers either together or, with the agreement of the parties, separately, and may, in advance, provide the

parties with a list of matters or questions to which the Welsh Ministers would like them to give special consideration, or

(b) consult other persons whose expertise the Welsh Ministers considers is likely to assist the Welsh Ministers consideration of the dispute.

(9) Where the Welsh Ministers consult another person under sub-paragraph (8)(b), the Welsh Ministers must—

(a) give notice in writing to that effect to the parties, and

(b) where the Welsh Ministers consider that the interests of any party might be substantially affected by the results of the consultation, give to the parties such opportunity as the Welsh Ministers consider reasonable in the circumstances to make observations about those results.

(10) In considering the dispute, the Welsh Ministers must take into account—

(a) any written representations made in response to a request under sub-paragraph (5)(b), but only if those representations are made before the end of the specified period,

(b) any written observations made in response to a request under sub-paragraph (7), but only if those written observations are made before the end of the specified period,

(c) any oral representations made in response to an invitation under sub-paragraph (8)(a),

(d) the results of any consultation under sub-paragraph (8)(b), and

(e) any observations made in accordance with an opportunity given under sub-paragraph (9).

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

(12) In this paragraph, "specified period" means—

(a) such period as the Welsh Ministers specify in the request being a period of not less than 7 days and not more than 14 days beginning with the date on which the notice referred to is given, or

(b) such longer period as the Welsh Ministers may allow for the determination of the dispute where the period for determination of the dispute has been extended in accordance with sub-paragraph (16), and where the Welsh Ministers do so allow, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to sub-paragraph (16), the Welsh Ministers must—

(a) determine the dispute before the end of the period of 21 days beginning with the date on which the matter was referred to the Welsh Ministers,

(b)determine whether the Local Health Board may assign new patients to contractors which have closed their lists of patients, and

(c)if the Welsh Ministers determine that the Local Health Board may assign new patients to those contractors, determine the contractors to which the new patients may be assigned.

(14) The Welsh Ministers must not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 45(7)(b).

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

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

(a)the Welsh Ministers,

(b)the Local Health Board, and

(c)the contractor (or contractors) which referred the matter to dispute resolution.

(17) The Welsh Ministers must—

(a)record the determination, and the reasons for it, in writing, and

(b)give notice in writing of the determination (including the record of the reasons) to the parties.

Assignments to closed lists: assignments of patients by the Local Health Board

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

(a)enter into discussions with the contractor regarding the additional support that the Local Health Board can offer the contractor, and

(b)use its best endeavours to provide such appropriate support.

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

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

(a)to the first assignment of a patient to a particular contractor, and

(b)to any subsequent assignment to that contractor to the extent that it is reasonable and appropriate having regard to—

(i)the numbers of patients who have been or may be assigned to it, and

(ii)the period of time since the last discussions under sub-paragraph (1)(a) took place.

PART 5 Prescribing and dispensing

Prescribing: general

48.—(1) The contractor must ensure that—

(a) any prescription form or repeatable prescription for drugs, medicines or appliances issued by a prescriber, and

(b) any home oxygen order form issued by a health care professional,

complies, as appropriate, with the requirements in this Part.

(2) In this Part, a reference to “drugs” includes contraceptive substances and a reference to “appliances” includes contraceptive appliances.

Orders for drugs, medicines and appliances

49.—(1) Subject to sub-paragraphs (2) and (4) and to the restrictions on prescribing in paragraphs 55 and 56, a prescriber must order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract by—

(a) issuing to the patient a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with sub-paragraph (6), or

(b) creating and transmitting an electronic prescription in circumstances to which paragraph 50(1) applies, and a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription that is for health service use must not be used in any other circumstances.

(2) If, on a particular occasion when a drug, medicine or appliance is needed as mentioned in sub-paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription,

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser, and

(c) none of the reasons for issuing a non-electronic prescription form or a non-electronic repeatable prescription given in sub-paragraph (3) apply,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(3) The reasons given in this sub-paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that the prescriber has to the Electronic Prescription Service is reliable, or

(ii) the Electronic Prescription Service is functioning reliably,

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in Wales, or

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or, a non-electronic repeatable prescription for a particular prescription and in the professional judgement of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued.

(4) A health care professional must order any home oxygen services which are needed for the treatment of any patient who is receiving treatment under the contract by issuing a home oxygen order form.

(5) A prescriber may order drugs, medicines or appliances on a repeatable prescription only where the drugs, medicines or appliances are to be provided more than once.

(6) In issuing a non-electronic prescription form or a non-electronic repeatable prescription, the prescriber must—

(a) sign the prescription form or repeatable prescription in ink in the prescriber's own handwriting, and not by means of a stamp, with the prescriber's initials, or forenames, and surname, and

(b) only sign the prescription form or repeatable prescription after particulars of the order have been inserted in the prescription form or repeatable prescription.

(7) A prescription form or repeatable prescription must not refer to any previous prescription form or repeatable prescription.

(8) A separate prescription form or repeatable prescription must be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 57.

(9) A home oxygen order form must be signed by a health care professional.

(10) Where a prescriber orders the drug buprenorphine or diazepam or a drug specified in Part 1 of Schedule 2 to the Misuse of Drugs Regulations 2001(59) (controlled drugs to which regulations 14 to 16, 16A, 18 to 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, the prescriber must—

(a) use only the prescription form provided specially for the purposes of supply by instalments,

(b) specify the number of instalments to be dispensed and the interval between each instalment, and

(c) order only such quantity of the drug as provides treatment for a period not exceeding 14 days.

(11) The prescription form provided specially for the purpose of supply by instalments must not be used for any purpose other than ordering drugs in accordance with sub-paragraph (10).

(12) In an urgent case, a prescriber may request an NHS pharmacist to dispense a drug or medicine before a prescription form or repeatable prescription is issued or created, only if—

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

(b)the drug is not a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (5) (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Part 1 of Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23, 26 and 27) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001, and

(c)the prescriber undertakes to—

(i)provide the NHS pharmacist, within 72 hours beginning with the time of the request, with a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with sub-paragraph (6), or

(ii)transmit an electronic prescription by the Electronic Prescription Service within 72 hours, beginning with the time of the request.

(13) In an urgent case, a prescriber may request an NHS pharmacist to dispense an appliance before a prescription form or repeatable prescription is issued or created, only if—

(a)the appliance does not contain a Scheduled drug, or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26),

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

(c)the prescriber undertakes to—

(i)provide the NHS pharmacist, within 72 hours beginning with the time of the request, with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (6), or

(ii)transmit an electronic prescription by the Electronic Prescription Service within 72 hours, beginning with the time of the request.

Electronic prescriptions

50.—(1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if the prescription is not—

(a)for a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedules 2 to 5 to the Misuse of Drugs Regulations 2001, or

(b)a bulk prescription issued for a school or institution under paragraph 57.

(2) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to sub-paragraph (4), an EPS token, and

(b) if the patient, or where appropriate the patient's authorised person, so requests, a written record of the prescription that has been created.

(3) On and after the contractor's EPS go live date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

(4) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

(5) A health care professional may not order home oxygen services by means of an electronic prescription.

Nomination of dispensers for the purposes of electronic prescriptions

51.—(1) A contractor authorised to use the Electronic Prescription Service for its patients must, if a patient, or where appropriate the patient's authorised person, so requests, enter into the particulars relating to the patient which are held in the Welsh Demographic Service managed by Digital Health and Care Wales or the Personal Demographic Service managed by NHS England—

(a) where the patient does not have a nominated dispenser, the dispenser chosen by the patient, or where appropriate the patient's authorised person, and

(b) where the patient does have a nominated dispenser—

(i) a replacement dispenser, or

(ii) a further dispenser,

chosen by the patient, or where appropriate the patient's authorised person.

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

(3) A contractor must—

(a) not seek to persuade a patient or a patient's authorised person to nominate a dispenser recommended by the prescriber or the contractor, and

(b) if asked by a patient or a patient's authorised person to recommend an NHS pharmacist whom the patient or the patient's authorised person might nominate as the patient's dispenser, provide the patient or, as the case may be, the patient's authorised person with the list given to the contractor by the Local Health Board containing all NHS pharmacists in the area who provide an Electronic Prescription Service.

Repeatable prescribing services

52.—(1) A contractor may only provide repeatable prescribing services to a person on its list of patients if the contractor—

(a) satisfies the conditions in sub-paragraph (2), and

(b) has notified the relevant Local Health Board of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).

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

(a) the contractor has access to computer systems and software which enable it to issue non-electronic repeatable prescriptions and batch issues, and

(b) the practice premises at which the repeatable prescribing services are to be provided are located in an area of the Local Health Board in which there is also located the premises of at least one NHS pharmacist who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

(3) The notification referred to in sub-paragraph (1)(b) is a notification, in writing, by the contractor to the relevant Local Health Board that it—

(a) wishes to provide repeatable prescribing services,

(b) intends to begin to provide those services from a date specified in the notification, and

(c) satisfies the conditions in sub-paragraph (2).

(4) The date specified by the contractor under sub-paragraph (3)(b) must be at least 10 days after the date on which the notification specified in sub-paragraph (1) is given.

(5) Nothing in this paragraph requires a contractor or prescriber to provide repeatable prescribing services to any person.

(6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if—

(a) that person has agreed to receive such services on that occasion, and

(b) the prescriber considers that it is clinically appropriate to provide such services to that person on that occasion.

(7) The contractor may not provide repeatable prescribing services to any person on its list of patients to whom any person specified in sub-paragraph (8) is authorised or required by the Local Health Board to provide pharmaceutical services in accordance with arrangements under section 80 (arrangements for pharmaceutical services) and section 86 (persons authorised to provide pharmaceutical services) of the Act.

(8) The persons referred to in sub-paragraph (7) are—

(a) in the case of a contract with an individual medical practitioner, that medical practitioner,

(b) in the case of a contract with two or more individuals practising in partnership, any medical practitioner who is a partner,

(c)in the case of a contract with a company limited by shares, any medical practitioner who is both a legal and beneficial shareholder in that company, or

(d)any medical practitioner employed by the contractor.

Repeatable prescriptions

53.—(1) A prescriber who issues a non-electronic repeatable prescription must at the same time issue the appropriate number of batch issues.

(2) Where a prescriber wants to make a change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription, the prescriber must—

(a)in the case of a non-electronic repeatable prescription—

(i)give notice to the person, and

(ii)make reasonable efforts to give notice to the NHS pharmacist providing repeat dispensing services to that person,

that the original repeatable prescription is no longer to be used to obtain or provide repeat dispensing services and make arrangements for a replacement repeatable prescription to be issued to the person, or

(b)in the case of an electronic repeatable prescription—

(i)arrange with the Electronic Prescription Service for the cancellation of the original repeatable prescription, and

(ii)create a replacement repeatable prescription in respect of the person and give notice to the person that this has been done.

(3) Where a prescriber has created an electronic repeatable prescription for a person, the prescriber must, as soon as practicable, arrange with the Electronic Prescription Service for its cancellation if, before the expiry of that prescription—

(a)the prescriber considers that it is no longer safe or appropriate for the person to—

(i)receive the drugs, medicines or appliances ordered on the person's electronic repeatable prescription, or

(ii)continue to receive repeatable prescribing services,

(b)the prescriber has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription, or

(c)it comes to the prescriber's notice that the person on whose behalf the prescription was issued has been removed from the list of patients of the contractor.

(4) Where a prescriber has cancelled an electronic repeatable prescription in respect of a person in accordance with sub-paragraph (3), the prescriber must give notice of the cancellation to the person as soon as possible.

(5) A prescriber who has issued a non-electronic repeatable prescription in respect of a person must, as soon as possible, make reasonable efforts to give notice to the NHS pharmacist that that repeatable prescription must no longer be used to provide repeat dispensing services to that person, if, before the expiry of that repeatable prescription—

(a) the prescriber considers that it is no longer safe or appropriate for the person to—

(i) receive the drugs, medicines or appliances ordered on the person's repeatable prescription, or

(ii) to continue to receive repeatable prescribing services,

(b) the prescriber issues or creates a further repeatable prescription in respect of the person to replace the original repeatable prescription other than in the circumstances referred to in sub-paragraph (2)(a) (for example, because the person wants to obtain the drugs, medicines or appliances from a different NHS pharmacist), or

(c) it comes to the prescriber's notice that the person on whose behalf the prescription was issued has been removed from the list of patients of the contractor.

(6) Where the circumstances in sub-paragraph (5)(a) to (c) apply in respect of a person, the prescriber must, as soon as possible, give notice to that person that their repeatable prescription must no longer be used to obtain repeat dispensing services.

Prescribing for electronic repeat dispensing

54.—(1) Subject to paragraphs 49, 50, 52 and 53(2)(b) to (4), where a prescriber orders a drug, medicine or appliance by means of an electronic repeatable prescription, the prescriber must issue the prescription in a format appropriate for electronic repeat dispensing where it is clinically appropriate to do so for that patient on that occasion.

(2) In this paragraph, "electronic repeat dispensing" means dispensing as part of pharmaceutical services or local pharmaceutical services which involves the provision of drugs, medicines or appliances in accordance with an electronic repeatable prescription.

Restrictions on prescribing by medical practitioners

55.—(1) A medical practitioner, in the course of treating a patient to whom the practitioner is providing treatment under the contract, must comply with the following sub-paragraphs.

(2) The medical practitioner must not order on a listed medicines voucher, prescription form or a repeatable prescription, drugs, medicines or other substances specified in any directions given by the Welsh Ministers in regulations made under section 46 of the Act (GMS contracts: prescription of drugs etc) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract.

(3) The medical practitioner must not order on a listed medicines voucher, a prescription form or repeatable prescription drugs, medicines or other substances specified in any directions given by the Welsh

Ministers under section 46 of the Act (GMS contracts: prescription of drugs etc) as being a drug, medicine or other substance which can only be ordered for specified patients and for specified purposes unless—

- (a) the patient is a person of the specified description,
- (b) the drug, medicine or other substance is prescribed for that patient only for the specified purpose, and
- (c) if the order is on a prescription form, the practitioner includes on the form the reference "SLS".

(4) The medical practitioner must not order on a prescription form or repeatable prescription a restricted availability appliance unless—

- (a) the patient is a person, or the restricted availability appliance is for a purpose, specified in the Drug Tariff, and
- (b) the practitioner includes on the prescription form the reference "SLS".

(5) The medical practitioner must not order on a repeatable prescription a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23 26 and 27) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001.

(6) Subject to regulation 21(2)(b) and to sub-paragraph (7), nothing in the preceding sub-paragraphs prevents a medical practitioner, in the course of treating a patient to whom this sub-paragraph refers, from prescribing a drug, medicine or other substance or, as the case may be, a restricted availability appliance or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), for the treatment of that patient under a private arrangement.

(7) Where, under sub-paragraph (6), a drug, medicine or other substance is prescribed under a private arrangement, if the order is to be transmitted as an electronic communication to an NHS pharmacist for the drug, medicine or appliance to be dispensed—

- (a) if the order is not for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 16A, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001, it may be transmitted by the Electronic Prescription Service, but
- (b) if the order is for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 16A, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001, it must be transmitted by the Electronic Prescription Service.

Restrictions on prescribing by supplementary prescribers

56.—(1) The contractor must have arrangements in place to secure that an individual who is a supplementary prescriber may—

- (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 only under the conditions set out in sub-paragraph (2).

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

(a) the individual satisfies the applicable conditions set out in regulation 215 of the Human Medicines Regulations 2012(**60**) (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 Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(c) the drug, medicine or other substance is not specified in any directions given by the Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

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

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

(iii) if the supplementary prescriber is giving a prescription, he or she endorses the face of the form with the reference “SLS”.

(3) Where the functions of a supplementary prescriber include prescribing, the contractor must have arrangements in place to secure that that person may only give 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 set out in this paragraph are that—

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

(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 Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the 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 Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

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

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

(iii)when giving the prescription, the supplementary prescriber endorses the face of the form with the reference "SLS",

(e)if it is a prescription for an appliance, the appliance is listed in Part 9 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 9 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 giving the prescription, the supplementary prescriber endorses the face of the form with the reference "SLS".

(5) In sub-paragraph (4)(a), "clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

- (a) the patient to whom the plan relates,
- (b) the medical practitioner or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.

Bulk prescribing

57.—(1) A prescriber may use a single non-electronic prescription form where—

- (a) a contractor is responsible under the contract for the treatment of 10 or more persons in a school or other institution in which at least 20 persons normally reside, and
- (b) the prescriber orders, for any 2 or more of those persons for whose treatment the contractor is responsible, drugs, medicines or appliances to which this paragraph applies.

(2) Where a prescriber uses a single non-electronic prescription form for the purpose mentioned in sub-paragraph (1)(b), the prescriber must (instead of entering on the form the names of the persons for whom the drugs, medicines or appliances are ordered) enter on the form—

- (a) the name of the school or other institution in which those persons reside, and
- (b) the number of persons residing there for whose treatment the contractor is responsible.

(3) This paragraph applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which in the case of—

- (a) a drug or medicine, is not a prescription only medicine, or
- (b) an appliance, does not contain such a product.

Excessive prescribing

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

(2) In considering whether a contractor has breached its obligations under sub-paragraph (1), the Local Health Board must seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.

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

59.—(1) Subject to sub-paragraphs (2) and (3), a contractor—

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

(b) may provide to a patient a drug, medicine or appliance, which is not a Scheduled drug, which the contractor personally administers or applies to the patient.

(2) A contractor must only provide a restricted availability appliance under sub-paragraph (1)(a) or (b) if it is for a person or a purpose specified in the Drug Tariff.

(3) Nothing in sub-paragraph (1) or (2) authorises a person to supply a prescription only medicine to a patient otherwise than in accordance with Part 12 of the Human Medicines Regulations 2012 (which relates to dealings with medicinal products).

Provision of dispensing services

60.—(1) The contractor may only provide, and must ensure that those employed or engaged by it only provide, pharmaceutical services or dispensing services in the circumstances provided for in the Pharmaceutical Regulations.

(2) Where the contractor, or a person employed or engaged by the contractor, is included in the Local Health Board's dispensing doctor list, the contractor must ensure that in the provision of any pharmaceutical services or dispensing services the contractor, and the dispensing doctor (and any person authorised to dispense on their behalf under the Pharmaceutical Regulations)—

(a) complies with the terms of service applicable to the person providing those pharmaceutical services or dispensing services by virtue of regulation 12(2) of the Pharmaceutical Regulations, and

(b) ensures that the patient to whom they are seeking to provide those services is aware that the relevant drugs or appliances are not only available from them (or by a person with whom the contractor is associated) and that the patient has the option to obtain those drugs or appliances from any NHS pharmacist.

PART 6 Persons who perform services

Qualifications of performers: medical practitioners

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

(a) included in a medical performers' list for a Local Health Board in Wales,

(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 order).

(2) Sub-paragraph (1) does not apply to any medical practitioner who is an exempt medical practitioner within the meaning of sub-paragraph (3) but only in so far as any medical services that the medical practitioner performs constitute part of a post-registration programme.

(3) For the purposes of this paragraph, an “exempt medical practitioner” is—

(a)a medical practitioner employed by an NHS trust(61), an NHS foundation trust(62), a Health Board, or 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 the Medical Act 1983 and who is acting in the course of the person's employment in a resident medical capacity,

(c)a GP Specialty Registrar who has applied to a Local Health Board to have their name included in its medical performers list until the first of the following events arises—

(i)the Local Health Board notifies the GP Specialty Registrar of its decision on that application, or

(ii)the end of a period of 12 weeks, starting with the date on which that GP Specialty Registrar begins a postgraduate medical education and training scheme necessary for the award of a Certificate of Completion of Training,

(d)a medical practitioner who is already included in the medical performers list of another primary care organisation and who has submitted an application to a Local Health Board in accordance with regulation 4A of the National Health Service (Performers Lists) (Wales) Regulations 2004 until the first of the following events arises—

(i)the Local Health Board notifies the medical practitioner of its decision on that application, or

(ii)the end of a period of 12 weeks, starting with the date on which the application was submitted, or

(e)a medical practitioner, who—

(i)is not a GP Specialty Registrar,

(ii)is undertaking a post-registration programme of clinical practice supervised by the General Medical Council,

(iii)has notified the Local Health Board that they are to undertake part or all of a post-registration programme in its area at least 24 hours before commencing any part of that programme taking place in the Local Health Board's area, and

(iv)has, with that notification, provided the Local Health Board with evidence sufficient for it to satisfy itself that they are undertaking a post-registration programme,

but only in so far as any medical services that the medical practitioner performs constitute part of a post-registration programme.

Qualifications of performers: health care professionals

62. A health care professional (other than one to whom paragraph 61 applies) may not perform clinical services under the contract unless—

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

Conditional registration or inclusion in primary care list

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

Clinical experience

64. 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: medical practitioner

65.—(1) Subject to sub-paragraphs (2) to (4), a contractor must not employ or engage a medical practitioner (other than an exempt medical practitioner within the meaning of sub-paragraph 61(3)) unless—

- (a) that practitioner has provided the contractor with the name and address of the Local Health Board on whose medical performers list the practitioner appears, and
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 61.

(2) Where—

- (a) the employment or engagement of a medical practitioner is urgently needed, and
 - (b) it is not possible for the contractor to check that the medical practitioner meets the requirements referred to in paragraph 61 before employing or engaging the health care professional,
- the contractor may employ or engage the medical practitioner on a temporary basis for a single period of up to 7 days while such checks are undertaken.

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

- (a) the name and address provided under sub-paragraph (1) may be the name and address of the Local Health Board on whose list the GP Specialty Registrar has applied for inclusion, and
- (b) confirmation that the GP Specialty Registrar's name appears on that list is not to be required until the end of the first 12 weeks of the GP Specialty Registrar's training period.

(4) Where the prospective employee is a medical practitioner who is already included in the medical performers list of another primary care organisation and who has submitted an application to the Local Health Board in accordance with regulation 4A of the National Health Service (Performers Lists) (Wales) Regulations 2004, the requirements set out in sub-paragraph (1) apply with the modifications that—

(a) the name and address provided under sub-paragraph (1) may be the name and address of the Local Health Board on whose list the medical practitioner has applied for inclusion, provided that the name and address of the primary care organisation on whose list the medical practitioner is already included is provided in addition; and

(b) confirmation that the medical practitioner's name appears on that list means confirmation that the medical practitioner is provisionally included in the Local Health Board's medical performers list in accordance with regulation 4A of the National Health Service (Performers Lists) (Wales) Regulations 2004.

(5) In this paragraph "primary care organisation" has the meaning given in regulation 2 of the National Health Service (Performers Lists) (Wales) Regulations 2004.

Conditions for employment or engagement: health care professionals

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

(a) the contractor has checked that the health care professional meets the requirements of paragraph 62, and

(b) the contractor has taken reasonable steps to satisfy itself that the health care professional meets the requirements of paragraph 64.

(2) Where—

(a) the employment or engagement of a health care professional is urgently needed, and

(b) it is not possible for the contractor to check that the health care professional meets the requirements referred to in paragraph 62 before employing or engaging the health care professional,

the contractor may employ or engage the health care professional on a temporary basis for a single period of up to 7 days while such checks are undertaken.

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

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

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

Clinical references

67.—(1) The contractor may not employ or engage a health care professional to perform clinical services under the contract (other than an exempt medical practitioner to whom paragraph 61(3)(e) applies) unless—

- (a) that person has provided two clinical references, relating to two recent posts (which may include any current post) as a health care professional which lasted for at least 12 weeks without a significant break or, where this is not possible, a full explanation of why this is the case and details of alternative referees, and
- (b) the contractor has checked and is satisfied with the references.

(2) Where—

- (a) the employment or engagement of a health care professional is urgently needed, and
 - (b) it is not possible for the contractor to obtain and check the references in accordance with sub-paragraph (1)(b) before employing or engaging that health care professional,
- the contractor may employ or engage the health care professional on a temporary basis for a single period of up to 14 days while the references are checked and considered, and for an additional period of a further 7 days if the contractor believes that the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the contractor employs or engages the same person on more than one occasion within a period of 12 weeks, the contractor may rely on the references provided on the first occasion, provided that those references are not more than a year old.

Verification of qualifications and competence

68.—(1) The contractor must, before employing or engaging any person—

- (a) comply with the Pre-employment Checks Standards in relation to that person, and
- (b) take reasonable steps to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which that person is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 61 to 67.

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

- (a) that person's academic and vocational qualifications,
- (b) that person's education and training, and
- (c) that person's previous employment or work experience.

Training

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

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

there are in place arrangements for the purpose of maintaining and updating the health care professional's skills and knowledge in relation to the services which they are performing or assisting in performing.

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

Terms and conditions

70. The contractor 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(63).

Arrangements for GP Specialty Registrars

71.—(1) The contractor may only employ a GP Specialty Registrar subject to the conditions in sub-paragraph (2).

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

(3) A contractor employing 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 Welsh Ministers to Local Health Boards under section 12 of the Act (Functions of Local Health Board) concerning the grants, fees, travelling and other allowances payable to GP Registrars, and

(b) take into account the guidance contained in the document entitled "A Reference Guide For Postgraduate Foundation and Specialty Training in the UK"(64).

Notice requirements in respect of relevant prescribers

72.—(1) For the purposes of this paragraph, "a relevant prescriber" is—

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

(2) The contractor must give notice to the Local Health Board where—

(a) a relevant prescriber is employed or engaged by a contractor to perform functions which include prescribing,

(b) a relevant prescriber whose functions include prescribing is a party to the contract, or

(c) the functions of a relevant prescriber whom the contractor already employs or has already engaged are extended to include prescribing.

(3) The notice under sub-paragraph (2) must be given in writing to the Local Health Board before the expiry of the period of 7 days beginning with the date on which—

(a) the relevant prescriber was employed or engaged by the contractor or, as the case may be, became a party to the contract (unless, immediately before becoming such a party, sub-paragraph (2)(a) applied to that relevant prescriber), or

(b) the functions of the relevant prescriber were extended to include prescribing.

(4) The contractor must give notice to the Local Health Board where—

(a) the contractor ceases to employ or engage a relevant prescriber in the contractor's practice whose functions include prescribing in the contractor's practice,

(b) a relevant prescriber ceases to be a party to the contract,

(c) the functions of a relevant prescriber employed or engaged by the contractor in the contractor's practice are changed so that they no longer include prescribing in the contractor's practice, or

(d) the contractor becomes aware that a relevant prescriber whom it employs or engages has been removed or suspended from the relevant register.

(5) The notice under sub-paragraph (4) must be given in writing to the Local Health Board before the end of the second working day after the day on which an event described in sub-paragraphs (4)(a) to (d) occurred in relation to the relevant prescriber.

(6) The contractor must provide the following information when it gives notice to the Local 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 the person's entry in the relevant register was annotated to the effect that the person was qualified to order drugs, medicines and appliances for patients,

(e) the date on which—

(i) the person was employed or engaged (if applicable),

(ii) the person became a party to the contract (if applicable), or

(iii) the functions of the person were extended to include prescribing in the contractor's practice.

(7) The contractor must provide the following information when it gives notice to the Local Health Board in accordance with sub-paragraph (4)—

(a) the person's full name,

(b) the person's professional qualifications,

(c) the person's identifying number which appears in the relevant register,

(d) the date on which—

(i) the person ceased to be employed or engaged in the contractor's practice,

(ii) the person ceased to be a party to the contract,

(iii) the functions of the person were changed so as to no longer include prescribing in the contractor's practice, or

(iv) the person was removed or suspended from the relevant register.

Signing of documents

73.—(1) The contractor must ensure—

(a) that the documents specified in sub-paragraph (2) include—

(i) the clinical profession of the health care professional who signed the document, and

(ii) the name of the contractor on whose behalf the document is signed, and

(b) that the documents specified in sub-paragraph (3) include the clinical profession of the health care professional who signed the document.

(2) The documents specified in this sub-paragraph are—

(a) certificates issued in accordance with regulation 19, unless regulations relating to particular certificates provide otherwise, and

(b) any other clinical documents apart from—

(i) home oxygen order forms, and

(ii) the documents specified in sub-paragraph (3).

(3) The documents specified in this paragraph are batch issues, prescription forms and repeatable prescriptions.

(4) This paragraph is in addition to any other requirements relating to the documents specified in sub-paragraphs (2) and (3) whether in these Regulations or elsewhere.

Level of skill and compliance with pathways

74. The contractor must, and the contractor must ensure that those it employs or engages must—

- (a) carry out the contractor's obligations under the contract with reasonable care and skill, and
- (b) consider the application of national condition pathways relevant for each patient.

Appraisal and assessment

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

- (a) participates in the appraisal system provided by the Local Health Board unless that medical practitioner participates in an appropriate appraisal system provided by another health service body or is an armed forces GP, and
- (b) co-operates with the Local Health Board in relation to the Local Health Board's patient safety functions.

(2) The Local Health Board must provide an appraisal system for the purposes of sub-paragraph (1)(a) after consultation with the Local Medical Committee (if any) for the area in which the practitioner provides services under the contract and such other persons as appear to it to be appropriate.

(3) In 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 armed forces of the Crown.

PART 7 Sub-contracting

Sub-contracting

76.—(1) Subject to sub-paragraph (2), the contractor must not sub-contract any of its rights or duties under the contract in relation to clinical matters, or non-clinical matters directly affecting patients, unless—

- (a) in all cases it has taken reasonable steps to satisfy itself that—
 - (i) it is reasonable in all the circumstances to do so, and
 - (ii) that person to whom any of those rights or duties is sub-contracted is qualified and competent to provide the service, and
- (b) the contractor has given notice in writing to the Local 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 effect.

(2) Sub-paragraph (1)(b) does not apply to—

- (a) a contract for services with a health care professional for the provision by that professional personally of clinical services, or
- (b) a contract between the contractor and another practice in the contractor's GP Collaborative under which that other practice is to provide, as part of that GP Collaborative's activities, primary medical services to the contractor's patients.

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

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

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

(5) The contractor must not proceed with the sub-contract or, if the sub-contract has already taken effect, the contractor must take all reasonable steps to terminate it, where the Local Health Board gives notice in writing of its objection to the sub-contract on the grounds that—

(a) the sub-contract would—

- (i) put the safety of the contractor's patients at risk, or
- (ii) put the Local Health Board at risk of material financial loss,

(b) the sub-contractor would be unable to meet the contractor's obligations under the contract,

and such notice is given by the Local Health Board before the end of the period of 28 days beginning with the date on which the Local Health Board received a notice from the contractor under sub-paragraph (1)(b).

(6) A notice given by the Local Health Board under sub-paragraph (5)(a) must include a statement of the reasons for the Local Health Board's objection.

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

(8) Where the notification by the contractor pursuant to sub-paragraph (3) relates to clinical matters and the Local Health Board does not give notice of an objection under sub-paragraph (5), the parties to the contract are deemed to have agreed a variation of the contract which, subject to any notice served under sub-paragraph (1)(b), has the effect of adding to the list of practice premises any premises the address of which was notified to the Local Health Board under sub-paragraph (3)(d) and, in these circumstances, paragraph 109(1) does not apply.

(9) Subject to sub-paragraph (10), a sub-contract entered into by a contractor must prohibit the sub-contractor from sub-contracting any of the clinical services that it has agreed with the contractor to provide under the sub-contract.

(10) A sub-contract entered into by the contractor falling within sub-paragraph (2)(b) may allow the sub-contractor to sub-contract clinical services provided the contractor obtains the written approval of the Local Health Board prior to the sub-contractor sub-contracting those services.

(11) The contractor must not sub-contract any of its rights or duties under the contract in relation to the provision of unified services to a company or firm—

(a) owned wholly or partly by the contractor, or by any former or current employee of, or partner or shareholder in, the contractor,

(b) formed by or on behalf of the contractor, or from which it derives or may derive a pecuniary benefit, or

(c) formed by or on behalf of a former or current employee of, or partner or shareholder in, the contractor, or from which such a person derives or may derive a pecuniary benefit,

where sub-paragraph (12) applies to that company or firm.

(12) This sub-paragraph applies to a company or firm which is or was formed wholly or partly for the purpose of avoiding the restrictions on the sale of goodwill of a medical practice in regulation 3 of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) (Wales) Regulations 2004(65).

Withdrawal and variation of approval and right to subsequently object to a sub-contract under paragraph 76

77.—(1) Without prejudice to any other remedies which it may have under the contract, where a Local Health Board is deemed to have approved an application made under paragraph 76, it is entitled to serve notice on the contractor withdrawing or varying that approval with immediate effect if—

(a) it is no longer satisfied that the proposed arrangement enables the contractor to satisfactorily meet its obligations under the contract, or

(b) it is satisfied that immediate withdrawal of variation is necessary to protect—

(i) the safety of the contractor's patients, or

(ii) the Local Health Board from material financial loss.

(2) A notice served under this paragraph takes effect on the date on which it is received by the contractor.

PART 8 Records, information, notifications and rights of entry

Patient records

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

(a) on forms supplied to it for the purpose by the Local Health Board, or

(b) with the written consent of the Local Health Board, by way of computerised records,

or in a combination of those two ways.

(2) The contractor must include in the records referred to in sub-paragraph (1) clinical reports sent in accordance with paragraph 10 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 Local Health Board required by sub-paragraph (1)(b) must not be withheld or withdrawn provided the Local Health Board is satisfied, and continues to be satisfied, that—

(a) the GP digital services upon which the contractor proposes to keep the records meet the requirements set out in the National Framework Agreement for GP Clinical Systems and Services in Wales,

(b) the security measures, audit and system management functions incorporated into the GP digital services are compliant with the National Framework Agreement for GP Clinical Systems and Services in Wales have been enabled, and

(c) the contractor is aware of, and has signed an undertaking that it must have regard to the guidelines contained in “The Good Practice Guidelines for GP electronic patient records (Version 4)” published on 21 March 2011.

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

(5) Where a patient on the contractor’s list of patients dies, the contractor must send the complete records relating to that patient to the Local Health Board—

(a) in a case where the contractor was informed by the Local Health Board of that patient’s death, before the end of the period of 14 days beginning with the date on which the contractor was so informed, or

(b) in any other case, before the end of the period of 4 weeks beginning with the date on which the contractor learned of that patient’s death.

(6) Where a patient on a contractor’s list of patients has registered with another provider of primary medical services and the contractor receives a request from that provider for the complete records relating to that patient, the contractor must, as soon as possible and in any event before the end of the period of 28 days beginning with the day on which it receives the request from the provider, send to that provider the complete records (other than any part held only in paper form), via the GP2GP facility in accordance with paragraph 80 and send to the Local Health Board—

(a) the complete records, or any part of the records, sent via the GP2GP facility in accordance with paragraph 80 for which the contractor does not receive confirmation of safe and effective transfer via that facility, and

(b) any part of the records held by the contractor only in paper form.

(7) Where a patient on a contractor’s list of patients—

(a) is removed from that list at that patient’s request under paragraph 28, or by reason of the application of any of paragraphs 29 to 36, and

(b)the contractor has not received a request from another provider of medical services with which that patient has registered for the transfer of the complete records relating to that patient,
the contractor must send a copy of those records to the Local Health Board.

(8) Where a contractor's responsibility for a patient terminates in accordance with paragraph 37, the contractor must send any records relating to that patient that it holds to—

- (a)if known, the provider of primary medical services with which that patient is registered, or
- (b)in all other cases, the Local Health Board.

(9) For the purposes of this regulation, "GP2GP facility" has the same meaning as in sub-paragraph (2) of paragraph 80.

(10) To the extent that a patient's records are computerised records, the contractor complies with sub-paragraphs (5), (7) or (8) if it sends to the Local Health Board a copy of those records—

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

(11) The consent of the Local Health Board to the transmission of information other than in written form for the purposes of sub-paragraph (10)(b) must not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with the following matters—

- (a)the contractor's proposals as to how the record is to be transmitted,
- (b)the contractor's proposals as to the format of the transmitted record,
- (c)how the contractor is to ensure that the record received by the Local Health Board is identical to that transmitted, and
- (d)how a written copy of the record can be produced by the Local Health Board.

(12) A contractor whose patient records are computerised 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).

(13) In this paragraph, "computerised records" means records created by way of entries on a computer.

Welsh GP record

79.—(1) Subject to sub-paragraph (2), a contractor must, in any case where there is a change to the information included in a patient's medical record, enable the automated retrieval of summary information from the Welsh GP Record and the NHS Wales App, when the change occurs, using approved systems provided to it by the Local Health Board.

(2) The enabling of automated retrieval of summary information from the Welsh GP Record must be for clinical use.

(3) In this paragraph—

“NHS Wales App” (“*Ap GIG Cymru*”) means the system managed by Digital Health and Care Wales for accessing and managing health appointments, prescriptions and personal details;

“Welsh GP Record” (“*Cofnod Meddyg Teulu Cymru*”) means the system approved by the Local Health Board for the automated retrieval, storing and displaying of patient data relating to medications, allergies, adverse reactions and, where agreed with the contractor and subject to the patient’s consent, any other data taken from the patient’s electronic record;

“summary information” (“*gwybodaeth gryno*”) means items of patient data that comprise the Welsh GP Record.

Electronic transfer of patient records between GP practices

80.—(1) A contractor must use the GP2GP facility for the safe and effective transfer of any patient records—

(a) in a case where a new patient registers with the contractor’s practice, to the contractor’s practice from the practice of another provider of primary medical services (if any) with which the patient was previously registered, or

(b) in a case where the contractor receives a request from another provider of primary medical services with which the patient has registered, in order to respond to that request.

(2) In this paragraph, “GP2GP facility” means the facility provided by the Local Health Board to a contractor’s practice which enables the electronic health records of a registered patient which are held on the computerised clinical systems of a contractor’s practice to be electronically transferred securely and directly to another provider of primary medical services with which the patient has registered.

(3) The requirements of this paragraph do not apply in the case of a temporary resident.

Clinical correspondence: requirement for NHS number

81.—(1) A contractor must include the NHS number of a registered patient as the primary identifier in all clinical correspondence issued by the contractor which relates to that patient.

(2) The requirement in sub-paragraph (1) does not apply where, in exceptional circumstances outside of the contractor’s control, it is not possible for the contractor to ascertain the patient’s NHS number.

(3) In this paragraph—

“clinical correspondence” (“*gohebiaeth glinigol*”) means all correspondence in writing, whether in electronic form or otherwise, between the contractor and other health service providers concerning or arising out of patient attendance and treatment at practice premises including referrals made by letter or by any other means;

“NHS number” (“*rhif G/G*”), in relation to a registered patient, means the number, consisting of ten numeric digits, which serves as the national unique identifier used for the purpose of safely, accurately and efficiently sharing information relating to that patient across the whole of the health service in Wales.

Use of fax machines

82.—(1) Where a contractor can transmit information securely and directly by electronic means other than facsimile transmission, the contractor must not—

- (a) transmit information to a relevant person by facsimile transmission, or
- (b) agree to receive any information from a relevant person by facsimile transmission.

(2) Sub-paragraph (1) does not apply to information which relates solely to a patient under a private arrangement for the provision of clinical services or treatment.

(3) In this paragraph “relevant person” means—

- (a) an NHS body,
- (b) another health service provider,
- (c) a patient, or
- (d) a person acting on behalf of a patient.

Confidentiality of personal data: nominated person

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

Provision of information to patients

84.—(1) The contractor must—

- (a) have an online resource,
- (b) provide the information specified in Schedule 4 digitally on the practice’s online resource and ensure that a written practice leaflet containing the information specified in Schedule 4 is also available,
- (c) review the information provided in paragraphs (a) and (b) at least once every year, and
- (d) make its patients and prospective patients aware of the information contained on their practice’s online resource or how they can access this information in a written practice leaflet.

(2) The contractor must make any amendments necessary to maintain the accuracy of the information on its online resource following—

- (a) a review under sub-paragraph (1)(c),
- (b) a change to—
 - (i) the address of any of the contractor’s practice premises,

(ii) the contractor's telephone number,

(iii) the contractor's electronic-mail address (if made available on its online resource), or

(iv) any other stated means by which a patient may contact the contractor to book or amend an appointment, or to order repeat prescriptions for drugs, medicines or appliances.

Provision of information (or access to information) at the request of the Local Health Board

85.—(1) Subject to sub-paragraph (2), the contractor must, at the request of the Local Health Board, produce to the Local Health Board or to a person authorised in writing by the Local Health Board, or allow the Local Health Board or a person authorised in writing by it, to access—

(a) any information which is reasonably required by the Local Health Board for the purposes of or in connection with the contract, and

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

(2) The contractor is not required to comply with any request made in accordance with sub-paragraph (1) unless it has been made by the Local Health Board in accordance with directions relating to the provision of information by contractors given to it by the Welsh Ministers under section 12(3) of the Act.

(3) The contractor must produce the information requested, or, as the case may be, allow the Local Health Board access to that information—

(a) by a date agreed as reasonable between the contractor and the Local Health Board, or

(b) in the absence of such agreement, within 28 days beginning with the date the request is made.

Clinical audits

86.—(1) A contractor must record and allow Digital Health and Care Wales to access any data required by the Local Health Board for the purposes of the National Clinical Audit and Outcome Review Programme for NHS Wales in accordance with sub-paragraph (2).

(2) The data referred to in sub-paragraph (1) must be appropriately coded by the contractor using standardised coding and uploaded onto the contractor's computerised clinical systems in line with the requirements of guidance published by Digital Health and Care Wales for these purposes.

(3) The contractor must permit the extraction of patient level data by Digital Health and Care Wales for the purpose of undertaking clinical audits included in the National Clinical Audit and Outcome Review Programme (NCAORP) to support the management of the health and care system.

(4) Contractors must consider practice level data from national clinical audits and take relevant and proportionate action to reduce any significant and unwarranted variation that is identified.

Information relating to indicators no longer in the Quality Assurance and Improvement Framework

87.—(1) A contractor must allow the extraction from the contractor's computerised clinical systems by the Local Health Board of the information specified in the table below (Indicators relocated from the Quality

Assurance and Improvement Framework) at such intervals during each financial year as are notified to the contractor by the Local Health Board.

(2) A contractor must—

(a) establish and maintain the registers specified in the clinical indicators listed in the column “Indicator Description” of the table below (Indicators relocated from the Quality Assurance and Improvement Framework),

(b) where an indicator specifies a particular statistic, contemporaneously record the related data as part of chronic disease management, and

(c) where the indicator specifies a particular requirement or activity, continually record details of the contractor’s compliance with any such requirements or activities.

Table (Indicators relocated from the Quality Assurance and Improvement Framework)

<i>Indicator ID</i>	<i>Indicator Description</i>
AF001	The contractor establishes and maintains a register of patients with atrial fibrillation
CHD001	The contractor establishes and maintains a register of patients with coronary heart disease
HF001	The contractor establishes and maintains a register of patients with heart failure
HYP001	The contractor establishes and maintains a register of patients with established hypertension
STIA001	The contractor establishes and maintains a register of patients with stroke or TIA
DM001	The contractor establishes and maintains a register of all patients aged 17 or over with diabetes mellitus, which specifies the type of diabetes where a diagnosis has been confirmed
AST001	The contractor establishes and maintains a register of patients with asthma, excluding patients with asthma who have been prescribed no asthma-related drugs in the preceding 12 months
COPD001	The contractor establishes and maintains a register of patients with COPD
DEM001	The contractor establishes and maintains a register of patients diagnosed with dementia
MH001	The contractor establishes and maintains a register of patients with schizophrenia, bipolar affective disorder and other psychoses and other patients on lithium therapy
CAN001	The contractor establishes and maintains a register of all cancer patients defined as a “register of patients with a diagnosis of cancer excluding non-melanocytic skin cancers diagnosed on or after 1 April 2003”
EP001	The contractor establishes and maintains a register of patients aged 18 or over receiving drug treatment for epilepsy
LD001	The contractor establishes and maintains a register of patients with learning disabilities
OST001	The contractor establishes and maintains a register of patients—

1. Aged 50 or over and who have not attained the age of 75 with a record of a fragility fracture on or after 1 April 2012 and a diagnosis of osteoporosis confirmed on DXA scan, and
2. Aged 75 or over with a record of a fragility fracture on or after 1 April 2012

RA001	The contractor establishes and maintains a register of patients aged 16 or over with rheumatoid arthritis
PC001	The contractor establishes and maintains a register of all patients in need of palliative care/support irrespective of age
OB001	The contractor establishes and maintains a register of patients aged 16 or over with a BMI of 30 in the preceding 15 months
AF006	The percentage of patient with atrial fibrillation in whom stroke risk has been assessed using CHA2DS2-VASx score risk stratification system in the preceding 3 years (excluding those patients with a previous CHADS2 or CHA2DS2-VASc score of 2 or more) and a record of counselling regarding the risks and benefits of anticoagulation therapy has been made
AF007	In those patients with atrial fibrillation with a record of a CHA2DS ² -VASc score of 2 or more, the percentage of patients who are currently treated with anticoagulation drug therapy
DM002	The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 15 months) is 150/90 mmHg or less
DM003	The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 15 months) is 140/80 mmHg or less
DM007	The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 15 months
DM012	The percentage of patients with diabetes, on the register, with a record of a foot examination and risk classification; 1) low risk (normal sensation, palpable pulse), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer or 4) ulcerated foot within the preceding 15 months
DM014	The percentage of patients newly diagnosed with diabetes, on the register, in the preceding 1 April to 31 March who have a record of being referred to a structured education programme within 9 months after entry on to the diabetes register
COPD003	The percentage of patients with COPD who have had a review, undertaken by a healthcare professional, including an assessment of breathlessness using the Medical Research Council dyspnoea scale in the preceding 15 months
MH011W	The percentage of patients with Schizophrenia, Bipolar affective disorder and other psychoses who have a record of blood pressure, BMI, smoking status and alcohol consumption in the preceding 15 months and in addition to those aged 40 or over, a record of blood glucose or HbA1c in the preceding 15 months
PC002W	The contractor has regular (at least 2 monthly) multi-disciplinary case review meetings where all patients on the palliative care register are discussed

- FLU001W The percentage of the registered population aged 65 years or more who have had influenza immunisation in the preceding 1 August to 31 March
- FLU002W The percentage of patients aged under 65 years included in (any of) the registers for CHD, COPD, Diabetes or stroke who have had influenza immunisation in the preceding 1 August to 31 March

The Wales National Workforce Reporting System

88.—(1) The contractor must update the workforce elements of the Wales National Workforce Reporting System to include—

- (a) head count and whole-time equivalents, and
- (b) a record of all new starters and leavers.

(2) The contractor must access, review and (if necessary) update their Wales National Workforce Reporting System dashboard view at least once per month.

General Practice Escalation Tool

89. The contractor must enter their escalation submission in the General Practice Escalation Tool by 3.30pm on the last working day of each month and also on each occasion that there is a significant change in practice circumstances.

Medicines and Healthcare Products Regulatory Agency Central Alerting System

90. A contractor must—

- (a) provide to the Medicines and Healthcare Products Regulatory Agency (“the MHRA”) on request, an electronic mail address which is registered to the contractor’s practice,
- (b) monitor that address,
- (c) if that address ceases to be registered to the practice, notify the MHRA immediately of its new electronic mail address, and
- (d) provide to the MHRA on request, one or more mobile telephone numbers for use in the event that the contractor is unable to receive electronic mail.

Inquiries about prescriptions and referrals

91.—(1) The contractor must, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether they are oral or in writing from the Local Health Board concerning—

- (a) any prescription form or repeatable prescription issued by a prescriber,
 - (b) the considerations by reference to which prescribers issue such forms,
 - (c) the referral by or on behalf of the contractor of any patient to any other services provided under the Act,
- or

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

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

(3) The contractor is not obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made—
(a) in the case of sub-paragraph (1)(a) or (b), by an appropriately qualified health care professional, or
(b) in the case of sub-paragraph (1)(c) or (d), by an appropriately qualified medical practitioner.

(4) The appropriately qualified person referred to in sub-paragraph (3)(a) or (b) must—
(a) be appointed by the Local Health Board in either case to assist it in the exercise of its functions under this paragraph, and
(b) produce, on request, written evidence of that person's authority from the Local Health Board to make such an inquiry on the Local Health Board's behalf.

Provision of information to a medical officer etc.

92.—(1) The contractor must, if satisfied that the patient consents—
(a) supply in writing to any person specified in sub-paragraph (3) (a "relevant person"), 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 contractor or a person acting on behalf of the contractor has issued or has refused to issue a medical certificate, and
(b) answer any inquiries by a relevant person about—
(i) a prescription form or medical certificate issued or created by, or on behalf of, the contractor, or
(ii) any statement which the contractor or a person acting on behalf of the contractor has made in a report.

(2) For the purposes of being satisfied that a patient consents, a contractor may rely on an assurance in writing from a relevant person that the consent of the patient has been obtained, unless the contractor has reason to believe that the patient does not consent.

(3) For the purposes of sub-paragraph (1) and (2), a "relevant person" is—
(a) a medical officer,
(b) a nursing officer,
(c) an occupational therapist,
(d) a physiotherapist, or
(e) an officer of the Department for Work and Pensions who is acting on behalf of, and at the direction of, any person specified in paragraphs (a) to (d).

(4) In this paragraph—

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

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

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

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

“occupational therapist” (“*therapydd galwedigaethol*”) means a health care professional who is registered in the part of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001 (establishment and maintenance of register) relating to occupational therapists and who is—

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

“physiotherapist” (“*ffisiotherapydd*”) means a health care professional who is registered in the part of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001 (establishment and maintenance of register) relating to physiotherapists and who is—

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

Annual return and review

93.—(1) The contractor must submit an annual return relating to the contract to the Local Health Board which requires the same categories of information from all persons who hold contracts with that Local Health Board.

(2) The Local Health Board may request a return relating to the contract at any time during each financial year in relation to such period (not including any period covered by a previous annual return) as may be specified in the request.

(3) The contractor must submit the completed return to the Local Health Board—

- (a) by a date agreed as reasonable between the contractor and the Local Health Board, or
- (b) in the absence of such agreement, before the end of the period of 28 days beginning with the date on which the request was made.

(4) Following receipt of the return referred to in sub-paragraph (1), the Local Health Board must arrange with the contractor an annual review of its performance in relation to the contract.

(5) The contractor or the Local Health Board may, if desired, invite the Local Medical Committee (if any) for the area in which the contractor is providing services under the contract to participate in the annual review.

(6) The Local Health Board must prepare a draft record of the review referred to in sub-paragraph (4) for comment by the contractor and, having regard to such comments, produce a final written record of the review.

(7) The Local Health Board must send a copy of the final record of the review referred to in sub-paragraph (6) to the contractor.

Notifications to the Local Health Board

94.—(1) In addition to any requirements of notification elsewhere in these Regulations, the contractor must notify the Local Health Board in writing, as soon as reasonably practicable, of—

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

(b) any circumstances which give rise to the Local Health Board's right to terminate the contract under Part 11;

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

(d) any change of which the contractor is aware in the address of a registered patient;

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

(2) The contractor must, unless it is impracticable for it to do so, notify the Local Health Board in writing within 28 days of any occurrence requiring a change in the information about it published by the Local Health Board in accordance with regulations made under section 41 of the Act (primary medical services).

(3) The contractor must notify the Local 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 unified services described in regulation 17(7) or (9) within the period of 28 days beginning on the day that the services were provided.

Co-operation with the Local Health Board

95. The Contractor must co-operate with the Local Health Board in the discharge of any of the Local Health Board's obligations, or the obligations of the Local Health Board's accountable officers, under the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008(66).

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

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

(a) the contractor is aware of any proposal for—

(i) any share in the company to be transmitted or transferred (whether legally or beneficially) to another person, or

(ii) a new director or secretary of the company to be appointed,

(b) circumstances arise which may entitle a creditor or a court to appoint a receiver, administrator or administrative receiver in respect of the company,

(c) circumstances arise which would enable the court to make a winding up order in respect of the company,

(d) a company resolution is passed, or a court of competent jurisdiction makes an order, that the company is to be wound up, or

(e) the company is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986(67) (definition of inability to pay debts).

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

(a) is either—

(i) a medical practitioner, or

(ii) a person who satisfies the conditions specified in section 44(2)(b)(i) to (iv) of the Act (persons eligible to enter into GMS contracts), and

(b) meets the further conditions imposed on shareholders by virtue of regulations 5 and 6.

(3) A notice under sub-paragraph (1)(a) must confirm that any proposed new director or, as the case may be, secretary meets the conditions imposed on directors and secretaries by virtue of regulation 6.

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

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

(a) any partner in the partnership—

(i) leaves the partnership, or

(ii) informs the other partners in the partnership that they intend to leave the partnership, or

(b) a new partner joins the partnership.

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

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

(a) state the date on which the new partner joined the partnership,

(b) confirm that the new partner is—

(i) a medical practitioner, or

(ii) a person who satisfies the conditions specified in section 44(2)(b)(i) to (iv) of the Act (persons eligible to enter into GMS contracts),

(c) confirm that the new partner meets the conditions imposed by regulations 5 and 6, and

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

Notification of deaths

98.—(1) The contractor must report in writing to the Local Health Board the death on its 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 the patient's death,

(d) a brief description of the circumstances, as known, surrounding the patient's death,

(e) the name of any medical practitioner or other person treating the patient while the patient was on the contractor's practice premises, and

(f) the name, where known, of any other person who was present at the time of the patient's death.

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

Notifications to patients following variation of the contract

99.—(1) This paragraph applies where a contract is varied in accordance with Part 11 of this Schedule and, as a result of that variation—

(a) there is to be a change in the range of services provided to the contractor's registered patients, or

(b) patients who are on the contractor's list of patients are to be removed from that list.

(2) Where this paragraph applies, the Local Health Board must—

(a) give notice in writing to those patients of the variation and of its effect, and

(b) inform those patients of the steps that they may take to—

(i) obtain the services in question elsewhere, or

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

Entry and inspection by the Local Health Board

100.—(1) Subject to the conditions in sub-paragraph (2), the contractor must allow any persons authorised in writing by the Local Health Board to enter and inspect the contractor's 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 contractor on request, and

(c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

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

PART 9 Concerns, complaints and investigations

Concerns and complaints

101. The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011⁽⁶⁸⁾ to deal with any concerns or complaints about any matter reasonably connected with the provision of services under the contract.

Co-operation with investigations

102.—(1) The contractor must co-operate with—

(a) any investigation of a complaint or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 in relation to any matter reasonably connected with the provision of services under the contract undertaken by—

(i) the Local Health Board,

(ii) the Welsh Ministers,

(iii) the Public Services Ombudsman for Wales, and

(b) any investigation of a complaint or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 by an NHS body or local authority which relates to a patient or former patient of the contractor.

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

(a) answering questions reasonably put to the contractor by the Local Health Board,

(b) providing any information relating to the complaint or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 reasonably required by the Local Health Board, and

(c)attending any meeting to consider the complaint or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given) if the contractor's presence at the meeting is reasonably required by the Local Health Board.

(3) In this paragraph—

"NHS body" ("*corff GIG*") means a Local Health Board, (in England and Wales and Scotland) an NHS trust, an NHS foundation trust, an Integrated Care Board, NHS England, a Health Board, a Health and Social Services Board or a Health and Social Care Trust;

"local authority" ("*awdurdod lleol*") means—

- (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970(69) (local authorities) (constitution of councils),
- (b) the Council of the Isles of Scilly,
- (c) a council constituted under section 2 of the Local Government etc (Scotland) Act 1994 (constitution of councils), or
- (d) a council of a county or county borough in Wales.

Provision of information about complaints

103. The contractor must inform the Local Health Board, at such intervals as required, of the number of complaints it has received under the procedure established in accordance with this Part.

PART 10 Dispute resolution

Local resolution of contract disputes

104.—(1) The contractor and the Local Health Board must make reasonable efforts to communicate and co-operate with each other with a view to resolving any dispute which arises out of or in connection with the contract before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

(2) Sub-paragraph (1) does not apply to a dispute relating to the assignment of patients to a closed list which falls to be determined under the NHS dispute resolution procedure by virtue of paragraph 46(1) where it is not practicable for the parties to attempt local resolution before the expiry of the period of 7 days specified in paragraph 46(4).

(3) The contractor or the Local Health Board may invite the Local Medical Committee (if any) for the area in which the contractor is providing services under the contract to participate in discussions which take place by virtue of sub-paragraph (1).

Dispute resolution: non-NHS contracts

105.—(1) In the case of a contract that is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the procedures for notifying concerns or complaints pursuant to Part 9 of this Schedule, may be referred for consideration and determination to the Welsh Ministers—

(a) if it relates to a period when the contractor was treated as a health service body, by the contractor or by the Local Health Board, or

(b) in any other case, by the contractor or, if the contractor agrees in writing, by the Local Health Board.

(2) In the case of a dispute referred to the Welsh 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

106.—(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 107 applies in the case of any dispute arising out of or in connection with the contract which is referred to the Welsh Ministers—

(a) in accordance with section 7(6) of the Act (where the contract is an NHS contract), or

(b) in accordance with paragraph 105(1) (where the contract is not an NHS contract).

(2) The procedure specified in this paragraph does not apply where a contractor refers a matter for determination in accordance with paragraph 46, and in such a case the procedure specified in that paragraph applies instead.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send to the Welsh 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 contract, and

(c) a brief statement describing the nature of, and circumstances giving rise to, 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 3 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) Where the dispute relates to a contract which is not an NHS contract, the Welsh Ministers may determine the matter themselves or, if the Welsh Ministers consider it appropriate, appoint a person or persons to consider and determine it.

(6) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (5) or under section 7(8) of the Act, the Welsh Ministers must, within the period of 7 days beginning with the date on which a matter under dispute was referred to it, 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 Welsh 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 Welsh Ministers must give a copy of any representation 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 Welsh Ministers must, if they decide to appoint a person or persons to hear the dispute—

(a) inform the parties in writing of the name of the person or persons whom it has appointed, and

(b) pass to the person or persons so appointed any documents received from the parties under or pursuant to sub-paragraph (3), (6) or (8).

(10) For the purpose of assisting the adjudicator in the 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 the adjudicator wishes them to give special consideration, or

(b) consult other persons whose expertise the adjudicator considers can assist in the 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 the adjudicator 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 Welsh Ministers specify in the request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Welsh Ministers may, if they consider that there is good reason for doing so, extend any such period (even after it has expired) and, where they do 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 107 and to any agreement by the parties, the adjudicator has wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

Determination of the dispute

107.—(1) The determination of the adjudicator and the reasons for it, must be recorded in writing and the adjudicator must give notice of the determination (including the record of the reasons) to the parties.

(2) Where a dispute in relation to a contract is referred for determination in accordance with paragraph 105(1)—

(a) section 7(12) and (13) of the Act apply in the same manner as those subsections apply to a dispute referred for determination in accordance with section 7(6) or (7) of the Act, and

(b) section 48(5) of the Act applies to any dispute referred for determination in relation to a contract which is not an NHS contract as if it were referred for determination in accordance with section 7(6) of the Act.

Interpretation of this Part

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

(2) Any term of the contract that makes provision in respect of the requirements in this Part is to survive even where the contract has terminated.

PART 11 Variation and termination of contracts

Variation of a contract: general

109.—(1) Subject to sub-paragraph (2) and paragraphs 76(8), 110, 111 and 124 of this Schedule no amendment or variation has effect unless it is in writing and signed by or on behalf of the Local Health Board and the contractor.

(2) In addition to the specific provision made in paragraphs 110(6), 111(11), and 124 the Local Health Board may vary the contract without the contractor’s consent where it—

(a) is reasonably satisfied that it is necessary to vary the contract so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Welsh Ministers pursuant to that Act, and

(b) notifies the contractor 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 must not be less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

Variation provisions specific to a contract with an individual medical practitioner

110.—(1) If a contractor which is an individual medical practitioner proposes to practise in partnership with one or more persons during the existence of the contract, the contractor must notify the Local Health Board in writing of—

(a) the name of the person or persons with whom it proposes to practise in partnership, and

(b) the date on which the contractor wishes to change its status as a contractor from that of an individual medical practitioner to that of a partnership which must not be less than 28 days after the date upon which it has served the notice on the Local Health Board pursuant to this sub-paragraph.

(2) A notice under sub-paragraph (1) must in respect of the person or each of the persons with whom the contractor is proposing to practise in partnership, and also in respect of itself as regards the matters specified in paragraph (c)—

(a) confirm that the person is either—

(i) a medical practitioner, or

(ii) a person who satisfies the conditions specified in section 44(2)(b)(i) to (iv) of the Act,

(b) confirm that the person satisfies the conditions imposed by regulations 5 and 6,

(c) state whether the partnership is to be a general partnership or a limited partnership and give the names of the limited partners and the general partners in the partnership, and

the notice must be signed by the individual medical practitioner and by the person, or each of the persons (as the case may be), with whom the medical practitioner is proposing to practise in partnership.

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

(4) If the Local Health Board is satisfied as to the accuracy of the matters specified in sub-paragraph (2) that are included in the notice, the Local Health Board must give notice in writing to the contractor confirming that the contract continues with the partnership entered into by the contractor and its partners, from a date that the Local Health Board specifies in that notice.

(5) Where it is reasonably practicable, the date specified by the Local Health Board pursuant to sub-paragraph (4) is the date requested in the notice served by the contractor pursuant to sub-paragraph (1), or, where that date is not reasonably practicable, the date specified is to be a date after the requested date that is as close to the requested date as is reasonably practicable.

(6) Where a contractor has given notice to the Local Health Board pursuant to sub-paragraph (1), the Local Health Board—

(a) may vary the contract but only to the extent that it is satisfied it is necessary to reflect the change in status of the contractor from an individual medical practitioner to a partnership, and

(b) if it does propose to so vary the contract, it must include in the notice served on the contractor pursuant to sub-paragraph (4) the wording of the proposed variation and the date upon which that variation is to take effect.

Variation provisions specific to a contract with two or more individuals practising in partnership

111.—(1) Subject to sub-paragraph (4), where a contractor consists of two or more individuals practising in partnership, in the event that the partnership is terminated or dissolved, the contract continues with that partnership unless the contract is terminated by the contractor or Local Health Board under the provisions of this Part and the contract may only continue with just one of the former partners if that partner is—

(a) nominated in accordance with sub-paragraph (3), and

(b) a medical practitioner who meets the condition in regulation 5(1)(a),

and provided that the requirements in sub-paragraphs (2) and (3) are met.

(2) A contractor must notify the Local Health Board in writing at least 28 days in advance of the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner pursuant to sub-paragraph (1).

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

(a) specify the date on which the contractor proposes to change its status from that of a partnership to that of an individual medical practitioner,

(b) specify the name of the medical practitioner with whom the contract is to continue, which must be one of the partners, and

(c) be signed by all of the persons who are practising in partnership.

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

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

(6) If the remaining partner in the partnership is not a general medical practitioner, the Local Health Board—

(a) must enter into discussions with that partner and use reasonable endeavours to reach an agreement to enable the provision of clinical services to continue under the contract,

(b) may, if it considers it appropriate, consult the Local Medical Committee (if any) for the area in which the partnership was providing clinical services under the contract or such other person as the Local Health Board considers necessary,

(c) may, if it considers it appropriate to enable the provision of clinical services under the contract to continue, offer the remaining partner in the partnership reasonable support, and

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

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

(a) the terms upon which the Local Health Board agrees to the contract continuing with that partner including the period, as specified by the Local Health Board, during which the contract is to continue ("the interim period") and such a period must not exceed 6 months,

(b) that the partner agrees to the employment or engagement of a general medical practitioner for the interim period to assist in the provision of clinical services under the contract, and

(c) the support, if any, which the Local Health Board is to provide to enable the provision of clinical services under the contract to continue during the interim period.

(8) If—

(a) the remaining partner in the partnership does not wish to employ or engage a medical practitioner,

(b) an agreement in accordance with sub-paragraph (6) cannot be reached, or

(c) the remaining partner in the partnership would like to withdraw from the agreed arrangements at any stage during the interim period,

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

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

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

(a) acknowledge receipt of the notice in writing, and

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

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

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

(13) In this paragraph "general medical practitioner" has the same meaning as in regulation 5(1).

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

Termination by agreement

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

Termination on the death of an individual medical practitioner

113.—(1) Where the contractor is an individual medical practitioner and the contractor dies, the contract terminates at the end of the period of 7 days beginning with the date of the contractor's death unless, before the end of that period sub-paragraph (2) applies.

(2) This sub-paragraph applies where—

(a) the Local Health Board agrees in writing with the contractor's personal representatives that the contract is to continue for a further period, not exceeding 28 days, from the end of the period of 7 days, and

(b) the contractor's personal representatives confirm in writing to the Local Health Board that they wish to employ or engage one or more general medical practitioners to assist in the continuation of the provision of clinical services under the contract and, after discussion with the Local Health Board—

(i) the Local Health Board agrees to provide reasonable support which would enable clinical services under the contract to continue;

(ii) the Local Health Board and the contractor's personal representatives agree the terms on which the provision of clinical services can continue; and

(iii) the Local Health Board and the contractor's personal representatives agree the period during which clinical services must be provided being a period of not more than 28 days beginning on the day after the end of the period of 7 days referred to in sub-paragraph (1).

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

Termination by the contractor

114.—(1) A contractor may terminate the contract by serving notice in writing on the Local Health Board at any time.

(2) Where a contractor serves notice pursuant to sub-paragraph (1), the contract must, 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 contract must instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the contractor is an individual medical practitioner and sub-paragraph (2) applies to the contractor, the Local Health Board has discretion to agree an earlier termination date if exceptional circumstances exist which make it reasonable for the termination date to be brought forward. If the termination date is to be brought forward, this date is to be agreed by the Local Health Board and the contractor.

(4) This paragraph is without prejudice to any other rights to terminate the contract that the Local Health Board or contractor may have.

Late payment notices

115.—(1) The contractor may give notice in writing (a "late payment notice") to the Local Health Board if the Local Health Board has failed to make any payments due to the contractor in accordance with any term of the contract regarding prompt payment which has the effect specified in regulation 20(1) and the contractor must specify in the late payment notice the payments that the Local Health Board has failed to make in accordance with that regulation.

(2) Subject to sub-paragraph (3), the contractor may, at least 28 days after having served a late payment notice, terminate the contract by a further written notice if the Local Health Board has still failed to make the payments due to the contractor, and that were specified in the late payment notice served on the Local Health Board pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Local 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 contractor in writing that it has done so within that period of time, the contractor may not terminate the contract pursuant to sub-paragraph (2) until—

(a) there has been a determination of the dispute pursuant to paragraph 106 and that determination permits the contractor to terminate the contract, or

(b) the Local Health Board ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(4) This paragraph is without prejudice to any other rights to terminate the contract that the contractor may have.

Termination by the Local Health Board: general

116. The Local Health Board may only terminate the contract in accordance with—

(a) the provisions in this Part, or

(b) such other termination provisions as the contractor and Local Health Board include in the contract.

Termination by the Local Health Board for breach of conditions in regulation 5

117.—(1) Subject to sub-paragraph (2), the Local Health Board must serve notice in writing on the contractor terminating the contract with immediate effect where, in any case, a contractor who is an individual medical practitioner has ceased to be a general medical practitioner.

(2) Where the contractor referred to in sub-paragraph (1) has ceased to satisfy the condition specified in regulation 5(1)(a) as a result of a suspension specified in sub-paragraph (6), sub-paragraph (1) does not apply unless—

(a) the contractor is unable to satisfy the Local Health Board that it has in place adequate arrangements for the provision of clinical services under the contract for so long as the suspension continues, or

(b) the Local Health Board is satisfied that the circumstances of the suspension are such that if the contract is not terminated forthwith—

(i) the safety of the contractor's patients is at serious risk, or

(ii) the Local Health Board is at risk of material financial loss.

(3) Except in a case to which paragraph 111(4) applies, where the contractor is—

(a) two or more persons practising in partnership, and the condition specified in regulation 5(1)(b) is no longer satisfied, or

(b) a company limited by shares, and the condition specified in regulation 5(1)(c) is no longer satisfied, sub-paragraph (4) applies.

(4) Where sub-paragraph (3)(a) or (b) applies, the Local Health Board must, subject to sub-paragraph (8)—

(a) serve notice in writing on the contractor terminating the contract forthwith, or

(b) serve notice in writing on the contractor confirming that the Local Health Board is to allow the contract to continue, for a period specified by the Local Health Board in accordance with sub-paragraph (5) (the "interim period"), during which time the Local Health Board must, with the consent of the contractor, employ or supply one or more general medical practitioners to the contractor for the interim period to assist the contractor in the provision of clinical services under the contract.

(5) The period specified by the Local Health Board under sub-paragraph (4)(b) must not exceed—

(a) 6 months, or

(b) in a case where the failure of the contractor to continue to satisfy the condition in regulation 5(1)(b) or, as the case may be, 5(1)(c), is the result of a suspension referred to in sub-paragraph (6), the period for which that suspension continues.

(6) The suspensions referred to in sub-paragraphs (2) and (5)(b) are suspension—

(a) by a Medical Practitioners Tribunal under—

(i) section 35D (functions of a Medical Practitioners Tribunal) of the Medical Act 1983 in a health case, other than an indefinite suspension under section 35D(6), or

(ii) section 38(1) (power to order immediate suspension etc. after a finding of impairment of fitness to practise) of that Act, or

(b) by a Fitness to Practise Panel or an Interim Orders Tribunal under section 41A (interim orders) of that Act.

(7) In sub-paragraph (6), "health case" has the meaning given in section 35E(4) of the Medical Act 1983.

(8) Before deciding which of the options in sub-paragraph (4) to pursue, the Local Health Board must, whenever it is reasonably practicable to do so, consult the Local Medical Committee (if any) for its area.

(9) If the contractor does not, pursuant to sub-paragraph (4)(b), consent to the Local Health Board employing or supplying a general medical practitioner during the interim period, the Local Health Board must serve notice in writing on the contractor terminating the contract with immediate effect.

(10) If, at the end of the interim period, the contractor still falls within sub-paragraph (3)(a) or (b), the Local Health Board must serve notice in writing on the contractor terminating the contract with immediate effect.

(11) In this paragraph "general medical practitioner" has the same meaning as in regulation 5(2).

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

118. The Local Health Board may serve notice in writing on the contractor terminating the contract with immediate effect, or from such date as may be specified in the notice if, after the contract has been entered into, it comes to the attention of the Local Health Board that written information provided to the Local Health Board by the contractor—

(a) before the contract was entered into, or

(b) pursuant to paragraph 96(1)(a) or 97(1)(b),

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

Other grounds for termination by the Local Health Board

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

(a) during the existence of a contract, or

(b) if later, on or after the date on which a notice in respect of the contractor's compliance with the condition in regulations 5 and 6 was given under paragraph 96(1)(a) or 91(1).

(2) Sub-paragraph (3) applies—

(a) where the contract is with a general medical practitioner, to that general medical practitioner,

(b) where the contract is with two or more persons practising in partnership, to the partnership or any partner in the partnership, and

(c) where the contract is with a company limited by shares to—

(i) the company,

(ii) any person legally or beneficially owning a share in the company, or

(iii) any director or secretary of the company.

(3) This sub-paragraph applies if—

(a) the contractor does not satisfy the conditions prescribed in sections 44(2) or (3) of the Act (persons eligible to enter into GMS contracts);

(b) the contractor is the subject of a national disqualification;

(c) subject to sub-paragraph (4), the contractor has been disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill health) from practising by a licensing body anywhere in the world;

(d) subject to sub-paragraph (5), the contractor has been dismissed (otherwise than by reason of redundancy) from employment by a health service body unless, before the Local Health Board has given notice to the contractor terminating the contract under this paragraph, the contractor is employed by the health service body from which the contractor was dismissed or by another health service body;

(e) the contractor has been removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 107(2), (3) and (4) of the Act respectively) unless the contractor's name has subsequently been included in such a list;

(f) the contractor has been convicted in the United Kingdom of murder;

(g) the contractor has been convicted in the United Kingdom of a criminal offence other than murder and has been sentenced to a term of imprisonment of longer than 6 months;

(h) subject to sub-paragraph (6), the contractor has been convicted elsewhere of an offence which would, if it were committed in England and Wales constitute murder, and—

(i) the offence was committed on or after 26 August 2002, and

(ii) the contractor was sentenced to a term of imprisonment of longer than 6 months;

(i) the contractor has been convicted of an offence, referred to in Schedule 1 to the Children and Young Persons Act 1933(70) (offences against children and young persons, with respect to special provisions of this Act apply), or in Schedule 1 to the Criminal Procedure (Scotland) Act 1995(71) (offences against children under the age of 17 years to which special provisions apply);

(j) the contractor has at any time been included in—

(i) any barred list within the meaning of the Safeguarding Vulnerable Groups Act 2006(72), or

(ii) any barred list within the meaning of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007(73) (barred lists),

unless the contractor was removed from the list either on the grounds that it was not appropriate for the contractor to have been included in it or as the result of a successful appeal;

(k) the contractor has, within the period of 5 years before the signing of the contract, been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commission, the Charity Commission for Northern Ireland or the High Court, and that order was made on the grounds of misconduct or mismanagement in the administration of a charity for which the contractor was responsible or to which the contractor was privy, or which was contributed to, or facilitated by, the contractor's conduct;

(l) the contractor has, within the period of 5 years before the signing of the contract or commencement of the contract (whichever is earlier), been removed from being concerned with the management or control of a body in any case where removal was by virtue of section 34(5)(e) of the Charities and Trustees Investment (Scotland) Act 2005(74) (powers of Court of Session); or

(m) the contractor—

(i) has been made bankrupt and has not been discharged from the bankruptcy or the bankruptcy order has not been annulled, or

(ii) has had sequestration of the contractor's estate awarded and has not been discharged from the sequestration;

(n) the contractor is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(75) (bankruptcy restrictions order and undertaking), or Schedule 2A to the Insolvency (Northern Ireland) Order 1989(76) (bankruptcy restrictions order and undertaking) or Part 13 of the Bankruptcy (Scotland) Act 2016(77) (bankruptcy restrictions orders and interim bankruptcy restrictions orders), unless the contractor has been discharged from that order or that order has been annulled;

(o) the contractor—

(i) is subject to a moratorium period under a debt relief order under Part 7A of the Insolvency Act 1986 (debt relief orders), or

(ii) is the subject of a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4ZB to that Act (debt relief restrictions orders and undertakings), unless that order has ceased to have effect or has been annulled;

(p) the contractor has made a composition agreement or arrangement with, or a trust deed has been granted for, the contractor's creditors and the contractor has not been discharged in respect of it;

(q)the contractor is a company which has been wound up under Part 4 of the Insolvency Act 1986 (winding up of companies registered under the Companies Acts);

(r)the contractor has had an administrator, administrative receiver or receiver appointed in respect of it;

(s)the contractor has had an administration order made in respect of the contractor under Schedule B1 to the Insolvency Act 1986 (administration);

(t)the contractor is a partnership and—

(i)the partnership is dissolved by one of the partners, or a dissolution of the partnership is ordered by any competent court, tribunal or arbitrator, or

(ii)an event happens that makes it unlawful for the business of the partnership to continue, or for members of the partnership to carry on in partnership;

(u)the contractor is subject to—

(i)a disqualification order under section 1 of the Company Directors Disqualification Act 1986(78) (disqualification orders: general) or a disqualification undertaking under section 1A of that Act (disqualification undertakings: general),

(ii)a disqualification order or disqualification undertaking under article 3 (disqualification orders: general) or article 4 (disqualification undertakings: general) of the Company Directors Disqualification (Northern Ireland) Order 2002(79), or

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

(v)the contractor has refused to comply with a request by the Local Health Board for the contractor to be medically examined because the Local Health Board is concerned that the contractor is incapable of adequately providing services under the contract and, in a case where the contract is with two or more individuals practising in partnership or with a company and one or more of those individuals has refused to comply with a request by the Local Health Board to be medically examined, the Local Health Board is not satisfied that the contractor is taking adequate steps to deal with the matter; or

(w)the contractor or its employees or agents (or anyone acting on its or their behalf) commits any prohibited act in relation to the contract with or without the knowledge of the Local Health Board.

(4) The Local Health Board must not terminate the contract under sub-paragraph (3)(c) where the Local 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 contractor,

(b)a partner, in the case of a contract with two or more persons practising in a partnership, or

(c)in the case of a contract with a company limited by shares—

(i) a person legally or beneficially holding a share in the company, or

(ii) a director or secretary of the company,

as the case may be.

(5) The Local Health Board may not terminate the contract under sub-paragraph (3)(d)—

(a) until a period of at least 12 weeks has elapsed since the date of the dismissal of the person concerned, or

(b) if, during the period specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

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

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

(a) a contractor,

(b) a partner, in the case of a contract with two or more persons practising in partnership, or

(c) in the case of a contract with a company limited by shares—

(i) a person legally or beneficially holding a share in the company, or

(ii) a director or secretary of the company,

as the case may be.

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

120. The Local Health Board may serve notice in writing on the contractor terminating the contract forthwith or with effect from such date as may be specified in the notice if—

(a) the contractor has breached the contract and as a result of that breach, the safety of the contractor's patients is at serious risk if the contract is not terminated, or

(b) the contractor's financial situation is such that the Local Health Board considers that the Local Health Board is at risk of material financial loss.

Termination by the Local Health Board for unlawful sub-contracting

121. If the contractor breaches the condition specified in paragraph 76(11) and it comes to the Local Health Board's attention that the contractor has done so, the Local Health Board must serve a notice in writing on the contractor—

(a) terminating the contract with immediate effect, or

(b)instructing the contractor 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 Local Health Board must serve a notice in writing on the contractor terminating the contract forthwith.

Termination by the Local Health Board: remedial notices and breach notices

122.—(1) Where a contractor has breached the contract other than as specified in paragraphs 117 to 121 and the breach is capable of remedy, the Local Health Board must, before taking any action it is otherwise entitled to take by virtue of the contract, serve a notice on the contractor requiring it to remedy the breach (“remedial notice”).

(2) A remedial notice must specify—

(a)details of the breach,

(b)the steps the contractor must take to the satisfaction of the Local 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 must, unless the Local Health Board is satisfied that a shorter period is necessary to—

(a)protect the safety of the contractor’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 Local Health Board is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Local Health Board may terminate the contract with effect from such date as the Local Health Board may specify in a further notice to the contractor.

(5) Where a contractor has breached the contract other than as specified in paragraphs 117 to 121 and the breach is not capable of remedy, the Local Health Board may serve notice on the contractor requiring the contractor not to repeat the breach (“breach notice”).

(6) If, following a breach notice or a remedial notice, the contractor—

(a)repeats the breach that was the subject of the breach notice or the remedial notice, or

(b)otherwise breaches the contract resulting in either a remedial notice or a further breach notice,

the Local Health Board may serve notice on the contractor terminating the contract with effect from such date as may be specified in that notice.

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

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

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

123.—(1) Where the contractor is a company limited by shares, if the Local Health Board becomes aware that the contractor is carrying on any business which the Local Health Board considers to be detrimental to the contractor's performance of its obligations under the contract—

(a) the Local Health Board is entitled to give notice to the contractor requiring that it 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 contractor has not satisfied the Local Health Board that it has ceased carrying on that business by the end of the notice period, the Local Health Board may, by a further written notice, terminate the contract forthwith or from such date as may be specified in the notice.

(2) Where the contractor is two or more persons practising in partnership, the Local Health Board is entitled to terminate the contract by notice in writing on such date as may be specified in that notice where one or more partners have left the practice during the existence of the contract if in its reasonable opinion, the Local Health Board considers that the change in membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Local Health Board to perform its obligations under the contract.

(3) A notice given to the contractor pursuant to sub-paragraph (2) must specify—

(a) the date upon which the contract is to be terminated, and

(b) the Local Health Board's reasons for considering that the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Local Health Board to perform its obligations under the contract.

Contract sanctions

124.—(1) In this paragraph and paragraph 125, "contract sanction" means—

(a) termination or suspension of specified reciprocal obligations under the contract; and/or

(b) withholding or deducting monies otherwise payable under the contract.

(2) Subject to sub-paragraph (4), where the Local Health Board is entitled to terminate the contract under paragraphs 118, 119, 120, 122(4) or 122(6) or 123, it may instead impose any of the contract sanctions if the Local Health Board is reasonably satisfied that the contract sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Local Health Board's entitlement to terminate the contract.

(3) If the Local Health Board decides to impose a contract sanction, it must notify the contractor in writing of the contract sanction that it proposes to impose, the date upon which that sanction is to be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(4) Subject to paragraph 125, the Local Health Board must not impose the contract sanction until at least 28 days have elapsed, beginning with the date on which it served notice on the contractor pursuant to sub-paragraph (5) unless the Local Health Board is satisfied that it is necessary to do so in order to—

- (a) protect the safety of the contractor's patients,
- (b) ensure continuity of care for the contractor's patients, or
- (c) protect itself from material financial loss.

(5) Where the Local Health Board imposes a contract sanction, the contractor must provide all information and assistance to the Local Health Board, throughout the period that the contract sanction applies, as the Local Health Board may reasonably require.

(6) Where the Local Health Board imposes a contract sanction, the Local Health Board is entitled to charge the contractor the reasonable costs that the Local Health Board has incurred in order to impose, or as a result of imposing, the contract sanction.

Contract sanctions and the NHS dispute resolution procedure

125.—(1) If there is a dispute between the Local Health Board and the contractor in relation to a contract sanction that the Local Health Board is proposing to impose, the Local Health Board must not, subject to sub-paragraph (4), impose the proposed contract sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the contractor refers the dispute relating to the contract sanction to the NHS dispute resolution procedure within 28 days beginning with the date on which the Local Health Board served notice on the contractor in accordance with paragraph 124(3) (or such longer period as may be agreed in writing with the Local Health Board), and notifies the Local Health Board in writing that it has done so, the Local Health Board must not impose the contract sanction unless—

- (a) there has been a determination of the dispute pursuant to paragraph 106 and that determination permits the Local Health Board to impose the contract sanction, or
 - (b) the contractor ceases to pursue the NHS dispute resolution procedure,
- whichever is the sooner.

(3) If the contractor does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Local Health Board is entitled to impose the contract sanction with immediate effect.

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

(a) protect the safety of the contractor's patients, or

(b) protect itself from material financial loss,

the Local Health Board is entitled to impose the contract sanction forthwith, pending the outcome of that procedure.

Termination and the NHS dispute resolution procedure

126.—(1) Where the Local Health Board is entitled to serve written notice on the contractor terminating the contract pursuant to paragraph 118, 119, 120, 122(4) or 122(6) or 123(2), the Local Health Board must, in the notice served on the contractor pursuant to those provisions, specify a date on which the contract terminates that is not less than 28 days after the date on which the Local Health Board has served that notice on the contractor unless sub-paragraph (2) applies.

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

(a) protect the safety of the contractor's patients, or

(b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1) where the exception in sub-paragraph (2) does not apply, where the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Local Health Board in writing that it has done so, the contract does not terminate at the end of the notice period but instead only terminates in the circumstances specified in sub-paragraph (4).

(4) The contract only terminates if and when—

(a) there has been a determination of the dispute pursuant to paragraph 106 and that determination permits the Local Health Board to terminate the contract, or

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

whichever is the sooner.

(5) If the Local Health Board is satisfied that it is necessary to terminate the contract before the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the contractor's patients, or

(b) protect itself from material financial loss,

sub-paragraphs (3) and (4) do not apply and the Local Health Board is entitled to confirm, by written notice to be served on the contractor, that the contract is to nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 118, 119, 120, 122(4) or 122(6) or 123(2).

Consultation with the Local Medical Committee

127.—(1) Whenever the Local Health Board is considering—

(a)terminating the contract pursuant to paragraph 118, 119, 120, 122(4) or 122(6) or 123,
(b)which of the alternative notices in writing available under the provisions of paragraph 121 it will serve, or
(c)imposing a contract sanction,
it must, whenever it is reasonably practicable to do so, consult the Local Medical Committee for its area before it terminates the contract, serves a notice in writing or imposes a contract sanction.

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

PART 12 Miscellaneous

Clinical governance

128.—(1) The contractor must have in place an effective system of clinical governance which includes appropriate standard operating procedures in relation to the management and use of controlled drugs.

(2) The contractor must nominate a person who has responsibility for ensuring the effective operation of the system of clinical governance.

(3) The contractor must engage in discussion and peer review of clinical incidents that have occurred within the practice and local services.

(4) Components of the 'system of clinical governance' include, but are not limited to, the contractor—

(a)undertaking annually by 31 March—

(i)the Clinical Governance Practice Self-Assessment Tool, and

(ii)the Information Governance Toolkit,

and submitting evidence of completion to the Local Health Board on request, and

(b)complying with the Assurance Framework and the Local Health Board's use of that Assurance Framework in relation to the contractor.

(5) The person nominated under sub-paragraph (2) must be a person who performs or manages performance of services under the contract.

(6) In this paragraph—

"system of clinical governance" ("*system llywodraethu clinigol*") means a framework through which the contractor 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;

"controlled drugs" ("*cyffuriau a reolir*") has the meaning given in section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act).

Co-operation with Health Education and Improvement Wales

129. The contractor must co-operate with Health Education and Improvement Wales where Health Education and Improvement Wales is discharging functions it has been directed to exercise by the Welsh Ministers relating to—

(a) the provision of services under Part 4 of the Act, or

(b) persons who are employed or engaged, or who are considering becoming employed or engaged, in any activity which involves or is connected with the provision of services under Part 4 of the Act.

Insurance

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

(2) The contractor must not sub-contract its obligations to provide clinical services under the contract unless it has satisfied itself that the sub-contractor has in force in relation to it an indemnity arrangement which provides appropriate cover.

(3) The Local Health Board, to the extent it considers reasonable and to the extent it may be reimbursed in accordance with the Clinical Negligence Scheme for NHS Trusts and Local Health Boards established by regulation 3 of the 2019 Regulations, must indemnify the contractor in respect of that contractor's qualifying liabilities as specified in regulation 9(4) of the 2019 Regulations, provided the contractor—

(a) complies with the Local Health Board's claims management protocol for contractors (as amended from time to time); and

(b) does not have any other indemnity arrangement in force in connection with clinical services which the contractor provides under the contract at the time the qualifying liability arose.

(4) For the purposes of this paragraph a contractor is regarded as having in force in relation to it an indemnity arrangement—

(a) if there is an indemnity arrangement in force in relation to a person employed or engaged by it in connection with clinical services which that person provides under the contract or, as the case may be, sub-contract, or

(b) for its qualifying liabilities specified in regulation 9(4) of the 2019 Regulations, to the extent provided for under sub-paragraph (3).

(5) In this paragraph—

“the 2019 Regulations” (“*Rheoliadau 2019*”) means the National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019(**80**);

“appropriate cover” (“*yswariant priodol*”) means cover against liabilities that may be incurred by the contractor in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;

"indemnity arrangement" (*"trefniant indemnïad"*) means a contract of insurance or other arrangement made for the purpose of indemnifying the contractor.

Public liability insurance

131. The contractor must at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the contract which are not covered by the indemnity arrangement referred to in paragraph 130.

Gifts

132.—(1) The contractor 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 provided or wishes to provide services to the contractor or its patients in connection with the contract, 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 contractor,

(b) where the contract is with two or more individuals practising in partnership, any partner;

(c) where the contract is with a company limited with shares—

(i) any person legally or beneficially holding a share in the company, or

(ii) a director or secretary of the company,

(d) any person employed by the contractor for the purposes of the contract,

(e) any general medical practitioner engaged by the contractor for the purposes of the contract,

(f) any spouse or civil partner of a contractor (where the contractor is an individual medical practitioner) or of a person specified in paragraphs (b) to (e), or

(g) any person whose relationship with a contractor (where the contractor is an individual medical practitioner) or with a person specified in paragraphs (b) to (e) has the characteristics of the relationship between spouses.

(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 contractor,

(b) the contractor is not aware of the gift, or

(c)the contractor is not aware that the donor wishes to provide services to the contractor or its patients.

(4) The contractor 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 (g).

(5) The register referred to in sub-paragraph (1) must include the following information—

(a)the name of the donor,

(b)in a case where the donor is a patient, the patient's National Health Service number or, if the number is not known, the patient's address,

(c)in any other case, the address of the donor,

(d)the nature of the gift,

(e)the estimated value of the gift, and

(f)the name of the person or persons who received the gift.

(6) The contractor must make the register available to the Local Health Board on request.

Bribery Act

133.—(1) The contractor must not commit any prohibited act.

(2) If the contractor or its employees or agents (or anyone acting on its or their behalf) commits any prohibited act in relation to the contract with or without the knowledge of the Local Health Board, the Local Health Board is entitled to—

(a)exercise its right to terminate under paragraph 119 and to recover from the contractor the amount of any loss resulting from the termination,

(b)recover from the contractor the amount or value of any gift, consideration or commission concerned, and

(c)recover from the contractor any loss or expense sustained in consequence of the carrying out of the prohibited act or the commission of the offence.

Advertising private services

134. A contractor who offers private services which are not available to patients through the NHS must advertise those private services clearly and separately to the services available under the contract.

Compliance with legislation and guidance

135.—(1) The contractor must comply (and the contractor must ensure that those it employs or engages comply) with—

(a)all relevant legislation, and

(b)all relevant guidance and codes of practice issued from time to time by—

(i)the Local Health Board, Welsh Ministers or local authorities in respect of the exercise of their functions under the Act, or

(ii) any regulatory or supervisory body.

(2) The contractor must provide the services under the contract in a manner that assists the Local Health Board to comply with the Health and Care Standards and Duty of Quality Guidance in which those standards are set.

Third party rights

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

Schedule 3 paragraph 84(1)

SCHEDULE 4 Provision of information to patients

Information to be included on a practice's online resource and written practice leaflet

1. A contractor's online resource and written practice leaflet must include—

(a) the name of the contractor;

(b) in the case of a contract with a partnership—

(i) whether or not it is a limited partnership, and

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

(c) in the case of a contract with a company—

(i) the names of the directors, the company secretary and the shareholders of that company, and

(ii) the address of the company's registered office;

(d) the full name of each person performing services under the contract;

(e) in the case of each health care professional performing services under the contract the health care professional's professional qualifications;

(f) whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals;

(g) the contractor's practice area, by reference to a sketch diagram, plan or postcode;

(h) the address of each of the practice premises;

(i) the contractor's telephone and fax numbers and the address of its online resource;

(j) whether the practice premises have suitable access for disabled patients and, if not, the alternative arrangements for providing services to such patients;

(k) how to register as a patient;

(l) the right of patients to express a preference of practitioner in accordance with paragraph 27 of Schedule 3 and the means of expressing such a preference;

- (m)the services available under the contract;
- (n)the opening hours of the practice premises and the method of obtaining access to services throughout the core hours;
- (o)the criteria for home visits and the method of obtaining such a visit;
- (p)the consultations available to patients under regulation 17 and Part 1 of Schedule 3;
- (q)the arrangements for services in the out of hours period (whether or not provided by the contractor) and how the patient may contact such services;
- (r)if the services in sub-paragraph (q) are not provided by the contractor, the fact that the Local Health Board referred to in sub-paragraph (bb) is responsible for commissioning the services;
- (s)the name and address of any local walk-in centre;
- (t)the telephone number of NHS 111 Wales and details of NHS 111 Wales online;
- (u)the method by which patients are to obtain repeat prescriptions;
- (v)if the contractor offers repeatable prescribing services, the arrangements for providing such services;
- (w)if the contractor is a dispensing contractor, the arrangements for dispensing prescriptions subject to paragraph 60(2)(b) of Schedule 3;
- (x)how patients may notify a concern or complaint in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, or comment on the provision of the contractor's services;
- (y)the rights and responsibilities of the patient, including keeping appointments;
- (z)the action that may be taken where a patient is violent or abusive to the contractor or his staff or other persons on the practice premises or in the place where treatment is provided under the contract or other persons specified in paragraph 30 of Schedule 3;
- (aa)details of who has access to patient information (including information from which the identity of the individual can be ascertained), the patient's rights in relation to disclosure of such information and how patients can access the contractor's privacy notice or privacy policy;
- (bb)the name, address and telephone number of the Local Health Board which is a party to the contract and from whom details of primary medical services in the area may be obtained; and
- (cc)the fees charged for non-NHS services that are not private services.

Regulation 32

SCHEDULE 5Consequential amendments

1.—(1) The National Health Service (Performers Lists) (Wales) Regulations 2004(**81**) are amended as follows.

2.—(1) The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(**82**) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) in paragraph (1) in the definition of—

(i) “appropriate non-proprietary name” for—

(aa) “42(2)” substitute “56(2)”, and

(bb) “6” substitute “3”;

(ii) “GMS Regulations” for “2004” substitute “2023”;

(iii) “patient list” for—

(aa) “14” substitute “22”, and

(bb) “6” substitute “3”;

(iv) “repeatable prescriber” in each place it occurs for—

(bb) “6” substitute “3”;

(b) in paragraph (3)(b) for—

(ii) “6” substitute “3”.

(3) In Schedule 7—

(a) in paragraph 5 (dispensing of drugs and appliances ordered by the dispensing doctor)—

(i) in sub-paragraph (a) for “paragraph 39 of Schedule 6” substitute “paragraphs 49 and 50 of Schedule 3”,
and

(b) in paragraph 9(1) (fees and charges) for “regulation 24 of, and Schedule 5 to,” substitute “regulations 21
and 22 of”;

Regulation 33

SCHEDULE 6 Revocation

1. The 2004 Regulations are revoked.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set out, for Wales, the framework for general medical services contracts under section 42 of the National Health Service (Wales) Act 2006 (“the Act”).

Part 2 of the Regulations prescribes the conditions which, in accordance with section 44 of the Act, must be met by a contractor before the Local Health Board may enter into a general medical services contract with it.

Part 3 of the Regulations prescribes the procedure for pre-contract dispute resolution, in accordance with section 48(2) of the Act. Part 3 applies to cases where the contractor is not a health service body. In cases where the contractor is such a body, the procedure for dealing with pre-contract disputes is set out in section 7 of the Act.

Part 4 of the Regulations sets out the procedures, in accordance with section 48(3) of the Act, by which the contractor may obtain health service body status.

Part 5 of (and Schedules 1 to 4 to) the Regulations prescribe the terms which, in accordance with sections 47 and 48 of the Act, must be included in a general medical services contract (in addition to those contained in the Act). It includes, in regulation 17, a description of the services which must be provided to patients under general medical services contracts pursuant to section 43 of the Act.

The prescribed terms include terms relating to—

- (a) the type and duration of the contract (regulations 14 to 16);
- (b) the services to be provided (regulations 17 and 18 and Schedule 2) and the manner in which they are to be provided (Schedule 3);
- (c) the issuing of medical certificates (regulation 19 and Schedule 1);
- (d) finance, fees and charges (regulations 20 to 22);
- (e) patient registration and removal, lists closures and assignments (Schedule 3, Parts 2 to 4);
- (f) prescribing and dispensing (Schedule 3, Part 5);
- (g) the conditions to be met by those who perform services or are employed or engaged by the contractor (Schedule 3, Part 6);
- (h) sub-contracting (Schedule 3, Part 7);
- (i) patient records, the provision of information and rights of entry (Schedule 3, Part 8 and Schedule 4);
- (j) concerns, complaints and investigations (Schedule 3, Part 9);
- (k) procedures for dispute resolution (Schedule 3, Part 10);
- (l) procedures for variation and termination of contracts (Schedule 3, Part 11).

Part 6 of the Regulations prescribes functions for Local Medical Committees.

Part 7 of the Regulations and Schedules 5 to 6 make transitional provisions and provision for saving, consequential amendments and revocations.

(1)

2006 c. 42. Section 44 as made exercisable by regulation 4 of S.I. 2009/1511, section 203(9)(10) applied by 2006 (c. 28), section 70(3).

(2)

S.I. 2004/478 (W. 48) was amended by section 6(4) and (5) of the Charities Act 2006 (c. 50), and S.I. 2004/1016, S.I. 2004/477.

(3)

S.I. 2010/473, as amended by S.I. 2019/593.

(4)

2009 c. 1. Section 15B was inserted into the Health and Social Care (Reform) Act (Northern Ireland) 2009 by section 4(1) of the Health and Social Care Act (Northern-Ireland) 2022 (c. 3).

(5)

2006 c. 52. A relevant amendment to section 374 was made by section 44(3) and (4) of the Defence Reform Act 2014 (c. 20).

(6)

2016 anaw 2. Paragraph 1(2) of Schedule 1 to the Regulation and Inspection of Social Care (Wales) Act 2016 prescribes places which do not constitute care home services, those places are excluded from the definition of care homes for the purposes of these Regulations.

(7)

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

(8)

1984 c. 24. Section 14 was amended by S.I. 2005/2011, S.I. 2006/1671, S.I. 2007/3101, S.I. 2019/593, and S.I. 2020/1394.

(9)

S.I. 2020/1451.

(10)

2000 c. 7. The definition of "electronic communication" was amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

(11)

Section 2 was amended by S.I. 2002/3135, S.I. 2006/1914, S.I. 2007/3101, S.I. 2008/1774 and S.I. 2014/1101.

(12)

Section 34I was inserted by S.I. 2010/234.

(13)

S.I. 1991/194 (N.I. 1). Article 10 was amended by sections 43 and 44 of the Health and Personal Social Services Act (Northern Ireland) 2001 (c. 3), and section 11 of, and paragraphs 1 and 13 of Schedule 6 to, the Health and Social Care Reform Act (Northern Ireland) 2009 (c. 1) (N.I.) and S.I. 1997/1177.

(14)

1978 c. 29. Section 2 was amended by paragraph 1 of Schedule 7 to S.I. 1991/194 (N.I. 1); section 14(2) of, and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications

Act 1983 (c. 41); paragraph 1(2)(a) and (b) of Schedule 1 to the National Health Service Reform (Scotland) Act 2004 (asp 7); sections 2(1)(a) and 28(a)(ii), (b), and (c) of Schedule 1, and paragraph 19(1) of Schedule 9 and paragraph 1 of Schedule 10 to, the National Health Service and Community Care Act 1990 (c. 19); paragraph 2(2) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13); and sections 2(1), 4, 6(2) and (3), 7 and 11(1) of the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5).

(15)

2002 c. 17. Section 25(3) was amended by paragraph 10(2) of Schedule 4 to S.I. 2010/231, paragraph 17(2) and 17(3) of Schedule 10 to the Health and Social Care Act 2008 (c. 14), paragraph 56(b) of Schedule 15 to the Health and Social Care Act 2012 (c. 7), and paragraph 2(2) of Schedule 4 to the Children and Social Work Act 2017 (c. 16).

(16)

Section 7(4) was amended by section 306(4) of, and paragraph 21 of Schedule 7, paragraph 11 of Schedule 17 and paragraphs 13(a), (b), (c), (d), (e), (f) of Schedule 21 to, the Health and Social Care Act 2012 (c.7), section 186(6) of, and paragraph 1(1) of Schedule 1 and paragraph 140 of Schedule 4 to the Health and Care Act 2022 (c. 31), sections 95 and 170 of, and paragraph 87 of Schedule 5 to the Health and Social Care Act 2008 (c. 14), S.I. 2022/1174, and S.I. 2023/98.

(17)

1989 c. 41.

(18)

S.I. 2012/1916. Regulation 6 was amended by regulation 3 of the Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352).

(19)

1907 c. 24. Section 5 was amended by section 5 of the Legislative Reform (Limited Partnerships) Order 2009 (S.I. 2009/1940).

(20)

S.I. 2004/1020 (W. 117), amended by S.I. 2006/945 (W. 94).

(21)

Section 2 was amended by S.I. 2002/3135, S.I. 2006/1914, S.I. 2007/3101, S.I. 2008/1774 and S.I. 2014/1101.

(22)

1968 c. 67.

(23)

S.I. 2002/253, amended by S.I. 2009/1182 and S.I. 2018/838.

(24)

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

(25)

S.I. 2020/1073 (W. 241).

(26)

S.I. 1976/1213 (N.I. 22).

(27)

S.I. 2002/254, amended by S.I. 2009/1182.

(28)

S.I. 2002/254.

(29)

S.I. 2009/177, amended by S.I. 2022/251.

(30)

S.I. 2010/231, as amended by paragraph 9(a), 9(b), 9(c), 9(d) and 9(e) of Schedule 2(1) to S.I. 2019/593.

(31)

S.I. 1976/1213, as amended by regulation 5 of S.R. 2008/192, and paragraph 6(a), 6(b) and 6(c) of Part 1 of the Schedule to S.I. 2019/585.

(32)

Section 7(a) as amended by article 7(1)(b) of S.I. 2005/848.

(33)

S.I. 2002/254.

(34)

S.I. 2004/1022, as amended by S.I. 2005/366 (W. 32), S.I. 2009/1838 (W. 166), S.I. 2009/1977 (W. 176), S.I. 2012/1916, S.I. 2013/683 (W. 81), S.I. 2014/109 (W. 09), S.I. 2016/90 (W. 43) and S.I. 2020/1396 (W. 309).

(35)

2016 anaw 2.

(36)

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

(37)

S.I. 1998/5, as amended by S.I.1998/669 and S.S.I. 2000/23 and revoked by S.I. 2003/1250.

(38)

S.R. 1998/13, revoked by S.I. 2003/1250.

(39)

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

(40)

1933 c. 12. Schedule 1 was amended by section 51 of, and Schedule 4 to, the Sexual Offences Act 1956 (c. 99); paragraph 8 of Schedule 15 to, and section 170(2) of, and Schedule 16 to, the Criminal Justice Act 1988 (c. 33); section 139 of, and paragraph 7 of Schedule 6 to, the Sexual Offences Act 2003 (c. 42); section 58(1) of, and Schedule 10 to, the Domestic Violence, Crime and Victims Act 2004 (c. 28); paragraph 53 of Schedule 21 to the Coroners and Justice Act 2009 (c. 25); section 115(1) of, and paragraph 136(a) and (b) of Schedule 9 to, the Protection of Freedoms Act 2012 (c. 9); and section 57(1) of, and paragraph 1 of Schedule 5 to, the Modern Slavery Act 2015 (c. 30).

(41)

1995 c. 46. Schedule 1 was amended by paragraph 2 of Schedule 1 to the Protection of Children and Prevention of Sexual Offences (Scotland) Act 2005 (asp 9), paragraph 2(8)(a) of Schedule 5 to the Sexual Offences (Scotland) Act 2009 (asp 9) and section 41(2) of the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13).

(42)

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

(43)

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

(44)

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

(45)

1986 c. 45. Schedule 4A was inserted by Schedule 20 of the Enterprise Act 2002 (c. 40), and was amended by section 71(3) of, and paragraph 63(1), (3)(a), (2)(a) and (b) to, the Enterprise and Regulatory Reform Act 2013 (c. s24).

(46)

S.I. 1989/2405 (N.I. 19). Schedule 2A was inserted by Article 13(2) of, and Schedule 5 to, S.I. 2005/1455 (N.I. 10).

(47)

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

(48)

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

(49)

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

(50)

1986 c. 46. Section 1 was amended by sections 5(1) and (2) and 8 of the Insolvency Act 2000 (c. 40), section 204(1) and (3) of the Enterprise Act 2002 (c. 40), and sections 111 and 164(1) of, and paragraphs 1 and 2 of Schedule 7 to, the Small Business, Enterprise and Employment Act 2015 (c. 26).

(51)

Section 1A was inserted by section 6(1) and (2) of the Insolvency Act 2000 (c. 39), and was amended by section 111 of, and paragraphs 1, 3(1) and (2) of Schedule 7 to, the Small Business Enterprise and Employment Act 2015.

(52)

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

(53)

Section 429 was amended by section 269 of, and Schedule 23 to, the Enterprise Act 2002, and by section 106 of, and Schedule 16 to, the Tribunals, Courts and Enforcement Act 2007 (c.15).

(54)

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

(55)

S.I. 1976/615. Regulation 2(1) was substituted by S.I. 2010/137.

(56)

S.I. 1985/1604. Regulation 2(1) was substituted by S.I. 2010/137.

(57)

1989 c. 41

(58)

2005 c. 9.

(59)

Schedule 2 was amended by S.I. 2003/1432, S.I. 2009/3136, S.I. 2011/448, S.I. 2014/1275 and 3277, S.I. 2015/891, S.I. 2018/1055 and S.I. 2018/1383.

(60)

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

(61)

Established under section 25 of the National Health Service Act 2006 (c. 41).

(62)

Established under section 30 of the National Health Service Act 2006 (c. 41).

(63)

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(64)

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(65)

S.I. 2004/1017 (W. 114).

(66)

S.I. 2008/3239 (W. 286).

(67)

1986 c. 45.

(68)

S.I. 2011/704 (W. 108) amended by S.I. 2011/1706 (W. 192).

(69)

1970 c. 42.

(70)

1933 c. 12.

(71)

1995 c. 46.

(72)

2006 c. 47.

(73)

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

(74)

2005 asp 10.

(75)

1986 c. 45.

(76)

S.I. 1989/2405 (N.I. 19).

(77)

2016 asp 21.

(78)

1986 c. 46.

(79)

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

(80)

S.I. 2019/422 (W. 97).

(81)

S.I. 2004/1020 (W. 117), amended by S.I. 2005/258, S.I. 2006/358 (W. 46), S.I. 2006/945, S.I. 2008/1425 (W. 147), S.I. 2010/22, S.I. 2013/235, S.I. 2016/101 (W. 49). There are other amendments but none are relevant.

(82)

S.I. 2020/1073 (W. 241).

(83)

Section 8B(1)(a) of the Act was repealed by the European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593). Paragraph 26 of Schedule 5 to those regulations saves the provision indefinitely but with the condition the person in question does not practice for more than 90 days in a calendar year.