WELSH STATUTORY INSTRUMENTS

2023 No. 953

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

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 National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(1) 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(**2**);

"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,

⁽¹⁾ 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.

⁽²⁾ S.I. 2010/473, as amended by S.I. 2019/593.

- (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);

"Area Integrated Partnership Board" ("*Bwrdd Partneriaeth Integredig Ardal*") means an Area Integrated Partnership Board established under section 15B of the Health and Social Care (Reform) Act (Northern Ireland) 2009(**3**);

"armed forces of the Crown" ("*lluoedd arfog y Goron*") means the forces that are "regular forces" or "reserve forces" within the meaning given to those terms in section 374 of the Armed Forces Act 2006(4) (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 Sicrwydd*") 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;

"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(5);

"CCT" ("*TCH*") means Certificate of Completion of Training awarded under section 34L(1) of the Medical Act 1983(6) (award and withdrawal of a Certificate of Completion of Training);

^{(3) 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).

^{(4) 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).
(5) 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.

^{(6) 1983} c. 54. Section 34L was inserted by S.I. 2010/234.

"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" ("gwasanaethu 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 the Dentists Act 1984(7);

"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(**8**);

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

"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 (arrangement 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(9) (general interpretation);

^{(7) 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.

⁽⁸⁾ S.I. 2020/1451.

^{(9) 2000} c. 7. The definition of "electronic communication" was amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

"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(10) (registration of medical practitioners);

"General Practice Escalation Tool" ("*Offeryn Uwchgyfeirio Ymarfer Cyffredinol*") means the tool agreed by Welsh Ministers, Local Health Boards and the General Practitioner Committee (Wales) 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);

⁽¹⁰⁾ 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.

"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(11) for the purpose of providing training under that section, whether as part of training leading to the award of a CCT or otherwise;

"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(**12**) (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(**13**) (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(14);

"health service body" ("*corff gwasanaeth iechyd*") has the meaning given in section 7(4)(15) 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,

⁽¹¹⁾ Section 34I was inserted by S.I. 2010/234.

⁽¹²⁾ 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.

^{(13) 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).

^{(14) 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).

⁽¹⁵⁾ 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.

- (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(16), 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 GMBILI*") means a practice providing Local Health Board Medical Services;

"licensing authority" ("*awdurdod trwyddedu*") is to be interpreted in accordance with regulation 6 of the Human Medicines Regulations 2012(**17**);

"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(**18**) (registration of limited partnerships required);

"Local Health Board" ("*Bwrdd Iechyd Lleol*") means, unless the context otherwise requires, 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(**19**);

"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(**20**) (registration of medical practitioners);

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

^{(16) 1989} c. 41.

⁽¹⁷⁾ 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).

 ^{(18) 1907} c. 24. Section 5 was amended by section 5 of the Legislative Reform (Limited Partnerships) Order 2009 (S.I. 2009/1940).
 (19) S.I. 2004/1020 (W. 117), amended by S.I. 2006/945 (W. 94).

⁽²⁰⁾ 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.

"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) sections 83, 86, 103 or 105 (performers of pharmaceutical services and assistants) 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(21),

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;

^{(21) 1968} c. 67.

"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(**22**) (establishment and maintenance of register);

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

- (a) which is on a website (other than the 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(23) (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)(56) 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 17(9), and
- (d) any other person to whom the contractor has agreed to provide services under the contract;

⁽²²⁾ S.I. 2002/253, amended by S.I. 2009/1182 and S.I. 2018/838.

^{(23) 1989} c. 44. Section 7 was amended by S.I. 2005/848.

⁽⁵⁶⁾ 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.

"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(24);

"pharmaceutical services" ("gwasanaethau fferyllol") means pharmaceutical services that fall within sections 80 and 81 of the Act and includes directed services;

"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(25) (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 and Social Work Professions Order 2002(26) 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(27) (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 regulation 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 preappointment checks that an employer must undertake as part of their recruitment process before

⁽²⁴⁾ S.I. 2020/1073 (W. 241).

⁽²⁵⁾ S.I. 1976/1213 (N.I. 22).

⁽²⁶⁾ S.I. 2002/254, amended by S.I. 2009/1182.

⁽²⁷⁾ S.I. 2002/254.

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 and 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 and Part 8 of the Act, or
- (c) a list corresponding to any of the above in England, Scotland or Northern Ireland;

"primary carer" ("*prif of alwr*") 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(**28**);

"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(2) 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(29) or the register maintained under Article 6 (the Register) and Article 9 (the Registrar) of the Pharmacy (Northern Ireland) Order 1976(30),

⁽²⁸⁾ S.I. 2009/177, amended by S.I. 2022/251.

⁽²⁹⁾ 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.

⁽³⁰⁾ 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.

- (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)(**31**), and
- (d) the part of the register maintained by the Health and Care Professions Council under article 5 of the Health Professions Order 2001(**32**) (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 amlragnodi") 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 2006 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 2006 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 2006 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,

⁽³¹⁾ Section 7(a) as amended by article 7(1)(b) of S.I. 2005/848.

⁽**32**) S.I. 2002/254.

- (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(**33**) (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(**34**);

"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—
 - 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" ("*preswylydd 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;

 ⁽³³⁾ 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).

⁽**34**) 2016 anaw 2.

"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 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 Heath 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(**35**),
- (b) regulation 5(1)(d) of the National Health Service (Vocational Training for General Medical Practice) (Scotland) Regulations 1998(**36**), or
- (c) regulation 5(1)(d) of the National Health Service (Vocational Training) Regulations (Northern Ireland) 1998(37).

(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(**38**), 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.

(37) S.R. 1998/13, revoked by S.I. 2003/1250.

⁽**35**) S.I. 1997/2817, as amended by S.I. 1998/669 and revoked by S.I. 2003/1250.

⁽³⁶⁾ 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⁾ Family Health Services Authorities no longer exist. They were merged with Health Authorities in 1994. Health Authorities have now been abolished.

(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(**39**) (offences against children and young persons, with respect

^{(39) 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

to which special provisions of this Act apply), or in Schedule 1 to the Criminal Procedure (Scotland) Act 1995(40) (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(41) (barred lists), or
 - (ii) any barred list within the meaning of Article 6 of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007(42)(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(43) (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(44) (bankruptcy restrictions order and undertaking), Schedule 2A to the Insolvency (Northern Ireland) Order 1989(45) (bankruptcy restrictions order and undertaking), or sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(46) (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—

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).

^{(40) 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).

^{(41) 2006} c. 47. Section 2 was amended by articles 3(a) and 4 of S.I. 2012/3006.

⁽⁴²⁾ 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).

^{(43) 2005} asp 10. Section 34 was amended by section 122 of the Public Services Reform (Scotland) Act 2010 (asp 8).
(44) 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). (45) 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).

^{(46) 1985} c. 66. Sections 56A to 56K were inserted by section 2(1) of the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3).

- (i) is subject to moratorium period under a debt relief order under Part VIIA of the Insolvency Act 1986(47) (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(48) (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(49) (disqualification orders: general) or a disqualification undertaking under section 1A of that Act(50) (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(51), or
 - (iii) a disqualification order under section 429(2) of the Insolvency Act 1986(52) (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(53) (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—

⁽⁴⁷⁾ Part VIIA was inserted by section 108(1) of, and Schedule 17 to, the Tribunals, Courts and Enforcement Act 2007 (c. 15).

⁽⁴⁸⁾ Schedule 4ZB was inserted by section 108(2) of, and Schedule 19 to, the Tribunals, Courts and Enforcement Act 2007.

^{(49) 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).

⁽⁵⁰⁾ 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.

⁽⁵¹⁾ S.I. 2002/3150 (N.I. 4).

⁽⁵²⁾ 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).

⁽⁵³⁾ Schedule B1 was inserted by section 248(2) of, and Schedule 16 to, the Enterprise Act 2002.

(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 regulation 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 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 in 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 regulation 12(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 general medical services 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 its 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 mentioned 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(54) (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(55) (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.

⁽⁵⁴⁾ S.I. 1976/615. Regulation 2(1) was substituted by S.I. 2010/137.

⁽⁵⁵⁾ S.I. 1985/1604. Regulation 2(1) was substituted by S.I. 2010/137.

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 sections 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 selfreported 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), (5), (6), (7) and (8) and must provide for those provisions to survive the termination of the contract.

(4) Subject to paragraphs (5), (6), (7) and (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 (and 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; and

"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