WELSH STATUTORY INSTRUMENTS

2020 No. 1073

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

PART 1 E+W

Introductory

Title, commencement and application E+W

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

(2) The following provisions come into force on 1 October 2020—

(a) this Part;

(b) Parts 2 to 4;

(c) Parts 9 to 11.

(3) Parts 5 to 8 come into force on 1 October 2021.

(4) These Regulations apply in relation to Wales.

Commencement Information

I1 Reg. 1 in force at 1.10.2020, see **reg. 1(2)(a)**

Interpretation E+W

2.—(1) In these Regulations—

"the 2006 Act" ("*Deddf 2006*") means the National Health Service (Wales) Act 2006;

"the 1992 Regulations" ("*Rheoliadau 1992*") means the National Health Service (Pharmaceutical Services) Regulations 1992(**1**) as in force immediately before 10 May 2013;

"the 2005 Regulations" ("*Rheoliadau 2005*") means the National Health Service (Pharmaceutical Services) Regulations 2005(**2**) as in force immediately before 1 September 2012;

"the 2013 Regulations" ("*Rheoliadau 2013*") means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013(**3**) as in force immediately before 1 October 2020;

(**1**) S.I. 1992/662, revoked by S.I. 2013/898 (W. 102).
(**2**) S.I. 2005/641, revoked by S.I. 2012/1909.
(**3**) S.I. 2013/898 (W. 102), amended by S.I. 2004/478 (W. 48).

"additional opening hours" ("*oriau agor ychwanegol*") is to be construed, as the context requires, in accordance with paragraph 23(11) of Schedule 5 or paragraph 13(10) of Schedule 6, or both;

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

(a) it is uniquely linked to the signatory,

(b) it is capable of identifying the signatory,

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

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

"APMS" ("*GMDdA*") means primary medical services provided in accordance with an APMS contract;

"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 2006 Act (primary medical services);

"APMS contractor" ("*contractwr GMDdA*") means a party to an APMS contract, other than a 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 2006 Act (arrangements for pharmaceutical services);

"appliance use review service" ("*gwasanaeth adolygu defnyddio cyfarpar*") means arrangements made in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services) for an NHS pharmacist or NHS appliance contractor to review a person's use of any specified appliance;

"appropriate batch issue" ("*swp-ddyroddiad priodol*") means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

"appropriate non-proprietary name" ("*enw amherchnogol priodol*") means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;

"bank holiday" ("*gŵyl banc*") means any day that is specified or proclaimed as a bank holiday in Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(**4**);

"batch issue" ("*swp-ddyroddiad*") 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 a 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);

(**4**) 1971 c. 80.

"Charges Regulations" ("*Rheoliadau Ffioedd*") means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(**5**);

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

"Community Health Council" ("*Cyngor Iechyd Cymuned*") means a Community Health Council retained or established under section 182 of the 2006 Act (community health councils);

"conditional inclusion" ("*cynnwys yn amodol*") means inclusion in a pharmaceutical list or the grant of preliminary consent to be included in a pharmaceutical list subject to conditions imposed under Part 7 of these Regulations;

"contingent removal" ("*dileu yn ddigwyddiadol*") means removal from a pharmaceutical list contingently, within the meaning of section 108 of the 2006 Act (contingent removal);

"controlled locality" ("*ardal reoledig*") means an area which a Local Health Board has determined to be rural in accordance with regulation 13 (areas that are controlled localities), which the Welsh Ministers have determined on appeal, in accordance with Parts 1 and 2 of Schedule 4, to be rural or which is a controlled locality by virtue of the operation of regulation 13(1);

"core hours" ("*oriau craidd*") means the hours during which pharmacy, or appliance contractor, premises must be open by virtue of paragraph 23(1) of Schedule 5, or paragraph 13(1) of Schedule 6;

[[F1]"coronavirus" ("*coronafeirws*") has the meaning given in section 1(1) of the Coronavirus Act 2020(**2**) (meaning of "coronavirus" and related terminology);**]**

"dentist" ("*deintydd*") means a dental practitioner;

"directed services" ("*gwasanaethau cyfeiriedig*") means additional pharmaceutical services provided in accordance with directions under section 81 of the 2006 Act (arrangements for additional pharmaceutical services);

"director" ("*cyfarwyddwr*") means—

(a) a director of a body corporate, or

(b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

"dispensing doctor" ("*meddyg fferyllol*") means a doctor who provides pharmaceutical services under arrangements with a Local Health Board made under regulation 26 (arrangements for the provision of pharmaceutical services by doctors);

"dispensing doctor list" ("*rhestr meddygon fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 11 (preparation and maintenance of dispensing doctor lists);

"doctor" ("*meddyg*") means a registered medical practitioner;

"Drug Tariff" ("*Tariff Cyffuriau*") has the meaning given to it in regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

"drugs" ("*cyffuriau*") includes medicines;

"EEA" ("*AEE*") means the European Economic Area created by the EEA agreement;

"electronic communication" ("*cyfathrebiad electronig*") has the meaning given in section 15(1) of the Electronic Communications Act 2000(**6**) (general interpretation);

(**5**) S.I. 2007/121 (W. 11), amended by S.I. 2013/898 (W. 102).
(**2**) S.I. 2005/641, revoked by S.I. 2012/1909.
(**6**) 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 with a prescriber's advanced electronic signature,

(b) is transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service, and

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

"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;

"employment" ("*cyflogaeth*") includes unpaid employment and employment under a contract for services;

"equivalent body" ("*corff cyfatebol*") means the National Health Service Commissioning Board in England, a Health Board in Scotland, a Health and Social Services Board in Northern Ireland or any successor body in England, Scotland or Northern Ireland and, in relation to any time prior to 1 April 2003, a Health Authority in Wales or in relation to any time prior to 1 April 2013 and after 30 September 2002 a Primary Care Trust in England, or in relation to any time prior to 1 October 2002, a Health Authority in England;

"equivalent list" ("*rhestr gyfatebol*") means a list kept by an equivalent body;

"essential services" ("*gwasanaethau hanfodol*") for NHS pharmacists means the services specified in paragraph 3 of Schedule 5 and for NHS appliance contractors means the services specified in paragraphs 3 to 12 of Schedule 6;

"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 Pharmaceutical Council Register" ("*Cofrestr y Cyngor Fferyllol Cyffredinol*") means the register maintained under article 19 of the Pharmacy Order 2010(**7**) (establishment, maintenance of and access to the Register);

"GMS contract" ("*contract GMC*") means a general medical services contract under section 42 of the 2006 Act (general medical services contracts: introductory);

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

"GMS Regulations" ("*Rheoliadau GMC*") means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**8**);

(**7**) S.I. 2010/231.

(**8**) S.I. 2004/478 (W. 48), amended by S.I. 2004/1017 (W. 114), S.I. 2006/358 (W. 46), S.I. 2006/945 (W. 94), S.I. 2007/121 (W. 11), S.I. 2007/205 (W. 19), S.I. 2008/1329 (W. 138), S.I .2008/1425 (W. 147), S.I. 2010/729 (W. 70), S.I. 2010/1647 (W. 155), S.I. 2011/704 (W. 108), S.I. 2012/1479, S.I. 2012/1916, S.I. 2012/2404, S.I. 2013/235, S.I. 2013/898 (W. 102), S.I. 2014/1887, S.I. 2014/2291 (W. 226), S.I. 2016/90 (W. 43), S.I. 2016/211 (W. 84), S.I. 2016/481, S.I. 2016/1221 (W. 292). There are other amendments but none are relevant.

"the Health and Care Professions Council register" ("*cofrestr y Cyngor Proffesiynau Iechyd a Gofal*") means the register established and maintained by the Health and Care Professions Council under article 5 of the Health and Social Work Professions Order 2002(**9**);

"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 Healthcare Professions Act 2002(**10**);

"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;

"joint discipline committee" ("*cyd-bwyllgor disgyblu*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**11**) (interpretation);

"LHBMS" ("*GMBILl*") means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act (primary medical services);

"LHBMS practice" ("*practis GMBILl*") means a practice providing LHBMS;

"licensing or regulatory body" ("*corff trwyddedu neu reoleiddio*") means any body that licences or regulates any profession of which the person is or has been a member, and includes any body which licences or regulates any such profession in a country other than the United Kingdom;

"list" ("*rhestr*"), unless the context otherwise requires, means a pharmaceutical list or a dispensing doctor list;

"listed premises" ("*mangre restredig*") means the premises that are included in—

(a) a pharmaceutical list, or

(b) a dispensing doctor list pursuant to regulation 11 (preparation and maintenance of dispensing doctor lists);

"Local Health Board" ("*Bwrdd Iechyd Lleol*") means a Local Health Board established under section 11 of the 2006 Act (local health boards);

"Local Medical Committee" ("*Pwyllgor Meddygol Lleol*") means a committee recognised under section 54 of the 2006 Act (local medical committees);

"Local Pharmaceutical Committee" ("*Pwyllgor Fferyllol Lleol*") means a committee recognised under section 90 of the 2006 Act (local pharmaceutical committees);

"local pharmaceutical services" ("*gwasanaethau fferyllol lleol*") means services of a kind which may be provided under section 80, or by virtue of section 81, of the 2006 Act, other than practitioner dispensing services, and which are provided under a pilot scheme;

"medical performers list" ("*rhestr cyflawnwyr meddygol*") means a list of doctors prepared and published pursuant to regulation 3(1) of the National Health Service (Performers Lists) (Wales) Regulations 2004(**12**);

"national disqualification" ("*anghymhwysiad cenedlaethol*") means—

(**9**) S.I. 2002/254, amended by paragraph 2 of Schedule 2 to the Health Care and Associated Professions (Miscellaneous Amendments and Practitioner Psychologists) Order 2009 (S.I. 2009/1182). There are other amendments to the Order but none are relevant.

(**10**) 2002 c. 17, amended by the Health and Social Care Act 2008 (c. 14) and the Pharmacy Order 2010 (S.I. 2010/231). There are other amendments but none are relevant.

(**11**) S.I. 1992/664. The definition of "joint discipline committee" was inserted by S.I. 1996/703.

(**12**) S.I. 2004/1020 (W. 117), amended by S.I. 2006/945 (W. 94).

(a) a national disqualification as mentioned in section 115(2) and (3) of the 2006 Act (national disqualification),

(b) a national disqualification as mentioned in section 159(2) and (3) of the National Health Service Act 2006(**13**) (national disqualification),

(c) any decision in Scotland or Northern Ireland corresponding to a national disqualification under section 115(2) and (3) of the 2006 Act, and

(d) any other decision that was a national disqualification for the purposes of the 2005 Regulations;

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

"NHS Business Services Authority" ("*Awdurdod Gwasanaethau Busnes y GIG*") means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**14**);

"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(**15**),

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

"NHS services" ("*gwasanaethau GIG*") means services provided as part of the health service in Wales;

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

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

"non-proprietary name" ("*enw amherchnogol*") means a name which is, or which is a permitted variation of—

(a) an International Nonproprietary Name (INN),

(b) an International Nonproprietary Name Modified (INNM),

(c) a British Approved Name (BAN),

(d) a British Approved Name Modified (BANM), or

(e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published by the British Pharmacopoeia Commission and which has not been superseded(**16**);

"notice" ("*hybysiad*") means a notice in writing;

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

(**13**) 2006 c. 41. Section 159 has been amended by S.I. 2010/22 and the Health and Social Care Act 2012 (c. 7).
(**14**) S.I. 2005/2414, amended by S.I. 2006/632, S.I. 2007/1201, S.I. 2013/235, S.I. 2015/1862, S.I. 2017/959 and S.I. 2018/378.
(**15**) 1968 c. 67.
(**16**) The British Pharmacopoeia 2020 is the leading collection of standards for UK medicinal products and pharmaceutical substances and is available at www.pharmacopoeia.com.

(a) whose name is registered in the Nursing and Midwifery Register,

(b) against whose name in that register is recorded an annotation or entry signifying that they are qualified to order drugs, medicines and appliances as—

(i) a nurse independent prescriber, or

(ii) a nurse independent/supplementary prescriber, and

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

"Nursing and Midwifery Register" ("*Cofrestr Nyrsio a Bydwreigiaeth*") means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**17**) (establishment and maintenance of register);

"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(**18**) (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) 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;

"originating events" ("*digwyddiadau cychwynnol*") means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;

"outline consent" ("*cydsyniad amlinellol*") has the meaning given to it in regulation 30(1)(a) (outline consent and premises approval);

"outstanding pharmacy application" ("*cais am fferyllfa yn yr arfaeth*") has the meaning given to it in regulation 31(11) (taking effect of outline consent and premises approval);

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

(a) who is registered as a paramedic in Part 8 of the Health and Care Professions Council register, and

(b) 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;

"patient list" ("*rhestr cleifion*") means a list of patients kept in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations or in respect of an APMS contractor or an LHBMS practice, in accordance with directions given by the Welsh Ministers under section 12(3) of the 2006 Act;

"pharmaceutical discipline committee" ("*pwyllgor disgyblu fferyllol*") has the same meaning as in regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992(**19**);

"pharmaceutical list" ("*rhestr fferyllol*") means a list that a Local Health Board is required to prepare and maintain under regulation 10 (preparation and maintenance of pharmaceutical lists);

"pharmaceutical services" ("*gwasanaethau fferyllol*") means pharmaceutical services that fall within sections 80 and 81 of the 2006 Act and includes directed services;

(**17**) S.I. 2002/253, amended by S.I. 2009/1182 and S.I. 2018/838.
(**18**) 1989 c. 44, amended by S.I. 2005/848.
(**19**) S.I. 1992/664. The definition of "pharmaceutical discipline Committee" was inserted by S.I. 1996/703.

"pharmacist independent prescriber" ("*fferyllydd-ragnodydd annibynnol*") means 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(**20**) (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;

"pharmacy" ("*fferyllfa*") means—

(a) listed premises under regulation 10 (preparation and maintenance of pharmaceutical lists) at which pharmaceutical services are provided by an NHS pharmacist pursuant to arrangements made to section 80 of the 2006 Act, or

(b) premises where under a pharmacy pilot scheme under section 92 of the 2006 Act (pilot schemes) the range of pharmaceutical services and the hours on which they are provided are comparable to a pharmacy falling within paragraph (a);

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

(a) who is a physiotherapist, and

(b) against whose name in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2002(**21**) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"pilot scheme" ("*cynllun peilot*") has the same meaning as in section 92(2) of the 2006 Act (pilot schemes);

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

(a) who is a podiatrist or a chiropodist, and

(b) against whose name in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2002 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

"practice premises" ("*mangre practis*"), in relation to a provider of primary medical services, means the address or addresses specified in the contract (in the case of a GMS or APMS contractor) or practice statement (in the case of an LHBMS practice) at which pharmaceutical services are to be provided under the contract or practice statement;

"preliminary consent" ("*cydsyniad rhagarweiniol*") has the meaning given to it in regulation 18 (applications for preliminary consent and effect of preliminary consent);

"premises approval" ("*cymeradwyaeth mangre*") has the meaning given to it in regulation 30(1)(b) (outline consent and premises approval) and includes temporary premises approval granted under regulation 34(13) (premises approval: additional and new premises after outline consent has taken effect) or residual premises approval granted under regulation 35(9) (premises approval: practice amalgamations);

"prescriber" ("*rhagnodydd*") means a doctor, dentist, pharmacist independent prescriber, independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist or chiropodist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or a supplementary prescriber;

(**20**) S.I. 1976/1213 (N.I. 22).
(**21**) S.I. 2002/254, amended by S.I. 2009/1182.

"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 of Drugs Regulations" ("*Rheoliadau Rhagnodi Cyffuriau*") means the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004(**22**);

"provider of primary medical services" ("*darparwr gwasanaethau meddygol sylfaenol*") means a GMS contractor, APMS contractor or an LHBMS practice;

"Regional Partnership Board" ("*Bwrdd Partneriaeth Rhanbarthol*") has the meaning given to it in regulation 1(4) of the Partnership Arrangements (Wales) Regulations 2015(**23**);

"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;

"relevant APMS contractor" ("*contractwr GMDdA perthnasol*"), in relation to any doctor, means—

(a) the APMS contractor, where the doctor is an APMS contractor, or

(b) where the doctor is not the APMS contractor, the APMS contractor by whom the doctor is employed or engaged;

"relevant European State" ("*Gwladwriaeth Ewropeaidd perthnasol*") means an EEA State or Switzerland;

"relevant GMS contractor" ("*contractwr GMC perthnasol*"), in relation to any doctor, means—

(a) the GMS contractor, where the doctor is a GMS contractor, or

(b) where the doctor is not a GMS contractor, the GMS contractor by whom the doctor is employed or engaged;

"relevant list" ("*rhestr berthnasol*") means—

(a) a pharmaceutical list or an equivalent list, or

(b) a list maintained by a Local Health Board or an equivalent body of approved performers or providers of primary medical, dental or ophthalmic services;

"relevant patient list" ("*rhestr cleifion berthnasol*") means—

(a) in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or APMS contractor, the patient list for that contractor, or

(b) where the doctor is not a contractor, the patient list for the GMS contractor or APMS contractor by whom the doctor is employed or engaged or for the LHBMS practice within which the doctor provides primary medical services;

"relevant pharmaceutical needs assessment" ("*asesiad perthnasol o anghenion fferyllol*") means the pharmaceutical needs assessment of the relevant Local Health Board that is current at the time that the Local Health Board takes its decision to grant or refuse an application, unless

(**22**) S.I. 2004/1022 (W. 119), 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) and S.I. 2016/90 (W. 43).
(**23**) S.I. 2015/1989 (W. 299), amended by S.I. 2019/760 (W. 143).

in the opinion of the Local Health Board (or on appeal the Welsh Ministers) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment;

"Remission of Charges Regulations" ("*Rheoliadau Peidio â Chodi Tâl*") means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007(**24**);

"repeat dispensing services" ("*gwasanaethau amlweinyddu*") means pharmaceutical services which involve the provision of drugs or appliances by an NHS pharmacist or an NHS appliance contractor in accordance with 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 40 (repeatable prescribing services) of Schedule 6 to the GMS Regulations,

(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 40 of Schedule 6 to the GMS Regulations, 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 40 of Schedule 6 to the GMS Regulations,

(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 40 of Schedule 6 to the GMS Regulations, 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 LHBMS which is the equivalent provision to paragraph 40 of Schedule 6 to the GMS Regulations;

"repeatable prescription" ("*presgripsiwn amlroddadwy*") means a prescription contained in a form provided by a Local Health Board which—

(a) is either—

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

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

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

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

"reserved location" ("*lleoliad neilltuedig*") has the meaning given to it by regulation 17(4) (locations in controlled localities that are reserved locations);

(**24**) S.I. 2007/1104 (W. 116), amended by S.I. 2008/1480 (W. 153), S.I. 2008/2568 (W. 226), S.I. 2009/54 (W. 18), S.I. 2009/709 (W. 61), S.I. 2009/1824 (W. 165), S.I. 2009/2365 (W. 193), S.I. 2010/1237 (W. 107), S.I. 2010/2759 (W. 231), S.I. 2011/681 (W. 100), S.I. 2011/1940 (W. 208), S.I. 2012/800 (W. 109), S.I. 2013/684 (W. 82), S.I. 2014/460 (W. 53), S.I. 2014/1099 (W. 109), S.I. 2015/631 (W. 51), S.I. 2016/97 (W. 46), S.I. 2016/211 (W. 84), S.I. 2017/340 (W. 84) and S.I. 2018/48 (W. 15).

"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 Prescription of Drugs Regulations (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);

"serious shortage protocol" ("*protocol prinder difrifol*") means—

(a) in the case of a prescription only medicine, a serious shortage protocol for the purposes of regulation 226A of the Human Medicines Regulations 2012(**25**) (sale etc. by a pharmacist in accordance with a serious shortage protocol), or

(b) in the case of any other drug or appliance, a written protocol that—

(i) is issued by the Welsh Ministers in circumstances where Wales or any part of Wales is, in the opinion of the Welsh Ministers, experiencing or may experience a serious shortage of—

(aa) a specified drug or appliance, or

(bb) drugs or appliances of a specified description,

(ii) provides for the supply by an NHS pharmacist or an NHS appliance contractor providing pharmaceutical or local pharmaceutical services, where there is an order on a prescription form or a repeatable prescription for—

(aa) the specified drug or appliance, or

(bb) a drug or appliance of the specified description,

of a different product or quantity of product to the product or quantity of product ordered, subject to such conditions as may be specified in the protocol, and

(iii) specifies the period for which, and the parts of Wales (which may be all of Wales) in which, the protocol is to have effect;

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

"specified appliance" ("*cyfarpar penodedig*") means—

(a) any of the following appliances listed in Part IXA of the Drug Tariff—

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a wound drainage pouch,

(b) an incontinence appliance listed in Part IXB of the Drug Tariff, or

(c) a stoma appliance listed in Part IXC of the Drug Tariff;

"stoma appliance customisation" ("*addasu cyfarpar stoma*") means the customisation of a quantity of more than one stoma appliance, where—

(a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff,

(b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance, and

(**25**) S.I. 2012/1916; regulation 226A was inserted by S.I. 2019/62.

(c) that modification is based on the patient's measurements or a record of those measurements and, if applicable, a template;

"SSP" ("*PPD*") means a serious shortage protocol;

"superintendent" ("*uwcharolygydd*") has the same meaning as in section 71 of the Medicines Act 1968(**26**) (bodies corporate);

"supplementary opening hours" ("*oriau agor atodol*") is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 5 or paragraph 13(3)(a) of Schedule 6, or both;

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

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

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

(c) a person—

(i) who is registered in a part of the register maintained under article 5 of the Health and Social Work Professions Order 2001(**27**) (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;

"therapeutic radiographer independent prescriber" ("*radiograffydd therapiwtig-ragnodydd annibynnol*") means a person—

(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", and

(ii) an annotation signifying that they are qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;

"Tribunal" ("*Tribiwnlys*") means the First-tier Tribunal established under the Tribunals, Courts and Enforcement Act 2007(**28**).

(2) Where reference is made in these Regulations to a decision of a Local Health Board and that decision is changed on appeal, unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision changed on appeal.

(3) In these Regulations—

(**26**) Section 71 was substituted by section 28 of the Health Act 2006 (c. 28).
(**27**) S.I. 2002/254. Article 5 has been amended by S.I. 2009/1182. The Order was renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).
(**28**) 2007 c. 15.

(a) the term "pharmaceutical services", in the context of arrangements for the provision of pharmaceutical services by a doctor, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 86(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services), and

(b) the term "dispensing services", in relation to a doctor or GMS contractor, means any corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations.

(4) Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations may be given or sent by delivering it to the person or, in the case of a body, to the secretary or general manager of that body, or by sending it in a prepaid letter addressed to that person or, in the case of a body, to the secretary or general manager of that body at his usual or last known address, and delivering it includes sending it electronically to an electronic address which that person has notified for the purpose.

(5) Where the term "community practitioner nurse prescriber" appears in the Human Medicines Regulations 2012(**29**) or the Nursing and Midwifery Register it is to be construed for the purposes of these Regulations as a reference to an "independent nurse prescriber".

Textual Amendments

F1 Words in reg. 2(1) inserted (6.1.2023) by The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022 (S.I. 2022/1314), regs. 1, **3**

Commencement Information

I2 Reg. 2 in force at 1.10.2020, see **reg. 1(2)(a)**

PART 2 E+W

Pharmaceutical needs assessments

Pharmaceutical needs assessments E+W

3.—(1) The statement of the needs for pharmaceutical services which each Local Health Board is required to publish by virtue of section 82A of the 2006 Act(**30**), whether it is the statement of its first assessment or of any revised assessment, is referred to in these Regulations as a "pharmaceutical needs assessment".

(2) The pharmaceutical services to which each pharmaceutical needs assessment must relate are all the pharmaceutical services that may be provided under arrangements made by a Local Health Board for—

(a) the provision of pharmaceutical services by a person on a pharmaceutical list,

(b) the provision of local pharmaceutical services under a pilot scheme, or

(c) the dispensing of drugs and appliances with a person on a dispensing doctors list (but not other NHS services that may be provided under arrangements made by a Local Health Board with a dispensing doctor).

(**29**) S.I. 2012/1916, amended by S.I. 2013/235, S.I. 2013/1855, S.I. 2013/2593, S.I. 2014/490, S.I. 2014/1878, S.I. 2015/323, S.I. 2015/903, S.I. 2015/1503, S.I. 2015/1862, S.I. 2015/1879, S.I. 2016/186, S.I. 2016/190, S.I. 2016/696, S.I. 2017/715, S.I. 2017/1322, S.I. 2018/199, S.I. 2018/378 and S.I. 2019/62.

(**30**) Section 82A was inserted by section 111 of the Public Health (Wales) Act 2017 (anaw 2).

Commencement Information
I3 Reg. 3 in force at 1.10.2020, see **reg. 1(2)(b)**

Information to be contained in pharmaceutical needs assessments E+W

4.—(1) Each pharmaceutical needs assessment must contain the information set out in Schedule 1.

(2) Each Local Health Board must, so far as is practicable, keep up to date the map which it includes in its pharmaceutical needs assessment pursuant to paragraph 5 of Schedule 1 (without needing to republish the whole assessment or publish a supplementary statement).

Commencement Information
I4 Reg. 4 in force at 1.10.2020, see **reg. 1(2)(b)**

Date by which the first pharmaceutical needs assessment is to be published E+W

5. Each Local Health Board must publish its first pharmaceutical needs assessment within 12 months of the date on which these Regulations come into force.

Commencement Information
I5 Reg. 5 in force at 1.10.2020, see **reg. 1(2)(b)**

Subsequent assessments E+W

6.—(1) After it has published its first pharmaceutical need assessment, each Local Health Board must publish a statement of its revised assessment—

(a) no later than 5 years after its previous publication of a pharmaceutical needs assessment, or

(b) at any point within 5 years of its previous publication of a pharmaceutical needs assessment, having regard to any other needs assessments the Local Health Board is under a statutory duty to publish.

(2) A Local Health Board must make a revised assessment as soon as is reasonably practicable after identifying changes, which are of a significant extent, since the publication of its pharmaceutical needs assessment which are relevant to the granting of applications referred to in section 83 of the 2006 Act, unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

(3) Pending the publication of a statement of a revised assessment, a Local Health Board may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its pharmaceutical needs assessment (which becomes part of the assessment), where—

(a) the changes are relevant to the granting of applications referred to in section 83 of the 2006 Act, and

(b) the Local Health Board—

(i) is satisfied that making a revised assessment would be a disproportionate response to those changes, or

(ii) is in the course of making a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent detriment to the provision of pharmaceutical services in its area.

(4) Where a Local Health Board publishes a supplementary statement in accordance with paragraph (3), the Local Health Board must notify those bodies listed in regulation 7(1) of its publication as soon as reasonably practicable.

Commencement Information

I6 Reg. 6 in force at 1.10.2020, see **reg. 1(2)(b)**

Consultation on pharmaceutical needs assessments E+W

7.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must consult on the contents of the assessment with the following—

(a) the Local Pharmaceutical Committee for Wales,

(b) the Local Medical Committee for its area (including one for its area and that of one or more other Local Health Boards relevant to the assessment);

(c) the persons on its pharmaceutical lists,

(d) any pilot scheme pharmacy with whom the Local Health Board has made arrangements for the provision of any local pharmaceutical services,

(e) the persons on its dispensing doctors list (if it has one),

(f) any person with whom the Local Health Board has made arrangements for the provision of dispensing services,

(g) any provider of primary medical services in its area,

(h) any Community Health Council for its area and any other group representing patients, consumers or a community in its area which in the opinion of the Local Health Board has an interest in the provision of pharmaceutical services in its area,

(i) any Regional Partnership Board for its area,

(j) any local authority for its area,

(k) any NHS Trust in its area, and

(l) any neighbouring Local Health Board.

(2) A draft of the proposed pharmaceutical needs assessment must be published on the website of the Local Health Board for a minimum of 60 days.

(3) The Local Health Board must, no later than 24 hours after the draft pharmaceutical needs assessment is published in accordance with paragraph (2), notify the persons listed in paragraph (1) that—

(a) a draft of the proposed pharmaceutical needs assessment has been published on the website of the Local Health Board, and

(b) the date by which any consultation response must be provided to the Local Health Board.

(4) If a person listed in paragraph (1) requests a copy of the draft pharmaceutical needs assessment in hard copy form, the Local Health Board must as soon as is practicable, and in any event within 14 days, supply a hard copy of the draft to that person (free of charge).

(5) Where a Local Health Board is notified in accordance with paragraph (3) and there is a Local Medical Committee for its area that is different to the Local Medical Committee consulted under paragraph (1)(b), the Local Health Board notified—

(a) must consult that Committee before making its response to the consultation, and

(b) must have regard to any representation received from the Committee when making its response to the consultation.

Commencement Information

I7 Reg. 7 in force at 1.10.2020, see **reg. 1(2)(b)**

Matters for consideration when making assessments E+W

8.—(1) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must have regard, in so far as it is practicable to do so, to the following matters—

(a) any assessment or further assessment of relevant needs prepared under section 82A of the 2006 Act—

(i) where it relates to the area of the Local Health Board, and

(ii) which has not been superseded by a further assessment under that section,

(b) the demography of its area,

(c) any different needs of different localities within its area,

(d) the pharmaceutical services provided under arrangements with any neighbouring Local Health Board which affect the need for pharmaceutical services in its area, and

(e) any dispensing services or other NHS services provided in or outside its area (which are not covered by sub-paragraph (d)) which affect the need for pharmaceutical services in its area.

(2) When making an assessment for the purposes of publishing a pharmaceutical needs assessment, each Local Health Board must take account of the likely future needs—

(a) to the extent necessary to make a proper assessment of the matters mentioned in paragraph 3 of Schedule 1, and

(b) having regard to changes to the number of people in its area who will require pharmaceutical services.

Commencement Information

I8 Reg. 8 in force at 1.10.2020, see **reg. 1(2)(b)**

Publication of pharmaceutical needs assessments E+W

9.—(1) A Local Health Board must publish on its website—

(a) the pharmaceutical needs assessment for its area,

(b) any subsequent assessment made pursuant to regulation 6(1), and

(c) any supplementary statement made pursuant to regulation 6(3).

(2) If a Local Health Board receives a request for a copy of any of the documents in paragraph (1) in hard copy form, the Local Health Board must, as soon as is practicable and in any event within 14 days, supply a hard copy (free of charge).

Commencement Information
I9 Reg. 9 in force at 1.10.2020, see **reg. 1(2)(b)**

PART 3 E+W

Pharmaceutical lists and dispensing doctor lists

Preparation and maintenance of pharmaceutical lists E+W

10.—(1) Each Local Health Board must prepare and maintain pharmaceutical lists of NHS pharmacists and NHS appliance contractors who have applied in accordance with Part 5 of these Regulations and Schedule 2, to provide pharmaceutical services from premises in the Local Health Board's area and whose applications have been approved by the Local Health Board in accordance with Schedule 3 or on appeal by the Welsh Ministers in accordance with Schedule 4 and who are authorised—

(a) to provide pharmaceutical services in particular by way of the provision of drugs, or

(b) to provide pharmaceutical services only by way of the provision of appliances.

(2) Each pharmaceutical list must include—

(a) the address of the premises at which the listed person has undertaken to provide pharmaceutical services,

(b) the days on which and times at which at those premises the listed person provides pharmaceutical services, and

(c) a description of the pharmaceutical services that the listed person has undertaken to provide.

(3) Part 7 of these Regulations makes provision for the removal of persons from pharmaceutical lists.

(4) A pharmaceutical list of a Local Health Board that is the current list immediately before these Regulations come into force is also the current pharmaceutical list when these Regulations come into force, unless the Local Health Board is required or entitled to give effect to a decision reached before the coming into force date to change, remove or include an entry from or in the list from the start of the coming into force date, in which case the current list at the start of the coming into force date is the list as modified to give effect to that decision.

Commencement Information
I10 Reg. 10 in force at 1.10.2020, see **reg. 1(2)(b)**

Preparation and maintenance of dispensing doctor lists E+W

11.—(1) Each Local Health Board must prepare and maintain a dispensing doctor list of doctors with whom the Local Health Board has made an arrangement in accordance with regulation 26 (arrangements for the provision of pharmaceutical services by doctors) to provide pharmaceutical services to their patients in the area of the Local Health Board.

(2) Each dispensing doctor list must include—

(a) the name of the doctor—

(i) whose application under Part 6 for outline consent and premises approval has been approved by the Local Health Board in accordance with Schedule 3 or on appeal by the Welsh Ministers in accordance with Schedule 4, and

(ii) who has made arrangements with the Local Health Board under regulation 26 to provide pharmaceutical services,

(b) the area in relation to which outline consent has been granted and the date on which the outline consent took effect,

(c) the address of the practice premises which have been granted premises approval, specifying—

(i) the date on which premises approval took effect or, where it has not taken effect, the date on which it was granted, and

(ii) if premises approval is deemed, temporary or residual, that this is the case,

(d) the address of any practice premises in relation to which the doctor has outstanding applications for premises approval, and

(e) where the doctor whose name is included in the dispensing doctor list provides primary medical services with an LHBMS practice, the name and address of the Local Health Board.

(3) A doctor included in a dispensing doctor list maintained by a Local Health Board who is a provider of primary medical services or who is employed or engaged by a provider of primary medical services may make a request to that Local Health Board for another doctor who is a provider of primary medical services or who is employed or engaged by a provider of primary medical services to be included in the dispensing doctor list in their place.

(4) A Local Health Board that receives a request described in paragraph (3) must agree to that request and—

(a) the doctor that made the request ("the original doctor") must be substituted by the other doctor ("the new doctor") by the Local Health Board in the dispensing doctor list that it maintains,

(b) the arrangements that the Local Health Board had with the original doctor become arrangements with the new doctor, and

(c) the outline consents and premises approvals of the original doctor become the outline consents and premises approvals of the new doctor.

(5) A Local Health Board must remove a listed doctor from a dispensing doctor list if—

(a) the doctor has died,

(b) the doctor is no longer performing primary medical services within the area of the Local Health Board,

(c) outline consent and premises approval has lapsed under regulation 32 (lapse of outline consent and premises approval),

(d) the doctor has been removed from the medical performers list, or

(e) more than 12 months have elapsed since the doctor last provided drugs, medicines or appliances under an arrangement made pursuant to regulation 26.

(6) A dispensing doctor list of a Local Health Board that is the current list immediately before these Regulations come into force is also the current dispensing doctor list when these Regulations come into force unless the Local Health Board is required or entitled to give effect to a decision reached before the coming into force date to change, remove or include an entry in the list from the

start of the coming into force date, in which case the current list at the start of the coming into force date is the list as modified to give effect to that decision.

Commencement Information
I11 Reg. 11 in force at 1.10.2020, see **reg. 1(2)(b)**

Terms of service E+W

12.—(1) The terms on which a person is included in a pharmaceutical list (and therefore the person's terms of service) are those that are included—

(a) in the terms of service—

(i) for NHS pharmacists who provide pharmaceutical services in particular by the provision of drugs, set out in Schedule 5, or

(ii) for NHS appliance contractors who provide pharmaceutical services only by way of the provision of appliances, set out in Schedule 6,

as may be varied by conditions imposed by a Local Health Board by virtue of regulation 38 (conditional inclusion on fitness grounds),

(b) in the Drug Tariff, in so far as the rights and liabilities in the Drug Tariff relate to NHS pharmacists or NHS appliance contractors and are applicable in the case of the NHS pharmacist or NHS appliance contractor, and

(c) in an arrangement made by a Local Health Board with the NHS pharmacist or NHS appliance contractor for the provision of any pharmaceutical services.

(2) The terms on which a person is included in a dispensing doctor list (and therefore the person's terms of service) are those that are—

(a) included in the terms of service for doctors providing pharmaceutical services set out in Schedule 7,

(b) in accordance with any conditions imposed regarding the postponement or termination of the provision of pharmaceutical services to eligible patients made under paragraph 6 of Schedule 3, paragraph 13 of Schedule 3 or regulation 17(6), and

(c) in accordance with any conditions imposed in relation to the dispensing doctor's ability to provide pharmaceutical services by virtue of regulation 9(7) of the 1992 Regulations or regulation 6(4) of, and paragraph 6 of Schedule 2 to, the 2013 Regulations.

Commencement Information
I12 Reg. 12 in force at 1.10.2020, see **reg. 1(2)(b)**

PART 4 E+W

Determination of controlled localities

Areas that are controlled localities E+W

13.—(1) Any area that was, or was part of, a controlled locality for the purposes of the 2013 Regulations—

(a) immediately before these Regulations come into force, or

(b) following a determination made in accordance with regulation 63(2),

continues to be, or to be part of, a controlled locality for the purposes of these Regulations (unless or until it is determined that the area is no longer, or is no longer part of, a controlled locality).

(2) Subject to paragraph (3), a Local Health Board must in response to an application submitted in writing by a Local Medical Committee or a Local Pharmaceutical Committee, or may at any other time that it may decide, consider the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality.

(3) Where the question of whether or not any particular area is, or is part of, a controlled locality has been determined by a Local Health Board or on appeal by the Welsh Ministers (whether under these Regulations or the 2013 Regulations) that question must not be considered again in relation to the particular area—

(a) for 5 years, beginning on the date of the determination of the Local Health Board or, if that determination was appealed, the date of the decision of the appeal, unless

(b) the Local Health Board is satisfied (within that 5 years) that there has been a substantial change in circumstances affecting the area since the question was last determined.

(4) Parts 1 and 2 of Schedule 4 specify the procedures to be followed by a Local Health Board when determining whether or not an area is a controlled locality under this regulation.

Commencement Information
I13 Reg. 13 in force at 1.10.2020, see **reg. 1(2)(b)**

Appeals against decisions under Part 4 E+W

14. Parts 1 and 2 of Schedule 4 make provision for appeals to the Welsh Ministers in respect of decisions made under this Part.

Commencement Information
I14 Reg. 14 in force at 1.10.2020, see **reg. 1(2)(b)**

PART 5 E+W

Applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to pharmaceutical lists

Applications to be included in or make amendment to a pharmaceutical list E+W

15.—(1) A person may submit an application to a Local Health Board where that person—

(a) wishes to be included in a pharmaceutical list maintained by the Local Health Board,

(b) is already included in a pharmaceutical list maintained by the Local Health Board but wishes, within the Local Health Board's area, to—

(i) open additional premises from which to provide the same or different pharmaceutical services,

(ii) relocate to different premises and at those premises to provide the same or different pharmaceutical services, or

(iii) provide from the listed premises pharmaceutical services that are of a different description to those pharmaceutical services already listed in relation to that person, or

(c) is already included in a pharmaceutical list maintained by a neighbouring Local Health Board but wishes to relocate to different premises in the area of the Local Health Board to which the application is made and, at those premises, to provide the same or different pharmaceutical services.

(2) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 1 of Schedule 2.

(3) Subject to regulation 60 (home Local Health Board), a person making an application under paragraph (1)(a) must provide the information and undertakings specified in Part 2 of Schedule 2.

(4) If a Local Health Board considers that an application does not contain all of the information required under paragraphs (2) and (3)—

(a) it may request the missing relevant information or documentation from the applicant, and

(b) the applicant must, within the period reasonably specified by the Local Health Board in the request under sub-paragraph (a)—

(i) provide any information or documentation reasonably requested,

(ii) notify the Local Health Board that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or

(iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the Local Health Board of that and seek a review by the Local Health Board of the reasonableness of the request.

(5) If an applicant refuses to comply with a request under paragraph (4)(a)—

(a) within the period—

(i) reasonably specified by the Local Health Board under paragraph (4)(b), or

(ii) ending on the date specified by the applicant in accordance with paragraph (4)(b)(ii), if the Local Health Board is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,

unless sub-paragraph (b) applies, the application is to be treated as withdrawn;

(b) in circumstances where the applicant has, in accordance with paragraph (4)(b)(iii), sought a review by the Local Health Board of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—

(i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the Local Health Board for the provision of that information or documentation, or

(ii) need not be provided by the applicant, the request of the Local Health Board is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.

(6) The Local Health Board may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application.

(7) An application to be included in a pharmaceutical list by a person not already included must be refused if the applicant is an individual who qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom, unless that person satisfies the Local Health Board they have the level of knowledge of English which, in the interests of that individual and the persons making

use of the pharmaceutical services to which the application relates, is necessary for the provision of those pharmaceutical services in the area of the Local Health Board.

(8) All applications made under regulation 15(1) will be determined in accordance with regulation 16 (determination of applications to be included in or to make amendment to a pharmaceutical list) except for applications to which—

(a) regulation 19 (applications involving relocation within a Local Health Board's area),

(b) regulation 20 (applications involving relocation between neighbouring Local Health Board areas),

(c) regulation 21 (applications involving temporary relocation), or

(d) regulation 22 (applications involving a change of ownership),

applies and which are determined in accordance with those regulations.

(9) Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications made under this Part.

Commencement Information

I15 Reg. 15 in force at 1.10.2021, see **reg. 1(3)**

Determination of applications to be included in or to make amendment to a pharmaceutical list E+W

16.—(1) Where the premises specified in an application are not in a controlled locality, the Local Health Board may grant the application only if it is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant Local Health Board and which have been included in the pharmaceutical needs assessment of that Local Health Board in accordance with Schedule 1.

(2) Where the premises specified in an application are in a controlled locality but not in a reserved location (as defined in regulation 17(4) and (5)), the Local Health Board may—

(a) refuse the application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality within which the premises specified in the application are situated (the "prejudice test"), and

(b) where the application has not been refused under the prejudice test, grant the application only if it is satisfied that it meets a need identified in the pharmaceutical needs assessment of the relevant Local Health Board.

(3) The prejudice test does not apply to the Local Health Board's determination of an application where the premises specified in an application are situated in a reserved location.

(4) A Local Health Board must refuse an application in which the applicant does not meet a need that is identified in the pharmaceutical needs assessment of the relevant Local Health Board.

(5) In determining an application under this regulation, which has been made in accordance with regulation 15(1), (except where the application is made by a person who has been granted preliminary consent pursuant to regulation 18 which is valid in accordance with regulation 18(5)), or in accordance with regulation 18 where the applicant is not already included in that Local Health Board's pharmaceutical list, a Local Health Board may—

(a) defer consideration of the application on fitness grounds in accordance with regulation 36 (deferral of applications on fitness grounds),

(b) refuse the application on fitness grounds in accordance with regulation 37 (refusal of applications on fitness grounds), or

(c) impose conditions on the grant of the application in accordance with regulation 38 (conditional inclusion on fitness grounds).

Commencement Information

I16 Reg. 16 in force at 1.10.2021, see **reg. 1(3)**

Locations in controlled localities that are reserved locations E+W

17.—(1) A Local Health Board must determine whether premises specified in an application submitted to it under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) or premises or the relevant location from which the applicant wishes to provide pharmaceutical services, specified in an application submitted to it under regulation 18 (applications for preliminary consent and effect of preliminary consent) that are in a controlled locality are also in a reserved location.

(2) Where it has been determined by the Local Health Board, or on appeal by the Welsh Ministers (under paragraph (1) and Schedule 4 respectively) or pursuant to regulation 11 of, or Part 2 of Schedule 3 to, the 2013 Regulations, in relation to premises or a relevant location, from which pharmaceutical services are to be or are being provided, that those premises are or the relevant location is in a reserved location, the person included in the pharmaceutical list in relation to those premises, or that relevant location, may make an application in writing to the Local Health Board to make a further determination as to whether, on the date of the application, those premises are, or that relevant location is, in a reserved location.

(3) For the purposes of this regulation the "relevant location" means, where the location of the premises from which the pharmaceutical services are to be provided is specified in writing by the applicant before the Local Health Board makes its determination, that location, and where that location is not so specified, the best estimate the Local Health Board is able to make of where those premises may be.

(4) Subject to paragraph (5), a reserved location is a location in a controlled locality in respect of which the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location of the premises is less than 2,750 persons.

(5) A location is not a reserved location under paragraph (4) if the Local Health Board considers that if a pharmacy were to operate from the location, the extent to which it would be used would be similar to or greater than might be expected if the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location were equal to or more than 2,750 persons.

(6) Where in making a further determination applied for in accordance with paragraph (2) the Local Health Board determines that those premises are, or the relevant location is, not in a reserved location, or there is an appeal against a determination by the Local Health Board and it is determined on appeal that the premises are not, or that the relevant location is not, in a reserved location—

(a) the Local Health Board may determine that the premises are, or the relevant location is, to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Local Health Board itself), dispensing services or pharmaceutical services in any controlled locality, or

(b) if the Local Health Board considered that the provision of primary medical services by a provider of primary medical services (other than one employed by the Local Health Board), pharmaceutical services by a NHS pharmacist or NHS appliance contractor,

local pharmaceutical services provided under a pilot scheme or pharmaceutical services provided by a doctor is likely to be adversely affected by a determination that the premises are not in a reserved location, it may make such determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 26 (or equivalent under the GMS Regulations) for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients.

Commencement Information

I17 Reg. 17 in force at 1.10.2021, see **reg. 1(3)**

Applications for preliminary consent and effect of preliminary consent E+W

18.—(1) A person who wishes to be granted the right to be included in a pharmaceutical list maintained by the Local Health Board on a subsequent application under regulation 15(1)(a) or 15(1)(b)(i) (applications to be included in or make amendment to a pharmaceutical list) may submit an application to a Local Health Board for preliminary consent under this regulation.

(2) An application made under this regulation must be made in writing and must provide the information and undertakings set out in—

(a) Part 1 of Schedule 2, and

(b) subject to regulation 60 (home Local Health Board), Part 2 of Schedule 2.

(3) A Local Health Board must determine an application for preliminary consent as if it were an application made pursuant to regulation 15(1)(a) or 15(1)(b)(i).

(4) A preliminary consent will be valid for a period of 6 months from the date on which it is granted, which is the later of either—

(a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 3, or

(b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers give notice of their decision on the appeal under paragraph 8 of Schedule 4.

(5) A Local Health Board must grant a subsequent application made under regulation 15(1)(a) or 15(1)(b)(i) by a person who has been granted preliminary consent if—

(a) the date on which the application was received by the Local Health Board is within the period specified in paragraph (4),

(b) the pharmaceutical services specified in the application are the same as those that were specified in the application for preliminary consent, and

(c) the premises specified in the application are in the same location as the premises or a location that is relevant to a need identified in the pharmaceutical needs assessment of the Local Health Board.

(6) Where sub-paragraphs (a) and (b) in respect of paragraph (5) are satisfied but the premises specified in the application have a different location from that in respect of which preliminary consent was granted, the Local Health Board must treat the application as though it were an application made pursuant to regulation 15(1)(b)(ii).

(7) The grant of an application under paragraph (5) must be subject to any conditions that were imposed by the Local Health Board, or the Welsh Ministers on appeal, in relation to the final grant of the corresponding preliminary consent.

(8) In determining an application under this regulation from a person who is not already included in the Local Health Board's pharmaceutical list (apart from an application from a person who has a valid preliminary consent in accordance with paragraph (4)), a Local Health Board may—

(a) defer consideration of the application on fitness grounds under regulation 36 (deferral of application on fitness grounds),

(b) refuse the application on fitness grounds under regulation 37 (refusal of applications on fitness grounds), or

(c) impose conditions on the grant of the application under regulation 38 (conditional inclusion on fitness grounds).

Commencement Information

I18 Reg. 18 in force at 1.10.2021, see **reg. 1(3)**

Applications involving relocation within a Local Health Board's area E+W

19.—(1) A person who has made an application under regulation 15(1)(a) (applications to be included in or make amendment to a pharmaceutical list) may at any time after making the application, but before the end of the relevant period (as defined in regulation 23 (procedure following grant of an application)), notify the Local Health Board that they wish to change the premises from which they intend to provide pharmaceutical services specified in the application and the Local Health Board may amend the premises specified in the original application if it is satisfied that—

(a) the change is a relocation,

(b) the pharmaceutical services specified in the application that would have been provided at the premises specified in the original application will be provided at the new premises, and

(c) the relocation still meets the need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment.

(2) A Local Health Board may grant an application made by a person under regulation 15(1)(b)(ii) to relocate from listed premises to new premises at which the person intends to provide pharmaceutical services, if it is satisfied that—

(a) the relocation is to meet a need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment and—

(i) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),

(ii) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation), and

(iii) would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises, or

(b) the relocation is not to meet a need for pharmaceutical services, or pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment but—

(i) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,

(ii) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises,

(iii) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),

(iv) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation), and

(v) would not, if granted, result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises.

(3) A person who has had an application granted under this regulation may not, within 12 months of the date of the grant of the application (as defined in regulation 23(3)(a)), submit another application for determination pursuant to this regulation or regulation 20.

Commencement Information

I19 Reg. 19 in force at 1.10.2021, see **reg. 1(3)**

Applications involving relocation between neighbouring Local Health Board areas E+W

20.—(1) A Local Health Board may grant an application made by a person under regulation 15(1)(c) (applications to be included in or make amendment to a pharmaceutical list) to relocate from listed premises in the area of neighbouring Local Health Board to new premises in the area of the Local Health Board to which the application is made, and at those premises the person intends to provide pharmaceutical services, if—

(a) the Local Health Board, to which the application is made, is satisfied that—

(i) the change is a relocation to meet a need identified in the relevant pharmaceutical needs assessment of the Local Health Board,

(ii) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,

(iii) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good reason permit),

(iv) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 21 (applications involving temporary relocation),

(v) the application would not, if granted, result in a significant change in the arrangements that are in place for the provision of pharmaceutical services (other than those provided by a person on a dispensing doctor list) in any part of the Local Health Board's area, or in a controlled locality in the area of a neighbouring Local Health Board where that controlled locality is within 1.6 kilometres of the new premises, and

(b) the person consents to the removal of the premises from the pharmaceutical list maintained by the Local Health Board in whose area the current listed premises are located with effect from the date on which the provision of pharmaceutical services from the new premises commences.

(2) A person who has had an application granted pursuant to this regulation may not, within 12 months of the date of the grant of the application (as defined in regulation 23(3)(a)), submit another application for determination under this regulation or regulation 19.

Commencement Information
I20 Reg. 20 in force at 1.10.2021, see **reg. 1(3)**

Applications involving temporary relocation E+W

21.—(1) A Local Health Board may make a temporary amendment to an entry in a pharmaceutical list by granting an application made by a person under regulation 15(1)(b)(ii) (applications to be included in or make amendment to a pharmaceutical list) to relocate to different premises on a temporary basis if it is satisfied that—

(a) the circumstances in which the application is made require the flexible provision of pharmaceutical services,

(b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the temporary premises is not significantly less accessible,

(c) the same pharmaceutical services will be provided at the temporary premises as are provided at the listed premises, and

(d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) A temporary amendment to an entry in the pharmaceutical list will have effect from the date on which the Local Health Board approved the application made to it and will be valid for such period of up to 6 months and any further periods of up to 3 months each that the Local Health Board considers necessary.

(3) A person may revert to the overridden entry in the pharmaceutical list maintained by the Local Health Board before the end of the period determined by the Local Health Board under paragraph (2) on giving the Local Health Board at least 7 days' notice in writing.

(4) Where, in accordance with this regulation, an entry in a pharmaceutical list is overridden by a temporary amendment, any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed for other reasons) and if, as a result of those proceedings the overridden arrangements require amendment before the end of the temporary amendment, the reversion to the overridden arrangements is to be to the original overridden amendments as amended as a result of those proceedings.

Commencement Information
I21 Reg. 21 in force at 1.10.2021, see **reg. 1(3)**

Applications involving a change of ownership E+W

22.—(1) A Local Health Board must grant an application made by a person under regulation 15(1)(a), (b)(i) or (ii) (applications to be included in or make amendment to a pharmaceutical list) who intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by another person who is included in a pharmaceutical list maintained by the Local Health Board under regulation 10 (preparation and maintenance of pharmaceutical lists) if the Local Health Board is satisfied that—

(a) the premises are already included in a pharmaceutical list maintained by the Local Health Board,

(b) the same pharmaceutical services will continue to be provided from the premises, and

(c) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) In determining an application under this regulation which has been made under regulation 15(1)(a) (except where the application has been made by a person who has been granted preliminary consent under regulation 18 which is valid in accordance with regulation 18(5)), or under regulation 18 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

(a) defer consideration of the application on fitness grounds under regulation 36 (deferral of applications on fitness grounds),

(b) refuse the application on fitness grounds under regulation 37 (refusal of applications on fitness grounds), or

(c) impose conditions on the grant of the application under regulation 38 (conditional inclusion on fitness grounds).

Commencement Information

I22 Reg. 22 in force at 1.10.2021, see **reg. 1(3)**

Procedure following grant of an application E+W

23.—(1) Following the date of the grant of an application made under regulation 15 (applications to be included in or make amendment to a pharmaceutical list), a Local Health Board must not include a person in a pharmaceutical list or amend a pharmaceutical list unless—

(a) the condition in paragraph (2) is satisfied, and

(b) the requirements of regulation 38 (conditional inclusion on fitness grounds), if any, are met as regards the imposition of conditions on any person.

(2) A person will be included in the relevant pharmaceutical list or the relevant pharmaceutical list will be amended as appropriate if, not less than 14 days before the end of the relevant period, that person notifies the Local Health Board in writing, providing the information specified in Part 3 of Schedule 2, that they will within the next 14 days commence the provision at the premises of the pharmaceutical services that were specified in the application.

(3) For the purposes of this regulation and, where relevant, regulation 24—

(a) "the date of the grant of an application" is the date which is the later of either—

(i) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 3, or

(ii) the date of the determination of any appeal that is brought against the decision of the Local Health Board, and

(b) "the relevant period" is—

(i) the period of 6 months from the date of the grant of an application, or

(ii) such further period in addition to that specified in paragraph (i) not exceeding 3 months that the Local Health Board may for good reason allow.

Commencement Information
I23 Reg. 23 in force at 1.10.2021, see **reg. 1(3)**

Application to extend the relevant period E+W

24.—(1) A person may make an application to the Local Health Board to extend the relevant period no later than 5 months after the date of the grant of an application.

(2) In accordance with regulation 23(3)(b)(ii) a person may apply for an extension of up to 3 months.

(3) An application to the Local Health Board under this regulation must be made in writing and must provide reasons why an extension of the relevant period is sought.

(4) Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications made under this regulation.

(5) For the purposes of this regulation, "person" means the person who would be entitled to provide notification to a Local Health Board in accordance with regulation 23(2) of commencement of provision of pharmaceutical services.

Commencement Information
I24 Reg. 24 in force at 1.10.2021, see **reg. 1(3)**

Appeals E+W

25.—(1) Schedule 4 makes provision for appeals to the Welsh Ministers in respect of decisions of Local Health Boards made under this Part, save for those regulations listed in paragraph (2).

(2) There is no right of appeal in respect of a decision of a Local Health Board—

(a) to make or not to make, or to extend, a temporary amendment to a pharmaceutical list under regulation 21 (applications involving temporary relocation), or

(b) to extend or not to extend the relevant period under regulation 24 (application to extend the relevant period).

Commencement Information
I25 Reg. 25 in force at 1.10.2021, see **reg. 1(3)**

PART 6 E+W

Applications by doctors for inclusion in or amendment to dispensing doctors lists

Arrangements for the provision of pharmaceutical services by doctors E+W

26.—(1) A Local Health Board may make an arrangement with a doctor who falls within paragraph (8) for the doctor to provide pharmaceutical services to a patient included on the doctor's patient list or the patient list of a provider of primary medical services by whom the doctor is employed or engaged, if the patient—

(a) would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy because of distance or inadequacy of means of communication, and the conditions in paragraph (2) are satisfied,

(b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy, and the conditions specified in paragraph (4) are satisfied, or

(c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination and the conditions specified in paragraph (4) are satisfied.

(2) The conditions referred to in paragraph (1)(a) are—

(a) the patient has made a request in writing to the Local Health Board for the doctor to provide them with pharmaceutical services for the reasons specified in paragraph (1)(a), and

(b) the Local Health Board is satisfied that the patient would have serious difficulty in obtaining any necessary drugs or appliances for those reasons.

(3) In making an arrangement with a doctor for the doctor to provide a patient under paragraph (1)(a) with pharmaceutical services from practice premises, the Local Health Board must give reasonable notice in writing to the doctor of when the arrangement is to take effect unless the doctor satisfies the Local Health Board that—

(a) the doctor does not normally provide pharmaceutical services to patients, or

(b) the patient would not have serious difficulty in obtaining drugs and appliances from a pharmacy because of distance or inadequacy of means of communication.

(4) The conditions referred to in paragraph (1)(b) and (c) are that—

(a) outline consent has been granted to the doctor or the provider of primary medical services by whom the doctor is employed or engaged,

(b) premises approval has been granted in relation to the premises from which the doctor will provide pharmaceutical services to that patient,

(c) the outline consent and premises approval has taken effect under regulation 31 (taking effect of outline consent and premises approval), and

(d) any conditions imposed under these Regulations in connection with the grant of outline consent or premises approval are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to patients under paragraph (1)(b) or (c).

(5) References in paragraph (4) to outline consent, premises approval and conditions imposed include references to those in effect under the 2013 Regulations.

(6) A doctor with whom an arrangement has been made to provide pharmaceutical services to a patient under this regulation may, with the consent of the patient, instead of providing the drugs or appliances order them by issuing a prescription to the patient.

(7) Where an arrangement for a doctor to provide pharmaceutical services to a patient was in effect immediately before these Regulations came into force, that arrangement will have effect as though made under this regulation notwithstanding that the conditions in paragraph (4) are not satisfied.

(8) A doctor falls within this paragraph if they are—

(a) a GMS contractor or an APMS contractor,

(b) engaged or employed by a GMS contractor or an APMS contractor, or

(c) is engaged by a Local Health Board for the purposes of providing primary medical services to a LHBMS practice.

(9) A doctor may appeal to the Welsh Ministers against a decision of a Local Health Board under paragraph (3). The appeal must be made in writing within 30 days beginning with the date on which notice of the decision was sent to the doctor and must contain a concise statement of the grounds of appeal.

(10) The Welsh Ministers must, on receipt of any notice of appeal under paragraph (9), send a copy of that notice to the Local Health Board and the relevant GMS contractor or APMS contractor, and the Local Health Board and the relevant GMS contractor or APMS contractor may, within 30 days from the date on which the Welsh Ministers sent a copy of the notice of appeal, make representations in writing to the Welsh Ministers.

(11) The Welsh Ministers may determine an appeal pursuant to paragraph (9) in such manner as they see fit, taking into consideration the preliminary matters in Part 1 of Schedule 4.

(12) The Welsh Ministers must, upon determination by them of any appeal under paragraph (9), give notice of their decision in writing, together with the reasons for it, to the appellant, to the Local Health Board, and to the relevant GMS contractor or APMS contractor.

Commencement Information
I26 Reg. 26 in force at 1.10.2021, see **reg. 1(3)**

Necessary services for temporary patients E+W

27. A doctor who provides pharmaceutical services to patients on a patient list by arrangement made with a Local Health Board under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) may provide necessary pharmaceutical services to a person who has been accepted by the doctor as a temporary patient.

Commencement Information
I27 Reg. 27 in force at 1.10.2021, see **reg. 1(3)**

Provision of pharmaceutical services for immediate treatment or personal administration E+W

28.—(1) Subject to paragraph (2), a doctor whose name is included in a medical performers list may—

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

(b) provide to a patient any appliance or drug, not being a Scheduled drug, which the doctor personally administers or applies to the patient.

(2) A doctor may only provide a restricted availability appliance if it is for a person or a purpose specified in the Drug Tariff.

Commencement Information
I28 Reg. 28 in force at 1.10.2021, see **reg. 1(3)**

Discontinuation of arrangements for the provision of pharmaceutical services by doctors E+W

29.—(1) A Local Health Board must give reasonable notice in writing to a doctor that they must discontinue the provision of pharmaceutical services to a patient under an arrangement pursuant to regulation 26 where the patient no longer falls within regulation 26(1)(a), (b) or (c).

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

(a) is subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under paragraph 6 of Schedule 3, paragraph 13 of Schedule 3 or regulation 17(6), and

(b) must not be given—

(i) pending any appeal against a decision of the Local Health Board to postpone the making of or the termination of the arrangement, or

(ii) where paragraph 5 of Schedule 3 applies.

Commencement Information

I29 Reg. 29 in force at 1.10.2021, see **reg. 1(3)**

Outline consent and premises approval E+W

30.—(1) A doctor who is a provider of primary medical services or who is engaged or employed by a provider of primary medical services and who wishes to make an arrangement with a Local Health Board to provide pharmaceutical services to patients under regulation 26(1)(b) or (c) (arrangements for the provision of pharmaceutical services by doctors) must submit an application in writing to the Local Health Board for—

(a) consent, specifying the area in which the doctor wishes to provide pharmaceutical services ("outline consent"), and

(b) approval of any practice premises from which the doctor wishes to dispense ("premises approval").

(2) A doctor who has outline consent which has taken effect under regulation 31 (taking effect of outline consent and premises approval) may submit an application for premises approval only in relation to—

(a) additional practice premises from which to provide pharmaceutical services, or

(b) practice premises to which the doctor wishes to relocate from listed premises.

(3) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 4 of Schedule 2

(4) A Local Health Board must return an application if it does not contain all of the information required under paragraph (3).

(5) The Local Health Board—

(a) must refuse outline consent in relation to any part of the area specified in the application which is not in a controlled locality or which is within 1.6 kilometres of any pharmacy;

(b) must refuse premises approval in relation to any premises specified in the application which are within 1.6 kilometres of any pharmacy;

(c) must refuse an application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical

services in the controlled locality within which the premises specified in the application are situated ("the prejudice test");

(d) where an application has not been refused under the prejudice test, must refuse the application unless it is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant locality and which has been included in the relevant pharmaceutical needs assessment and which the doctor has applied for outline consent;

(e) may, where the Local Health Board has considered two or more applications together and in relation to each other, refuse one or more of them (notwithstanding that it would, if determining the applications in isolation, grant them) where the number of applications is such that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any controlled locality.

(6) Any refusal of an application outlined at paragraph (5)(a) to (e) may relate to all or any part of the area within the controlled locality, or, as the case may be, all or some of the premises for which approval is sought.

(7) Subject to any specific requirements that are contained within this Part, Parts 1 and 3 of Schedule 3 specify the procedures to be followed by a Local Health Board when determining applications under this Part.

(8) An application under this regulation is granted on the date which is the later of—

(a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 15 of Schedule 3, or

(b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers gave notice of their decision on the appeal under paragraph 8 of Schedule 4.

Commencement Information

I30 Reg. 30 in force at 1.10.2021, see **reg. 1(3)**

Taking effect of outline consent and premises approval E+W

31.—(1) When granting an application made under regulation 30 (outline consent and premises approval), the Local Health Board must determine the date on which outline consent and premises approval are to take effect.

(2) Where there are no outstanding pharmacy applications (as defined in paragraph (11)) outline consent and premises approval take effect on the date on which the application is granted.

(3) Where there are outstanding pharmacy applications on the day before the application under regulation 30 is granted, the date on which outline consent and premises approval take effect is to be determined in accordance with paragraphs (4) to (9).

(4) The Local Health Board must in respect of an application to which paragraph (3) applies notify the doctor who made the application under regulation 30, and the Welsh Ministers if the application is subject to appeal, of—

(a) any outstanding pharmacy applications,

(b) the withdrawal of outstanding pharmacy applications,

(c) the provisional date (as defined in paragraph (11)) on which the doctor can request the Local Health Board to determine that outline consent and premises approval should come into effect, and

(d) the lapse of the doctor's application for outline consent and premises approval if, before the provisional date, the provision of pharmaceutical services is commenced from the premises which were the subject of an outstanding pharmacy application which has been granted.

(5) On, or as soon as reasonably practicable after, the provisional date, the Local Health Board must notify the doctor who made the application under regulation 30 that—

(a) the doctor may within 3 months of the Local Health Board's notification submit a request in writing to the Local Health Board asking it to determine whether the outline consent and premises approval should come into effect, and

(b) the Local Health Board must determine the request as soon as practicable and in accordance with paragraphs (6) and (7).

(6) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are practice premises, the Local Health Board must determine that the outline consent and premises approval in respect of those premises will come into effect on that date.

(7) Where on the date of the determination under paragraph (5), the premises in respect of which premises approval is sought are not practice premises outline consent and premises approval will lapse.

(8) The Local Health Board must notify its determination under paragraph (5) to the applicant and those persons to whom notice of the application under regulation 30 was required to be given under paragraph 8 of Schedule 3.

(9) Where the Local Health Board has determined that outline consent and premises approval will lapse by virtue of paragraph (7) or that the provisional date is to be extended under paragraph (11), the doctor who made the application under regulation 30 may appeal to the Welsh Ministers.

(10) If, in the circumstances outlined in paragraph (9), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

(a) 6(3)(b) and (c),

(b) 7(1) and (3), and

(c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

(11) In this regulation—

"outstanding pharmacy application" ("*cais am fferyllfa yn yr arfaeth*") means an application made under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) or regulation 18 (applications for preliminary consent and effect of preliminary consent)—

(a) where the premises specified in that application are within 1.6 kilometres of the premises for which premises approval has been sought, and

(b) which has either—

(i) been made but not yet determined, including on appeal, or

(ii) has been granted as defined in regulation 23 (procedure following grant of an application) but the provision of pharmaceutical services from those premises has not been commenced;

"provisional date" ("*dyddiad dros dro*") means the day after the end of a period of 1 year or such further period not exceeding 3 months as the Local Health Board may determine (and it must notify the doctor who made the application under regulation 30 of any extension) beginning with the date on which the application is granted in accordance with regulation 30(9).

Commencement Information
I31 Reg. 31 in force at 1.10.2021, see **reg. 1(3)**

Lapse of outline consent and premises approval E+W

32.—(1) Outline consent will cease to have effect—

(a) where the provision of dispensing services has not commenced within 12 months of outline consent or premises approval taking effect under regulation 31 (taking effect of outline consent and premises approval),

(b) where more than 12 months have elapsed since the last provision of dispensing services,

(c) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval, or

(d) where outline consent has lapsed under regulation 31.

(2) Premises approval will cease to have effect in relation to—

(a) listed premises which have permanently ceased to be practice premises,

(b) listed premises which have not been used for dispensing by any doctor authorised to dispense from those premises for 6 months or such longer period as the Local Health Board may for good cause allow,

(c) listed premises where the doctor under whose name those premises are listed in the dispensing doctors list has notified the Local Health Board that all the doctors who have authority to dispense from those premises have ceased to do so,

(d) listed premises where there is no doctor with premises approval in respect of them remaining on the dispensing doctor list, or

(e) listed premises which were granted premises approval under regulation 35(3), where no practice amalgamation takes place within the period specified in regulation 35(7).

(3) Premises approval will cease to have effect where the related outline consent ceases to have effect.

Commencement Information
I32 Reg. 32 in force at 1.10.2021, see **reg. 1(3)**

Premises approval: change of premises before outline consent takes effect E+W

33.—(1) Where—

(a) outline consent has been granted but has not yet taken effect under regulation 31 (taking effect of outline consent and premises approval), and

(b) before the provisional date defined in regulation 31(11) the doctor intends to change the practice premises from which they wish to provide pharmaceutical services,

the doctor may apply in writing to the Local Health Board providing the information set out in Part 4 of Schedule 2 for the Local Health Board to determine whether premises approval should be given in relation to the new premises, and the Local Health Board must make the determination in accordance with paragraph (2).

(2) If the Local Health Board is satisfied that the change of premises is a minor relocation it may grant the premises approval for those new premises, but if it is not so satisfied, premises approval for the new premises must be refused.

(3) The Local Health Board must notify those persons to whom notice of the application made under regulation 30 (outline consent and premises approval) was required to be given of its determination under paragraph (2).

(4) The determination by the Local Health Board under paragraph (2) may be appealed by the applicant to the Welsh Ministers.

(5) If, in the circumstances outlined in paragraph (4), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

(a) 6(3)(b) and (c),

(b) 7(1) and (3), and

(c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

(6) In this regulation—

"minor relocation" means a relocation of practice premises where—

(a) the pharmaceutical services specified in the application that would have been provided at the practice premises specified in the original application will be provided at the new practice premises, and

(b) the location of the new practice premises would not be significantly less accessible for the patients who access the practice premises specified in the original application.

Commencement Information

I33 Reg. 33 in force at 1.10.2021, see **reg. 1(3)**

Premises approval: additional and new premises after outline consent has taken effect E+W

34.—(1) A doctor who has outline consent which has taken effect and who wishes to be granted premises approval for premises in addition to those premises in respect of which premises approval has been given ("additional premises") may apply in writing providing the information set out in Part 4 of Schedule 2 to all of the appropriate Local Health Boards and the application will be determined by the relevant Local Health Board in accordance with paragraph (2).

(2) An application for additional premises must be determined by the relevant Local Health Board in accordance with regulation 30 (outline consent and premises approval) and regulation 31 (taking effect of outline consent and premises approval).

(3) For the purposes of this regulation—

(a) the "appropriate Local Health Boards" are those Local Health Boards that hold the dispensing doctor lists on which the doctor making the application is included, and

(b) the "relevant Local Health Board" is the Local Health Board in whose area the additional premises are situated.

(4) A doctor wishing to be granted premises approval in relation to premises ("new premises") where they wish to dispense instead of listed premises may apply to all the appropriate Local Health Boards providing the information set out in Part 4 of Schedule 2 and the application will be determined by the relevant Local Health Board in accordance with paragraphs (5) and (6).

(5) In the case of an application for new premises, the relevant Local Health Board must give notice of the application in accordance with paragraph 9 of Schedule 3 and the content of the notification must comply with paragraph 10 of that Schedule.

(6) In the case of an application for new premises the relevant Local Health Board must—

(a) grant an application, where it is satisfied that—

(i) for the patients that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible, and

(ii) granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical or dispensing services to any part of the controlled locality in which the new premises are located, or

(b) in any case, determine the application as if it were an application for premises approval made under regulation 30(1)(b).

(7) A Local Health Board must, unless it has good cause not to do so, refuse an application under paragraph (1) or (4) if an application made by the doctor has been granted under paragraph (6)(a) during the 12 months before the application was submitted under paragraph (1) or (4).

(8) The Local Health Board must notify its determination under paragraph (2) or paragraph (6)(b) to the persons to whom notice of the application is required to be given in accordance with regulation 30 and paragraph 8 of Schedule 3.

(9) The Local Health Board must notify its determination under paragraph (6)(a) to those persons to whom notification is required to be given in accordance with paragraph 15 of Schedule 3.

(10) A determination by the Local Health Board under paragraph (2), (6)(a) or (6)(b) may be appealed to the Welsh Ministers by the persons listed in paragraph 6(1) of Schedule 4.

(11) Subject to paragraph (12), the premises approval for the additional or new premises will take effect from the date of notification of the grant of premises approval, which is—

(a) where no appeal is made against the decision of the Local Health Board, the date after the expiry of 30 days beginning with the date on which notice of that decision is given under paragraph (8) or paragraph (9), or

(b) where such an appeal is made, the date on which the Welsh Ministers give notice of their decision on that appeal.

(12) Where—

(a) the premises approval is granted in relation to additional premises, and

(b) in relation to the premises for which the approval is granted there, at the date of the grant, outstanding pharmacy applications (as defined in regulation 31(11)),

the premises approval will take effect on the date which is the day after the end of a period of 1 year, or such further period (not exceeding 3 months) as the Local Health Board may for good cause allow, from the final resolution of any outstanding pharmacy application.

(13) The Local Health Board may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new premises where the Local Health Board considers it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant locality and which has been included in the relevant pharmaceutical needs assessment and in respect of which the doctor has applied for outline consent, and renew any such temporary approval granted, and where it does so it must—

(a) notify those persons to whom notice of the application under regulation 30 (outline consent and premises approval) was required to be given under paragraph 8 of Schedule 3 and the applicants in relation to the outstanding pharmacy applications,

(b) state the period during which the temporary premises approval is to apply, and

(c) include those premises in the dispensing doctor list in relation to that doctor.

(14) Temporary premises approval may be granted for a period not exceeding 12 months, and may be renewed for a further period not exceeding 3 months.

(15) The determination by the Local Health Board under paragraph (13) may be appealed by the applicant to the Welsh Ministers.

(16) If, in the circumstances outlined in paragraph (15), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

(a) 6(3)(b) and (c),

(b) 7(1) and (3), and

(c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

Commencement Information

I34 Reg. 34 in force at 1.10.2021, see **reg. 1(3)**

Premises approval: practice amalgamations E+W

35.—(1) A practice amalgamation occurs where two or more providers of primary medical services amalgamate as a single provider of primary medical services as a result of which two or more patient lists are combined.

(2) Following a practice amalgamation, if the practice premises of the single provider of primary medical services are all premises that immediately prior to the practice amalgamation were listed premises, the premises approvals for those premises and the related outline consents will continue to have effect.

(3) Following a practice amalgamation, if paragraph (2) does not apply but one or more of the doctors coming together as the single provider of primary medical services had, immediately prior to amalgamation, premises approval for premises—

(a) if any of those premises become practice premises of the single provider of primary medical services—

(i) the premises approvals for the premises and the related outline consents will continue to have effect, and

(ii) any applications for premises approvals for other practice premises must be treated as applications for additional premises under regulation 34 (premises approval: additional and new premises after outline consent has taken effect);

(b) if none of those premises become practice premises of the single provider of primary medical services—

(i) a doctor may submit an application for premises approval for premises under regulation 30 (outline consent and premises approval) and have that application treated as a relocation from listed premises of a doctor who was part of the practice amalgamation, and

(ii) any applications for premises approval in respect of other practice premises of the single provider of primary medical services are to be treated as applications for additional premises under regulation 34.

(4) An application mentioned in paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

(a) any premises approval in effect at the date of the practice amalgamation will have effect from the date of the amalgamation as if it were a temporary premises approval under regulation 34(13) for a period stated by the Local Health Board not exceeding 1 year, and

(b) the new practice will have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Local Health Board not exceeding 1 year.

(5) When the practice amalgamation takes effect the doctors must notify all Local Health Boards in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to paragraph (7), where an application made under paragraph (3) was granted before the practice amalgamation takes place, premises approval will take effect from the date of the practice amalgamation.

(7) Where an application was made under paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of 1 year beginning with the date that premises approval was granted under that paragraph, that grant will lapse.

(8) Where an application under paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the doctors who had premises approval prior to making the application, and any other doctor in the new practice after that date will have residual premises approval.

(9) For the purposes of this regulation, "residual premises approval" means premises approval to provide pharmaceutical services—

(a) from premises in respect of which the doctor or another doctor in the practice had premises approval at the time of the application in relation to the practice amalgamation, and

(b) to a patient falling within regulation 26(1) to whom the doctor making the application provides pharmaceutical services, but excluding any such patient who ceases to be a patient mentioned in regulation 26(1)(b) or (c).

(10) For the purposes of paragraph (9), regulation 26(1)(b) or (c) is to be read as if the words "and the conditions specified in paragraph (4) are satisfied" were omitted.

(11) Where a Local Health Board has determined an application for premises approval under paragraph (3), the persons who may make an appeal to the Welsh Ministers will be determined in accordance with—

(a) regulation 34 in respect of an application under paragraph (3)(a)(ii) or (b)(ii), or

(b) regulation 30 in respect of an application under paragraph (3)(b)(i).

(12) Where a Local Health Board has determined an application under paragraph (4), the applicant may make an appeal to the Welsh Ministers.

(13) If, in the circumstances outlined in paragraph (12), a notice of appeal is submitted to the Welsh Ministers, Part 1 of Schedule 4 and the following paragraphs of Schedule 4 will apply—

(a) 6(3)(b),

(b) 7(1) and (3), and

(c) 8,

as if the notice of appeal were submitted under paragraph 6(1) of Schedule 4.

Commencement Information
I35 Reg. 35 in force at 1.10.2021, see **reg. 1(3)**

PART 7 E+W

Fitness grounds and inclusion in and removal from pharmaceutical lists

Deferral of applications on fitness grounds E+W

36.—(1) This regulation applies to applications made under—

(a) regulation 15(1)(a) (applications to be included in or make amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 18(5), and

(b) regulation 18 (applications for preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.

(2) A Local Health Board may defer consideration or determination of an application where—

(a) there are criminal proceedings in the United Kingdom or proceedings elsewhere in the world relating to conduct which in the United Kingdom would constitute a criminal offence in respect of—

(i) the applicant (and where the applicant is a body corporate, in respect of the applicant or a director or superintendent of the applicant), or

(ii) a body corporate of which the applicant is, or has in the preceding 6 months been, or was at the time of the originating events, a director or superintendent, which, if they resulted in a conviction or the equivalent of a conviction, would be likely to lead to the applicant's removal from the Local Health Board's pharmaceutical list, if the applicant had been included in it;

(b) there is an investigation anywhere in the world by the applicant's (or where the applicant is a body corporate, any director or superintendent of the applicant) licensing or regulatory body or any other investigation (including one by another Local Health Board or equivalent body) relating to the applicant's professional capacity, that if the outcome of which was adverse would be likely to lead to the removal of the applicant from the Local Health Board's pharmaceutical list, if the applicant had been included in it;

(c) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is suspended from a relevant list;

(d) a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is suspended from a relevant list;

(e) the Tribunal is considering an appeal by the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) against a decision of a Local Health Board or an equivalent body—

(i) to refuse an application by the applicant for inclusion in a relevant list,

(ii) to conditionally include or remove or contingently remove the applicant from a relevant list, or

(iii) to refuse an application from the applicant for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body,

and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if they were to be included in it;

(f) the Tribunal is considering an appeal by a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent, against a decision of a Local Health Board or equivalent body—

(i) to refuse an application by that body corporate for inclusion in a relevant list,

(ii) to refuse an application by that body corporate for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body, or

(iii) to conditionally include it in, or to remove or contingently remove it from any relevant list,

and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if they were to be included in it;

(g) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is being investigated in relation to any fraud, where the outcome, if adverse, would be likely to lead to the removal of the applicant from the pharmaceutical list if the applicant had been included in it;

(h) a body corporate, of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is being investigated in relation to fraud, where the outcome if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if the body corporate had been included in it;

(i) the Tribunal is considering an application from a Local Health Board or equivalent body for a national disqualification of the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) or of a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent;

(j) a Local Health Board or equivalent body, for a reason relating to fraud, unsuitability or efficiency of service provision—

(i) is considering removal (other than voluntary removal) or contingent removal of the applicant from a relevant list, or

(ii) has taken a decision to remove (other than voluntary removal) or contingently remove the applicant from a relevant list but that decision has yet to take effect.

(3) A Local Health Board may only defer a decision under paragraph (2) until the proceedings, investigations or applications mentioned in that paragraph are concluded or the reason for the deferral no longer exists.

(4) A Local Health Board must, as soon as is practicable, notify the applicant in writing of a decision to defer consideration or determination of the application, and the reasons for this.

(5) Once the proceedings, investigations or applications mentioned in paragraph (2) are concluded, the Local Health Board must notify the applicant that within 30 days of the date of the notification (or such longer period as it may agree) the applicant—

(a) must confirm in writing that the applicant wishes to proceed with the application, and

(b) may update the application if the applicant wishes.

(6) If the applicant fails to confirm that they wish to proceed in accordance with paragraph (5), the Local Health Board must deem the application as having been withdrawn by the applicant.

Commencement Information
I36 Reg. 36 in force at 1.10.2021, see **reg. 1(3)**

Refusal of applications on fitness grounds E+W

37.—(1) This regulation applies to applications made under—

(a) regulation 15(1)(a) (applications to be included in or make amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 18(5), and

(b) regulation 18 (applications for preliminary consent and effect of preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.

(2) A Local Health Board may refuse to grant an application where—

(a) having considered the information and undertakings required by Part 2 of Schedule 2 and any other information in its possession in relation to the application, the Local Health Board considers that the applicant is unsuitable to be included in its pharmaceutical list,

(b) having contacted the referees nominated by the applicant in accordance with Part 2 of Schedule 2, it is not satisfied with the references given,

(c) having checked with the NHS Business Services Authority for any facts that it considers relevant relating to past or current fraud investigations involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), and having considered these and any other facts in its possession relating to fraud involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal,

(d) having checked with the Welsh Ministers for any facts that they consider relevant relating to past or current investigations or proceedings involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) and having considered these and any other facts in its possession involving or relating to the applicant (and where the applicant is a body corporate any director or superintendent of the applicant), it considers that these justify such a refusal, or

(e) it considers that admitting the applicant to the list would be prejudicial to the efficiency of the pharmaceutical service which they would undertake to provide.

(3) A Local Health Board must refuse to grant an application where—

(a) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of murder,

(b) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of a criminal offence, other than murder, which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over 6 months,

(c) the applicant is the subject of a national disqualification, or

(d) on appeal the Tribunal determines that the applicant may be included in the pharmaceutical list subject to conditions but the applicant has not, within 30 days of that decision notified the Local Health Board that they agree to the imposition of conditions.

(4) Where the Local Health Board is considering a refusal of an application under paragraph (2), it must consider all facts which appear to it to be relevant and must, in particular, take into consideration in relation to paragraph (2)(a), (c) and (d)—

(a) the nature of any offence, investigation or incident,

(b) the length of time since any offence, incident, conviction or investigation,

(c) whether there are other offences, incidents or investigations to be considered;

(d) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation,

(e) the relevance of any offence, investigation or incident to the provision by the applicant of pharmaceutical services and any likely risk to users of pharmaceutical services or public finances,

(f) whether any offence was a sexual offence to which Part 2 of the Sexual Offences Act 2003(**31**) applies, or if it had been committed in England and Wales would have applied,

(g) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from any list or equivalent list on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Local Health Board or equivalent body for such action, or

(h) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from any list or equivalent list, or is currently suspended from any such list on fitness to practise grounds, and if so, what the facts were in each such case and the reasons given by the Local Health Board or equivalent body in each case.

(5) When the Local Health Board takes into account the matters set out in paragraph (4), it must consider the overall effect of the matters being considered.

(6) If a Local Health Board refuses an application to which this regulation applies under grounds in paragraph (2) or (3), the Local Health Board must notify the applicant of that decision and it must include with the notification an explanation of—

(a) the reasons for the decision;

(b) the applicant's right of appeal against the decision to the Tribunal, and

(c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(**32**), the application notice must be sent to the Tribunal if an appeal is to be brought.

Commencement Information
I37 Reg. 37 in force at 1.10.2021, see **reg. 1(3)**

Conditional inclusion on fitness grounds E+W

38.—(1) A Local Health Board that receives an application from a person—

(a) under regulation 15(1)(a) (applications to be included in or make amendment to a pharmaceutical list), except where the application is made by a person who has been granted preliminary consent under regulation 18 (applications for preliminary consent and effect of preliminary consent) and which is valid in accordance with regulation 18(5), or

(**31**) 2003 c. 42.
(**32**) S.I. 2008/2699 (L. 16), see rule 19 of those Rules.

(b) under regulation 18 where the applicant is not already included in that Local Health Board's pharmaceutical list,

may determine that the person, whilst they are included in the pharmaceutical list or whilst their preliminary consent is valid, is to be subject to the imposition of conditions having regard to the requirements of section 104 (conditional inclusion in ophthalmic and pharmaceutical lists) of the 2006 Act.

(2) A Local Health Board may vary the terms of service on which a person is included in the pharmaceutical list for the purpose of paragraph (1).

(3) A condition imposed under paragraph (1) must be a condition imposed with a view to—

(a) preventing any prejudice to the efficiency of the pharmaceutical services, or any of the services, which the person has undertaken to provide, or

(b) preventing any act or omission within section 107(3)(a) of the 2006 Act (disqualification of practitioners).

(4) If a Local Health Board decides to grant an application subject to a condition imposed under paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—

(a) the reasons for the decision,

(b) the person's right of appeal against its decision to the Tribunal,

(c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought, and

(d) the effect of paragraph (5).

(5) If the person, in accordance with regulation 23(2), provides a notice of commencement before the Tribunal has determined an appeal against a condition imposed under paragraph (1), that person is to be included in the pharmaceutical list subject to the condition, but only until the outcome of the appeal if the appeal is successful.

(6) The appeal is to be by way of redetermination of—

(a) the decision of the Local Health Board to impose the condition, and

(b) if the person has, at the time the appeal is determined, been included in the pharmaceutical list, any decision under paragraph (2) to vary the terms of service of that person for the purpose of or in connection with the imposition of the condition.

(7) If at the time the appeal is determined, the person has not been included in the pharmaceutical list and the Tribunal—

(a) confirms the decision of the Local Health Board, or

(b) imposes a different condition,

the person must, within 30 days of being notified of the Tribunal's decision, notify the Local Health Board as to whether or not the person wishes to withdraw their application.

(8) If the person fails, in the circumstances described in paragraph (7), to notify the Local Health Board within that 30 days that they do not wish to withdraw their application, the grant of that person's application lapses.

(9) Where a person wishes to withdraw from a pharmaceutical list, that person must notify the Local Health Board at least 30 days in advance of that date, if—

(a) a condition is imposed under paragraph (1),

(b) the person appeals that condition to the Tribunal,

(c) on appeal, the Tribunal confirms the imposition of that condition or imposes another condition, and

(d) within 30 days of being informed of the decision of the Tribunal the person notifies the Local Health Board that they wish to withdraw from its pharmaceutical list,

unless it is impracticable for the person to do so in which case the person must notify the Local Health Board as soon as it is practicable to do so.

Commencement Information

I38 Reg. 38 in force at 1.10.2021, see **reg. 1(3)**

Removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act E+W

39.—(1) Where a Local Health Board is considering—

(a) removing a person's name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act, other than in cases specified in regulation 40 (removal from a pharmaceutical list for other reasons),

(b) contingently removing a person's name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act,

(c) removing a person's name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act,

(d) imposing any particular condition under section 108 of the 2006 Act, or varying any condition or imposing a different condition under that section, or varying a person's terms of service under section 108(4) of the 2006 Act, or

(e) removing a person's name from the pharmaceutical list for breach of a condition under regulation 38 (conditional inclusion relating to fitness grounds),

on fitness grounds, it must follow the procedure set out in this regulation.

(2) Before taking an action specified in paragraph (1), the Local Health Board must give the person—

(a) notice of any allegation against that person;

(b) notice of what action the Local Health Board is considering and on what grounds,

(c) the opportunity to make written representations within 30 days beginning on the date on which the notification is given under this paragraph, and

(d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(3) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (2)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(4) Once the Local Health Board has reached a decision it must notify the person of that decision and it must include with that notification an explanation of—

(a) the reasons for the decision,

(b) the person's right of appeal against its decision to the Tribunal, and

(c) the time limit within which in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(5) Where the Local Health Board has decided to impose a contingent removal, it must inform the person of their right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(6) The Local Health Board must not remove a person's name from the pharmaceutical list, or impose a contingent removal, until the time for bringing an appeal has expired or, where an appeal is made, it has been determined by the Tribunal.

(7) Where a Local Health Board is notified by the Tribunal that it has considered—

(a) an appeal by a person against a contingent removal and the Tribunal has decided to remove the person from the pharmaceutical list instead, or

(b) an appeal by a person who is subject to conditions under regulation 38 and the Tribunal has decided not to include the person in that pharmaceutical list,

the Local Health Board must remove the person from its pharmaceutical list and must notify the person immediately that it has done so.

Commencement Information
I39 Reg. 39 in force at 1.10.2021, see **reg. 1(3)**

Removal from a pharmaceutical list for other reasons E+W

40.—(1) Subject to paragraph (2), a Local Health Board must remove a person from a pharmaceutical list that it maintains where it becomes aware that the person (and where the person is a body corporate, any director or superintendent of that body)—

(a) has been convicted in the United Kingdom of murder,

(b) has been convicted in the United Kingdom of a criminal offence which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over 6 months, or

(c) is subject to a national disqualification.

(2) Where a Local Health Board is considering removing a person from its pharmaceutical list under grounds contained in paragraph (1), the Local Health Board must, before reaching its decision—

(a) notify the person of the action that it is considering taking and the grounds for considering taking that action, and

(b) as part of that notification—

(i) inform the person of any allegation made against them, and

(ii) advise the person that they may make—

(aa) written representations to the Local Health Board with regard to that action provided such representations are received by the Local Health Board within 30 days beginning with the date of notification by the Local Health Board, and

(bb) oral representations to the Local Health Board with regard to that action, provided the person notifies the Local Health Board of their wish to make oral representations within 30 days beginning with the date of the notification by the Local Health Board and the person (or a representative)

attends the hearing that the Local Health Board arranges for the purposes of hearing those representations, and

(c) in a case to which paragraph (1)(a) or (b) applies, if the person is a body corporate, advise the person that the Local Health Board will not remove the body corporate from its pharmaceutical list as a consequence of paragraph (1)(a) or (b) (without prejudice to any other action that it may take), provided that—

(i) the director or superintendent concerned ceases to be a director or superintendent of the body corporate within the period of 30 days commencing with the date of the notice, and

(ii) within that period, the body corporate notifies the Local Health Board of the date on which the director or superintendent has ceased or is to cease to be a director or superintendent of the body corporate.

(3) A Local Health Board must remove a person from a pharmaceutical list—

(a) if the person has not, in the preceding 6 months, provided pharmaceutical services from the premises in respect of which the person is included in the pharmaceutical list (but a period during which the person has been suspended does not count towards calculating the 6 month period), or

(b) if the person has died, but not if that person's business is carried on after their death by a representative under section 72 of the Medicines Act 1968 (representative of pharmacist in case of death or disability) so long as the business is carried on by the representative in accordance with the provisions of that Act, and the representative agrees to be bound by the terms of service, or

(c) if the person is no longer a registered pharmacist.

(4) Before removing a person from a pharmaceutical list under paragraph (3) the Local Health Board must—

(a) give the person or the person's representative mentioned under paragraph (3)(b) 30 days' notice of its intention to remove the person from the pharmaceutical list,

(b) give the person or the person's representative mentioned under paragraph (3)(b) the opportunity to make representations in writing or, if they so desire, in person, during that period, and

(c) consult the Local Pharmaceutical Committee.

(5) Once the Local Health Board has taken a decision to remove the person from the pharmaceutical list on grounds contained in paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—

(a) the reasons for the decision,

(b) the person's right of appeal against its decision to the Tribunal, and

(c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(6) The Local Health Board must notify the person immediately in writing of its decision under paragraph (3) to remove the person from the pharmaceutical list and of the person's right of appeal under paragraph (7).

(7) A person notified under paragraph (6) may, within 30 days of receiving the notice appeal the decision by notice in writing to the Welsh Ministers setting out the grounds of appeal.

(8) Upon receipt of an appeal under paragraph (7) the Welsh Ministers must notify the Local Health Board that an appeal has been received.

(9) The Welsh Ministers may determine the appeal in respect of which a valid notice of appeal has been given in accordance with paragraph (7) in such manner (including with regard to procedures) as the Welsh Ministers think fit.

(10) On determining an appeal under paragraph (9), the Welsh Ministers may—

(a) confirm the decision of the Local Health Board, or

(b) substitute for that decision any decision that the Local Health Board could have taken when it took that decision.

(11) A Local Health Board must not remove the person's name from the pharmaceutical list until—

(a) if no appeal is made, the period for bringing an appeal against the decision has elapsed, or

(b) if an appeal is made, the appeal is determined.

(12) Where an appeal is upheld, the Local Health Board must not remove the person's name from the pharmaceutical list.

Commencement Information

I40 Reg. 40 in force at 1.10.2021, see **reg. 1(3)**

Suspension from a pharmaceutical list E+W

41.—(1) Before making a decision under section 110(1) (suspension) or section 111(2) (suspension pending appeal) of the 2006 Act, the Local Health Board must give the person—

(a) notice of any allegation against that person,

(b) notice of the action the Local Health Board is considering and on what grounds,

(c) the opportunity to make written representations within 30 days beginning with the date the notification is given under this paragraph, and

(d) the opportunity to make representations at an oral hearing before the Local Health Board, provided the person notifies the Local Health Board that they wish to make representations within a specified period (of not less than 24 hours).

(2) The Local Health Board must take into account any representations made by the person before it reaches its decision.

(3) Once the Local Health Board has reached a decision it must as soon as is reasonable practicable notify the person in writing of its decision and the reasons for it (including any facts relied upon).

(4) Where the Local Health Board has suspended a person from the pharmaceutical list, it must inform the person of the reasons for the decision and, in the case of a suspension under section 110(1) of the 2006 Act, of that person's right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(5) The Local Health Board may at any time revoke the suspension and notify the person of its decision.

Commencement Information

I41 Reg. 41 in force at 1.10.2021, see **reg. 1(3)**

Notification of a decision to impose conditions E+W

42.—(1) Where a Local Health Board decides to—

(a) refuse to grant an application from a person under regulation 37,

(b) impose conditions under regulation 38,

(c) remove a person from its pharmaceutical list under regulation 39 or 40,

(d) suspend a person from its pharmaceutical list under regulation 41,

(e) impose or vary a condition under regulation 43, or

(f) impose or vary a condition under regulation 44,

it must notify the persons and bodies specified in paragraph (2) and additionally notify those specified in paragraph (3), if requested to do so by those persons or bodies in writing (including electronically), of the matters set out in paragraph (4).

(2) The persons to be notified are—

(a) the Welsh Ministers,

(b) any other Local Health Board or equivalent body that to the knowledge of the notifying Local Health Board has the applicant included in a relevant list,

(c) the Scottish Ministers,

(d) the Secretary of State,

(e) the Northern Ireland Executive,

(f) the General Pharmaceutical Council, the Pharmaceutical Society of Northern Ireland or any other appropriate regulatory body,

(g) the Local Pharmaceutical Committee for the Local Health Board's area,

(h) the National Health Service Commissioning Board, and

(i) in the case of fraud, the NHS Business Services Authority.

(3) The persons or bodies who may request to be additionally notified in accordance with paragraph (1) are—

(a) persons or bodies that can establish that they—

(i) are or were employing the person, are using or have used their services (or where the person is a body corporate, have used the services of any director or superintendent of that body corporate) in a professional capacity, or

(ii) are considering employing or using the services of the person (or where the person is a body corporate, using the services of any director or superintendent of that body corporate) in a professional capacity, and

(b) a partnership any of whose members provide or assist in the provision of pharmaceutical services and can establish that the person is or was a member of the partnership or that it is considering inviting the person to become a member.

(4) The matters referred to in paragraph (1) are—

(a) where the person is an individual or a partnership—

(i) the person's, or each member of the partnership's name, address and date of birth,

(ii) the person's or each member of the partnership's, professional registration number,

(iii) the date and copy of the decision of the Local Health Board, and

(iv) a contact name of a person in the Local Health Board for further enquiries;

(b) where the person is a body corporate—

(i) the body corporate's name, company registration number and the address of the registered office,

(ii) the professional registration number of body corporate's superintendent and of any director of the body corporate who is a registered pharmacist,

(iii) the date and copy of the decision of the Local Health Board, and

(iv) a contact name of a person in the Local Health Board for further enquiries.

(5) The Local Health Board must send to the person a copy of any information about them provided to the persons or bodies specified in paragraphs (2) and (3) and any correspondence with those persons or bodies relating to that information.

(6) Where the Local Health Board has notified any of the persons or bodies specified in paragraph (2) or (3) of the matters set out in paragraph (4), it may in addition, if so requested by that person or body, notify that person or body of any evidence that was considered, including representations made by the person.

(7) Where a Local Health Board is notified by the Tribunal that it has imposed a national disqualification on a person whom the Local Health Board has removed from its pharmaceutical list, the Local Health Board must notify the persons or bodies specified in paragraph (2)(b), (g), (h) and (i) and paragraph (3).

(8) Where a decision is changed on review or appeal, or a suspension lapses, the Local Health Board must notify any person or body that was notified of the original decision of the later decision, or of the fact that the suspension has lapsed.

Commencement Information

I42 Reg. 42 in force at 1.10.2021, see **reg. 1(3)**

Review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act E+W

43.—(1) Where in accordance with section 113 (review of decisions) of the 2006 Act, a Local Health Board must review its decision to contingently remove a person from the pharmaceutical list or suspend a person from the pharmaceutical list under section 110 (suspension) of the 2006 Act, or where it decides to review such a decision, it must give that person—

(a) notice that it intends to review its decision,

(b) notice of the decision that it is minded to take upon review, and the reasons for it,

(c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a), and

(d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(2) On such a review, the Local Health Board may—

(a) confirm the contingent removal or suspension,

(b) in the case of a suspension terminate it, or

(c) in the case of a contingent removal, vary the conditions, impose different conditions, revoke the contingent removal, or remove the person from the list.

(3) A person who has been suspended from a pharmaceutical list under section 110 of the 2006 Act or contingently removed from a pharmaceutical list under section 108 of the 2006 Act cannot request a review until the expiry of—

(a) 3 months beginning with the date of the decision of the Local Health Board to contingently remove, or

(b) 6 months beginning with the date of the decision on the previous review.

(4) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account or hold the oral hearing, as the case may be, before reaching its decision.

(5) Once the Local Health Board has made a decision under section 113(3) of the 2006 Act, it must notify the person of its decision and it must include with the notification of its decision an explanation of—

(a) the reasons for the decision;

(b) if the person has a right of appeal in relation to the decision—

(i) the right of appeal that the person has in relation to that decision under section 114 of the 2006 Act (appeals)(**33**), and

(ii) the time limit within which, in accordance with the Tribunal Procedure (First Tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought, and

(c) if the person has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 113(1) of the 2006 Act.

Commencement Information

I43 Reg. 43 in force at 1.10.2021, see **reg. 1(3)**

Review of a decision to impose conditions E+W

44.—(1) Where a Local Health Board has made a decision to impose conditions in accordance with regulation 38, it may review such a decision either of its own volition or at the request of the person whose application has been granted subject to conditions.

(2) A person whose application has been granted subject to conditions may not request a review of a Local Health Board's decision until the expiry of a 3 month period beginning with the date the Local Health Board—

(a) includes the person's name on its pharmaceutical list, or

(b) grants the person preliminary consent,

and cannot request a review within 6 months of a decision on a previous review.

(3) A Local Health Board must give the person whose application has been granted subject to conditions—

(a) notice that it intends to review its decision,

(b) notice of the decision that it is minded to take upon review, and the reasons for it,

(c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a), and

(d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(**33**) Note there is no right of appeal to the Tribunal against a decision to suspend a practitioner or to review a decision on suspension. However, there is a right of appeal to the Tribunal against any decision of a Local Health Board on a review of a contingent removal under section 113 of the 2006 Act. See section 114 of the 2006 Act.

(4) If the Local Health Board receives representations or a request for an oral hearing within the period specified in paragraph (3)(c), it must take the representations into account or hold the oral hearing, as the case may be, before reaching its decision.

(5) Upon review the Local Health Board may—

(a) maintain the current conditions,

(b) impose new conditions,

(c) vary the person's terms of service,

(d) vary the conditions, or

(e) where the person has breached a condition, remove the person from the pharmaceutical list.

(6) As soon as practicable after reaching a decision, the Local Health Board must notify the person of its decision, and it must include with the notification of its decision an explanation of—

(a) the reasons for the decision,

(b) the right of appeal that the person has to the Tribunal, and

(c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

Commencement Information

I44 Reg. 44 in force at 1.10.2021, see **reg. 1(3)**

Appeals E+W

45.—(1) A person, other than a person notified under regulation 42, who has been notified by a Local Health Board of its decision that—

(a) intends to—

(i) refuse to grant an application to which regulation 37 (refusal of applications on fitness grounds) applies under grounds contained in paragraph (2) or (3) of that regulation,

(ii) impose conditions on the person by virtue of regulation 38 (conditional inclusion relating to fitness grounds), or vary the person's terms of service pursuant to that regulation,

(iii) in accordance with regulation 39 (removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act)—

(aa) remove the person's name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act;

(bb) contingently remove the person's name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act;

(cc) remove the person's name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act;

(dd) impose any particular condition under section 108 of the 2006 Act, vary any condition, impose a different condition or vary the person's terms of service under that section;

(ee) remove the person's name from the pharmaceutical list for breach of a condition imposed under regulation 38, or

(iv) remove the person from the pharmaceutical list on grounds contained in regulation 40(1), or

(b) has reviewed a decision to impose conditions under regulation 44 (review of a decision to impose conditions) and has decided to take any of the actions in regulation 44(5), or

(c) has reviewed a decision to contingently remove the person from a pharmaceutical list by virtue of regulation 43 (review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act) and has—

(i) confirmed the contingent removal,

(ii) varied the conditions attached to the contingent removal or imposed different conditions, or

(iii) has removed the person from the pharmaceutical list,

may appeal that decision to the Tribunal.

(2) An appeal under paragraph (1) must be made in writing, setting out the grounds on which the appeal is made and must be submitted to the Tribunal within the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

(3) The Tribunal, on determining an appeal, may make any decision that the Local Health Board could make under this Part.

Commencement Information

I45 Reg. 45 in force at 1.10.2021, see **reg. 1(3)**

PART 8 E+W

Conditional inclusion in pharmaceutical lists: certain specific conditions that do not relate to fitness or performance

Core opening hours conditions E+W

46.—(1) Where, in the course of making an application to which regulation 15, 19, 20 or 22 applies—

(a) for inclusion in a pharmaceutical list as mentioned in regulation 10(1)(a), or from a person already included in such a list to relocate to different pharmacy premises or to open, within the area of the relevant Local Health Board, additional pharmacy premises—

(i) an NHS pharmacist undertook to provide pharmaceutical services at the proposed pharmacy premises for a specified number of core opening hours each week which is more than 40,

(ii) the NHS pharmacist and the Local Health Board agreed that pharmaceutical services are to be provided at the proposed pharmacy premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, and

(iii) the application was granted having regard to that undertaking and that agreement,

when it includes the premises in a pharmaceutical list, the Local Health Board must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for

the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed;

(b) for inclusion in a pharmaceutical list as mentioned in regulation 10(1)(b), or from a person already included in such a list to relocate to different appliance contractor premises or to open, within the area of the relevant Local Health Board, additional appliance contractor premises—

(i) an NHS appliance contractor undertook to provide pharmaceutical services at proposed appliance contractor premises for a specified number of core opening hours each week which is more than 30,

(ii) the NHS appliance contractor and the Local Health Board agreed that pharmaceutical services are to be provided at the appliance contractor premises during the additional opening hours specified (that is, the hours which are the difference between the total number of hours specified and 30) at set times and on set days, and

(iii) the application was granted having regard to that undertaking and that agreement,

when it includes the premises in a pharmaceutical list, the Local Health Board must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during the additional opening hours at the set times and on the set days so agreed.

(2) Where the Local Health Board has—

(a) invited an NHS pharmacist or NHS appliance contractor to increase the total number of core opening hours during which the NHS pharmacist or NHS appliance contractor is to provide pharmaceutical services at listed premises, and

(b) thereafter agreed with the NHS pharmacist or NHS appliance contractor—

(i) an increased number of core opening hours, and

(ii) in the case of an NHS pharmacist, that pharmaceutical services are to be provided at the pharmacy premises during any additional opening hours (that is, the hours which are the difference between the total number of hours specified and 40) at set times and on set days, or

(iii) in the case of an NHS appliance contractor, that pharmaceutical services are to be provided at the appliance contractor premises during any additional opening hours (that is, the difference between the total number of hours specified and 30) at set times and on set days,

the Local Health Board must direct that the person listed in relation to the premises is to provide pharmaceutical services at those premises for the specified number of core opening hours so undertaken, and during any additional opening hours at the set times and on the set days so agreed.

(3) Except as so provided for under paragraph (2) and subject to paragraph (4), the Local Health Board may only vary a direction given under paragraph (1) or (2) in accordance with paragraph 25 or 26 of Schedule 5 or paragraph 15 or 16 of Schedule 6.

(4) A direction given under paragraph (1) or (2) must not be varied within 3 years of the direction having been given.

Commencement Information

I46 Reg. 46 in force at 1.10.2021, see **reg. 1(3)**

Conditions relating to providing directed services E+W

47.—(1) Where in the course of making an application under these Regulations or the 2013 Regulations, an NHS pharmacist or an NHS appliance contractor undertook—

(a) to provide the directed services mentioned in the application, if a Local Health Board commissioned the services within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates,

(b) if the directed services were commissioned, to provide the services in accordance with an agreed service specification, and

(c) not to withhold agreement to a service specification unreasonably,

the inclusion in the pharmaceutical list of the person listed in relation to the premises that were listed as a consequence of that application is subject to the condition set out in paragraph (2).

(2) The condition is that the person listed in relation to the premises must—

(a) provide the directed services mentioned in the application (whether or not the person listed was the applicant), and

(b) not withhold agreement to a service specification for those directed services unreasonably,

if the Local Health Board commissions the services from the person listed in relation to the premises within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates, unless thereafter the Local Health Board ceases to commission the services (if it has commissioned them).

(3) Where a Local Health Board specifies that a requirement to provide directed services arising out of a condition imposed by virtue of this regulation is to take effect by a specified date, the requirement takes effect—

(a) on that date, or

(b) on the date on which provision of the directed service is commenced.

(4) The Local Health Board may not vary or remove the condition imposed by virtue of paragraph (2).

Commencement Information
I47 Reg. 47 in force at 1.10.2021, see **reg. 1(3)**

Conditions relating to local resolution of disputes over terms of service E+W

48.—(1) It is a condition of the inclusion of each NHS pharmacist or NHS appliance contractor in a pharmaceutical list by the Local Health Board that the NHS pharmacist or NHS appliance contractor will make every reasonable effort to communicate with the Local Health Board with a view to resolving any dispute between either the NHS pharmacist or NHS appliance contractor and the Local Health Board relating to compliance with the terms of service under which pharmaceutical services are provided.

(2) The Local Health Board may not vary or remove the condition imposed by virtue of paragraph (1).

Commencement Information
I48 Reg. 48 in force at 1.10.2021, see **reg. 1(3)**

PART 9 E+W

Performance related sanctions and Market Exit

Local dispute resolution before serving remedial notices or breach notices E+W

49.—(1) Subject to paragraph (3), before issuing a notice under regulation 50 or 51, the Local Health Board must make every reasonable effort to communicate and co-operate with an NHS pharmacist or NHS appliance contractor with a view to resolving any dispute between the NHS pharmacist or NHS appliance contractor and the Local Health Board relating to compliance by the NHS pharmacist or NHS appliance contractor with the terms of service.

(2) Where an NHS pharmacist or NHS appliance contractor invites a Local Pharmaceutical Committee to participate in the attempts to resolve the dispute, the Local Health Board must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the dispute.

(3) Paragraphs (1) and (2) do not apply where the Local Health Board is satisfied—

(a) the dispute relates to a matter that has already been the subject of dispute resolution between the Local Health Board and the NHS pharmacist or NHS appliance contractor and there are no new issues of substance that justify delay in issuing a notice under regulation 50 or 51, or

(b) that it is appropriate to proceed immediately to issuing a notice under regulation 50 or 51—

(i) because listed premises are not, or have not been, open during core opening hours or supplementary opening hours without good cause,

(ii) to protect the safety of any persons to whom an NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or

(iii) to protect the Local Health Board from material financial loss.

Commencement Information

I49 Reg. 49 in force at 1.10.2020, see **reg. 1(2)(c)**

Breaches of terms of service: remedial notices E+W

50.—(1) Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is capable of remedy, the Local Health Board may by a notice ("a remedial notice") require the NHS pharmacist or NHS appliance contractor to remedy the breach.

(2) To be valid, the remedial notice must include—

(a) the nature of the breach,

(b) the steps the NHS pharmacist or NHS appliance contractor must take, to the satisfaction of the Local Health Board, in order to remedy the breach,

(c) the period ("the notice period") during which the steps must be taken, and

(d) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(a) may be exercised.

(3) The notice period must be not less than 30 days, unless the Local Health Board is satisfied that a shorter period is appropriate—

(a) to protect the safety of any persons to whom the NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or

(b) to protect the Local Health Board from material financial loss.

(4) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service that an NHS pharmacist or NHS appliance contractor is required to provide, the remedial notice may provide that—

(a) as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor in respect of that period under the Drug Tariff or a determination as mentioned in regulation 56(2)(b);

(b) pending the NHS pharmacist or NHS appliance contractor taking the steps that either must take, to the satisfaction of the Local Health Board, in order to remedy the breach, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff or a determination as mentioned in regulation 56(2)(b), and in these circumstances—

(i) as regards any period for which the NHS pharmacist or NHS appliance contractor remains in breach, any withholding that is attributable to that period is to be permanent, and

(ii) once the NHS pharmacist or NHS appliance contractor has taken the steps required, to the satisfaction of the Local Health Board, any withholding that has taken place which is attributable to a period when the NHS pharmacist or NHS appliance contractor is no longer in breach is to be restored, provided that the NHS pharmacist or NHS appliance contractor submits a claim, in accordance with the Drug Tariff or a determination as mentioned in regulation 56(2)(b), for restoration of the withheld remuneration attributable to that period.

(5) The remedial notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 56(2)(b) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service.

(6) The period referred to in paragraph (4)(b)(i) may be a longer period than the notice period.

(7) If the Local Health Board refuses to restore all or part of any withheld remuneration which is claimed under paragraph (4)(b)(ii), it must notify the NHS pharmacist or NHS appliance contractor of that decision as soon as is practicable, and that notification must include—

(a) a statement of the reasons for the decision, and

(b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(b) may be exercised.

(8) A Local Health Board may vary or revoke a remedial notice issued in accordance with this regulation at any time after it has been issued.

Commencement Information

I50 Reg. 50 in force at 1.10.2020, see **reg. 1(2)(c)**

Breaches of terms of service: breach notices E+W

51.—(1) Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is not capable of remedy, the Local Health Board may by a notice ("a breach notice") require the NHS pharmacist or NHS appliance contractor not to repeat the breach.

(2) To be valid, the breach notice must include—

(a) the nature of the breach, and

(b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(c) may be exercised.

(3) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service that an NHS pharmacist or NHS appliance contractor is required to provide, the breach notice may provide that, as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff or a determination as mentioned in regulation 56(2)(b) in respect of that period.

(4) The breach notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 56(2)(b) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service.

(5) A Local Health Board may vary or revoke a breach notice issued in accordance with this regulation at any time after is has been issued.

Commencement Information
I51 Reg. 51 in force at 1.10.2020, see **reg. 1(2)(c)**

Payment withholdings: supplementary matters E+W

52.—(1) A remedial notice or breach notice may only provide for the withholding of all or any part of the remuneration of an NHS pharmacist or NHS appliance contractor if—

(a) the Local Health Board is satisfied that the breach to which the withholding relates is, or was, without good cause;

(b) the amount withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it;

(c) the Local Health Board includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and (where applicable) are to be, withheld.

(2) The Local Health Board need not take into account the reasons for the breach, pursuant to paragraph (1)(b), if it has made every reasonable effort to communicate with the NHS pharmacist or NHS appliance contractor to discover the reasons but it has been unable to discover them.

(3) Withholdings of payments provided for in remedial notices and breach notices are without prejudice to the arrangements in place for recovering overpayments under regulation 57 and the Drug Tariff.

(4) For the purposes of regulations 50(4) and 51(3), remuneration determined by the Welsh Ministers, or by the Local Health Board acting as determining authority pursuant to regulation 56(2)(b), is remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff.

Commencement Information
I52 Reg. 52 in force at 1.10.2020, see **reg. 1(2)(c)**

Removal of listings: cases relating to remedial notices and breach notices E+W

53.—(1) The Local Health Board may remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list, or remove the listing of a particular listed premises in relation to the NHS pharmacist or NHS appliance contractor, if the NHS pharmacist or NHS appliance contractor—

(a) fails to take the steps set out in a remedial notice, to the satisfaction of the Local Health Board, in order to remedy the breach, and the Local Health Board is satisfied that it is necessary to remove the NHS pharmacist or NHS appliance contractor from the pharmaceutical list, or remove the listing of a particular listed premises in relation to the NHS pharmacist or NHS appliance contractor—

(i) to protect the safety of any persons to whom the NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or

(ii) to protect the Local Health Board from material financial loss, or

(b) has breached terms of service for NHS pharmacists and NHS appliance contractors, and—

(i) has repeatedly been issued with remedial notices or breach notices (or both) in relation to the relevant term of service,

(ii) been previously issued with a remedial notice or breach notice in relation to the relevant term of service, and the Local Health Board is satisfied that the NHS pharmacist or NHS appliance contractor is likely to persist in breaching the term of service without good cause, or

(iii) has repeatedly been issued with remedial notices or breach notices (or both) in relation to different terms of service, and the Local Health Board is satisfied that the NHS pharmacist or NHS appliance contractor is likely to persist in breaching their terms of service without good cause.

(2) For the purpose of paragraph (1), the Local Health Board may only remove—

(a) particular premises from a NHS pharmacist or NHS appliance contractor's listing in a pharmaceutical list if the relevant breaches all relate to those particular premises, or

(b) an NHS pharmacist or NHS appliance contractor from a particular pharmaceutical list if the relevant breaches all relate to listed premises which are the only premises listed in that pharmaceutical list in relation to the NHS pharmacist or NHS appliance contractor.

(3) The Local Health Board may only remove an NHS pharmacist or NHS appliance contractor, or a premises listed in relation to an NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1) if—

(a) the removal is justifiable and proportionate, having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them, and

(b) the Local Health Board, when it notifies the NHS pharmacist or NHS appliance contractor of the decision, includes in the notice its duly justified reasons for the decision.

(4) The Local Health Board need not take into account the reasons for the breaches (or likely breaches), pursuant to paragraph (3)(a), if it has made every reasonable effort to communicate with the NHS pharmacist or NHS appliance contractor to discover the reasons but has been unable to discover them.

(5) Where the Local Health Board is considering removing an NHS pharmacist or NHS appliance contractor, or removing the listing of particular premises listed in relation to an NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1), it must—

(a) give notice to the NHS pharmacist or NHS appliance contractor, at least 30 days in advance of taking the decision, that the Local Health Board is minded to remove the NHS pharmacist, NHS appliance contractor or the premises from a pharmaceutical list,

(b) as part of that notification, advise the NHS pharmacist or NHS appliance contractor that they may make—

(i) written representations to the Local Health Board with regard to that action, provided the NHS pharmacist or NHS appliance contractor notifies the Local Health Board

with those representations within 30 days beginning with the date of the notification by the Local Health Board, and

(ii) oral representations to the Local Health Board with regard to that action, provided—

(aa) the NHS pharmacist or NHS appliance contractor notifies the Local Health Board of the NHS pharmacist or NHS appliance contractor's wish to do so within 30 days beginning with the date of the notification by the Local Health Board, and

(bb) the NHS pharmacist or NHS appliance contractor (or a representative) attends the hearing that the Local Health Board arranges for the purpose of hearing those representations, which the Local Health Board must give the NHS pharmacist or NHS appliance contractor reasonable notice of, and

(c) consult any Local Pharmaceutical Committee whose area includes the particular listed premises or the only premises of the NHS pharmacist or NHS appliance contractor on that pharmaceutical list.

(6) If the Local Health Board does decide to remove a NHS pharmacist or NHS appliance contractor, or to remove the listing of particular premises listed in relation to the NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1), it must, when it notifies the NHS pharmacist or NHS appliance contractor of that decision, include in that notification—

(a) a statement of the reasons for the decision, and

(b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(d) may be exercised.

Commencement Information

I53 Reg. 53 in force at 1.10.2020, see **reg. 1(2)(c)**

Appeals against decisions under Part 9 E+W

54.—(1) An NHS pharmacist or NHS appliance contractor may appeal against the following decisions by the Local Health Board—

(a) the issuing of a remedial notice under regulation 50, including—

(i) the specified steps that an NHS pharmacist or NHS appliance contractor must take that are in the notice,

(ii) the duration of the notice period in the notice,

(iii) any decision to provide for a withholding of remuneration that is included in the notice, and

(iv) the amount of any withholding;

(b) a decision not to restore remuneration to the NHS pharmacist or NHS appliance contractor, as provided for in a remedial notice in accordance with regulation 50(4)(b)(ii), or to restore a smaller amount than the amount that the NHS pharmacist or NHS appliance contractor considers should be restored;

(c) the issuing of a breach notice under regulation 51, including—

(i) any decision to provide for a withholding of remuneration that is included in the notice, and

(ii) the amount of any withholding;

(d) a decision to remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list, or remove the listing of particular listed premises in relation to the NHS pharmacist or NHS appliance contractor, under regulation 53(1);

provided that an NHS pharmacist or NHS appliance contractor notifies the Welsh Ministers with a valid notice of appeal within 30 days of the date on which the NHS pharmacist or NHS appliance contractor was notified of the decision that is being appealed.

(2) A notice under paragraph (1) is valid only if it includes a concise and reasoned statement of the grounds of appeal.

(3) The Local Health Board must not remove an NHS pharmacist, NHS appliance contractor or the listing of particular listed premises in relation to an NHS pharmacist or NHS appliance contractor (as the case may be) from a pharmaceutical list under regulation 53(1)—

(a) if no appeal is brought against the decision to remove, until the period for bringing the appeal has elapsed, or

(b) if an appeal is brought against the decision to remove but it is unsuccessful, before the appeal is determined by the Welsh Ministers.

(4) Schedule 4 has effect in relation to appeals to the Welsh Ministers against decisions under this Part.

Commencement Information
I54 Reg. 54 in force at 1.10.2020, see **reg. 1(2)(c)**

PART 10 E+W

Payments to NHS pharmacists and NHS appliance contractors

The Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors E+W

55.—(1) The Drug Tariff referred to in section 81(4) of the 2006 Act (arrangements for additional pharmaceutical services) is the aggregate of—

(a) the determinations of remuneration made by the Welsh Ministers, acting as a determining authority, under section 88 of the 2006 Act (remuneration for persons providing pharmaceutical services), and

(b) any other instruments that the Welsh Ministers are required by virtue of these Regulations or the 2006 Act to publish, or which they do publish, together with those determinations,

in the publication known as the Drug Tariff published by the Welsh Ministers in such format as they think fit.

(2) Determinations under section 88 of the 2006 Act by the Welsh Ministers—

(a) may be made by reference to scales, indices or formulae of any kind, and where a determination falls to be made by reference to any such scale, index or formula, the determination may provide that the relevant price calculation is to be made by reference to the scale, index or formula which is—

(i) in the form current at the time of the determination, and

(ii) in any subsequent form taking effect after that time, and

(b) may take effect in relation to remuneration in respect of a period beginning on or after the date specified in the determination, which may be the date of the determination or an earlier or later date, but it may be an earlier date only if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates.

(3) Where a determination included in the Drug Tariff does not specify a date as mentioned in paragraph (2)(b), it will have effect in relation to remuneration in respect of the period beginning on the date on which the change to the Drug Tariff is published in accordance with paragraph (4).

(4) Amendments that may be made to the Drug Tariff at such intervals as the Welsh Ministers think fit must be published by the Welsh Ministers in a consolidated version of the Drug Tariff that has the amendments included in it.

(5) The consultation that the Welsh Ministers undertake under section 89(1) of the 2006 Act (section 88: supplementary) prior to the inclusion of or a change to the price of a drug or appliance which is to form part of a calculation of remuneration must be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way).

(6) Payments under the Drug Tariff must be made—

(a) by the Local Health Board responsible for making the payment, and

(b) in accordance with arrangements for claiming and making payments which are to be set out in the Drug Tariff but subject, as appropriate, to any deduction that may or must be made from the remuneration of an NHS pharmacist or NHS appliance contractor under these Regulations or any other regulations under the 2006 Act.

Commencement Information
I55 Reg. 55 in force at 1.10.2020, see **reg. 1(2)(c)**

[F2Zero or nominal product reimbursement for coronavirus vaccines, coronavirus antivirals and influenza virus vaccines E+W

55A.—(1) In the case of the drugs or medicines to which paragraph (2) applies, determining authorities must ensure that determinations under section 88 of the 2006 Act (remuneration for persons providing pharmaceutical services) in respect of pharmaceutical remuneration that relates to the supply or administration of those drugs or medicines either—

(a) do not provide for or permit any reimbursement to be paid for the cost of the drug or medicine (and so the basic price of the drug or medicine, for the purposes of the Drug Tariff, is zero), or

(b) only provide for or permit nominal reimbursement to be paid for the cost of the drug or medicine.

(2) This paragraph applies to—

(a) a drug or medicine which is used for vaccinating or immunising people against coronavirus ("a coronavirus vaccine"), if the conditions set out in paragraph (3) are satisfied,

(b) an antiviral drug or medicine which is used for preventing or treating coronavirus ("a coronavirus antiviral"), if the conditions set out in paragraph (4) are satisfied, or

(c) a drug or medicine which is used for vaccinating or immunising people against an influenza virus ("an influenza vaccine"), if the conditions set out in paragraph (5) are satisfied.

(3) The conditions set out in this paragraph are—

(a) either the Welsh Ministers have or the Secretary of State has purchased coronavirus vaccines for supply as part of the health service,

(b) the Welsh Ministers have made arrangements for all or part of the stock of coronavirus vaccines, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists,

(c) a Local Health Board has made arrangements for the administration of coronavirus vaccines from the stock mentioned in sub-paragraph (b) in accordance with any directions given to them by the Welsh Ministers under section 12 of the 2006 Act (functions of Local Health Boards), and

(d) the coronavirus vaccine in question is from that stock and administered as part of the health service.

(4) The conditions set out in this paragraph are—

(a) either the Welsh Ministers have or the Secretary of State has purchased coronavirus antivirals of a particular type for supply as part of the health service,

(b) the Welsh Ministers have made arrangements for all or part of the stock of that particular type of coronavirus antiviral, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists, and

(c) the coronavirus antiviral in question—

(i) is from that stock, or

(ii) is not from that stock but is nevertheless of the particular type of coronavirus antiviral that is available at no cost to NHS pharmacists under the arrangements mentioned in sub-paragraph (b).

(5) The conditions set out in this paragraph are—

(a) either the Welsh Ministers have or the Secretary of State has purchased influenza virus vaccines for supply as part of the health service,

(b) the Welsh Ministers have made arrangements for all or part of the stock of influenza virus vaccines, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists,

(c) a Local Health Board has made arrangements for the administration of influenza virus vaccines from the stock mentioned in sub-paragraph (b) in accordance with any directions given to them by the Welsh Ministers under section 12 of the 2006 Act (functions of Local Health Boards), and

(d) the influenza virus vaccine in question is from that stock and administered as part of the health service.

(6) For the purposes of paragraph (4), the Welsh Ministers may characterise the particular type of coronavirus antivirals that are available at no cost to NHS pharmacists solely by reference to the presentation of the drug or medicine (as well as by reference to its active ingredient, strength or any, or a combination of any, other distinguishing characteristics).

(7) For the avoidance of doubt, determinations under section 88 of the 2006 Act that, in accordance with this regulation—

(a) do not provide for or permit any reimbursement to be paid for the cost of a drug or medicine (and so the basic price of the drug or medicine, for Drug Tariff purposes, is zero), or

(b) only provide for or permit nominal reimbursement to be paid for the cost of a drug or medicine,

may nevertheless provide for or permit remuneration to be paid for any service provided by a NHS pharmacist in the course of which the drug or medicine is supplied or administered.

(8) In this regulation—

(a) "nominal reimbursement" means, in the case of a drug or medicine that has been provided at no cost to a NHS pharmacist, payment of an amount that is paid in place of the amount that the NHS pharmacist would ordinarily make from the difference between—

(i) the amount that they paid for the drug or medicine when they purchased it, and

(ii) the amount that they are paid by the relevant Local Health Board in respect of the cost of that drug or medicine (most commonly the basic price listed in the Drug Tariff), if they supply or administer that drug or medicine under arrangements for the provision of pharmaceutical services, and

(b) "health service" has the meaning given in section 206(1) of the 2006 Act.**]**

Textual Amendments

F2 Reg. 55A inserted (6.1.2023) by The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022 (S.I. 2022/1314), regs. 1, **4**

Local Health Boards as determining authorities E+W

56.—(1) The Welsh Ministers may state in the Drug Tariff that the determining authority for a particular fee, allowance or other remuneration is to be the Local Health Board of the NHS pharmacist or NHS appliance contractor to whom the remuneration relates.

(2) Where a Local Health Board is authorised to be a determining authority, the Local Health Board must—

(a) consult the relevant Local Pharmaceutical Committee before making any determination,

(b) publish the determination in such manner as it thinks appropriate for bringing it to the attention of persons included in its pharmaceutical lists, and

(c) make the determination available for inspection.

(3) A determination made by a Local Health Board must include the arrangements for claiming and paying the remuneration and—

(a) claims by NHS pharmacists and NHS appliance contractors must be made in accordance with the arrangements, and

(b) payments of remuneration must be made in accordance with the arrangements subject, as appropriate, to any deduction that may or must be made from the remuneration under these Regulations or any other regulations under the 2006 Act.

Commencement Information

I56 Reg. 56 in force at 1.10.2020, see **reg. 1(2)(c)**

Overpayments E+W

57.—(1) Where a Local Health Board considers that a payment has been made to an NHS pharmacist or NHS appliance contractor as mentioned in regulation 55(6) or 56(3) in circumstances where it was not due, the Local Health Board must draw the overpayment to the attention of the NHS pharmacist or NHS appliance contractor and—

(a) where the overpayment is admitted by the NHS pharmacist or NHS appliance contractor, or

(b) where the NHS pharmacist or NHS appliance contractor does not admit there has been an overpayment but the Local Health Board or, on appeal, the Welsh Ministers under regulation 9(1)(c) of the National Health Service (Service Committees and Tribunal) Regulations 1992, decides that there has been an overpayment,

the amount overpaid will be recoverable either by deduction from the remuneration of the NHS pharmacist or NHS appliance contractor or in some other manner.

(2) Recovery of an overpayment under this regulation is without prejudice to the investigation of an alleged breach of the terms of service.

Commencement Information

I57 Reg. 57 in force at 1.10.2020, see **reg. 1(2)(c)**

Reward scheme E+W

58.—(1) An NHS pharmacist who is presented with an order under paragraph 5 of Schedule 5 or an NHS appliance contractor who is presented with an order under paragraph 4 of Schedule 6 will be eligible to claim a payment from the Local Health Board, in accordance with the Drug Tariff, if—

(a) in accordance with paragraph 10 of Schedule 5 or paragraph 9 of Schedule 6 the NHS pharmacist or the NHS appliance contractor refused to provide the drugs or medicines or listed appliances ordered and informed the Local Health Board of this action as soon as practicable, or

(b) the NHS pharmacist or the NHS appliance contractor provided the drugs or listed appliances but had reason to believe at that time or subsequently came to have reason to believe that the order was not a genuine order for the person named on the prescription form or repeatable prescription form and informed the Local Health Board of this belief as soon as practicable and in either case the NHS pharmacist or the NHS appliance contractor has sent the order referred to in this paragraph to the Local Health Board and the Local Health Board has established that the order referred to in this paragraph was not a genuine order for the person named on the prescription form or repeatable prescription form.

(2) The Local Health Board must in respect of any claim under paragraph (1) make such payment as is due to the NHS pharmacist or the NHS appliance contractor calculated in the manner specified in the Drug Tariff.

(3) In this regulation, "order" includes a purported order.

Commencement Information

I58 Reg. 58 in force at 1.10.2020, see **reg. 1(2)(c)**

Payments to suspended NHS pharmacists and NHS appliance contractors E+W

59.—(1) The Local Health Board must make payments to any NHS pharmacist or NHS appliance contractor who is suspended from a pharmaceutical list, in accordance with the Welsh Ministers' determination in relation to such payments.

(2) The Welsh Ministers must make the determination in accordance with paragraph (3) after consultation with such organisations as they may recognise as representing NHS pharmacists and

NHS appliance contractors with whom arrangements for the provision of pharmaceutical services exist, and must publish it in the Drug Tariff.

(3) The determination may be amended from time to time by the Welsh Ministers after consultation with the organisations referred to in paragraph (2), and any amendments must also be published with the Drug Tariff.

(4) The Welsh Ministers' determination may include provision that payments in accordance with the determination are not to exceed a specified amount in any specified period.

Commencement Information
I59 Reg. 59 in force at 1.10.2020, see **reg. 1(2)(c)**

PART 11 E+W

Miscellaneous

Home Local Health Board E+W

60.—(1) An applicant which is a body corporate that is required to provide the information specified in Part 2 of Schedule 2 may make a request to a Local Health Board for that Local Health Board to act as its home Local Health Board.

(2) Where a Local Health Board has agreed to a request made under paragraph (1), an applicant required to provide as part of an application the information specified in Part 2 of Schedule 2 may instead provide that information to its home Local Health Board and inform the Local Health Board to which the application is made that the home Local Health Board already has the information.

(3) The home Local Health Board must pass the information it has received from an applicant under this regulation to any Local Health Board to which the applicant makes a subsequent application and must do so within 30 days of a request for that information from the other Local Health Board.

(4) The applicant must either—

(a) confirm to the Local Health Board to which the application is made that the information is up to date, or

(b) update the information by sending it to the home Local Health Board.

Commencement Information
I60 Reg. 60 in force at 1.10.2020, see **reg. 1(2)(c)**

Publication of particulars E+W

61.—(1) A Local Health Board must publish in such manner as it sees fit and make available for inspection at its offices copies of—

(a) its pharmaceutical needs assessment,

(b) its pharmaceutical list,

(c) its dispensing doctor list,

(d) a map delineating the boundaries of any controlled localities and reserved locations that have been determined,

(e) details of any determinations made by the Local Health Board under these Regulations in the previous 3 years,

(f) the terms of service for NHS pharmacists in Schedule 5,

(g) the terms of service for NHS appliance contractors in Schedule 6,

(h) the terms of service for doctors providing pharmaceutical services in Schedule 7, and

(i) the Drug Tariff.

(2) A Local Health Board may—

(a) make such of the documents referred to in paragraph (1) available for inspection at such other places in the area for which it is established as appear to it convenient for informing all persons interested, or

(b) publish at such places in the area for which it is established a notice of the places and times at which copies of such documents may be seen.

(3) A Local Health Board must send a copy of its pharmaceutical needs assessment, pharmaceutical lists and of its dispensing doctor list to the Welsh Ministers, the Local Medical Committee and the Local Pharmaceutical Committee, and must, within 14 days of any alteration to those lists, inform them in writing of those alterations.

Commencement Information

I61 Reg. 61 in force at 1.10.2020, see **reg. 1(2)(c)**

Exercise of choice in certain cases E+W

62. An application to an NHS pharmacist or an NHS appliance contractor for pharmaceutical services may be made—

(a) on behalf of any child by either parent, or in the absence of both parents, the guardian or other person who has the care of the child,

(b) on behalf of any person under 18 years of age who is—

(i) in the care of an authority to whose care the person has been committed under the provisions of the Children Act 1989(**34**), by a person duly authorised by that authority, or

(ii) in the care of a voluntary organisation, by that organisation or a person duly authorised by them,

(c) on behalf of any adult who is incapable of making such an application or authorising such an application to be made on their behalf, by a relative or the primary carer of that person, or

(d) on behalf of any other person by any duly authorised person.

Commencement Information

I62 Reg. 62 in force at 1.10.2020, see **reg. 1(2)(c)**

(**34**) 1989 c. 41.

Transitional provisions E+W

63.—(1) Any application made under the 2013 Regulations that has been received by a Local Health Board on or before 30 September 2021 must be determined in accordance with the provisions of the 2013 Regulations until that application is finally determined.

(2) Any proposed determination by a Local Health Board under regulation 6(2) of the 2013 Regulations (areas that are controlled localities) on or before 30 September 2020, must be determined in accordance with the provisions of the 2013 Regulations until that application has been finally determined.

(3) Any appeal under the 2013 Regulations that is—

(a) received by the Welsh Ministers on or before 30 September 2020, or

(b) made after the coming into force of these Regulations in respect of an application determined in accordance with paragraph (1) or a determination made under paragraph (2),

must be determined in accordance with the provisions of the 2013 Regulations.

(4) Where, before 30 September 2020 or as a consequence of paragraph (1) or (3), a person is entitled on the basis of a decision (whether by a Local Health Board or on appeal)—

(a) to be included in a pharmaceutical list or a dispensing doctor list but has not been included in that list, or

(b) to have listed in relation to their entry in a pharmaceutical list or dispensing doctor list premises that have not been listed in relation to them,

the arrangements for the listing of that person or those premises, and the circumstances in which that decision lapses, are as set out in the 2013 Regulations.

(5) In respect of a determination made under paragraph (2), the procedure that must be followed is that in regulation 6(4) of, and Parts 1 and 2 of Schedule 2 to, the 2013 Regulations.

(6) Where preliminary consent was granted under regulation 12 of the 2013 Regulations (applications for preliminary consent and effect of preliminary consent) and no application had been made under regulation 12(6) of the 2013 Regulations before 30 September 2020, regulation 18 (applications for preliminary consent and effect of preliminary consent) will apply as if the preliminary consent had been granted under that regulation.

(7) Where paragraph (6) applies, regulation 12(6) of the 2013 Regulations is substituted for regulation 18(5).

(8) If a determination under regulation 6 of the 2013 Regulations has not been finally determined before 30 September 2020 ("an outstanding determination") a Local Health Board must defer consideration of any application submitted to it under Parts 5 and 6 of these Regulations if the application could be affected by an outstanding determination until such time as the outstanding determination is finally determined.

(9) For the purposes of this regulation, an application or a determination is not to be treated as finally determined until the end of the period for bringing an appeal against that application or determination, or until the determination of any such appeal, whichever is later.

Commencement Information

I63 Reg. 63 in force at 1.10.2020, see **reg. 1(2)(c)**

Minor and consequential amendments E+W

64. The Regulations listed in Schedule 8 are amended as set out in that Schedule.

Commencement Information
I64 Reg. 64 in force at 1.10.2020, see **reg. 1(2)(c)**

Revocation E+W

65.—(1) The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 are revoked in accordance with paragraphs (2) to (5).

(2) On 1 October 2020—

(a) Parts 1 to 3, and

(b) Parts 7 and 8.

(3) On 31 March 2021—

(a) in Part 4, regulation 8(1)(a), and

(b) in Part 5, regulation 20.

(4) On 1 October 2021—

(a) in Part 4, regulation 8(1)(b) to (7), and regulations 9 to 19,

(b) in Part 5, regulations 21 to 30, and

(c) Part 6.

(5) So far as they have not been revoked by paragraphs (2) to (4), the 2013 Regulations are revoked on 1 October 2021.

Commencement Information
I65 Reg. 65 in force at 1.10.2020, see **reg. 1(2)(c)**

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

Status:
Point in time view as at 06/01/2023.

Changes to legislation:
There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.