
WELSH STATUTORY INSTRUMENTS

2020 No. 1073 (W. 241)

NATIONAL HEALTH SERVICE, WALES

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

*Made - - - - 29 September 2020
Coming into force in accordance with regulation 1(2)
and (3)*

The Welsh Ministers, in exercise of the powers conferred on them by sections 15, 80, 82A, 83, 84, 86, 88, 104, 107, 110, 115, 116, 118, 203(9) and (10) and 205 of the National Health Service (Wales) Act 2006⁽¹⁾, make the following Regulations.

A draft of these Regulations has been approved by a resolution of Senedd Cymru in accordance with section 203(6A) of that Act.

PART 1

Introductory

Title, commencement and application

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.

⁽¹⁾ 2006 c. 42. See section 206(1) for the definitions of “prescribed” and “regulations”. Section 82A and section 203(6A) were inserted by section 111 of the Public Health (Wales) Act 2017 (anaw 2). Sections 83 and 84 were amended by section 112 of the Public Health (Wales) Act 2017.

Interpretation

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(2) as in force immediately before 10 May 2013;

“the 2005 Regulations” (“*Rheoliadau 2005*”) means the National Health Service (Pharmaceutical Services) Regulations 2005(3) as in force immediately before 1 September 2012;

“the 2013 Regulations” (“*Rheoliadau 2013*”) means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013(4) as in force immediately before 1 October 2020;

“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-ddyddiad 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;

(2) S.I. 1992/662, revoked by S.I. 2013/898 (W. 102).

(3) S.I. 2005/641, revoked by S.I. 2012/1909.

(4) S.I. 2013/898 (W. 102), amended by S.I. 2004/478 (W. 48).

“bank holiday” (“*gwyl 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⁽⁵⁾;

“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);

“Charges Regulations” (“*Rheoliadau Ffioedd*”) means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007⁽⁶⁾;

“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;

“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);

(5) 1971 c. 80.

(6) S.I. 2007/121 (W. 11), amended by S.I. 2013/898 (W. 102).

“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(7) (general interpretation);

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

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

- (a) is signed 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;

(7) The definition of “*electronic communication*” was amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

“General Pharmaceutical Council Register” (“*Cofrestr y Cyngor Fferyllol Cyffredinol*”) means the register maintained under article 19 of the Pharmacy Order 2010(8) (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(9);

“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(10);

“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(11);

“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(12) (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);

(8) S.I. 2010/231.

(9) 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.

(10) 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.

(11) 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.

(12) S.I. 1992/664. The definition of “joint discipline committee” was inserted by S.I. 1996/703.

“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⁽¹³⁾;

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

- (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⁽¹⁴⁾ (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⁽¹⁵⁾;

“NHS pharmacist” (“*fferylllydd 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⁽¹⁶⁾,

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”;

⁽¹³⁾ S.I. 2004/1020 (W. 117), amended by S.I. 2006/945 (W. 94).

⁽¹⁴⁾ 2006 c. 41. Section 159 has been amended by S.I. 2010/22 and the Health and Social Care Act 2012 (c. 7).

⁽¹⁵⁾ 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.

⁽¹⁶⁾ 1968 c. 67.

“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 (INNМ),
- (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⁽¹⁷⁾;

“notice” (“*hybysiad*”) means a notice in writing;

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

- (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⁽¹⁸⁾ (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⁽¹⁹⁾ (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

⁽¹⁷⁾ The British Pharmacopoeia 2020 is the leading collection of standards for UK medicinal products and pharmaceutical substances and is available at www.pharmacopoeia.com.

⁽¹⁸⁾ S.I. 2002/253, amended by S.I. 2009/1182 and S.I. 2018/838.

⁽¹⁹⁾ 1989 c. 44, amended by S.I. 2005/848.

- (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⁽²⁰⁾;

“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;

“pharmacist independent prescriber” (“*fferylllydd-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⁽²¹⁾ (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⁽²²⁾ 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;

⁽²⁰⁾ S.I. 1992/664. The definition of “pharmaceutical discipline Committee” was inserted by S.I. 1996/703.

⁽²¹⁾ S.I. 1976/1213 (N.I. 22).

⁽²²⁾ S.I. 2002/254, amended by S.I. 2009/1182.

“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;

“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⁽²³⁾;

“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⁽²⁴⁾;

“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

⁽²³⁾ 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).

⁽²⁴⁾ S.I. 2015/1989 (W. 299), amended by S.I. 2019/760 (W. 143).

- (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 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(25);

“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

(25) 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).

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);

“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(26) (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
- (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⁽²⁷⁾ (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⁽²⁸⁾ (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;

⁽²⁷⁾ Section 71 was substituted by section 28 of the Health Act 2006 (c. 28).

⁽²⁸⁾ 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).

“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(29).

(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—

- (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(30) 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”.

PART 2

Pharmaceutical needs assessments

Pharmaceutical needs assessments

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(31), 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”.

(29) 2007 c. 15.

(30) 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.

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

(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).

Information to be contained in pharmaceutical needs assessments

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).

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

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.

Subsequent assessments

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.

Consultation on pharmaceutical needs assessments

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.

Matters for consideration when making assessments

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.

Publication of pharmaceutical needs assessments

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).

PART 3

Pharmaceutical lists and dispensing doctor lists

Preparation and maintenance of pharmaceutical lists

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.

Preparation and maintenance of dispensing doctor lists

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.

Terms of service

- 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.

PART 4

Determination of controlled localities

Areas that are controlled localities

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.

Appeals against decisions under Part 4

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

PART 5

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

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.

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

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).

Locations in controlled localities that are reserved locations

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.

Applications for preliminary consent and effect of preliminary consent

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).

Applications involving relocation within a Local Health Board's area

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.

Applications involving relocation between neighbouring Local Health Board areas

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.

Applications involving temporary relocation

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.

Applications involving a change of ownership

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).

Procedure following grant of an application

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.

Application to extend the relevant period

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.

Appeals

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).

PART 6

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

Arrangements for the provision of pharmaceutical services by doctors

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.

Necessary services for temporary patients

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.

Provision of pharmaceutical services for immediate treatment or personal administration

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.

Discontinuation of arrangements for the provision of pharmaceutical services by doctors

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.

Outline consent and premises approval

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.

Taking effect of outline consent and premises approval

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).

Lapse of outline consent and premises approval

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.

Premises approval: change of premises before outline consent takes effect

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.

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

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.

Premises approval: practice amalgamations

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.

PART 7

Fitness grounds and inclusion in and removal from pharmaceutical lists

Deferral of applications on fitness grounds

- 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.

Refusal of applications on fitness grounds

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⁽³²⁾ 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⁽³³⁾, the application notice must be sent to the Tribunal if an appeal is to be brought.

Conditional inclusion on fitness grounds

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
- (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.

⁽³²⁾ 2003 c. 42.

⁽³³⁾ S.I. 2008/2699 (L. 16), see rule 19 of those Rules.

(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.

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

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.

Removal from a pharmaceutical list for other reasons

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.

Suspension from a pharmaceutical list

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.

Notification of a decision to impose conditions

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.

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

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)⁽³⁴⁾, 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.

Review of a decision to impose conditions

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.

⁽³⁴⁾ 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.

(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).

(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.

Appeals

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.

PART 8

Conditional inclusion in pharmaceutical lists: certain specific conditions that do not relate to fitness or performance

Core opening hours conditions

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.

Conditions relating to providing directed services

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).

Conditions relating to local resolution of disputes over terms of service

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).

PART 9

Performance related sanctions and Market Exit

Local dispute resolution before serving remedial notices or breach notices

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.

Breaches of terms of service: remedial notices

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.

Breaches of terms of service: breach notices

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 it has been issued.

Payment withholdings: supplementary matters

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.

Removal of listings: cases relating to remedial notices and breach notices

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.

Appeals against decisions under Part 9

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.

PART 10

Payments to NHS pharmacists and NHS appliance contractors

The Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors

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.

Local Health Boards as determining authorities

- 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.

Overpayments

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.

Reward scheme

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.

Payments to suspended NHS pharmacists and NHS appliance contractors

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.

PART 11

Miscellaneous

Home Local Health Board

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.

Publication of particulars

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.

Exercise of choice in certain cases

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⁽³⁵⁾, 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.

Transitional provisions

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

(35) 1989 c. 41.

(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.

Minor and consequential amendments

64. The Regulations listed in Schedule 8 are amended as set out in that Schedule.

Revocation

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.

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29 September 2020

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

SCHEDULE 1

Regulation 4

Information to be contained in pharmaceutical needs assessments

Current provision of pharmaceutical services

1. A statement of the pharmaceutical services that the Local Health Board has identified as services that are provided—

- (a) in the area of the Local Health Board and which are necessary to meet the need for pharmaceutical services in its area,
- (b) outside the area of the Local Health Board but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the Local Health Board has identified such services), or
- (c) in or outside the area of the Local Health Board and, whilst not being services of the types described in sub-paragraph (a) or (b), they nevertheless affect the assessment by the Local Health Board of the need for pharmaceutical services in its area.

Other NHS services

2. A statement of any NHS services provided or arranged by the Local Health Board, another Local Health Board, a dispensing doctor or NHS Trust to which the Local Health Board has had regard in its assessment, which affect the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Gaps in provision of pharmaceutical services

3. A statement of the pharmaceutical services that the Local Health Board has identified (if it has) as services that are not provided in the area of the Local Health Board but which the Local Health Board is satisfied—

- (a) need to be provided (whether or not they are located in the area of the Local Health Board) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;
- (b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the Local Health Board) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

How the assessment was carried out

4. An explanation of how the assessment has been carried out, and in particular—

- (a) how it has determined what are the localities in its area,
- (b) how it has taken into account (where applicable)—
 - (i) the different needs of different localities in its area, and
 - (ii) the different needs of members of different groups in its area who share a common attribute in respect of one, or more than one, of the following characteristics—
 - (aa) age,
 - (bb) gender,
 - (cc) proposed, commenced or completed reassignment of gender,
 - (dd) disability,
 - (ee) race,

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- (ff) religion or belief, and
- (gg) sexual orientation;
- (c) a report on the consultation that it has undertaken.

Map of provision

5. A map that identifies the premises at which pharmaceutical services and dispensing services are provided in the area of the Local Health Board.

SCHEDULE 2

Regulations 15, 18, 23, 30, 33 and 34

Information to be included in applications to provide pharmaceutical services

PART 1

Application for inclusion in or for amendment to a pharmaceutical list

Information required from all applicants

Details of the application

1. Name of the Local Health Board to which the application is made.
2. Type of consent applied for (full or preliminary).
3. Type of application (for example: new inclusion; relocation within a Local Health Board's area; relocation between neighbouring Local Health Board areas; relocation; change of ownership; preliminary consent).

Details of the applicant

4. Name and address of the applicant.
5. If the applicant is an individual or a partnership carrying on a retail pharmacy business, the applicant's or each partner's registration number in the General Pharmaceutical Council register.
6. If the applicant is a body corporate carrying on a retail pharmacy business, the name and registration number of the applicant's superintendent in the General Pharmaceutical Council register.

Details of the premises and opening hours

7. The address of the premises from which the applicant applies to provide pharmaceutical services; or the location of the premises from which the applicant intends to provide pharmaceutical services if the application is for preliminary consent.
8. Whether the applicant is currently in possession of the premises or whether, for example, the premises are under construction or negotiation.
9. The days on which the pharmacy will be open for the provision of pharmaceutical services and the opening hours on those days.

Pharmaceutical services to be provided

10. Confirmation that all essential services will be provided and, if applicable, which appliances the applicant undertakes to supply.

11. Details of directed services that the applicant applies to provide.

12. If the application is to provide pharmaceutical services of a different description to those currently provided at the listed premises, details of those services.

Information relating to applications to be included in, or amend, a pharmaceutical list

13. Where regulation 16 applies to the determination of an application, the applicant must state the reasons why the applicant considers the application will meet a need identified in the relevant pharmaceutical needs assessment of the Local Health Board in which the premises specified in the application are situated.

Information relating to the prejudice test

14. Where the prejudice test in regulation 16 applies to the determination of an application, the applicant must state the reasons why they consider that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

Information relating to applications involving relocations

15. Where the applicant applies to relocate (whether within the Local Health Board's area under regulation 19, between neighbouring Local Health Board areas under regulation 20 or on a temporary relocation basis under regulation 21) the applicant must provide details of the proposed relocation including the address of the applicant's existing listed premises.

16. Where the application involves a relocation between neighbouring Local Health Board area under regulation 20 the applicant must state—

- (a) the name of the Local Health Board where the existing premises are located,
- (b) that the applicant consents to the removal of their name from the pharmaceutical list maintained by the Local Health Board in whose area the existing premises are located and in respect of those existing listed premises with effect from the date on which the provision of pharmaceutical services from the new premises will commence, and
- (c) how the applicant intends to meet a need identified in the pharmaceutical needs assessment of the neighbouring Local Health Board, if the application involves a relocation to meet such a need.

17. The applicant must provide details of whether—

- (a) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is significantly less accessible,
- (b) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises, and
- (c) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

18. If the application is for a temporary relocation, the applicant must state the circumstances that require a temporary relocation.

Information relating to applications involving a change of ownership

19. Name of the person included in the pharmaceutical list currently providing pharmaceutical services from the premises.

20. The applicant must provide details of whether—

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- (a) the same pharmaceutical services will continue to be provided from the premises, and
- (b) the provision of pharmaceutical services will be continuous or interrupted and the reasons for any interruption.

Applicant's undertaking

21. The applicant must give an undertaking that if the application is granted the applicant will provide the pharmaceutical services, and if applicable supply the appliances, at the premises in respect of which the application is granted in accordance with the applicable terms of service.

PART 2

Information and undertakings for applications for inclusion in a pharmaceutical list

Applicant's details

22.—(1) An applicant (other than an applicant which is a body corporate) must provide the following information—

- (a) full name,
- (b) gender,
- (c) date of birth,
- (d) address and telephone number,
- (e) a declaration that they are a registered pharmacist, and
- (f) professional registration number and date of first registration in the register.

(2) An applicant which is a body corporate must provide the following information—

- (a) full name,
- (b) company registration number,
- (c) registered office and telephone number relating to that office,
- (d) a declaration that it is a person who is or who will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968,
- (e) registration number in the Register of Premises maintained by the General Pharmaceutical Council, and
- (f) details of any relevant list from which it has been removed or contingently removed, or to which it has been refused admission or in which it has been conditionally included, on fitness grounds, with an explanation as to why.

Investigation, proceedings and convictions

23. An applicant must supply in writing information as to whether they, or where the applicant is a body corporate any of its directors or its superintendent—

- (a) has any criminal convictions in the United Kingdom,
- (b) has been bound over following a criminal conviction in the United Kingdom,
- (c) has accepted a police caution in the United Kingdom,
- (d) has in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),

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- (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995 (fixed penalty: conditional offer by procurator fiscal) or agreed to pay a penalty under section 115A of the Social Security Administration Act 1992 (penalty as alternative to prosecution),
- (f) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales, or is subject to a penalty which would be the equivalent of being bound over or cautioned,
- (g) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board,
- (h) has been subject to any investigation into their professional conduct by any licensing, regulatory or other body, where the outcome was adverse,
- (i) is currently subject to any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) is or has been where the outcome was adverse, the subject of any investigation into their professional conduct in respect of any current or previous employment,
- (k) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to removal from any relevant list,
- (l) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (m) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list kept by another Local Health Board or equivalent body, or has been or is currently suspended from such a list, on fitness grounds, and if so, why and the name of that Local Health Board or equivalent body, or
- (n) is, or ever has been, subject to a national disqualification, and, if so, the applicant must give details including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings, and any outcome.

24. If the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is, has been in the preceding 6 months, or was at the time of the originating events, a director or superintendent of a body corporate, they must in addition supply information in writing to the Local Health Board as to whether the body corporate—

- (a) has any criminal convictions in the United Kingdom,
- (b) has been convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is currently the subject of any proceedings which might lead to such a conviction, which have not yet been notified to the Local Health Board,
- (d) has been subject to any investigation into its provision of professional services by any licensing, regulatory or other body, where the outcome was adverse,
- (e) is currently subject to any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) is the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from any relevant list,
- (g) is, or has been where the outcome was adverse, the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (h) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list, or has been or is currently suspended from such a list, on fitness grounds, or

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- (i) is or ever has been, subject to a national disqualification, and if so, the applicant must give the name and registered office of the body corporate and details, including approximate dates, or where any investigation or proceedings were or are to be brought, the nature of that investigation or proceedings and any outcome.

Pharmaceutical qualifications, referees etc.

25. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply details of their pharmaceutical qualifications (including where obtained) and chronological details of their professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why they were dismissed from any post.

26. Where the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is a registered pharmacist, the applicant must supply names and addresses of two referees who are willing to provide references in respect of two recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, a full explanation and alternative referees.

27. Where the applicant is a body corporate, the name and address of each director and superintendent of the body corporate must be supplied.

28. The applicant must supply the name of any Local Health Board (or equivalent body) in whose pharmaceutical list the applicant, and where the applicant is a body corporate, any director or superintendent of the applicant, is included, and particulars of any outstanding applications (including deferred applications) for inclusion in, or preliminary consent to be included in, any pharmaceutical list of a Local Health Board (or equivalent body) with the name of the Local Health Board (or body) in question.

29. If the applicant is the director or superintendent of a body corporate that is included in any relevant list, or which has an outstanding application (including a deferred application) for inclusion in any relevant list, the applicant must supply the name of the Local Health Board or equivalent body in question, and the name and registered office of any such body corporate.

Undertakings

30.—(1) The applicant must give a written undertaking to notify the Local Health Board within 7 days of any material changes to the information provided in the application until—

- (a) their name is entered on the pharmaceutical list,
- (b) the period specified in regulation 23(2) for them to notify the Local Health Board that they will commence the provision of the pharmaceutical services in respect of which the application was made has expired,
- (c) they withdraw the application, or
- (d) in the case of an applicant who has been granted preliminary consent under regulation 18, the period during which the preliminary consent has effect in accordance with regulation 18(5) has expired.

(2) The applicant must give a written undertaking to notify the Local Health Board if they are included or apply to be included in a relevant list.

PART 3

Notification of commencement date

Information to be provided prior to the commencement of the provision of pharmaceutical services

31. The applicant must provide the following information—
- (a) name of the applicant,
 - (b) date of grant of application,
 - (c) premises specified in the application from which the pharmaceutical services will be provided,
 - (d) confirmation that the premises are registered with the General Pharmaceutical Council (including reference number),
 - (e) details of the pharmaceutical services to be provided,
 - (f) date on which the provision of pharmaceutical services will commence,
 - (g) name and registration number of the registered pharmacist in charge at the premises, and
 - (h) an undertaking that the applicant will, in accordance with the application granted by the Local Health Board, provide the pharmaceutical services from the premises in accordance with the terms of services.

PART 4

Applications for outline consent and premises approval

Details of the application

32. Name of the Local Health Board to which the application is made.
33. Type of application (outline consent, premises approval or both).

Details of the applicant

34. Name and address of the applicant.
35. The General Medical Council reference number under which the applicant is included in the List of Registered Medical Practitioners maintained by the General Medical Council.

Application for outline consent

36. Description and map of the area within which the applicant wishes to provide pharmaceutical services.
37. Address of any pharmacy within the area described and delineated under paragraph 36.

Application for premises approval

38. The address of the practice premises from which the applicant applies to provide pharmaceutical services and whether those practice premises are listed premises in relation to a different area.

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39. Distance between those premises and the nearest pharmacy (and the address of that pharmacy).

40. Whether the application is for premises approval for additional premises or to relocate to new premises (and if the latter the distance from the new premises to the premises in respect of which the applicant currently has premises approval).

41. Whether the application arises because a practice amalgamation has taken place or will be taking place and, if so, the names of the doctors or contractors participating in the amalgamation.

42. If outline consent has already been granted a description and map of the area in respect of which consent has been granted.

43. Details of any other medical practice premises which have been granted premises approval or in respect of which an application has already been made but not yet determined by the Local Health Board.

Pharmaceutical services to be provided

44. The pharmaceutical services to be provided and the opening hours and days on which those services will be provided.

Prejudice test

45. The reasons why the applicant considers that granting the application will not prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality in which the premises specified in the application are situated.

Meeting identified needs

46. The reasons why the applicant considers it is necessary to grant the application in order to meet a need identified in a relevant pharmaceutical needs assessment.

Applicant's undertaking

47. The applicant must give an undertaking that if the application is granted and outline consent and premises approval is in effect the applicant will provide the pharmaceutical services from the practice premises in respect of which the application is granted in accordance with the terms of service.

SCHEDULE 3

Regulations 13, 15 and 30

Procedures to be followed by Local Health Boards
to determine applications under the Regulations

PART 1

Preliminary matters

General principles

1.—(1) Except in so far as these Regulations provide to the contrary, a Local Health Board may determine an application submitted to it in such manner as it thinks fit.

(2) A Local Health Board must follow the procedure in regulation 15(4) in respect of an application submitted to it which does not contain all of the information that an applicant is required to provide in accordance with Schedule 2.

(3) A Local Health Board may if it thinks fit consider two or more applications together and in relation to each other but where it intends to do so it must give notice of that intention in writing to—

- (a) the respective applicants, and
- (b) where the application is one in respect of which notice must be given under paragraph 8, any other person that must be given notice of that application.

(4) Where in accordance with sub-paragraph (3) a Local Health Board considers two or more applications to which regulation 16(2) applies together and in relation to each other, it may refuse an application (notwithstanding the fact that it would if determining the application in isolation grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the application are situated.

Timetable for determining applications

2. A Local Health Board must endeavour to determine an application as soon as is practicable after its receipt.

Persons prohibited from taking part in decision-making on applications

3.—(1) No person is to take part in determining an application if they—

- (a) are a person who is included in the pharmaceutical list or dispensing doctor list maintained by the Local Health Board, or are an employee of such a person,
- (b) are a shareholder, director or company secretary of a company which runs a retail pharmacy business in the area of the Local Health Board,
- (c) are a provider of primary medical services in the area of the Local Health Board,
- (d) are an APMS contractor in the area of the Local Health Board, or is an officer, trustee or other person concerned with the management of a company, society or voluntary organisation or other body which is an APMS contractor, or is employed or engaged by such an APMS contractor, or
- (e) are employed or engaged by the Local Health Board for the purposes of providing primary medical services within an LHBMS practice.

(2) No other person is to take part in determining an application if, because of an interest or an association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

PART 2

Determination of controlled localities

Notice of proposed determination in respect of controlled localities

4.—(1) If a Local Health Board decides that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 13(3) (areas that are controlled localities), the Local Health Board must take no action in relation to that application

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other than to notify the applicant of that fact and of its right of appeal against that decision under regulation 14 (appeals).

(2) In all other cases, before making a determination under regulation 13(2) a Local Health Board must give a written notice of proposed determination to—

- (a) the Local Medical Committee in its area,
- (b) the Local Pharmaceutical Committee in its area,
- (c) the Community Health Council for the area, and
- (d) any person included in a pharmaceutical list maintained by the Local Health Board and any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established who, in the opinion of the Local Health Board, may be affected by the determination.

(3) A notice of proposed determination must inform the person notified of their right to make representations (or in the case of a Local Medical Committee or Local Pharmaceutical Committee being notified that applied for the determination any further representations) in writing on the proposed determination within 30 days of the date on which the notice was sent to them.

Deferral of applications

5. Where a Local Health Board has issued a notice of proposed determination it must defer consideration of any application submitted under Part 5 or Part 6 of these Regulations but not determined by it if the application could be affected by the proposed determination until—

- (a) it has determined whether or not the locality is or is part of a controlled locality and the period for bringing an appeal relating to that determination has ended, or
- (b) the date of the determination of any such appeal.

Imposition of conditions

6. Where a Local Health Board determines 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 it—

- (a) must consider whether the provision of—
 - (i) primary medical services by a provider of such services (other than itself),
 - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
 - (iii) local pharmaceutical services provided under a pilot scheme, or
 - (iv) pharmaceutical services by a doctor,is likely to be adversely affected as a consequence of that determination, and
- (b) may, where it is of the opinion that any of those services are likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision under the GMS Regulations for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

Notification of determination and action following determination

7.—(1) Once a Local Health Board has determined 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 it must—

- (a) as soon as practicable after reaching a determination give notice in writing to those notified under paragraph 4(2) informing them of—
 - (i) the determination and the reasons for it,
 - (ii) any conditions that it has imposed under paragraph 6, and
 - (iii) any rights of appeal under Schedule 4, and
 - (b) as soon as practicable after the relevant date—
 - (i) delineate precisely on a map the boundaries of the controlled locality or remove the delineated boundary of a locality that has ceased to be a controlled locality,
 - (ii) give a doctor that is affected reasonable notice of any conditions that have been imposed under paragraph 6 as a result of the determination, and
 - (iii) proceed to determine any applications that have been deferred under paragraph 5.
- (2) For the purposes of this paragraph, “the relevant date” is the later of—
- (a) the date on which the period for bringing an appeal relating to the determination ends, or
 - (b) the date of the determination of any such appeal.

PART 3

Applications for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

Notice of certain applications

- 8.—(1) This paragraph applies to applications for—
- (a) inclusion in, or to make an amendment to, a—
 - (i) pharmaceutical list made under Part 5 of these Regulations, except for applications under regulation 22 (applications involving a change of ownership), and
 - (ii) dispensing doctor list made under Part 6 of these Regulations,
 - (b) an extension of the relevant time period under regulation 24, and
 - (c) a further determination as to whether premises are, or a relevant location is, in a reserved location under regulation 17(2).
- (2) The Local Health Board to which the application was submitted must give notice in writing of the application in accordance with paragraph 9.
- (3) Those notified of an application may within 30 days of the date on which the notification was sent to them, make representations on the application, in writing, to the Local Health Board to which the application was submitted, except for applications made pursuant to regulation 21 (applications involving temporary relocation).

Persons and bodies to be notified

- 9.—(1) The persons and bodies that must be notified by a Local Health Board are—
- (a) the Local Pharmaceutical Committee,
 - (b) the Local Medical Committee,
 - (c) any person—
 - (i) included in a pharmaceutical list maintained by it, or

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- (ii) who has been granted preliminary consent for inclusion in a pharmaceutical list, whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,
 - (d) any provider of local pharmaceutical services under a pilot scheme in the area for which the Local Health Board is established whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,
 - (e) any Community Health Council serving the area of the Local Health Board,
 - (f) any patient group, consumer group or community group in the area of the Local Health Board that it considers has a significant interest in the provision of pharmaceutical services in the area,
 - (g) where the premises specified in the application are in a controlled locality, any person (except itself) who is a provider of primary medical services within the Local Health Board's area or who is included in the dispensing doctor list maintained by the Local Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted,
 - (h) any Local Health Board or equivalent body any part of whose area is within 2 kilometres of the premises or the location of the premises specified in the application, and
 - (i) in the case of an application made under regulation 20 (applications involving relocation between neighbouring Local Health Board areas), the Local Health Board from whose area the applicant wishes to relocate.
- (2) A Local Health Board that provided the notification under sub-paragraph (1)(h) must—
- (a) within 14 days of receiving the notification give notice in writing to the persons and bodies specified in sub-paragraph (1)(a) to (g) that are within or that serve the area for which the Local Health Board is established, and
 - (b) notify the Local Health Board that provided the notification under sub-paragraph (1) that it has provided the notification required by sub-paragraph (2)(a).
- (3) An equivalent body notified under sub-paragraph (1)(h) may request the Local Health Board to give notification to such persons in the area for which the equivalent body is established whose interests might in the opinion of the equivalent body, be significantly affected if the application is granted and the Local Health Board must comply with any such request.

Content of notification

- 10.** A notification of an application under paragraph 8 must—
- (a) inform the person or body notified—
 - (i) of their right to make representations on the application under paragraph 8(3),
 - (ii) the circumstances in which the Local Health Board may require an oral hearing to be held under paragraph 11, and
 - (iii) if the Local Health Board intends to consider the application together with and in relation to any other application, of that intention,
 - (b) provide a copy of the application submitted by the applicant to enable the person or body notified to make informed representations with regard to whether or not the application should be granted, and
 - (c) where regulation 17(1) applies to an application under paragraph 8(1)(a) inform the person or body notified that the Local Health Board will be determining whether the premises or relevant location specified in the application that are in a controlled locality are also in a reserved location.

Oral hearings

11.—(1) In the case of an application falling within paragraph 8, a Local Health Board may require an oral hearing to be held if it considers it is necessary to hear oral representations before determining such an application.

(2) If the Local Health Board does decide to hold an oral hearing, it must—

(a) give not less than 14 days' notice of the time and place of the hearing to—

(i) the applicant, and

(ii) any person who has made representations on the application under paragraph 8(3),

(b) advise the applicant who has been given notice of the hearing, and

(c) advise those notified that they may make oral representations relating to the application at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) A Local Health Board may determine the procedure to be followed at the oral hearing.

(5) A Local Health Board is not bound by any recommendations arising from an oral hearing.

Information to which a Local Health Board must have regard

12. In determining an application falling within paragraph 8, a Local Health Board must have regard, in particular, to—

(a) any representations received by the Local Health Board under paragraph 8(3),

(b) any recommendations arising from an oral hearing, if one is held under paragraph 11,

(c) the relevant pharmaceutical needs assessment and relevant locality, and

(d) any other information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application.

Imposition of conditions

13.—(1) This sub-paragraph applies where a Local Health Board decides to grant an application falling within—

(a) paragraph 8(1)(a)(i) where the premises specified in the application are in a controlled locality, or

(b) paragraph 8(1)(a)(ii).

(2) Where sub-paragraph (1) applies, a Local Health Board—

(a) must consider whether the provision of—

(i) primary medical services by a provider of such services (other than itself),

(ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,

(iii) local pharmaceutical services provided under a pilot scheme, or

(iv) pharmaceutical services by a doctor,

is likely to be adversely affected as a consequence of its decision to grant the application, and

(b) may, where it is of the opinion that the provision of any of those services listed in sub-paragraph (2)(a) is likely to be adversely affected, impose conditions to postpone, for such

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period as it thinks fit, the making or termination of arrangements under regulation 26 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant list.

Notification of decisions: applications for inclusion in or to make an amendment to a pharmaceutical list

14.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(i), give notice in writing of its decision (including the questions of the imposition of conditions under paragraph 13 and the determination of a reserved location under regulation 17(1)) to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) In the case of an application which is determined under regulation 22 (applications involving a change of ownership), a Local Health Board must as soon as practicable after reaching a decision give notice in writing in accordance with paragraph 9.

(3) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists

15.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(ii), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13) to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications under regulation 24 for extension of the relevant period

16.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(b), give notice in writing of its decision to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).

(2) Any notification of a decision under this paragraph must include a statement of the reasons for the decision.

Notification of decisions: applications under regulation 17(2)

17.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(c), give notice in writing of its decision to—

- (a) the applicant, and

- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(3).
- (2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Action following determination in respect of reserved locations

18.—(1) After determining an application under regulation 17(2) or making a determination in accordance with regulation 17(1), as soon as practicable after the relevant date, the Local Health Board must delineate precisely on a map the boundaries of any reserved location that it has determined, or remove the delineated boundary of a location that has ceased to be a reserved location, as the case may be.

- (2) For the purposes of this paragraph, “the relevant date” is the later of—
 - (a) the date on which the period for bringing an appeal relating to the determination ends, or
 - (b) the date of the determination of any such appeal.

SCHEDULE 4

Regulations 14, 25, 35 and 54

Appeals to the Welsh Ministers

PART 1

Preliminary matters

General principles

1. Except in so far as these Regulations provide to the contrary, the Welsh Ministers may determine an appeal submitted to them in such manner as they think fit and may, in particular—

- (a) consider all information available to them which, in their opinion, is relevant to the determination of an appeal;
- (b) consider two or more appeals together and in relation to each other (but they are not obliged to do so where the Local Health Board has determined two or more applications together and in relation to each other) but where they intend to do so they must give notice of that intention to each appellant and those given notice of each appeal in accordance with this Schedule;
- (c) where in accordance with sub-paragraph (b) the Welsh Ministers consider two or more appeals to which regulation 15(2) applies together and in relation to each other, they may refuse an appeal (notwithstanding the fact that they would if determining the appeal in isolation grant it) where the number of appeals is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the appeal are situated;
- (d) remit an appeal submitted to them to a Local Health Board for re-determination in cases where the information that the applicant is required to provide in accordance with Schedule 2 was incomplete;
- (e) dismiss an appeal if they are of the opinion that the notice of appeal—

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- (i) is not valid because it does not comply with the requirements of this Schedule,
- (ii) does not disclose any reasonable grounds of appeal, or
- (iii) is otherwise vexatious or frivolous.

Oral hearings

2.—(1) The Welsh Ministers may require an oral hearing to be held if they consider that it is necessary to hear oral representations before determining an appeal submitted to them.

(2) If the Welsh Ministers decide to hold an oral hearing, they must—

- (a) appoint one or more persons to hear and to report to them on the appeal,
- (b) give not less than 14 days' notice of the time and place of the hearing to the appellant and to any person sent a copy of the notice of appeal under paragraph 4 or 7,
- (c) advise the appellant who has been given notice of the hearing, and
- (d) advise those notified that they may make oral representations relating to the appeal at the hearing.

(3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.

(4) The person or persons appointed by the Welsh Ministers to hear the appeal may determine the procedure to be followed at the hearing.

(5) The Welsh Ministers are not bound by any recommendations arising from an oral hearing.

PART 2

Appeals against decisions determining controlled localities

Right of appeal to the Welsh Ministers

3.—(1) Where a Local Health Board has decided that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 13(3) (areas that are controlled localities), the applicant may submit a notice of appeal against that decision to the Welsh Ministers.

(2) Where a Local Health Board has determined under regulation 13(2) 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, the persons entitled to submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee,
- (b) the Local Pharmaceutical Committee, and
- (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 3.

(3) Where a Local Health Board has determined that it should or should not postpone the making or termination of arrangements, as mentioned in paragraph 6(b) of Schedule 3, those that may submit a notice of appeal against that determination to the Welsh Ministers are—

- (a) the Local Medical Committee,
 - (b) the Local Pharmaceutical Committee, and
 - (c) any person included in a pharmaceutical list maintained by the Local Health Board, any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established and who were given notice of the determination by the Local Health Board under paragraph 7(1) of Schedule 3.
- (4) A notice of appeal is valid if—
- (a) it is submitted by a person with the right of appeal under sub-paragraph (1), (2) or (3),
 - (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal, and
 - (c) it contains a statement of the grounds of appeal.

Notification of appeals

4.—(1) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(1) send a copy of the notice to the Local Health Board.

(2) The Welsh Ministers must on receipt of a notice of appeal submitted under paragraph 3(2) or 3(3) send a copy of the notice to—

- (a) the Local Health Board, and
- (b) those persons to whom the Local Health Board has given notice of its determination under paragraph 7(1) of Schedule 3.

(3) Those sent a copy of the notice of appeal under sub-paragraphs (1) to (3) must, at the same time, be informed by the Welsh Ministers—

- (a) that they may within 30 days of the date on which the notice of appeal was sent to them, make representations on the appeal in writing to the Welsh Ministers, and
- (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held.

Decision on appeals

5.—(1) The Welsh Ministers must after reaching a decision on an appeal submitted under paragraph 3 give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 4.

(2) The Welsh Ministers—

- (a) must, where they allow an appeal against a decision by a Local Health Board that an application cannot be considered by virtue of regulation 13(3), either—
 - (i) themselves determine the question of whether or not the particular locality is or is part of a controlled locality, or
 - (ii) remit the question to the Local Health Board for determination,
- (b) may, where the Local Health Board, on determining the application, considered the imposition of conditions under paragraph 6 of Schedule 3, themselves consider whether to impose conditions,
- (c) may, where the Local Health Board, on determining the application, has not considered the imposition of conditions under paragraph 6 of Schedule 3 either—
 - (i) themselves consider whether to impose conditions, or
 - (ii) remit the question to the Local Health Board for determination,

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- (d) may, where the Local Health Board, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 26 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients, themselves postpone, for such period as they think fit, the making or termination of such arrangements, or
- (e) must, where the Local Health Board, did not consider the question whether to postpone the making or termination of arrangements under regulation 26 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients, remit the question to the Local Health Board for determination.

PART 3

Appeals against decisions for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

Right of appeal to the Welsh Ministers

6.—(1) For applications to which paragraph 8(1)(a) and (c) of Schedule 3 apply, the persons entitled to submit a notice of appeal against the decision of the Local Health Board to the Welsh Ministers are—

- (a) the applicant;
- (b) any of the following who made representations on the application to the Local Health Board under paragraph 8(3) of Schedule 3—
 - (i) any person included in a pharmaceutical list,
 - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
 - (iii) any provider of local pharmaceutical services under a pilot scheme, and
 - (iv) where the premises specified in an application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.

(2) In the case of an application determined under regulation 22 (applications involving a change of ownership), the persons entitled to submit a notice of appeal to the Welsh Ministers are—

- (a) the applicant, and
- (b) any of the following who were, under paragraph 14(2) of Schedule 3, given notice of the Local Health Board's decision on the application—
 - (i) any person included in a pharmaceutical list,
 - (ii) any person who has been granted preliminary consent for inclusion in a pharmaceutical list,
 - (iii) any provider of local pharmaceutical services under a pilot scheme, and
 - (iv) where the premises specified in the application are in a controlled locality, any person who is a provider of primary medical services or who is included in the dispensing doctor list.

(3) A notice of appeal is valid if—

- (a) it is submitted by a person with the right of appeal under sub-paragraph (1) or (2),

- (b) it is sent to the Welsh Ministers within 30 days of the date on which notice of the decision being appealed was sent by the Local Health Board to the person making the appeal, and
- (c) it contains a statement of the grounds of appeal which do not amount to a challenge to the legality or reasonableness of a pharmaceutical needs assessment, or to the fairness of the process by which the Local Health Board undertook that assessment.

Notification of appeals

7.—(1) The Welsh Ministers must, on receipt of a notice of appeal submitted under paragraph 6(1), send a copy of the notice to—

- (a) the applicant, if the applicant has not submitted the notice of appeal,
- (b) the Local Health Board, and
- (c) those notified of and who made representations on the application under paragraph 8(3) of Schedule 3.

(2) The Welsh Ministers must, on receipt of a notice of appeal submitted under paragraph 6(2), send a copy of the notice to—

- (a) the applicant, if the applicant has not submitted the notice of appeal,
- (b) the Local Health Board, and
- (c) those given notification of the Local Health Board's decision under paragraph 14(2) of Schedule 3.

(3) The persons to whom a copy of the notice of appeal is sent under this paragraph must, at the same time, be informed by the Welsh Ministers—

- (a) that they may, within 30 days of the date on which the notice of appeal was sent to them, make representations on the appeal in writing to the Welsh Ministers,
- (b) of the circumstances in which the Welsh Ministers may require an oral hearing to be held, and
- (c) where the Welsh Ministers intend to consider two or more appeals together and in relation to each other, of that intention.

Decision on appeals

8.—(1) On determining an appeal made under paragraph 6, the Welsh Ministers must either—

- (a) allow the appeal, or
- (b) confirm the decision of the Local Health Board.

(2) In the case where the premises specified in an application that is subject to appeal are in a controlled locality, the Welsh Ministers—

- (a) may, where the Local Health Board, on determining the application, considered whether to impose conditions under paragraph 13 of Schedule 3 or regulation 17(6)(b), themselves consider whether to impose conditions to postpone, for such period as they think fit, the making or termination of such arrangements, or
- (b) must, where the Local Health Board on determining the application has not considered whether to impose conditions under paragraph 13 of Schedule 2 or regulation 17(6)(b) either—
 - (i) themselves consider whether to impose conditions, or
 - (ii) remit the question to the Local Health Board for determination.

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(3) The Welsh Ministers must after reaching a decision on an appeal, including the imposition of conditions under sub-paragraph (2), give written notice of their decision together with the reasons for it to those persons sent a copy of the notice of appeal under paragraph 7.

Effect of decisions by the Welsh Ministers

9. For the purposes of these Regulations, the Welsh Ministers' decision becomes the Local Health Board's decision on the matter (but no further appeal to the Welsh Ministers on that decision is possible, unless the Welsh Ministers' decision is overruled by a court).

SCHEDULE 5

Regulation 12

Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provisions of drugs

PART 1

General

Interpretation

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

Incorporation of provisions

2. Any provisions of the following affecting the rights and obligations of NHS pharmacists who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations,
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services),
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—
 - (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and,
 - (ii) appeals to the Welsh Ministers from decisions of the Local Health Board, and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010⁽³⁶⁾ (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by the NHS pharmacist or where pharmaceutical services are provided by that NHS pharmacist.

(36) S.I. 2010/288 (W. 37).

PART 2

Essential services

Essential services

3. For the purposes of this Schedule, “essential services” means—
- (a) the services described in this Part, and
 - (b) the activities described in this Part to be carried out in connection with those services.

Dispensing services

4. An NHS pharmacist must, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting a prescription for that drug or appliance signed by a prescriber in pursuance of their functions in the health service in Wales, England, Scotland or Northern Ireland.

Dispensing of drugs and appliances

5.—(1) Subject to the following provisions of this Part, where a person presents on a prescription form—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by, and endorsed on its face with the reference “SLS” by a prescriber, or
- (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference “SLS” by a prescriber,

an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the prescriber in the prescription form, provide the drugs so ordered, and such of the appliances so ordered they supply in the normal course of business.

(2) Subject to the following provisions of this Part, where any person—

- (a) presents a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(37), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(38) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a repeatable prescriber,
 - (ii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
 - (iii) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference “SLS” by a repeatable prescriber,

and also presents an associated batch issue, or

- (b) requests the provision of drugs or appliances in accordance with an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iii),

(37) 1971 c. 38. See section 2(1)(a) of that Act which defines “controlled drug” for the purposes of that Act.

(38) S.I. 2001/3998.

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an NHS pharmacist must, with reasonable promptness and in accordance with any directions given by the repeatable prescriber in the repeatable prescription, provide the drugs so ordered, and such of the appliances so ordered as they supply in the normal course of their business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances is to be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the NHS pharmacist has that prescription in their possession, and
- (b) that person presents, or the NHS pharmacist has in their possession, an associated batch issue.

Supply in accordance with a SSP

6.—(1) This sub-paragraph applies where—

- (a) a person requests a drug or appliance from an NHS pharmacist in accordance with a prescription form or repeatable prescription, and
- (b) a SSP has effect in respect of—
 - (i) the requested drug or appliance, or
 - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, the NHS pharmacist must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, the NHS pharmacist may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

- (a) the NHS pharmacist is able to do so with reasonable promptness,
- (b) to do so is in accordance with the SSP, and
- (c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a registered pharmacist who is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where an NHS pharmacist, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

- (a) the registered pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription), and
- (b) if the patient to or for whom the product is provided is on a patient list, and the supply—
 - (i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012 (sale etc. by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or
 - (ii) is of any other type, and the Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists, acting jointly, have issued and

publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS pharmacist must notify the provider of primary medical services on whose patient list the patient is, of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(5) Where—

- (a) sub-paragraph (1) applies,
- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 5(1) and (2) are to be read as requirements to act within a reasonable timescale.

Urgent supply without a prescription

7.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist to provide a drug or appliance.

(2) The NHS pharmacist may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—

- (a) in the case of a request for a drug, the drug is neither—
 - (i) a Scheduled drug, nor
 - (ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, and
- (b) in the case of a request for a drug or an appliance, the prescriber undertakes to—
 - (i) give the NHS pharmacist a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or
 - (ii) give the NHS pharmacist an electronic prescription form or electronic repeatable prescription complying with the ETP service within 72 hours of the request being made.

Preliminary matters before providing ordered drugs or appliances

8.—(1) If the person presenting the prescription form or repeatable prescription, or requesting the provision of drugs or appliances in accordance with a repeatable prescription, asks the NHS pharmacist to do so—

- (a) the NHS pharmacist must give an estimate of the time when the drugs or appliances will be ready, and
- (b) if they are not ready by then, the NHS pharmacist must give a revised estimate of the time when they will be ready (and so on).

(2) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription—

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- (a) the NHS pharmacist must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
 - (i) entitlement to exemption under regulation 8(1) (exemptions) of the Charges Regulations, or
 - (ii) entitlement to remission of such charges under regulation 5 of the Remission of Charges Regulations (remissible NHS charges),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of sub-paragraphs (a) to (f) of regulation 5(2) of the Remission of Charges Regulations, and at the time of the declaration such evidence is already available to the NHS pharmacist, and

- (b) if no satisfactory evidence, as required by paragraph (a), is produced to the NHS pharmacist, the NHS pharmacist must endorse the form on which the declaration is made to that effect.

(3) Sub-paragraph (2) applies to the provision of a drug or appliance in accordance with a SSP as it does to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes, the prescription for product reimbursement purposes, as mentioned in paragraph 6(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).

Providing ordered drugs or appliances

9.—(1) Where an NHS pharmacist is presented with a prescription form or a repeatable prescription, the NHS pharmacist must only provide the drugs or appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and endorsed as described in paragraph 5(1) or (2), and
- (b) in accordance with the order and any directions given by the prescriber on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985⁽³⁹⁾ and the following provisions of this Part.

(2) Drugs or appliances so ordered must be provided either by or under the direct supervision of a registered pharmacist.

(3) Where the pharmacist referred to in sub-paragraph (2) is employed by an NHS pharmacist, the registered pharmacist must not be someone—

- (a) who is disqualified from inclusion in a relevant list, or
- (b) who is suspended from the General Pharmaceutical Council Register.

(4) If the order is for, or a product to be provided in accordance with a SSP is, an appliance of a type requiring measuring and fitting (for example a truss), the NHS pharmacist must make all necessary arrangements—

- (a) for measuring the person named on the prescription form or repeatable prescription for the appliance, and
- (b) for fitting the appliance.

(39) 1985 c. 72.

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(5) If the order is for, or a product to be provided in accordance with a SSP is, a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with the standard or formula specified therein.

(6) If the order—

- (a) is an order for a drug, but
- (b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971 other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001,

and does not prescribe its quantity, strength or dosage, an NHS pharmacist may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care they consider to be appropriate and, subject to sub-paragraph (7), in such quantity as they consider to be appropriate for a course of treatment for a period not exceeding 5 days.

(7) Where an order to which sub-paragraph (6) applies is for—

- (a) an oral contraceptive substance;
- (b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs, or
- (c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, the NHS pharmacist may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by an NHS pharmacist in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

- (a) sterile,
- (b) effervescent or hygroscopic,
- (c) a liquid preparation for addition to bath water,
- (d) a coal tar preparation,
- (e) a viscous preparation, or
- (f) packed at the time of its manufacture in a calendar pack or special container,

the NHS pharmacist must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) In this paragraph, “special container” means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(10) Where a drug is ordered by a prescriber, or is to be provided in accordance with a SSP is, in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a marketing authorisation holder for the drug, the NHS pharmacist must provide the drug in an original pack (or in original packs) of that size which have been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

- (a) it is not possible for the NHS pharmacist to obtain such a pack (or packs) with reasonable promptness in the normal course of business, or

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(b) it is not practicable for the NHS pharmacist to provide such a pack (or packs) in response to the order (for example because of patient needs or the method of administration of the drug).

(11) Except as provided in sub-paragraph (12), an NHS pharmacist must not provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription.

(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, an NHS pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph must apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

(14) An NHS pharmacist must provide any drug which they are required to provide under paragraph 5, or provides under paragraph 6, in a suitable container.

(15) Where an NHS pharmacist provides a drug or appliance under paragraph 6, the NHS pharmacist must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.

Refusal to provide drugs or appliances ordered

10.—(1) An NHS pharmacist may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the NHS pharmacist reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because they reasonably believe the form has been stolen or forged),
- (b) it appears to the NHS pharmacist that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to the NHS pharmacist's clinical judgement,
- (c) the NHS pharmacist or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription, or by any person accompanying that person, or
- (d) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(2) An NHS pharmacist must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) An NHS pharmacist must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
 - (i) the requested drug or appliance, or
 - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description, and
- (b) alternative provision has already taken place in accordance with the SSP.

(4) An NHS pharmacist may refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

- (a) a SSP has effect in respect of—
 - (i) the requested drug or appliance, or
 - (ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description,
- (b) a registered pharmacist is of the opinion, in the exercise of their professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS pharmacist is unable to provide the drug or appliance within a reasonable timescale,

but if the NHS pharmacist does refuse to do so, they must provide the patient or the person requesting the drug or appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

(5) An NHS pharmacist must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the NHS pharmacist has no record of that prescription,
- (b) the NHS pharmacist does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and such batch issue is not presented to them,
- (c) it is not signed by a repeatable prescriber,
- (d) to do so would not be in accordance with any intervals specified in the prescription,
- (e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously,
- (f) the repeatable prescription was signed more than 1 year previously,
- (g) the expiry date on the repeatable prescription has passed, or
- (h) the NHS pharmacist has been informed by the repeatable prescriber that the prescription is no longer required.

(6) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that they make such a request), an NHS pharmacist must only provide the drugs and appliances so ordered if they are satisfied—

- (a) that the patient in respect of whom the prescription was written—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment,
- (b) that the medication regimen of, or manner of utilisation of the appliance by, the patient in respect of whom the prescription was written has not altered in a way which indicates the need or desirability of reviewing the patient's treatment, and
- (c) there have been no changes to the health of the patient in respect of whom the prescription was written which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

11.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist must—

- (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—

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- (i) to enable them to utilise the drugs or appliances appropriately, and
- (ii) to meet the patient's reasonable needs for general information about the drugs or appliances,
- (b) provide appropriate advice to persons to whom they provide drugs or appliances on—
 - (i) the safe keeping of the drugs or appliances, or
 - (ii) returning unwanted drugs or appliances to the pharmacy for safe destruction,
- (c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need,
- (d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
 - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question,
- (e) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when the drug or appliance becomes available,
- (f) keep and maintain records—
 - (i) of drugs and appliances provided, where it is necessary or desirable to do so in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (in particular of clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under paragraph (e),
- (g) undertake appropriate training in respect of repeat prescribing, having regard to any recommendations in respect of such training set out in the Drug Tariff,
- (h) if they take possession of a repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue,
- (i) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied),
- (j) destroy any surplus batch issues relating to drugs or appliances—
 - (i) which are not required, or
 - (ii) where a patient is refused the drugs or appliances pursuant to paragraph 10,
- (k) ensure that where a person is refused drugs or appliances pursuant to paragraph 10(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice,
- (l) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification,
- (m) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 10(4),
- (n) when providing appliances, provide a patient with a written note of the NHS pharmacist's name, address and telephone number, and

- (o) when providing specified appliances, comply with the additional requirements set out in paragraph 12.
- (2) Where, on presentation of a prescription form or repeatable prescription in connection with dispensing services under paragraph 4, an NHS pharmacist is unable (having regard to any relevant SSP) to provide an appliance, or stoma appliance customisation is required and the NHS pharmacist is unable to provide that, the NHS pharmacist must—
 - (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
 - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

Additional requirements in relation to specified appliances

12.—(1) This paragraph sets out the additional requirements referred to in paragraph 11(1)(o) relating to the provision of specified appliances.

(2) An NHS pharmacist who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS pharmacist must offer to deliver the specified appliance to the patient’s home,
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient,
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content, and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS pharmacist must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance, or
- (b) if the NHS pharmacist believes it is appropriate to do so, must—
 - (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.

(4) If the NHS pharmacist is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), the NHS pharmacist must give the patient the contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS pharmacist.

(5) Where an NHS pharmacist provides a telephone care line in respect of the dispensing of any specified appliance, the NHS pharmacist must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line, or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales⁽⁴⁰⁾, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

(40) NHS Direct Wales telephone number 0845 46 47, website address www.nhsdirect.wales.nhs.uk.

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“expert clinical advice” (“*cyngor clinigol arbenigol*”), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

“out of hours periods” (“*cyfnodau y tu allan i oriau*”), in relation to a pharmacy, means the periods outside the periods during which the NHS pharmacist—

- (a) is obliged to provide pharmaceutical services at the pharmacy by virtue of paragraph 22(1) or 26(1), or
- (b) does provide pharmaceutical services at the pharmacy in accordance with a notification under paragraph 22(2).

Disposal service in respect of unwanted drugs

13. An NHS pharmacist must, to the extent paragraph 14 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs provided to the NHS pharmacist for disposal.

Basic procedure in respect of unwanted drugs

14.—(1) Subject to sub-paragraph (2), where a person presents to an NHS pharmacist or any of the NHS pharmacist’s staff any drugs provided for a patient in, and which have been kept in—

- (a) a private household, or
- (b) a residential care home,

the NHS pharmacist must accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) An NHS pharmacist must not be required to accept any drugs for disposal unless the Local Health Board in whose pharmaceutical list the NHS pharmacist is included has made arrangements with the NHS pharmacist for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, the NHS pharmacist must—

- (a) where required to do so by the Local Health Board or by a waste disposal contractor retained by the Local Health Board, separate solid drugs or ampoules, liquids and aerosols from each other,
- (b) store the drugs in containers provided by the Local Health Board, or by a waste disposal contractor retained by the Local Health Board for the purpose of storing drugs of that description, and
- (c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and must co-operate with any suitable arrangements that the Local Health Board has in place for regular collection of the drugs from the NHS pharmacist’s premises by or on behalf of the Local Health Board.

Further activities to be carried out in connection with the disposal of unwanted drugs

15. In connection with the services provided under paragraph 13, an NHS pharmacist must—

- (a) ensure that they and any of their staff, are aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks, and
- (b) ensure that they and any of their staff have readily available and close to any place where waste drugs are stored appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

Promotion of healthy lifestyles

16. An NHS pharmacist must, to the extent paragraphs 17 and 18 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

Prescription linked intervention

17.—(1) Where a person using a pharmacy—

- (a) presents a prescription form or repeatable prescription to an NHS pharmacist, and
- (b) it appears to the NHS pharmacist that the person—
 - (i) has diabetes,
 - (ii) is at risk of coronary heart disease or high blood pressure, or
 - (iii) smokes or is overweight,

the NHS pharmacist must, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

- (a) by the provision of written material (for example leaflets), and
- (b) by referring the person to other sources of information or advice.

(3) An NHS pharmacist must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person who has been given the advice.

Public health campaigns

18. An NHS pharmacist must, at the request of the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, ensure that—

- (a) they, and any of their staff, participate, in the manner reasonably requested by the Local Health Board, in up to six campaigns in each calendar year to promote public health messages to users of the NHS pharmacist's pharmacy, and
- (b) where requested to do so by the Local Health Board, record the number of people that have been provided information as part of one of those campaigns.

Signposting

19. An NHS pharmacist must, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

Service outline in respect of signposting

20.—(1) Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the NHS pharmacist's pharmacy—

- (a) requires advice, treatment or support that the NHS pharmacist cannot provide, but
- (b) another provider, of which the NHS pharmacist is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

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the NHS pharmacist must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, an NHS pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the NHS pharmacist's normal course of business, the NHS pharmacist must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor, or
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS pharmacist.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Support for self-care

21. An NHS pharmacist must, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

Service outline in respect of support for self-care

22.—(1) Where it appears to an NHS pharmacist or their staff, having regard to the need to minimise the inappropriate use of health and social care services, that a person using the NHS pharmacist's pharmacy would benefit from advice from the NHS pharmacist to help the person manage a medical condition (including, in the case of a carer, to help the carer in assisting in the management of another person's medical condition), the NHS pharmacist must provide advice to the person using the pharmacy as regards managing the medical condition, including as appropriate advice—

- (a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines, and
- (b) on changes to the patient's lifestyle.

(2) The NHS pharmacist must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS pharmacist, and
- (b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

Pharmacy opening hours

Pharmacy opening hours: general

23.—(1) An NHS pharmacist must ensure that pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services—

- (a) for not less than 40 hours each week, or
- (b) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist may provide pharmaceutical services at the premises for fewer than 40 hours per week, provided that the NHS pharmacist provides those services at set times and on set days, at the times and on the days so set, or
- (c) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week, at set times and on set days, at the times and on the days so set, or
- (d) if the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, or on appeal the Welsh Ministers, has directed that the NHS pharmacist must provide pharmaceutical services at the premises for more than 40 hours per week—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional hours for which the NHS pharmacist is required to provide pharmaceutical services by virtue of that direction, at the days on which and the times at which the NHS pharmacist is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of pharmaceutical services for a set period, where it has received 3 months' notice of the proposed suspension from the NHS pharmacist.

(2) An NHS pharmacist must notify the Local Health Board in whose pharmaceutical list the NHS pharmacist is included of other hours during which the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services will be open, which are hours in addition to those during which the pharmacy is obliged to open by virtue of sub-paragraph (1) (and which are referred to in these Regulations as “supplementary opening hours”).

(3) At each of the premises from which an NHS pharmacist has undertaken to provide pharmaceutical services, the NHS pharmacist must exhibit—

- (a) a notice specifying the times at which the premises are open for the provision of drugs and appliances, and
- (b) at times when the premises are not open, a notice based on information provided by the Local Health Board, legible from outside the premises, specifying the addresses of other NHS pharmacists included in the pharmaceutical list and the times at which drugs and appliances may be obtained from those addresses.

(4) An NHS pharmacist must, on request, submit a return to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included setting out—

- (a) the times at which pharmaceutical services are provided at each of the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services (including the times at which the NHS pharmacist is providing pharmaceutical services when they are not obliged to do so by virtue of sub-paragraph (1)), and

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(b) the pharmaceutical services which the NHS pharmacist ordinarily provides at each of those premises.

(5) Where an NHS pharmacist changes—

(a) the days on which or the times at which pharmaceutical services are to be provided at premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or

(b) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

the NHS pharmacist must supply the Local Health Board on whose pharmaceutical list the NHS pharmacist is included with a return informing it of the change.

(6) Where an NHS pharmacist has submitted a return under sub-paragraph (4) or (5) in respect of any premises, or where the NHS pharmacist has set out in an application under these Regulations for inclusion in the pharmaceutical list the days on which and the times at which pharmaceutical services will be provided at the premises to which the application relates if the application is granted—

(a) the NHS pharmacist must ensure that pharmaceutical services are provided at the premises to which the return or application relates on the days and at the times set out in the return or application (unless the return or application has been superseded by a return, or a further return, under sub-paragraph (5)), and

(b) the NHS pharmacist must not change—

(i) the days on which or the times at which pharmaceutical services are to be provided at those premises, or

(ii) the pharmaceutical services which the NHS pharmacist is ordinarily to provide at those premises,

as set out in that return or application, for a period of at least 3 months after that return or application was received by the Local Health Board.

(7) Where an NHS pharmacist is prevented by illness or other reasonable cause from complying with their obligations under sub-paragraph (1), they must, where practicable, make arrangements with one or more other NHS pharmacists whose premises are situated in the neighbourhood for the provision of pharmaceutical services during that time.

(8) Where there is a temporary suspension in the provision of pharmaceutical services for a reason beyond the control of the NHS pharmacist, the NHS pharmacist will not be in breach of sub-paragraphs (1), (2) and (3) provided that—

(a) the NHS pharmacist notifies the Local Health Board on whose pharmaceutical list the NHS pharmacist is included of that suspension as soon as practicable, and

(b) the NHS pharmacist uses all reasonable endeavours to resume provision of pharmaceutical services as soon as practicable.

(9) Planned refurbishment of a pharmacy is neither a “reasonable cause” for the purposes of sub-paragraph (7), nor a “reason beyond the control of the NHS pharmacist” for the purposes of sub-paragraph (8).

(10) For the purposes of calculating the number of hours that a pharmacy is open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it must be deemed that the pharmacy was open on that day at the times at which it would ordinarily have been open on that day of the week.

(11) In this Part—

“additional hours” (“*oriau ychwanego!*”) for which an NHS pharmacist is to be required to provide pharmaceutical services are those hours during which the NHS pharmacist would not

be providing pharmaceutical services, were the NHS pharmacist subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d);

“existing direction” (“*cyfarwyddyd presennol*”) means one that has been made in accordance with this Part or one that was in existence on the date that these Regulations come into force.

Matters to be considered when issuing directions in respect of pharmacy opening hours

24.—(1) Where a Local Health Board issues a direction setting any times or days under this Part, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that the pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1) the Local Health Board may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the NHS pharmacist is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS pharmacist may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in the neighbourhood is likely to be adequate to meet the need for such services at times when the NHS pharmacist is not providing pharmaceutical services.

(4) The Local Health Board may only direct that an NHS pharmacist must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that the NHS pharmacist will receive reasonable remuneration in respect of the additional hours for which they are required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as a consequence of regulation 42 in respect of those hours is “reasonable remuneration” for these purposes).

Determination of pharmacy opening hours instigated by the Local Health Board

25.—(1) Where it appears to the Local Health Board in whose pharmaceutical list the NHS pharmacist is included, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the times at which a pharmacy is or will be open for the provision of pharmaceutical services will not, or no longer meet, the needs of—

- (a) people in the neighbourhood, or
- (b) other likely users of that pharmacy,

for pharmaceutical services, it may carry out an assessment as to whether to issue a direction requiring the NHS pharmacist whose pharmacy it is to provide pharmaceutical services at the pharmacy at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1), the Local Health Board must—

- (a) give notice to the NHS pharmacist of any proposed changes to the times at which or the days on which the pharmacy is to be open, and
- (b) allow the NHS pharmacist 30 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5),
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the

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existing direction would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph, or

- (c) either—
 - (i) revoke (without replacing it) any existing direction setting the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 23(1)(a), the pharmacy must be open for not less than 40 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS pharmacist must provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 40 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at that pharmacy.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(6) The Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services at the pharmacy, it must include with the notification a statement in writing of—

- (a) the reasons for the change, and
- (b) the NHS pharmacist's right of appeal under sub-paragraph (7).

(7) An NHS pharmacist may, within 30 days of receiving notification under sub-paragraph (6) appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS pharmacist is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the times at which or the days on which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if they have not appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (6), or

- (b) if they have appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive notification under sub-paragraph (9).

Determination of pharmacy opening hours instigated by the NHS pharmacist

26.—(1) An NHS pharmacist may apply to a Local Health Board on whose pharmaceutical list the NHS pharmacist is included for it to change the days on which or the times at which the NHS pharmacist is obliged to provide pharmaceutical services at the NHS pharmacist's pharmacy in a way that—

- (a) reduces the total number of hours for which the NHS pharmacist is obliged to provide pharmaceutical services each week, or
- (b) keeps the total number of hours the same.

(2) Where an NHS pharmacist makes an application under sub-paragraph (1), as part of that application the NHS pharmacist must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part,
- (b) confirm any existing direction setting the days on which and the times at which the NHS pharmacist must provide pharmaceutical services at the pharmacy provided that the existing direction would meet the requirements of sub-paragraphs (5) and (6), or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the times at which or the days on which the NHS pharmacist must provide pharmaceutical services at the pharmacy, where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 23(1)(a), the pharmacy must be open for not less than 40 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of a pharmacy that is required to be open—

- (a) for more than 40 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS pharmacist is required to provide pharmaceutical services at the pharmacy, and
 - (ii) as regards the additional hours for which the NHS pharmacist is to provide pharmaceutical services, the days on which and the times at which the NHS pharmacist is required to provide those services during those additional hours,

but it must not set out in that direction the days on which or the times at which the NHS pharmacist is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 40 hours each week, it must set out in that direction the days on which and the times at which pharmaceutical services are to be provided at that pharmacy.

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(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring a pharmacy to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring a pharmacy to be open for either more or less than 40 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (4)(c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the NHS pharmacist in writing of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS pharmacist a statement in writing setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part, and
- (b) the NHS pharmacist's right of appeal under sub-paragraph (9).

(9) An NHS pharmacist may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the NHS pharmacist in writing of their determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which an NHS pharmacist is to provide pharmaceutical services at a pharmacy have been changed in accordance with this paragraph, the NHS pharmacist must introduce the changes—

- (a) if they have not appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (8), or
- (b) if they have appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive notification under sub-paragraph (11).

Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

27.—(1) Notwithstanding the provisions of this Schedule, during an emergency requiring the flexible provision of pharmaceutical services, the Local Health Board in whose pharmaceutical list the NHS pharmacist is included may, on application from the NHS pharmacist, permit the NHS pharmacist a temporary change to the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises from which the NHS pharmacist has undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS pharmacist gives at least 24 hours' notice of the change or closure, and
- (b) the reasons given by the NHS pharmacist for the request are, in the opinion of the Local Health Board, adequate reasons.

(2) The Local Health Board need not approve the request in advance of the change or closure, and if it does not do so but decides subsequently that the NHS pharmacist's reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS pharmacist is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to the NHS pharmacist.

PART 4

Clinical governance and complaints

Clinical governance

28.—(1) An NHS pharmacist must, in connection with all the pharmaceutical services that the NHS pharmacist provides, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in an acceptable system of clinical governance.

- (2) A system of clinical governance is “acceptable” if it provides for—
- (a) compliance with the clinical governance components set out in sub-paragraph (3), and
 - (b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.
- (3) The clinical governance components comprise of the following—
- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the NHS pharmacist should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of the NHS pharmacist’s pharmacy,
 - (ii) a requirement that the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy,
 - (iii) a requirement that where the NHS pharmacist publicises the NHS services that are available at or from the NHS pharmacist’s pharmacy (whether the NHS pharmacist is producing their own publicity material or advertising services in material published by another person), the NHS pharmacist does so in a manner which makes clear that those services are funded as part of the health service,
 - (iv) a requirement that the NHS pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS pharmacist intends to take,
 - (v) monitoring arrangements for drugs or appliances owed to patients but which are out of stock,
 - (vi) an approved complaints system (which meets the requirements of this Part),
 - (vii) a requirement that the NHS pharmacist co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
 - (viii) a requirement that the NHS pharmacist co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
 - (ix) monitoring arrangements for compliance with the Equality Act 2010⁽⁴¹⁾,
 - (b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
 - (c) a risk management programme, which includes—

(41) 2010 c. 15.

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- (i) arrangements for ensuring that all stock is handled in an appropriate way,
- (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
- (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
 - (aa) a patient safety incident log, and
 - (bb) a near-miss log,
- (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,
- (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
- (vi) appropriate waste disposal arrangements (in addition to those required under paragraphs 14 and 15) for clinical and confidential waste,
- (vii) a clinical governance lead person for each pharmacy, appointed as such by the NHS pharmacist (or that is the NHS pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,
- (viii) appropriate child protection procedures, and
- (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974(42),
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS pharmacist—
 - (i) in respect of the provision of drugs in accordance with a repeatable prescription,
 - (ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (iii) to people caring for themselves or their families,

and arrangements for ensuring that the NHS pharmacist, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 11(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question,

- (e) a staffing and staff management programme, which includes—
 - (i) arrangements for appropriate induction training for staff, including any locum,
 - (ii) appropriate training for all staff in respect of any role they are asked to perform,
 - (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
 - (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of pharmaceutical, or other NHS, services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
 - (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and

(42) 1974 c. 37.

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- (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum, who, arising out of their employment with the NHS pharmacist—
 - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996⁽⁴³⁾ (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
 - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,
- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised, and
 - (ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

Professional standards

29. An NHS pharmacist must provide pharmaceutical services and exercise any professional judgments in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements

30.—(1) An NHS pharmacist or their staff must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of the person presenting an order for drugs or appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a compliance aid or a home delivery service is not a “gift or reward” for the purposes of sub-paragraph (1).

(3) In the case of the provision of appliances, neither an NHS pharmacist nor any person employed or engaged by that NHS pharmacist must accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 11(2)(b), 12(4) or 20(2)(b), or

(43) 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

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- (b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 11(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness to practice matters as they arise

31.—(1) Subject to paragraph 32, an NHS pharmacist, and where the NHS pharmacist is part of a body corporate each of its directors, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS pharmacist or a director—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,
- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995⁽⁴⁴⁾ (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992⁽⁴⁵⁾ (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them,
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,
- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness grounds,

and if so, the NHS pharmacist must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 32, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,

⁽⁴⁴⁾ 1995 c. 46.

⁽⁴⁵⁾ 1992 c. 5.

- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate,
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse,
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list, or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Local Health Board of bodies corporate

32. Where an NHS pharmacist is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 31 and 35(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 60). When the NHS pharmacist provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS pharmacist is included.

Complaints

33. An NHS pharmacist must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011⁽⁴⁶⁾, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

PART 5

Other terms of service

Directed services

34. An NHS pharmacist with whom a Local Health Board on whose pharmaceutical list the NHS pharmacist is included makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

⁽⁴⁶⁾ S.I. 2011/704 (W. 108), amended by S.I. 2011/1706 (W. 192).

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Information to be supplied

35.—(1) An NHS pharmacist must give notice to the Local Health Board on whose pharmaceutical list the NHS pharmacist is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about them in the pharmaceutical list which they have not otherwise notified in accordance with these Regulations,
- (b) in the case of an NHS pharmacist who is an individual, any change of private address, and
- (c) in the case of an NHS pharmacist that is a body corporate, any change to the address of its registered office.

(2) An NHS pharmacist must give the Local Health Board, if it so requests, the name of any pharmacist employed by them who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS pharmacist that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors and superintendent.

(4) Subject to sub-paragraph (6), if an NHS pharmacist that is a body corporate appoints a director or superintendent that was not listed on the NHS pharmacist's application for inclusion in a pharmaceutical list, the NHS pharmacist must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS pharmacist or the director or superintendent of an NHS pharmacist that is a body corporate must inform the Local Health Board—

- (a) if the NHS pharmacist, or a body corporate of which they are a director or superintendent, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application, and
- (b) if the NHS pharmacist becomes a director or superintendent of a body corporate which is in any of another Local Health Board's NHS performers or providers lists, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS pharmacist is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS pharmacist also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS pharmacist is included, or
- (b) to whom the NHS pharmacist makes an application to be included in its pharmaceutical list,

that requests it.

(7) In this paragraph, "NHS performers or providers list" means—

- (a) a pharmaceutical list, or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

Withdrawal from pharmaceutical lists

36. Where an NHS pharmacist intends to withdraw from the pharmaceutical list, they must notify the Local Health Board of this at least 3 months in advance of that date, unless it is impracticable to do so in which case they must notify the Local Health Board as soon as it is practicable to do so.

Charges for drugs and refunds

37.—(1) Subject to regulations made under section 121 of the 2006 Act (charges for drugs, medicines or appliances, or pharmaceutical services) all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where an NHS pharmacist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the NHS pharmacist, the container and equipment remains the property of the NHS pharmacist.

(3) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents an NHS pharmacist with a valid claim for repayment, the NHS pharmacist must make the repayment.

(4) For the purposes of sub-paragraph (3), a claim for repayment is only valid if it is duly made on Form WP57 0405 within 3 months of the date on which the charge was paid.

Inspections and access to information

38.—(1) An NHS pharmacist must allow persons authorised in writing by the Local Health Board in whose pharmaceutical list the NHS pharmacist is included to enter and inspect the NHS pharmacist's pharmacy at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS pharmacist is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the NHS pharmacist for patient care and treatment, and
 - (ii) the management by the NHS pharmacist of the pharmaceutical services they provide,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given,
- (b) the Local Pharmaceutical Committee for the area where the pharmacy is situated has been invited to be present at the inspection, where this is requested by the NHS pharmacist,
- (c) the person authorised in writing carries written evidence of their authorisation, which they produce on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS pharmacist must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow the Local Health Board or person authorised by it access to any information which the Local Health Board or person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1), or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

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Welsh language

39.—(1) Where an NHS pharmacist provides pharmaceutical services through the medium of Welsh, the NHS pharmacist must notify the Local Health Board on whose pharmaceutical list the NHS pharmacist is included, in writing.

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

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

(4) An NHS pharmacist must encourage the wearing of a badge, provided by the Local Health Board, by those delivering pharmaceutical services who are Welsh speaking, to convey that they are able to speak Welsh.

(5) An NHS pharmacist must encourage those delivering pharmaceutical services to utilise information and/or attend training courses and events provided by the Local Health Board, so that they can develop—

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

(b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.

(6) An NHS pharmacist must encourage those delivering pharmaceutical services to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

SCHEDULE 6

Regulation 12

Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances

Incorporation of provisions

1. Any provisions of the following affecting the rights and obligations of NHS appliance contractors who provide pharmaceutical services form part of the terms of service—

(a) the Regulations;

(b) the Drug Tariff in so far as it lists appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services);

(c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—

(i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and

(ii) appeals to the Welsh Ministers from decisions of the Local Health Board, and

(d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010⁽⁴⁷⁾ (entry and inspection of premises) as relate to the entry and inspection of premises either owned or controlled by, or where pharmaceutical services are provided by, the NHS appliance contractor.

⁽⁴⁷⁾ S.I. 2010/288 (W. 37).

Division of responsibilities between individuals and corporate bodies

2.—(1) To the extent that this Schedule imposes a requirement on an NHS appliance contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

- (a) if the NHS appliance contractor is a registered pharmacist—
 - (i) that registered pharmacist must comply with that requirement, or
 - (ii) if they employ or engage a registered pharmacist in connection with the provision of pharmaceutical services, that registered pharmacist must either comply with that requirement or secure compliance with that requirement by the person whom they employ or engage, and
- (b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by a person whom it employs or engages,

and references in this Schedule to an NHS appliance contractor must be construed accordingly.

(2) Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, breach of that requirement must be deemed to be a breach by the body corporate of its terms of service.

Dispensing services

3. An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances by health care professionals in pursuance of their functions.

Dispensing of appliances

4.—(1) In this paragraph, “signed” includes signature with a prescriber’s advanced electronic signature.

(2) Subject to the provisions of this Schedule, where—

- (a) any person presents a non-electronic prescription form which contains—
 - (i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or
 - (ii) an order for a restricted availability appliance, signed by a prescriber and including the reference “SLS”, “Selected List Scheme” or “Drug Tariff”, or
- (b) an NHS appliance contractor receives an electronic repeatable prescription complying with the ETP service which contains an order of a kind specified in paragraph (a)(i) and (ii) and—
 - (i) any person requests the provision of an appliance in accordance with that prescription, or
 - (ii) the NHS appliance contractor has previously arranged with the patient that they will dispense that prescription on receipt,

an NHS appliance contractor must, with reasonable promptness, provide such of the appliances so ordered as they supply in the normal course of business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for appliances is to be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where—

- (a) the NHS appliance contractor has that prescription in their possession, and
- (b) that person presents, or the NHS appliance contractor has in their possession, an associated batch issue.

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Supply in accordance with a SSP

5.—(1) This sub-paragraph applies where—

- (a) a person requests an appliance from an NHS appliance contractor in accordance with a prescription form or repeatable prescription, and
- (b) a SSP has effect in respect of—
 - (i) the requested appliance, or
 - (ii) appliances of a specified description, and the requested appliance is of that description.

(2) Where sub-paragraph (1) applies, an NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, an NHS appliance contractor may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

- (a) the NHS appliance contractor is able to do so with reasonable promptness,
- (b) to do so is in accordance with the SSP, and
- (c) the NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where an NHS appliance contractor, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

- (a) the NHS appliance contractor must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription), and
- (b) if—
 - (i) the patient to or for whom the product is provided is on a patient list, and
 - (ii) the supply is of a type in relation to which the Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS appliance contractors, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS appliance contractor must notify the provider of primary medical services on whose patient list the patient is, of the supply in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription.

(5) Where—

- (a) sub-paragraph (1) applies,
- (b) an NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
- (c) the NHS appliance contractor is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness, the requirement to act with reasonable promptness in paragraph 4(2) is to be read as a requirement to act within a reasonable timescale.

Urgent supply without a prescription

6.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor to provide an appliance.

(2) The NHS appliance contractor may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

- (a) give the NHS appliance contractor a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made, or
- (b) give the NHS appliance contractor an electronic prescription form complying with the ETP service within 72 hours of the request being made.

Preliminary matters before providing appliances

7.—(1) If the person specified in sub-paragraph (2) asks the NHS appliance contractor to do so—

- (a) the NHS appliance contractor must give an estimate of the time when the appliance will be ready, and
- (b) if it is not ready by then, the NHS appliance contractor must give a revised estimate of the time when it will be ready.

(2) A person specified in this sub-paragraph is a person—

- (a) presenting a non-electronic prescription form or non-electronic repeatable prescription, or
- (b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription—

- (a) the NHS appliance contractor must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3 of the Charges Regulations (supply of drugs and appliances by chemists) by virtue of either—
 - (i) entitlement to exemption under regulation 8 of the Charges Regulations (exemptions), or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations and at the time of the declaration such evidence has already been made available to the NHS appliance contractor,

- (b) if, in the case of a non-electronic prescription form or a non-electronic repeatable prescription no satisfactory evidence, as required by paragraph (a), is produced to the NHS appliance contractor, the NHS appliance contractor must endorse the form on which the declaration is made to that effect, and
- (c) in the case of an electronic prescription form or an electronic repeatable prescription, the NHS appliance contractor must comply with any requirements of the ETP service to provide—
 - (i) a record of the exemption from or remission of charges claimed and whether satisfactory evidence was produced, as referred to in paragraph (a), and

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(ii) in any case where a charge is due, confirmation that the relevant charge was paid.

(4) Sub-paragraph (3) applies to the provision of an appliance in accordance with a SSP as it applies to the provision of an appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes the prescription for product reimbursement purposes, as mentioned in paragraph 5(4)(a), is treated as being the prescription in accordance with which the appliance is provided (even though the supply is not in pursuance of that prescription).

Providing appliances

8.—(1) Where an NHS appliance contractor is presented with a prescription form or a repeatable prescription, the NHS appliance contractor must only provide the appliances so ordered—

- (a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4, and
- (b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985 and the following provisions of this Schedule.

(2) If the order is for, or a product to be provided in accordance with a SSP is, an appliance of a type requiring measuring and fitting by the NHS appliance contractor, the NHS appliance contractor must make all necessary arrangements for—

- (a) measuring the person named on the prescription form or repeatable prescription for the appliance, and
- (b) fitting the appliance.

(3) If the order is for, or a product to be provided in accordance with a SSP is, an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

(4) Where an NHS appliance contractor provides an appliance under paragraph 5, the NHS appliance contractor must include with it in a written note, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.

Refusal to provide appliances ordered

9.—(1) An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

- (a) the NHS appliance contractor reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription,
- (b) it appears to the NHS appliance contractor that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to the clinical judgement of the NHS appliance contractor,
- (c) the NHS appliance contractor or other persons are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with a prescription form or repeatable prescription or by any person accompanying that person, or

- (d) the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or electronic repeatable prescription or any other person accompanying that person, commits or threatens to commit a criminal offence.
- (2) An NHS appliance contractor must refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—
- (a) a SSP has effect in respect of—
 - (i) the requested appliance, or
 - (ii) appliances of a specified description, and the requested appliance is of that description, and
 - (b) alternative provision has already taken place in accordance with the SSP.
- (3) An NHS appliance contractor may refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—
- (a) a SSP has effect in respect of—
 - (i) the requested appliance, or
 - (ii) appliances of a specified description, and the requested appliance is of that description,
 - (b) the NHS appliance contractor is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate, and
 - (c) the NHS appliance contractor is unable to provide the appliance within a reasonable timescale,
but if the NHS appliance contractor does refuse to do so, they must provide the patient or the person requesting the appliance on behalf of the patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.
- (4) An NHS appliance contractor must refuse to provide appliances ordered on a repeatable prescription where—
- (a) they have no record of that prescription,
 - (b) they do not, in the case of a non-electronic repeatable prescription, have any associated batch issue and no such batch issue is presented,
 - (c) it is not signed by a repeatable prescriber,
 - (d) to do so would not be in accordance with any intervals specified in the prescription,
 - (e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously,
 - (f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously,
 - (g) the expiry date on the repeatable prescription has passed, or
 - (h) they have been informed by the repeatable prescriber that the prescription is no longer required.
- (5) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), an NHS appliance contractor must only provide the appliance ordered if satisfied that—
- (a) the patient to whom the prescription relates—
 - (i) is using and is likely to continue to use the appliance appropriately, and

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- (ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment,
- (b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment, and
- (c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

10.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor must—

- (a) ensure that appropriate advice is given to patients about any appliances provided to them—
 - (i) to enable them to utilise the appliances appropriately, and
 - (ii) to meet the patients' reasonable needs for general information about the appliances,
- (b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances,
- (c) when providing appliances to a patient in accordance with a prescription form or repeatable prescription—
 - (i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and
 - (ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question,
- (d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available,
- (e) provide a patient with a written note of the NHS appliance contractor's name, address and telephone number,
- (f) keep and maintain records—
 - (i) of appliances provided, in order to facilitate the continued care of the patient,
 - (ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and
 - (iii) of notes provided under paragraph (d),
- (g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff,
- (h) if the NHS appliance contractor takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue,
- (i) if the NHS appliance contractor provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it may be dispensed,
- (j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied),
- (k) destroy any surplus batch issues relating to appliances—

- (i) which are not required, or
 - (ii) where a patient is refused an appliance pursuant to paragraph 9,
- (l) ensure that where a person is refused appliances pursuant to paragraph 9(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;
 - (m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification,
 - (n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 9(3), and
 - (o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.
- (2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, an NHS appliance contractor is unable to provide an appliance, or stoma appliance customisation is required and the NHS appliance contractor is unable to provide that, the NHS appliance contractor must—
- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist, or
 - (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

Additional requirements in relation to specified appliances

11.—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(o) relating to the provision of specified appliances.

(2) An NHS appliance contractor who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

- (a) the NHS appliance contractor must offer to deliver the specified appliance to the patient's home,
- (b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient,
- (c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content, and
- (d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), the NHS appliance contractor must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

- (a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance, or
- (b) if the NHS appliance contractor believes it is appropriate to do so, must—
 - (i) refer the patient to a prescriber, or
 - (ii) offer the patient an appliance use review service.

(4) If the NHS appliance contractor is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), they must give the patient the contact details of at least

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two people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to the NHS appliance contractor.

(5) Where an NHS appliance contractor provides a telephone care line in respect of the dispensing of any specified appliance, they must ensure that during out of hours periods—

- (a) advice is made available to patients through that telephone care line, or
- (b) the telephone number of NHS Direct Wales, or the website address of NHS Direct Wales, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph—

“expert clinical advice” (“*cyngor clinigol arbenigol*”), in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

“out of hours periods” (“*cyfnodau y tu allan i oriau*”), in relation to each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, means the periods outside the periods during which the NHS appliance contractor is obliged to provide pharmaceutical services by virtue of paragraph 13.

Signposting

12.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within their normal course of business, the NHS appliance contractor must—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist, and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least two people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the NHS appliance contractor.

(2) The NHS appliance contractor must, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record must be in a form that facilitates—

- (a) auditing of the provision of pharmaceutical services by the NHS appliance contractor, and
- (b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Opening hours: general

13.—(1) An NHS appliance contractor must ensure that pharmaceutical services are provided at each of the premises from which they have undertaken to provide pharmaceutical services—

- (a) for not less than 30 hours each week,
- (b) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 5 to the 2013 Regulations), that the NHS appliance contractor may provide pharmaceutical services at the premises for fewer than 30 hours per week, provided that those services are provided at set times and on set days, at the times and on the days so set,
- (c) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed (either under this Schedule or Schedule 5 to the 2013 Regulations), that the NHS appliance contractor must provide

pharmaceutical services at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set, or

- (d) if the Local Health Board in whose pharmaceutical list the NHS appliance contractor is included, or on appeal the Welsh Ministers, have directed under this Schedule that the NHS appliance contractor must provide pharmaceutical services at the premises for more than 30 hours each week—
 - (i) for the total number of hours each week required by virtue of that direction, and
 - (ii) as regards the additional hours for which the NHS appliance contractor is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which the NHS appliance contractor is required to provide pharmaceutical services during those additional hours, as set out in that direction,

but a Local Health Board may, in appropriate circumstances, agree a temporary suspension of pharmaceutical services for a set period, where it has received 3 months' notice of the proposed suspension.

(2) At each of the premises from which an NHS appliance contractor has undertaken to provide pharmaceutical services, an NHS appliance contractor must exhibit a notice specifying the days on which and times at which the premises are open for the provision of appliances.

(3) An NHS appliance contractor must, on request, submit a return to the Local Health Board setting out—

- (a) the days on which and times at which pharmaceutical services are provided at each of the premises from which the NHS appliance contractor has undertaken to provide pharmaceutical services (including times at which they are providing pharmaceutical services when not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as “supplementary opening hours”), and
- (b) the pharmaceutical services which the NHS appliance contractor ordinarily provides at each of those premises.

(4) Where an NHS appliance contractor changes—

- (a) the days on which or times at which pharmaceutical services are to be provided at premises from which they have undertaken to provide pharmaceutical services, or
- (b) the pharmaceutical services which they are ordinarily to provide at those premises,

the NHS appliance contractor must supply the Local Health Board with a return informing it of the change.

(5) Subject to sub-paragraph (6), where an NHS appliance contractor is prevented by illness or other reasonable cause from complying with its obligations under sub-paragraph (1) the NHS appliance contractor must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists or providers of local pharmaceutical services under a pilot scheme whose premises are situated in the neighbourhood for the provision of pharmaceutical services or local pharmaceutical services during that time.

(6) An NHS appliance contractor may make an arrangement with a provider of local pharmaceutical services under a pilot scheme under sub-paragraph (5) only where that provider provides local pharmaceutical services which are of a similar description, and a similar extent to, the pharmaceutical services which the NHS appliance contractor ordinarily provides.

(7) Where there is a temporary suspension in the provision of pharmaceutical services by an NHS appliance contractor for a reason beyond its control, the NHS appliance contractor will not be in breach of sub-paragraphs (1) and (2), provided that the NHS appliance contractor—

- (a) notifies the Local Health Board of that suspension as soon as practicable, and

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(b) uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(8) Planned refurbishment of premises is neither a “reasonable cause” for the purposes of sub-paragraph (5) nor a “reason beyond its control” for the purposes of sub-paragraph (7).

(9) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(10) In this Schedule, the “additional hours” for which an NHS appliance contractor is to be required to provide pharmaceutical services are those hours during which the NHS appliance contractor would not be providing pharmaceutical services, were the NHS appliance contractor subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(d).

(11) Notwithstanding the provisions of paragraphs 14 to 17, during an emergency requiring the flexible provision of pharmaceutical services, a Local Health Board may, on application from an NHS appliance contractor, permit a temporary change to the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at the premises from which they have undertaken to provide pharmaceutical services, or permit temporary closure of those premises, if—

- (a) the NHS appliance contractor gives at least 24 hours’ notice of the change or closure, and
- (b) the reasons given by the NHS appliance contractor for the request are, in the opinion of the Local Health Board, adequate reasons.

(12) The Local Health Board need not approve the request referred to in sub-paragraph (11), in advance of the change or closure, and if it does not do so but decides subsequently that the NHS appliance contractor’s reasons are not, in its opinion, adequate reasons, then the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to the NHS appliance contractor.

Matters to be considered when issuing directions in respect of opening hours

14.—(1) Where a Local Health Board issues a direction setting any days or times under this Schedule, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in the neighbourhood, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the Local Health Board—

- (a) must treat any local pharmaceutical services being provided in that neighbourhood at the days and times in question as if they were pharmaceutical services being so provided, and
- (b) may have regard to any pharmaceutical services that are being provided in that neighbourhood in circumstances where the person providing the pharmaceutical services is not obliged to provide those services.

(3) The Local Health Board may only direct that an NHS appliance contractor may provide pharmaceutical services at premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in the neighbourhood are likely to be adequate to meet the need for such services at times when the NHS appliance contractor is not providing pharmaceutical services.

(4) A Local Health Board may only direct that an NHS appliance contractor must provide pharmaceutical services at premises for more than 30 hours in any week if a Local Health Board is

satisfied that the NHS appliance contractor will receive reasonable remuneration in respect of the additional hours for which they are required to provide pharmaceutical services (and any additional remuneration payable under the Drug Tariff in respect of those hours is “reasonable remuneration” for these purposes).

Determination of opening hours instigated by the Local Health Board

15.—(1) Where it appears to the Local Health Board, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee, that the days on which or times at which premises are or will be open for the supplying of appliances will not, or no longer meet, the needs of—

- (a) people in the neighbourhood, or
- (b) other likely users of the NHS appliance contractor’s premises,

for the supply of appliances, it may carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday, Easter Sunday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the Local Health Board must—

- (a) give notice to the NHS appliance contractor of any proposed changes to the days on which or times at which the premises are to be open, and
- (b) allow the NHS appliance contractor 60 days within which to make written representations to the Local Health Board about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (4) and (5), or
- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, would meet the requirements of sub-paragraphs (4) and (5) if it were issued under this paragraph, or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, or
 - (ii) in a case where there is no existing direction, issue no direction, in which case, by virtue of paragraph 13(1)(a), the premises must be open for not less than 30 hours each week.

(4) Where a Local Health Board issues a direction under sub-paragraph (3) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which they are required to provide those services during those additional hours,

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but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The Local Health Board must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The Local Health Board must notify the NHS appliance contractor in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises, it must include with the notification a statement of—

- (a) the reasons for the change, and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (7).

(7) An NHS appliance contractor may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Welsh Ministers against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services.

(8) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (3).

(9) The Welsh Ministers must notify the NHS appliance contractor in writing of a determination under sub-paragraph (8) and must in every case include with the notification a written statement of the reasons for the determination.

(10) If the days on which or times at which an NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if they have not appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive a notification under sub-paragraph (6), or
- (b) if they have appealed under sub-paragraph (7), not later than 8 weeks after the date on which they receive a notification under sub-paragraph (9).

Determination of opening hours instigated by the NHS appliance contractor

16.—(1) An NHS appliance contractor may apply to a Local Health Board in writing with 90 days' notice for it to change the days on which or times at which the NHS appliance contractor is obliged to provide pharmaceutical services at their premises, in a way that—

- (a) reduces the total number of hours for which the NHS appliance contractor is obliged to provide pharmaceutical services each week, or
- (b) keeps that total number of hours the same.

(2) Where an NHS appliance contractor makes an application under sub-paragraph (1), as part of that application they must provide the Local Health Board with such information as the Local Health Board may reasonably request in respect of any changes to the needs of the people in the neighbourhood, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The Local Health Board must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of the applicant in accordance with sub-paragraph (2)).

(4) In determining the application, the Local Health Board must—

- (a) issue a direction (which will replace any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part,
- (b) confirm any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, provided that the existing direction, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, would meet the requirements of sub-paragraphs (5) and (6), or
- (c) either—
 - (i) revoke (without replacing it) any existing direction in respect of the days on which and the times at which the NHS appliance contractor must provide pharmaceutical services at the premises, whether issued under this Schedule or Schedule 5 to the 2013 Regulations, where this has the effect of granting the application under this paragraph or granting it only in part, or
 - (ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of paragraph 13(1)(a), the premises must be open for not less than 30 hours each week.

(5) Where a Local Health Board issues a direction under sub-paragraph (4) in respect of premises that are to be required to be open—

- (a) for more than 30 hours each week, it must set out in that direction—
 - (i) the total number of hours each week for which the NHS appliance contractor must provide pharmaceutical services at the premises, and
 - (ii) as regards the additional hours for which the NHS appliance contractor is to provide pharmaceutical services, the days on which and the times at which they are required to provide those services during those additional hours,

but it must not set out in that direction the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services during hours which are not additional hours, or

- (b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The Local Health Board must not issue a direction under sub-paragraph (4) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(7) Where the Local Health Board is considering taking action under sub-paragraph (4)(a) or (4)(c)(i), it must consult the Local Pharmaceutical Committee before determining the application.

(8) A Local Health Board must notify the NHS appliance contractor of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send the NHS appliance contractor a statement setting out—

- (a) the reasons for the refusal or, as the case may be, for granting the application only in part, and
- (b) the right of appeal of the NHS appliance contractor under sub-paragraph (9).

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(9) An NHS appliance contractor may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal to the Welsh Ministers against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Welsh Ministers may, when determining an appeal, either confirm the action taken by the Local Health Board or take any action that the Local Health Board could have taken under sub-paragraph (4).

(11) The Welsh Ministers must notify the NHS appliance contractor in writing of its determination and must in every case include with the notification a written statement of the reasons for the determination.

(12) If the days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises have been changed in accordance with this paragraph, the NHS appliance contractor must introduce the changes—

- (a) if they have not appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive a notification under sub-paragraph (4), or
- (b) if they have appealed under sub-paragraph (9), not earlier than 30 days after the date on which they receive a notification under sub-paragraph (11).

Clinical governance

17.—(1) An NHS appliance contractor must, in connection with all the services that they provide, participate, in the manner reasonably required by the Local Health Board on whose pharmaceutical list they are included, in an acceptable system of clinical governance.

(2) A system of clinical governance is “acceptable” if it provides for—

- (a) compliance with the clinical governance components set out in sub-paragraph (3), and
- (b) submission of an annual self-assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.

(3) The clinical governance components comprise of the following—

- (a) a patient and public involvement programme, which includes—
 - (i) a requirement that the NHS appliance contractor should produce in an approved manner, and make available in an appropriate manner, a practice leaflet in respect of each of the premises from which they provide pharmaceutical services,
 - (ii) a requirement that the NHS appliance contractor publicises the NHS services that are available at or from the premises from which the NHS appliance contractor provides such services,
 - (iii) a requirement that where the NHS appliance contractor publicises the NHS services that are available at or from premises from which the NHS appliance contractor provides such services (whether they are producing their own publicity material or advertising services in material published by another person), the NHS appliance contractor does so in a manner which makes clear that those services are funded as part of the health service,
 - (iv) a requirement that the NHS appliance contractor should undertake an approved patient satisfaction survey annually, in an approved manner, including a requirement to publicise the results of the survey and any appropriate action the NHS appliance contractor intends to take,
 - (v) monitoring arrangements for appliances owed to patients but which are out of stock,
 - (vi) an approved complaints system (which meets the requirements of this Part),

- (vii) a requirement that the NHS appliance contractor co-operates appropriately with Local Community Health Council visits and takes appropriate action following the outcome of such visits,
- (viii) a requirement that the NHS appliance contractor co-operates appropriately with any reasonable inspection or review that the Local Health Board or any relevant statutory authority wishes to undertake, and
- (ix) monitoring arrangements for compliance with the Equality Act 2010⁽⁴⁸⁾,
- (b) a clinical audit programme (normally of 5 days), which includes at least one premises-based audit and one multi-disciplinary audit agreed by the Local Health Board in each financial year,
- (c) a risk management programme, which includes—
 - (i) arrangements for ensuring that all stock is handled in an appropriate way,
 - (ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,
 - (iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents, which comprises of—
 - (aa) a patient safety incident log, and
 - (bb) a near-miss log,
 - (iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh Ministers, the Medicines and Healthcare Products Regulatory Agency and the National Health Service Commissioning Board,
 - (v) appropriate standard operating procedures, including standard operating procedures in respect of repeatable prescriptions and providing advice and support to people caring for themselves or their families,
 - (vi) appropriate waste disposal arrangements for clinical and confidential waste,
 - (vii) a clinical governance lead person for each of the premises from which the NHS appliance contractor provides NHS services, who is knowledgeable about both the procedures of the NHS appliance contractor and the other NHS services that are available in the locality,
 - (viii) appropriate child protection procedures, and
 - (ix) monitoring arrangements for compliance with the Health and Safety etc. Act 1974⁽⁴⁹⁾,
- (d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by the NHS appliance contractor—
 - (i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or
 - (ii) to people caring for themselves or their families,and arrangements for ensuring that the NHS appliance contractor, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question,
- (e) a staffing and staff management programme, which includes—

⁽⁴⁸⁾ 2010 c. 15.

⁽⁴⁹⁾ 1974 c. 37.

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- (i) arrangements for appropriate induction training for staff, including any locum,
- (ii) appropriate training for all staff in respect of any role they are asked to perform,
- (iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,
- (iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services including continuing professional development for registered pharmacists and any necessary accreditation in respect of the provision of directed services,
- (v) arrangements for addressing poor performance (in conjunction with the Local Health Board as appropriate), and
- (vi) arrangements (which must include a written policy) for ensuring that all staff, including any locum who, arising out of their employment with the NHS appliance contractor—
 - (aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996⁽⁵⁰⁾ (meaning of “protected disclosure”) have the rights afforded in respect of such disclosures by that Act, and
 - (bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A of that Act, have the right not to be subjected to any detriment or to dismissal as a consequence of that act,
- (f) an information governance programme, which provides for—
 - (i) compliance with approved procedures for information management and security, and
 - (ii) submission of an annual self-assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Local Health Board to access that assessment, and
- (g) a premises standards programme, which includes—
 - (i) a system for maintaining cleanliness at the premises from which the NHS appliance contractor provides NHS services which is designed to ensure, in a proportionate manner, that the risk to people at the premises of healthcare acquired infection is minimised, and
 - (ii) arrangements for there to be a clear separation between the areas of the premises which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.

Professional standards

18. An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

⁽⁵⁰⁾ 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 which extends the meaning of “worker” for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Local Health Board under section 80 of the 2006 Act.

Inducements

19.—(1) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor must give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of them presenting an order for appliances on a prescription form or repeatable prescription.

(2) Promising, offering or providing a home delivery service is not a “gift or reward” for the purposes of sub-paragraph (1).

(3) Neither an NHS appliance contractor nor any person employed or engaged by an NHS appliance contractor may accept or receive any gift or reward in respect of only—

- (a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 11(4) or 12(1)(b), or
- (b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 10(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness to practise matters as they arise

20.—(1) Subject to paragraph 21, an NHS appliance contractor, and where the NHS appliance contractor is a body corporate every director of the body corporate, must, within 7 days of its occurrence, inform the Local Health Board in writing if the NHS appliance contractor or a director—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is bound over following a criminal conviction in the United Kingdom,
- (c) accepts a police caution in the United Kingdom,
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction),
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995⁽⁵¹⁾ (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992⁽⁵²⁾ (penalty as alternative to prosecution),
- (f) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (g) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (h) is notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them,
- (i) becomes the subject of any investigation into their professional conduct by any licensing, regulatory or other body,
- (j) becomes subject to an investigation into their professional conduct in respect of any current or previous employment, or is notified of the outcome of any such investigation and any finding against them,
- (k) becomes the subject of any investigation by the NHS Business Services Authority in relation to fraud,

⁽⁵¹⁾ 1995 c. 46.

⁽⁵²⁾ 1992 c. 5.

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- (l) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to the removal from a relevant list, or
- (m) is removed, contingently removed or suspended from, refused admission to, or conditionally included in, a relevant list on fitness to practise grounds,

and if so, the NHS appliance contractor must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) Subject to paragraph 21, if a person to whom sub-paragraph (1) applies is, or was at the time of the originating events, a director of a body corporate, the person must in addition inform the Local Health Board within 7 days if any such body corporate—

- (a) is convicted of any criminal offence in the United Kingdom,
- (b) is convicted elsewhere of an offence, or what would constitute a criminal offence if committed in England and Wales,
- (c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere with an offence which, if committed in England and Wales, would constitute a criminal offence,
- (d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate,
- (e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body,
- (f) becomes the subject of any investigation in relation to any fraud or is notified of the outcome of such an investigation where it is adverse,
- (g) becomes the subject of any investigation by another Local Health Board or equivalent body, which might lead to its removal from a relevant list, or
- (h) is removed, contingently removed or suspended from, refused admission to, or conditionally included in a relevant list on fitness to practise grounds,

and if so, that person must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) A person to whom sub-paragraph (1) or (2) applies must consent to a request being made by the Local Health Board to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Home Local Health Board of bodies corporate

21. Where an NHS appliance contractor is a body corporate with a registered office in England and Wales, the information to be provided under paragraphs 20 and 24(3) to (6) may be provided instead to a home Local Health Board (as defined in regulation 60). When the NHS appliance contractor provides the information to its home Local Health Board, it must also provide the home Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists the NHS appliance contractor is included.

Complaints

22. An NHS appliance contractor must have in place arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements)

(Wales) Regulations 2011, for the handling and consideration of any concerns or complaints about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

Directed services

23. An NHS appliance contractor with whom a Local Health Board makes an arrangement for the provision of any directed services must comply with the terms and conditions of the arrangement.

Information to be supplied

24.—(1) An NHS appliance contractor must give written notice to the Local Health Board on whose pharmaceutical list the NHS appliance contractor is included within 28 days (or if this is impracticable, as soon as practicable thereafter) of—

- (a) any occurrence requiring a change in the information recorded about the NHS appliance contractor in the pharmaceutical list which the NHS appliance contractor has not otherwise notified to the Local Health Board in accordance with these Regulations,
- (b) in the case of an NHS appliance contractor who is an individual, any change of their private address, and
- (c) in the case of an NHS appliance contractor that is a body corporate, any change to the address of its registered office.

(2) An NHS appliance contractor must give the Local Health Board, if it so requests, the name of any registered pharmacist employed by the NHS appliance contractor who is responsible for dispensing a particular prescription.

(3) Subject to sub-paragraph (6), an NHS appliance contractor that is a body corporate must give notice in writing to the Local Health Board within 28 days (or if this is impractical, as soon as practicable thereafter) of any changes to the names and addresses of its directors.

(4) Subject to sub-paragraph (6), if an NHS appliance contractor that is a body corporate appoints a director or superintendent that was not listed on the NHS appliance contractor's application for inclusion in a pharmaceutical list, the NHS appliance contractor must give notice in writing to the Local Health Board within 28 days (or if this is impracticable, as soon as practicable thereafter) of the fitness to practice information about that person.

(5) Subject to sub-paragraph (6), an NHS appliance contractor or the director or superintendent of an NHS appliance contractor that is a body corporate must inform the Local Health Board—

- (a) if they, or a body corporate of which they are a director or superintendent, applies to be included in any of another Local Health Board's NHS performers or providers lists, and of the outcome of any such application, and
- (b) if they become a director or superintendent of a body corporate which is on any of another Local Health Board's NHS performers or providers list, or which applies to be included in such a list, and the outcome of any such application.

(6) Where an NHS appliance contractor is a body corporate with a registered office in Wales, the information to be provided under sub-paragraphs (3) to (5) may be provided only to the Local Health Board in whose area that registered office is located, if the NHS appliance contractor also provides that Local Health Board with details of all the other Local Health Boards in whose pharmaceutical lists it is included, and in these circumstances that Local Health Board must pass the information on to any other Local Health Board—

- (a) in whose pharmaceutical list the NHS appliance contractor is included, or
- (b) to whom the NHS appliance contractor makes an application to be included in its pharmaceutical list, that requests it.

(7) In this paragraph, "NHS performers or providers list" means—

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- (a) a pharmaceutical list, or
- (b) a list maintained of approved performers or providers of primary medical, dental or ophthalmic services.

Withdrawal from pharmaceutical services

25. Where an NHS appliance contractor intends to withdraw from the pharmaceutical list in respect of particular premises, the NHS appliance contractor must notify the Local Health Board of this at least 3 months in advance of that date unless it is impracticable for the NHS appliance contractor to do so in which case the NHS appliance contractor must notify the Local Health Board as soon as it is practicable to do so.

Charges for appliances

26. Subject to regulations made under section 121 of the 2006 Act, all appliances provided under these terms of service must be provided free of charge.

Inspections and access to information

27.—(1) An NHS appliance contractor must allow persons authorised in writing by the Local Health Board to enter and inspect any premises the NHS appliance contractor uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the NHS appliance contractor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the NHS appliance contractor, in the course of providing pharmaceutical services, for patient care and treatment including any arrangement made with a person in respect of provision of appliances, and
 - (ii) the management by the NHS appliance contractor of the pharmaceutical services they provide, where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given,
- (b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by the NHS appliance contractor,
- (c) the person authorised in writing carries written evidence of their authorisation, which they produce on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) An NHS appliance contractor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow access to any information which the Local Health Board or that person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1), or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

Welsh language

28.—(1) Where an NHS appliance contractor provides pharmaceutical services through the medium of Welsh, the NHS appliance contractor must notify the Local Health Board on whose pharmaceutical list the NHS appliance contractor is included, in writing.

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

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

(4) An NHS appliance contractor must encourage the wearing of a badge, provided by the Local Health Board, by those delivering pharmaceutical services who are Welsh speaking, to convey that they are able to speak Welsh.

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

- (a) an awareness of the Welsh language (including awareness of its history and its role in Welsh culture), and
- (b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.

(6) An NHS appliance contractor must encourage those delivering pharmaceutical services to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

SCHEDULE 7

Regulation 12

Terms of service for doctors providing pharmaceutical services

Interpretation

1. In this Schedule, drugs or appliances are to be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the doctor has that prescription in their possession, and
- (b) that person presents, or the doctor has in their possession, an associated batch issue.

Incorporation of provisions

2. Any provisions of the following affecting the rights and obligations of doctors who provide pharmaceutical services form part of the terms of service—

- (a) the Regulations,
- (b) the Drug Tariff in so far as it lists drugs and appliances for the purposes of section 80 of the 2006 Act (arrangements for pharmaceutical services),
- (c) so much of Part 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992 as relates to—

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- (i) investigations made by the pharmaceutical discipline committee and the joint discipline committee and action which may be taken by the Local Health Board as a result of such investigations, and
- (ii) appeals to the Welsh Ministers from decisions of the Local Health Board, and
- (d) so much of regulation 29 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010⁽⁵³⁾ (entry and inspection of premises) as relate to the entry and inspection of premises either owned by the dispensing doctor or where pharmaceutical services are provided by that dispensing doctor.

Persons duly authorised to dispense on behalf of dispensing doctors

3. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which they have duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement, and
 - (b) that dispensing doctor must secure compliance with that requirement by that other person,
- and references in this Schedule to a dispensing doctor are to be construed accordingly.

Dispensing of drugs and appliances ordered by another prescriber

4.—(1) Subject to the following provisions of this Schedule, where any person presents to a dispensing doctor a prescription form which contains—

- (a) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor,
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances), signed by a prescriber other than the dispensing doctor, and including the reference “SLS”, or
- (c) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor and including the reference “SLS”,

and the dispensing doctor is authorised or required by virtue of regulation 26 (arrangements for the provision of pharmaceutical services by doctors) of these Regulations to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as they supply in the normal course of their practice or business.

(2) Subject to the following provisions of this Schedule, where—

- (a) any person presents to a dispensing doctor a non-electronic repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under those Regulations), signed by a prescriber other than the dispensing doctor who is a repeatable prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the

⁽⁵³⁾ S.I. 2010/288 (W. 37).

Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference “SLS”,

(iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, or

(iv) an order for a restricted availability appliance, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference “SLS”,

and also presents a batch issue, or

(b) the dispensing doctor receives an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—

(i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or

(ii) the dispensing doctor has previously arranged with the patient that they will dispense that repeatable prescription on receipt,

and the dispensing doctor is authorised or required by regulation 26 to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as they supply in the normal course of their practice or business.

(3) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances will be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

(a) the dispensing doctor has that prescription in their possession, and

(b) that person presents, or the dispensing doctor has in their possession, an associated batch issue.

(4) Drugs and listed appliances provided under this paragraph must be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

5. In circumstances where paragraph 4 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of Part 6 of these Regulations to provide drugs or appliances to a person, the dispensing doctor must—

(a) record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with a GMS contract which gives effect to paragraph 39 of Schedule 6 to the GMS Regulations (other contract terms: prescribing),

(b) provide those drugs or appliances in a suitable container,

(c) provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations (restrictions on prescribing by medical practitioners) are satisfied, and

(d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

6. Before providing drugs or listed appliances recorded on a prescription form in accordance with paragraph 4, or in the circumstances set out in paragraph 7—

(a) the dispensing doctor must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations (supply of drugs and appliances by doctors) by virtue of either—

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- (i) entitlement to an exemption under regulation 8(1) of the Charges Regulations (exemptions), or
- (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of remission by virtue of regulation 5(1)(e) or 5(2)(e) or (f) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor already has such evidence available to them, and

- (b) if no satisfactory evidence, as required by sub-paragraph (a) is produced to the dispensing doctor, the dispensing doctor must endorse the form on which the declaration is made to that effect.

Provision of Scheduled drugs

7.—(1) Subject to sub-paragraph (2), a dispensing doctor must not provide for a patient any Scheduled drug, except that, where the dispensing doctor or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, they may provide a drug which has the same specification notwithstanding that it is a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this Schedule prevents a dispensing doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

8.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example, because the dispensing doctor reasonably believes that it has been stolen or forged), or
- (b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber), or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which they are otherwise authorised or required to provide by virtue of regulation 26, where—

- (a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription or repeatable prescription, or by any person accompanying that person, or
- (b) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) A dispensing doctor must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the dispensing doctor has no record of that prescription,
- (b) it is not signed by a repeatable prescriber,
- (c) to do so would not be in accordance with any intervals specified in the prescription,

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- (d) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than 6 months previously,
 - (e) if the repeatable prescription was signed more than 1 year previously,
 - (f) the expiry date on the repeatable prescription has passed, or
 - (g) where the dispensing doctor has been informed by the repeatable prescriber that the prescription is no longer required.
- (4) Where the patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), a dispensing doctor may only provide the drugs or appliances ordered if satisfied—
- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment,
 - (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way that indicates the need or desirability of reviewing the patient's treatment, and
 - (c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Fees and charges

9.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to, the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in relation to prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services or provides any additional service associated with the dispensing of such drugs and appliances—

- (a) in accordance with this Schedule or an agreement with the Local Health Board, and
- (b) had the drug, appliance or additional service been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled by, by virtue of directions given by the Welsh Ministers under section 45 of the 2006 Act (GMS contracts: payments), to a payment—
 - (i) in respect of the drug or appliance, or
 - (ii) in respect of the additional service provision,

the Local Health Board will credit the dispensing doctor with the payment.

Complaints and concerns

10.—(1) Where a dispensing doctor—

- (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraphs 89A and 90 of Schedule 6 to the GMS Regulations (concerns and complaints);
- (b) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;
- (c) is employed or engaged by a Local Health Board for the purposes of providing pharmaceutical services within an LHBMS practice, the complaints procedure established

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by that LHBMS practice to deal with complaints in relation to the provision of primary medical services,

applies in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, a GMS contract which gives effect to paragraph 95 of Schedule 6 to the GMS Regulations (co-operation with investigations) also applies in relation to complaints or concerns notified about such matters.

Inspections and access to information

11.—(1) A dispensing doctor must allow persons authorised by the Local Health Board to enter and inspect any premises that they use for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Schedule;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and
 - (ii) the management by the dispensing doctor of the pharmaceutical services the dispensing doctor provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given,
- (b) the Local Medical Committee for the area in which the premises are situated has been invited to be present at the inspection, where this is requested by the dispensing doctor,
- (c) the person authorised in writing carries written evidence of their authorisation, which must be produced on request, and
- (d) the person authorised in writing does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or that person access to any information which it or that person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1), or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.

Welsh language

12.—(1) Where a dispensing doctor provides pharmaceutical services through the medium of Welsh, the dispensing doctor must notify the Local Health Board in writing.

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

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

(4) Where a dispensing doctor is Welsh speaking, they are encouraged to wear a badge provided by the Local Health Board, to convey that the dispensing doctor is able to speak Welsh.

(5) A dispensing doctor is encouraged to utilise information and/or attend training courses and events provided by the Local Health Board, so that the dispensing doctor can develop—

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

(b) an understanding of how the Welsh language can be used in connection with the pharmaceutical services provided.

(6) When delivering pharmaceutical services, a dispensing doctor is encouraged to establish and record the Welsh or English language preference expressed by or on behalf of a patient.

SCHEDULE 8

Regulation 64

Minor and consequential amendments

The National Health Service (Service Committees and Tribunal) Regulations 1992

1. In regulation 2 of the National Health Service (Service Committees and Tribunal) Regulations 1992⁽⁵⁴⁾ (interpretation)—

(a) in paragraph (1), in the definition of “Pharmaceutical Regulations”, for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”, and

(b) in paragraph (4)(c)⁽⁵⁵⁾, for “paragraph 33 of Schedule 4 to, or paragraph 21 of Schedule 5 to” substitute “paragraph 33 of Schedule 5 to, or paragraph 22 of Schedule 6 to”.

The National Health Service (Indicative Amounts) Regulations 1997

2. In regulation 1(2) of the National Health Service (Indicative Amounts) Regulations 1997 (citation, commencement and interpretation)⁽⁵⁶⁾, in the definition of “Drug Tariff”, for “regulation 41 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

The National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001

3. In regulation 2 (prescribed functions of Health Authorities in Wales) of the National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001⁽⁵⁷⁾, in paragraph (2)(d)⁽⁵⁸⁾, for “regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

⁽⁵⁴⁾ S.I. 1992/664.

⁽⁵⁵⁾ Paragraph (4) was inserted by S.I. 1996/703.

⁽⁵⁶⁾ S.I. 1997/980, amended by S.I. 2007/1112 (W. 117).

⁽⁵⁷⁾ S.I. 2001/1543 (W. 108), amended by S.I. 2007/1112 (W. 117).

⁽⁵⁸⁾ Paragraph (2)(d) was inserted by S.I. 2013/898 (W. 102).

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The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

4.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004⁽⁵⁹⁾ are amended in accordance with this paragraph.

- (2) In regulation 2(1) (interpretation)—
- (a) in the definition of “Drug Tariff”, for “regulation 41” substitute “regulation 55”, and
 - (b) in the definition of “Pharmaceutical Regulations”, for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.
- (3) In Schedule 6 (other contractual terms)—
- (a) in paragraph 47 (provision of dispensing services)—
 - (i) in sub-paragraphs (4)(b) and (9)(a), for “paragraph 6 of Schedule 2, paragraph 13 of Schedule 2 or paragraph 8(3) of Schedule 3 to”, in each place it occurs, substitute “paragraph 6 of Schedule 3, paragraph 13 of Schedule 3 or paragraph 8(3) of Schedule 4 to”, and
 - (ii) in sub-paragraph (9)(b)(ii), for “Part 2 of Schedule 3 to” substitute “Part 2 of Schedule 4 to”,
 - (b) in paragraph 48 (consent to dispense)—
 - (i) in sub-paragraph (2)—
 - (aa) for “regulation 24 of and Part 3 of Schedule 2 to” substitute “regulation 30 of, and Part 3 of Schedule 3 to”, and
 - (bb) for “regulation 24” substitute “regulation 30”,
 - (ii) in sub-paragraph (4), for “regulation 24(9)” substitute “regulation 30(9)”,
 - (iii) for sub-paragraph (5) substitute—

“(5) Regulation 30 of the Pharmaceutical Regulations will apply as if modified as follows: in paragraph (1), for “to provide pharmaceutical services to patients under regulation 26(1)(b) or (c) (arrangements for the provision of pharmaceutical services by doctors)” there were substituted a reference to the provision of dispensing services to patients under paragraph 47.”, and
 - (iv) for sub-paragraph (6) substitute—

“(6) Part 3 of Schedule 3 to the Pharmaceutical Regulations will apply as if modified as follows: in paragraph 8(1)(a)(ii), for “dispensing doctor list made under Part 6 of these Regulations” there were substituted a reference to an application under sub-paragraph (1) of this paragraph.”, and
 - (c) in paragraph 49(8)⁽⁶⁰⁾ (terms relating to the provision of dispensing services), in the words before paragraph (a), for “Schedule 6” substitute “Schedule 7”.

The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

5. In regulation 2(1) of the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007⁽⁶¹⁾, in the definition of “Drug Tariff”, for “regulation 41 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)” substitute “regulation 55 of

⁽⁵⁹⁾ S.I. 2004/478 (W. 48).

⁽⁶⁰⁾ Sub-paragraph (8) was substituted by S.I. 2013/898 (W. 102).

⁽⁶¹⁾ S.I. 2007/121 (W. 11). The definition of “Drug Tariff” was substituted by S.I. 2007/1112 (W. 117) and further amended by S.I. 2013/898 (W. 102).

the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors)”.

The Single Use Carrier Bags Charge (Wales) Regulations 2010

6. In paragraph 1(3) of Schedule 1 to the Single Use Carrier Bags Charge (Wales) Regulations 2010(62), in the definitions of—

- (a) “independent nurse prescriber”,
- (b) “paramedic independent prescriber”,
- (c) “physiotherapist independent prescriber”,
- (d) “podiatrist or chiropodist independent prescriber”, and
- (e) “therapeutic radiographer independent prescriber”,

for “National Health Service (Pharmaceutical Services) (Wales) Regulations 2013” substitute “National Health Service (Pharmaceutical Services) (Wales) Regulations 2020”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and replace the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I. 2013/898) (“the 2013 Regulations”) as the Regulations which, in Wales, govern the provision of pharmaceutical services as part of the National Health Service under Part 7 of the National Health Service (Wales) Act 2006.

Part 1 contains introductory provisions, including setting different dates on which provisions come into force. Parts 1 to 4 and Parts 9 to 11 come into force on 1 October 2020. Parts 5 to 8 come into force on 1 October 2021.

Part 2 sets out the requirements relating to the production of pharmaceutical needs assessments (“PNAs”). A PNA is a statement of the assessment that each Local Health Board must make, at least every 5 years, of the needs in its area for pharmaceutical services provided as part of the National Health Service in Wales. This Part includes the consultation requirements that have to be fulfilled before a PNA is completed and published (regulation 7) and the matters to which a Local Health Board must have regard when producing a PNA (regulation 8) – and Schedule 1 thereafter sets out the information that must be included in PNAs. Pending full revision of a PNA, a Local Health Board may address, in a supplementary statement, changes to the availability of pharmaceutical services since the PNA was published (regulation 6). A Local Health Board is required to publish its PNA and any subsequent PNAs on its website (regulation 9).

Part 3 sets out the requirements for each Local Health Board to prepare and maintain for their area—

- (a) pharmaceutical lists of NHS pharmacists and NHS appliance contractors who undertake to provide pharmaceutical services from premises in the area, and

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- (b) dispensing doctor lists of doctors who undertake to provide pharmaceutical services from premises in the area.

It also sets out the terms of service, which are the terms on which persons are included in a pharmaceutical or dispensing doctor list and on which they undertake to provide pharmaceutical services as part of the National Health Service.

Part 4 makes provision for a Local Health Board itself, or on application from a Local Medical Committee or Local Pharmaceutical Committee, to determine whether or not a particular area within the area for which the Local Health Board is established is, because it is rural in character, a controlled locality or part of a controlled locality. The significance of a locality being determined to be a controlled locality is that, in certain circumstances, doctors can provide pharmaceutical services to certain of their eligible patients (if those doctors are included in a dispensing doctor list). The procedures that a Local Health Board must follow in determining a question as to whether an area is a controlled locality or part of a controlled locality are set out in Schedule 3. Rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 5 sets out the types of applications in respect of inclusion in or amendment to pharmaceutical lists and the tests which a Local Health Board must apply to determine those applications. Under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) and regulation 18 (applications for preliminary consent and effect of preliminary consent) applications can be granted only if the Local Health Board 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 PNA of that Local Health Board. In addition, the general position is that if the premises are situated in a controlled locality, the Local Health Board must be satisfied that to grant the application will not prejudice the proper provision of primary medical, dispensing or pharmaceutical services in any locality (the prejudice test). The exception to the general position is where the premises specified in an application are determined by the Local Health Board to be in a reserved location (under regulation 17 (locations in controlled localities that are reserved locations)).

A person already included in a pharmaceutical list can apply to relocate the premises from which they provide pharmaceutical services. Regulation 19 (applications involving relocation within a Local Health Board's area) sets out when a Local Health Board may grant such an application. Applications that fall within regulation 20 (applications involving relocation between neighbouring Local Health Board areas), regulation 21 (applications involving a temporary relocation) and regulation 22 (applications involving a change of ownership) will be assessed in accordance with the specific criteria set out in the provisions of those regulations. The procedures that a Local Health Board must follow in determining applications under Part 5 are set out in Schedule 3, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 6 sets out the applications which doctors can make in order to be able to fulfil the conditions on which they can then make arrangements with a Local Health Board to provide pharmaceutical services to their eligible patients in controlled localities. Doctors must apply for outline consent and premises approval under regulation 30 (outline consent and premises approval) and Local Health Boards must consider such applications in accordance with the prejudice test and the proximity of the premises from which the doctor wishes to provide pharmaceutical services to nearby pharmacies. A doctor who has been granted outline consent and premises approval may make arrangements with a Local Health Board to provide pharmaceutical services under regulation 26 (arrangements for the provision of pharmaceutical services by doctors). The procedures that a Local Health Board must follow in determining applications under Part 6 are set out in Schedule 3, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 7 deals with fitness grounds and inclusion in and removal from pharmaceutical lists. It provides for the deferral and refusal of applications for inclusion in a pharmaceutical list on fitness grounds (regulations 36 and 37) together with an inclusion in a pharmaceutical list being subject to

conditions (regulation 38). For certain fitness matters, including where a person has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over 6 months, a Local Health Board must remove a person from a pharmaceutical list pursuant to regulation 40 (removal from a pharmaceutical list for other reasons).

Part 8 sets out some conditions that are to be imposed on NHS pharmacists and NHS appliance contractors as part of their terms of service with the Local Health Board, which include requirements relating to co-operation with the Local Health Board over local resolution of disputes (regulation 49). These Part 8 conditions are in addition to the principal terms of service for NHS pharmacists, which are in Schedule 5, and NHS appliance contractors, which are in Schedule 6.

The terms of service in Schedule 5 include obligations to provide what are described as the essential services that must be provided at each pharmacy. These essential services include not only dispensing services but other services, for example disposal services in respect of unwanted drugs and promotion of healthy lifestyles. As well as providing essential services, NHS pharmacists are subject to other compulsory requirements by virtue of Schedule 5, for example with regard to having acceptable systems of clinical governance and providing information about fitness matters. The range of necessary services required of NHS appliance contractors in Schedule 6 is more limited, but also includes requirements with regard to dispensing and additional compulsory requirements with regard to clinical governance and providing information about fitness matters. Both of these types of provider of pharmaceutical services are also subject to detailed requirements with regard to their opening hours and changes to them. Schedules 5 and 6 also set out the NHS terms of service for NHS pharmacists and NHS appliance contractors in relation to Serious Shortage Protocols (SSPs), where when a SSP is in place, the NHS pharmacist or NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP rather than fulfilling the NHS prescription for that product.

Part 9 sets out the arrangements for dealing with breaches of terms of service by NHS pharmacists and NHS appliance contractors (breaches by dispensing doctors are dealt with under their parallel arrangements for providing primary medical services to registered patients, which they must have in order to be providers of pharmaceutical services). Where a dispute between an NHS pharmacist, or an NHS appliance contractor, and the Local Health Board cannot be resolved under the local dispute resolution procedures (or where that procedure may be by-passed), the NHS pharmacist or NHS appliance contractor faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (regulations 50 to 52). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of an NHS pharmacist's or NHS appliance contractor's business premises from the relevant pharmaceutical list (regulation 53).

Part 10 deals with payments to NHS pharmacists and NHS appliance contractors. Regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliances contractors) provides for the publication of the Drug Tariff, the main statement of the financial entitlements of NHS pharmacists and NHS appliances contractors that sets out the determinations on such matters made by the Welsh Ministers as determining authority. Regulation 56 (Local Health Boards as determining authorities) makes provision for the Local Health Boards to be determining authorities where this is set out in the Drug Tariff. There are also provisions for supplemental matters including overpayments and payments to NHS pharmacists and NHS appliance contractors.

Part 11 deals with miscellaneous matters, including transitional provisions for applications and appeals made under the 2013 Regulations before and after these Regulations come into force, as well as setting out the different dates on which provisions within the 2013 Regulations are revoked.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Department for Health and Social Services, Welsh Government, Cathays Park, Cardiff, CF10 3NQ.

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