
STATUTORY INSTRUMENTS

2013 No. 349

**The National Health Service (Pharmaceutical and
Local Pharmaceutical Services) Regulations 2013**

PART 1

Introductory

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and come into force on 1st April 2013.

Interpretation

2.—(1) Subject to paragraph (7), in these Regulations—

“100 hours condition” is to be construed in accordance with regulation 65(1);

“the 1968 Act” means the Medicines Act 1968(1);

“the 1992 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992(2), as in force on 31st March 2005;

“the 2005 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(3), as in force on 31st August 2012;

“the 2006 Act” means the National Health Service Act 2006;

“the 2006 Regulations” means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(4), as in force immediately before the appointed day;

“the 2007 Act” means the Local Government and Public Involvement in Health Act 2007(5);

“the 2012 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2012(6), as in force immediately before the appointed day;

“additional opening hours” is to be construed, as the context requires, in accordance with paragraph 23(13) of Schedule 4 or paragraph 13(12) of Schedule 5, or both;

“advanced electronic signature” means an electronic signature which is—

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under their sole control; and

(1) 1968 c. 67.

(2) 1992/662; these Regulations were revoked by S.I. 2005/641.

(3) 2005/641; these Regulations were revoked by S.I. 2012/1909.

(4) S.I. 2006/552; these Regulations are revoked by Schedule 10.

(5) 2007 c. 28.

(6) S.I. 2012/1909; these Regulations are revoked by Schedule 10.

(d) linked to the date to which it relates in such a manner that any subsequent change of data is detectable;

“advanced services” means the directed services which the NHSCB is required (as opposed to authorised) to arrange by virtue of directions under section 127 of the 2006 Act⁽⁷⁾ (arrangements for additional pharmaceutical services);

“APMS contractor” means a person or partnership that provides primary medical services under contractual arrangements with the NHSCB under section 83(2)(b) of the 2006 Act (primary medical services);

“APMS practice” means an APMS contractor that has a patient list;

“appliance” means an appliance included in a list approved by the Secretary of State for the purposes of section 126 of the 2006 Act⁽⁸⁾ (arrangements for pharmaceutical services);

“appliance contractor premises” means listed chemist premises (or in the context of an applicant seeking the listing of premises, proposed listed chemist premises) of an NHS appliance contractor;

“appliance use review service” means arrangements made in accordance with directions under section 127 of the 2006 Act for a pharmacist or a specialist nurse to review a person’s use of a specified appliance;

“appointed day” means 1st April 2013;

“armed forces of the Crown” means the forces that are “regular forces” or “reserve forces” within the meanings given in section 374 of the Armed Forces Act 2006⁽⁹⁾ (definitions applying for the purposes of whole Act).

“arrangements for recharging” means arrangements under paragraph 3 of Schedule 12A to the 2006 Act⁽¹⁰⁾ (pharmaceutical remuneration – other pharmaceutical remuneration) under which the NHSCB requires a person to reimburse it for any pharmaceutical remuneration to which that paragraph applies;

“bank holiday” means any day that is by virtue of section 1 of or Schedule 1 to the Banking and Financial Dealings Act 1971⁽¹¹⁾ (which relate to bank holidays) a bank holiday in England;

“batch issue” means a form, in the format required by the NHSCB (or a person exercising its functions) and approved by the Secretary of State, which—

- (a) is issued by a prescriber at the same time as a non-electronic repeatable prescription to enable an NHS chemist, an LPS chemist or a dispensing doctor to receive payment for the provision of repeat dispensing services;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is generated by a computer and not signed by a prescriber;
- (d) 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
- (e) has included on it a number denoting its place in the sequence referred to in sub-paragraph (d);

(7) Section 127 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 64.

(8) See section 126(9) of that Act, which provides a definition of “listed” that includes the power for the Secretary of State to approve lists for the purposes of section 126.

(9) 2006 c. 52.

(10) Schedule 12A was inserted by the Health and Social Care Act 2012, Schedule 3.

(11) 1971 c.80.

“best estimate”, in the context of the location of proposed appliance contractor premises or pharmacy premises mentioned in a routine application, is to be construed in accordance with paragraph 1(10) of Schedule 2;

“breach notice” is to be construed in accordance with regulation 71(1);

“CCG” means a clinical commissioning group;

“change of ownership application” means an application pursuant to regulation 26;

“Charges Regulations” means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(12);

“child” means a person who has not attained the age of 16 years;

“chiropracist or podiatrist independent prescriber” means a chiropracist or podiatrist who is registered in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(13) (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropracist or podiatrist is qualified to order drugs and appliances as a chiropracist or podiatrist independent prescriber;

“continuity principles” is to be construed in accordance with paragraph 1(8) of Schedule 9;

“controlled locality” means an area that is a controlled locality by virtue of regulation 36(1) or is determined to be so in accordance with regulation 36(2) or paragraph 7(4) of Schedule 9;

“core opening hours” is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 4 or paragraph 13(2) of Schedule 5, or both;

“directed services” means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act;

“director” includes a member of a limited liability partnership;

“dispensing contractor” means an NHS chemist, an LPS chemist or a dispensing doctor whom or which a patient wishes to dispense their electronic prescriptions;

“dispensing doctor” is to be construed in accordance with regulation 46(1);

“dispensing doctor list” is to be construed in accordance with regulation 46(1);

“distance selling premises” are listed chemist premises, or potential pharmacy premises, at which essential services are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises;

“drugs” includes medicines;

“Drug Tariff” is to be construed in accordance with regulation 89(1);

“electronic communication” has the meaning given in section 15(1) of the Electronic Communications Act 2000(14) (general interpretation);

“electronic prescription” means an electronic prescription form or an electronic repeatable prescription;

“electronic prescription form” means data created in an electronic form for the purpose of ordering a drug or appliance, which—

- (a) is compatible with the systems used by the NHSCB (or a person exercising its functions) for—
 - (i) the remuneration of persons providing pharmaceutical services, and

(12) S.I. 2000/620.

(13) S.I. 2002/254; article 5 has been amended by S.I. 2009/1182. This Order was so renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).

(14) 2000 c.7. The definition of “electronic communication” has been amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

- (b) is signed with a prescriber's advanced electronic signature;
- (c) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service; and
- (d) does not indicate that the drug or appliance ordered may be provided more than once;

“electronic repeatable prescription” means data created in an electronic form, which—

 - (a) is signed with a prescriber's advanced electronic signature;
 - (b) is transmitted as an electronic communication to a nominated dispensing contractor by the Electronic Prescription Service;
 - (c) indicates that the drugs or appliances ordered may be provided more than once; and
 - (d) specifies the number of occasions on which they may be provided;

“employment” includes unpaid employment and employment under a contract for services, and “employed”, “employer” and “employs” are to be construed accordingly;

“enhanced services” means the directed services which the NHSCB is authorised (as opposed to required) to arrange by virtue of directions under section 127 of the 2006 Act;

“essential services”, except in the context of the definition of “distance selling premises”, is to be construed in accordance with paragraph 3 of Schedule 4;

“EPS list” is to be construed in accordance with regulation 10(4)(a);

“Electronic Prescription Service” means the service of that name which is managed by the Information Centre;

“excepted application” means an application to which section 129(2A) of the 2006 Act⁽¹⁵⁾ (regulations as to pharmaceutical services) does not apply by virtue of any provision of Part 4;

“general practitioner” means a medical practitioner who is on a medical performers list;

“GMS contract” means a general medical services contract;

“GMS practice” means a party (which may be a partnership) to a GMS contract other than the NHSCB;

“GMS Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004⁽¹⁶⁾;

“GPhC register” means the register maintained under article 19 of the Pharmacy Order 2010⁽¹⁷⁾ (establishment, maintenance of and access to the register);

“Health Board”, except in the context of “Local Health Board”, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978⁽¹⁸⁾ (Health Boards);

⁽¹⁵⁾ Section 129(2A) was inserted by the Health Act 2009 (c. 21), section 26(3), and has been amended by the Health and Social Care Act 2012 (c. 7), section 207(4), and Schedule 4, paragraph 66(5).

⁽¹⁶⁾ S.I. 2004/291.

⁽¹⁷⁾ S.I. 2010/231.

⁽¹⁸⁾ 1978 c. 29. Section 2 has been amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c.19), section 28, Schedule 9, paragraph 19(1), and Schedule 10; the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(2); the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(2); and the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5), section 2(1).

“health care professional” means a person other than a social worker who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002⁽¹⁹⁾ (the Professional Standards Authority for Health and Social Care);

“Health Education England” means Health Education England established by the Health Education England (Establishment and Constitution) Order 2012⁽²⁰⁾;

“home Primary Care Trust” has the same meaning as in the 2012 Regulations;

“HWB” means a Health and Wellbeing Board⁽²¹⁾;

“independent nurse prescriber” 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;

“Information Centre” means the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012 (the Health and Social Care Information Centre);

“licensing body” means any body anywhere in the world that licenses or regulates any profession;

“listed chemist premises” is to be construed in accordance with regulation 10(3)(a);

“listed dispensing premises” is to be construed in accordance with regulation 46(2)(a);

“Local Healthwatch organisation” is to be construed in accordance with section 222(2A) of the 2007 Act⁽²²⁾ (arrangements under section 221(1));

“LPS chemist” means a party, other than the commissioning body, to—

- (a) an LPS pilot scheme; or
- (b) an LPS scheme for the provision of LP services;

“LPS contractor” means a person who is an LPS chemist by virtue of being a party to an LPS scheme which is not an LPS pilot scheme;

“LPS pilot scheme” means a pilot scheme within the meaning given in section 134(2) of the 2006 Act⁽²³⁾ (pilot schemes);

“LPS scheme”, except in the context of Part 13 or Schedule 7, includes an LPS pilot scheme;

“medical performers list” means a list of medical practitioners prepared, maintained and published under regulations under section 91 of the 2006 Act⁽²⁴⁾ (persons performing primary medical services);

“medical practice premises” means—

- (a) in relation to a provider of primary medical services, premises which are identified in the provider’s arrangements with the NHSCB as the practice premises from which primary medical services are to be provided during core hours to patients on the provider’s patient list; or

⁽¹⁹⁾ Section 25 has been amended by: the Health and Social Care Act 2008 (c. 14), section 113, Schedule 10, paragraph 17, and Schedule 15, Part 2; and by S.I. 2010/231.

⁽²⁰⁾ S.I. 2012/1273.

⁽²¹⁾ See section 194 of the Health and Social Care Act 2012 (c. 7).

⁽²²⁾ Section 222(2A) was inserted by the Health and Social Care Act 2012, section 183(2).

⁽²³⁾ Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8, and by the Health and Social Care Act 2012, Schedule 4, paragraph 71(3).

⁽²⁴⁾ Section 91 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 35.

(b) in relation to a general practitioner on a dispensing doctor list who is not a provider of primary medical services but who performs services on behalf of a provider of primary medical services, the practice premises from which primary medical services are to be provided during core hours to patients on the provider’s patient list;

“member”, in relation to a provider of primary medical services, means—

(a) a member of or partner in the partnership that is the provider; or

(b) a shareholder in the company limited by shares that is the provider,

but no other providers of primary medical services are to be treated as having members;

“national disqualification” includes, in addition to a national disqualification as mentioned in section 159 of the 2006 Act⁽²⁵⁾ (national disqualification)—

(a) a national disqualification as mentioned in section 115 of the National Health Service (Wales) Act 2006 (national disqualification);

(b) any decision in Scotland or Northern Ireland corresponding to a national disqualification as mentioned in section 159 to the 2006 Act; and

(c) any other decision that was a national disqualification for the purposes of the 2012 Regulations;

“neighbouring HWB”, in relation to a HWB (HWB1), means the HWB of an area that borders any part of the area of HWB1;

“NHSCB” means the National Health Service Commissioning Board;

“NHS appliance contractor” means a person included in a pharmaceutical list of the type referred to in regulation 10(2)(b);

“NHS BSA” means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005⁽²⁶⁾;

“NHS chemist” means an NHS appliance contractor or an NHS pharmacist;

“NHS dispute resolution procedure”, in relation to an LPS scheme which is not an LPS pilot scheme, means the dispute resolution procedure set out in paragraphs 22 and 23 of Schedule 7;

“NHS Litigation Authority” means the National Health Service Litigation Authority established by the National Health Service Litigation Authority (Establishment and Constitution) Order 1995⁽²⁷⁾;

“NHS pharmacist” means a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a);

“NHS services” means services provided as part of the health service (so includes services provided as part of the health service in pursuance of the public health functions of the Secretary of State or local authorities);

“nominated dispensing contractor” means an NHS chemist, an LPS chemist or a dispensing doctor who has been nominated in a particular patient’s PDS patient details to dispense the electronic prescriptions of that patient;

“non-electronic prescription form” means a form for ordering a drug or appliance which—

(a) is compatible with the systems used by the NHSCB (or a person exercising its functions) for—

(i) the remuneration of persons providing pharmaceutical services, and

⁽²⁵⁾ Section 159 has been amended by [S.I. 2010/22](#).

⁽²⁶⁾ [S.I. 2005/2414](#).

⁽²⁷⁾ [S.I. 1995/2800](#); amended by [S.I. 2002/2621](#), [2005/503](#) and [1445](#), [2012/1641](#) and [2013/235](#).

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

(b) has been provided for use by a prescriber by—

- (i) the NHSCB,
- (ii) another primary care organisation,
- (iii) a local authority, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,
- (iv) the Secretary of State,
- (v) a CCG, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,
- (vi) an NHS Trust, or
- (vii) an NHS Foundation Trust;

(c) if—

- (i) it has been so provided for use by a prescriber in England, and
- (ii) a prescription charge may be payable in relation to the prescription or a prescription charge exemption in the Charges Regulations may apply to it,

is in a format that has been approved by the Secretary of State;

(d) has been issued by a prescriber; and

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

“non-electronic repeatable prescription” means a repeatable prescription which is not an electronic repeatable prescription;

“non-proprietary name” means a name which is, or which is a permitted variation of—

- (a) an International Nonproprietary Name (INN);
- (b) an International Nonproprietary Name Modified (INNMod);
- (c) a British Approved Name (BAN);
- (d) a British Approved Name Modified (BANMod); 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 in accordance with regulation 318 of the Human Medicines Regulations 2012(28) (lists of names) and which is in force;

“notice” or “notification”, except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and “notify” is to be construed accordingly;

“notice of commencement” means a notice given, or to be given, under paragraph 34(2) of Schedule 2;

“notifiable application” is to be construed in accordance with paragraph 18 of Schedule 2;

“Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001⁽²⁹⁾ (establishment and maintenance of register);

“optometrist independent prescriber” means an optometrist against whose name in the register of optometrists maintained under section 7 of the Opticians Act 1989⁽³⁰⁾ (which relates to the register of optometrists and the register of dispensing opticians) is recorded an annotation signifying that the optometrist is qualified to order drugs and appliances as an optometrist independent prescriber;

“other primary care organisation” or “another primary care organisation” means—

- (a) as regards Wales—
 - (i) a Local Health Board, or
 - (ii) in relation to any time prior to 1st April 2003 a Health Authority;
- (b) as regards Scotland, a Health Board;
- (c) as regards Northern Ireland—
 - (i) the Regional Health and Social Care Board, or
 - (ii) in relation to any time prior to 1st April 2010, a Health and Social Services Board; and
- (d) as regards England in relation to any time prior to 1st April 2013, a Primary Care Trust;

“outline consent”, in the context of—

- (a) an application for outline consent, is to be construed in accordance with regulation 51(1)(a); or
- (b) a subsisting outline consent, means outline consent—
 - (i) granted under these Regulations, or
 - (ii) which was outline consent for the purposes of the 2012 Regulations;

“outstanding pharmacy application” has the meaning given in regulation 53(7);

“patient list” means a list of patients that is a registered patient list for the purposes of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004⁽³¹⁾;

“PDS patient details” means the information held about a patient in the Patient Demographics Service managed by the Information Centre;

“pharmaceutical needs assessment” is to be construed in accordance with regulations 3(1) and 7;

“pharmaceutical needs assessment map” means the map which a HWB includes in its pharmaceutical needs assessment pursuant to paragraph 7 of Schedule 1;

“pharmacist independent prescriber” means a registered pharmacist (P)—

- (a) against whose name in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽³²⁾ (which relate to the registers and the registrar) is recorded an annotation signifying that P is qualified to order drugs and appliances as a pharmacist independent prescriber; and
- (b) who is prescribing under arrangements for the provision of NHS services which are neither—

⁽²⁹⁾ S.I. 2002/253; amended by S.I. 2009/1182.

⁽³⁰⁾ 1989 c.44; amended by S.I. 2005/848.

⁽³¹⁾ S.I. 2004/906. See regulation 2(2) of those Regulations.

⁽³²⁾ S.I. 1976/1213 (N.I. 22).

- (i) pharmaceutical services, unless they are arrangements for the provision of enhanced services, nor
- (ii) local pharmaceutical services, unless they are arrangements for the provision of services that are of the same type as enhanced services;

“pharmacy premises” means listed chemist premises (or in the context of an applicant seeking the listing of premises, proposed listed chemist premises) of an NHS pharmacist;

“pharmacy procedures” are the procedures required by section 72A(3) of the 1968 Act⁽³³⁾ (the responsible pharmacist);

“physiotherapist independent prescriber” means a physiotherapist who is registered in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2001, and against whose name in that register is recorded an annotation signifying that the physiotherapist is qualified to order drugs and appliances as a physiotherapist independent prescriber;

“PMS contractor” means—

- (a) a person with whom arrangements have been made under section 92 of the 2006 Act (which relates to arrangements for the provision of primary medical services), unless that person is in a partnership and the other members of the partnership have also made parallel arrangements under that section;
- (b) a partnership, the members of which have made arrangements in parallel under section 92 of the 2006 Act;

“PMS practice” means a PMS contractor that has, or each of whose members (in the case of a partnership) has, a patient list;

“the PMS Regulations” means the National Health Service (Personal Medical Services Agreements) Regulations 2004⁽³⁴⁾;

“practice amalgamation” is to be construed in accordance with regulation 59(1);

“premises approval”, in the context of—

- (a) an application for premises approval, is to be construed in accordance with regulation 51(1)(b); or
- (b) a subsisting premises approval, means premises approval—
 - (i) granted under these Regulations, or
 - (ii) which was a premises approval for the purposes of the 2012 Regulations;

“prescriber”, unless the context otherwise requires, means a medical practitioner, a dental practitioner, a pharmacist independent prescriber, a supplementary prescriber, a chiropodist or podiatrist independent prescriber, a physiotherapist independent prescriber, an independent nurse prescriber or an optometrist independent prescriber;

“prescription form”, except in the context of the expression “electronic prescription form” or “non-electronic prescription form”, means an electronic prescription form or a non-electronic prescription form;

“Prescription of Drugs Regulations” means the National Health Service (General Medical Services) (Prescription of Drugs etc.) Regulations 2004⁽³⁵⁾;

“prescription only medicine” has the same meaning as in the Human Medicines Regulations 2012⁽³⁶⁾;

⁽³³⁾ Section 72A was inserted by the Health Act 2006 (c. 28), section 30, and has been amended by S.I. 2006/2407.

⁽³⁴⁾ S.I. 2004/627.

⁽³⁵⁾ S.I. 2004/629.

⁽³⁶⁾ See regulation 5(3) of those Regulations.

“product with an appropriate non-proprietary name” means a product with a non-proprietary name which is not mentioned in—

- (a) Schedule 1 to the Prescription of Drugs Regulations (drugs and other substances not to be ordered under a general medical services contract); or
- (b) except where the conditions set out in paragraph 42(2)(a) and (b) of Schedule 6 to the GMS Regulations⁽³⁷⁾ (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations⁽³⁸⁾ (drugs, medicines and other substances that may be ordered only in certain circumstances);

“protected characteristic” means a characteristic listed in section 149(7) of the Equality Act 2010⁽³⁹⁾ (public sector equality duty), and references to people sharing a protected characteristic are to be understood by referral to the provisions of Chapter 1 of Part 2 of that Act (protected characteristics);

“provider of primary medical services” means a GMS practice, a PMS practice or an APMS practice, and “provides” in the context of primary medical services, is to be construed accordingly;

“provisional date” is to be construed in accordance with regulation 53(8)(b);

“Regional Health and Social Care Board” means the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009⁽⁴⁰⁾ (Regional Health and Social Care Board);

“registered pharmacist” means a person who is registered in Part 1 or 4 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

“registered pharmacy technician” means a person registered as a pharmacy technician in Part 2 or 5 of the GPhC register;

“relevant HWB” means—

- (a) in the context of an application for any entry of any type in a pharmaceutical list or dispensing doctor list (including from a person already included in the list), the HWB for the area to which the list relates;
- (b) as regards a person with an entry of any type in a pharmaceutical list or dispensing doctor list, the HWB for the area to which the list relates;
- (c) in the context of an application by a person for dispensing services, the HWB which is, as regards the dispensing doctor from whom the applicant is seeking dispensing services, the relevant HWB (by virtue of sub-paragraph (b)); and
- (d) in the context of a decision to suspend or remove any type of entry of a person in a pharmaceutical list or dispensing doctor list, the HWB for the area to which the list relates;

“relevant list” means—

- (a) a pharmaceutical list or an equivalent list maintained by another primary care organisation; or
- (b) a list maintained by the NHSCB or another primary care organisation of approved performers or providers of primary medical, dental or ophthalmic services;

⁽³⁷⁾ Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.

⁽³⁸⁾ Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.

⁽³⁹⁾ 2010 c. 15.

⁽⁴⁰⁾ 2009 c. 1 (N.I.).

“relevant NHS services” means pharmaceutical services, local pharmaceutical services and primary medical services;

“remedial notice” is to be construed in accordance with regulation 70(1);

“Remission of Charges Regulations” means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(41);

“repeat dispensing services” means pharmaceutical or local pharmaceutical services which involve the provision of drugs or appliances in accordance with a repeatable prescription;

“repeatable prescription” means an electronic repeatable prescription or a form for ordering drugs or appliances which—

(a) is compatible with the systems used by the NHSCB (or a person exercising its functions) for—

- (i) the remuneration of persons providing pharmaceutical services, and
- (ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless the NHS chemist, dispensing doctor or LPS chemist dispensing the prescription is to receive no pharmaceutical remuneration of any kind in respect of any drug or appliance ordered on the form;

(b) has been provided for use by a prescriber by—

- (i) the NHSCB,
- (ii) another primary care organisation,
- (iii) a local authority, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,
- (iv) the Secretary of State,
- (v) a CCG, under arrangements for providing NHS services which include, with the consent of the NHSCB, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,
- (vi) an NHS Trust, or
- (vii) an NHS Foundation Trust;

(c) if—

- (i) it has been so provided for use by a prescriber in England, and
- (ii) a prescription charge may be payable in relation to the prescription or a prescription charge exemption in the Charges Regulations may apply to it,

is in a format that has been approved by the Secretary of State;

(d) has been issued by a prescriber,

(e) indicates that the drugs or appliances ordered may be provided more than once; and

(f) specifies the number of occasions on which they may be provided;

“reserved location” means, unless the context otherwise requires, an area classified as such following a determination (that has not lapsed) under—

(a) regulation 41(2) or 42(1);

- (b) regulation 41(2) or 42(1) of the 2012 Regulations (which related to initial, second and subsequent determinations of reserved location status), whether or not by virtue of paragraph 8 of Schedule 9; or
- (c) regulation 35 of the 2005 Regulations⁽⁴²⁾ (pharmaceutical services in reserved locations), whether or not by virtue of—
 - (i) paragraph 8 of Schedule 9, or
 - (ii) paragraph 6 of Schedule 7 to the 2012 Regulations (transitional provisions – reserved locations);

“restricted availability appliance” means an appliance which is approved for particular categories of person or particular purposes only;

“routine application” is to be construed in accordance with regulation 12;

“the SCAT Regulations” means the National Health Service (Service Committees and Tribunal) Regulations 1992⁽⁴³⁾, as in force on 31st August 2012;

“Scheduled drug” means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations⁽⁴⁴⁾ (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);

“scheme premises” is to be construed in accordance with regulation 102(1)(b);

“specified appliance” 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 drainage wound 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” 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;

“superintendent” has the same meaning as in section 71 of the 1968 Act⁽⁴⁵⁾ (bodies corporate);

“staff” includes locums and other persons engaged on contracts for services who act as staff;

“supplementary opening hours” is to be construed, as the context requires, in accordance with paragraph 23(3) of Schedule 4 or paragraph 13(4)(a) of Schedule 5, or both;

“supplementary prescriber” means—

⁽⁴²⁾ Prior to its revocation, regulation 35 was amended by S.I. 2005/1501.

⁽⁴³⁾ S.I. 1992/664; these Regulations were revoked by S.I. 2012/1909.

⁽⁴⁴⁾ Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.

⁽⁴⁵⁾ Section 71 was substituted by the Health Act 2006 (c. 28), section 28, and has been subsequently amended by S.I. 2007/3101 and 2010/231.

- (a) a registered pharmacist against whose name in Part 1 of the GPhC 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 and appliances as a supplementary prescriber;
- (b) 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⁽⁴⁶⁾ (establishment and maintenance of register) which relates to chiropodists and podiatrists, physiotherapists or radiographers, and
 - (ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs and appliances as a supplementary prescriber; or
- (c) an optometrist against whose name in the register of optometrists maintained under section 7 of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs and appliances as a supplementary prescriber;

“transfer scheme” means a property transfer scheme under section 300 of the Health and Social Care Act 2012 (transfer schemes) that transfers the rights and liabilities of a Primary Care Trust under arrangements for the provision of pharmaceutical or local pharmaceutical services to other persons.

(2) In these Regulations, “pharmaceutical services”, in the context of—

- (a) Part 2 and Schedule 1, means the pharmaceutical services to which a pharmaceutical needs assessment must relate by virtue of regulation 3(2); or
- (b) arrangements made or to be made for the provision of pharmaceutical services by a medical practitioner, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 132(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services),

but otherwise (except in the phrase “local pharmaceutical services”) has the meaning given in section 126(8) of the 2006 Act (arrangements for pharmaceutical services).

(3) Where reference is made in these Regulations to proceedings (but not investigations) reaching their final outcome—

- (a) in relation to any proceedings where there are rights of appeal under these Regulations either to the Secretary of State or the First-tier Tribunal, means the outcome of the proceedings—
 - (i) once the period for bringing an appeal has expired without an appeal being brought, or
 - (ii) if an appeal is brought in accordance with those rights, once the Secretary of State or the First-tier Tribunal has determined the appeal, whether or not the matter is thereafter appealed through the courts; or
- (b) in relation to any other proceedings where there are rights of appeal (but not including appeals through the courts against decisions referred to in sub-paragraph (a)(ii)), means the outcome of the proceedings—
 - (i) once the period for bringing an appeal has expired without an appeal being brought, or
 - (ii) if an appeal is brought in accordance with those rights, once those rights have been exhausted.

⁽⁴⁶⁾ S.I. 2002/254; article 5 has been amended by S.I. 2009/1182. This Order was so renamed by section 213(4) and (6) of the Health and Social Care Act 2012 (c. 7).

(4) Where reference is made in these Regulations to a decision of the NHSCB and that decision is changed on appeal (whether by the Secretary of State, the First-Tier Tribunal or a court), unless the context otherwise requires, the reference to that decision is to be construed as a reference to the decision as changed on appeal.

(5) For the purposes of these Regulations, “emergency requiring the flexible provision of pharmaceutical services” means an emergency declared by means of directions given by the Secretary of State under section 168A of the 2006 Act⁽⁴⁷⁾ (exercise of functions) to the effect that, as a result of threatened or actual serious damage to human welfare caused or which may be caused by the circumstances specified in the directions, the NHSCB must for a specified period—

- (a) exercise, or
- (b) where a discretion is conferred, consider exercising,

one or more of their functions under regulation 29(2), regulation 61, paragraph 27 of Schedule 4, paragraph 17 of Schedule 5 or paragraph 26(3) of Schedule 7, subject to any conditions or limitations set out in the directions.

(6) Where—

- (a) directions of the type mentioned in paragraph (5) are given; and
- (b) the Secretary of State issues further directions changing the specified period of the emergency,

the duration of the emergency is to be construed in accordance with the specified period as so changed.

(7) Where a word or expression used in Schedule 9 has a different meaning in the 2005 Regulations, the 2006 Regulations or the 2012 Regulations from that given in paragraphs (1) to (3), that word or expression bears the meaning that it bears in the 2005 Regulations, the 2006 Regulations or 2012 the Regulations, or is given in paragraphs (1) to (3), as the context requires.

(47) Section 168A was inserted by the Health and Social Care Act 2012 (c. 7), section 49(4).