
STATUTORY INSTRUMENTS

2012 No. 1909

**The National Health Service
(Pharmaceutical Services) Regulations 2012**

PART 1

Introductory

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services) Regulations 2012 and come into force on 1st September 2012.

Interpretation

2.—(1) Subject to paragraph (5), 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 immediately before the appointed day;

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

“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
- (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 for which the Secretary of State determines the remuneration under section 164 of the 2006 Act(4) (remuneration for persons providing pharmaceutical services);

(1) 1968 c. 67.

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

(3) 2005/641; revoked by Schedule 7 to these Regulations.

(4) The amendments made to section 164 by the Health and Social Care Act 2008 (c. 14), section 141, and Schedule 15, Part 4, are not yet fully in force.

“APMS contractor” means a person or partnership that provides primary medical services under contractual arrangements with a Primary Care Trust 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⁽⁵⁾ (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 (arrangements for additional pharmaceutical services) for a pharmacist or a specialist nurse to review a person’s use of a specified appliance;

“appointed day” means 1st September 2012;

“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⁽⁶⁾ (definitions applying for the purposes of whole Act).

“bank holiday” means any day that is by virtue of section 1 of or Schedule 1 to the Banking and Financial Dealings Act 1971⁽⁷⁾ (which relate to bank holidays) a bank holiday in England;

“batch issue” means a form, provided by a Primary Care Trust and in the format required by the NHS BSA, which—

- (a) is issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable an NHS chemist or 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 repeatable 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 subparagraph (d);

“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);

“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⁽⁸⁾;

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

“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);

⁽⁵⁾ 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.

⁽⁶⁾ 2006 c. 52.

⁽⁷⁾ 1971 c.80.

⁽⁸⁾ S.I. 2000/620.

“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;

“dispensing contractor”, except in the context of Schedule 7, means an NHS 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(9) (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 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; and
- (c) 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 repeatable 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;

“emergency requiring the flexible provision of pharmaceutical services” has the meaning given in regulation 29(4);

“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 that are not advanced services;

“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 operated under the auspices of the Informatics Division of the Department of Health;

(9) 2000 c.7. The definition of “electronic communication” has been amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

“excepted application” means an application to which section 129(2A) and (2B) of the 2006 Act⁽¹⁰⁾ (regulations as to pharmaceutical services) do 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 a Primary Care Trust;

“GMS Regulations” means the National Health Service (General Medical Services Contracts) Regulations 2004⁽¹¹⁾, but in the context of Schedule 7 means those Regulations as in force immediately before the appointed day;

“GPhC register” means the register maintained under article 19 of the Pharmacy Order 2010⁽¹²⁾ (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⁽¹³⁾ (Health Boards);

“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⁽¹⁴⁾ (which relates to the Council for Healthcare Regulatory Excellence);

“home Primary Care Trust”, in relation to any body corporate with a registered office in England, means the Primary Care Trust in whose area that office is situated;

“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;

“Independent Prescribing Service” means a directed service commissioned as an Independent Prescribing Service by a Primary Care Trust;

“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 Health Board” means a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006⁽¹⁵⁾ (Local Health Boards);

“LPS chemist” means a party to an LPS scheme other than the commissioning body;

“LPS scheme” includes a pilot scheme within the meaning given in section 134(2) of the 2006 Act⁽¹⁶⁾ (pilot schemes);

(10) Inserted by the Health Act 2009 (c. 21), section 26(3).

(11) S.I. 2004/291.

(12) S.I. 2010/231.

(13) 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).

(14) 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.

(15) 2006 c. 42.

(16) Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8.

“LPS Regulations” means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(17);

“medical performers list” means a list of medical practitioners prepared and published under regulation 3(1) of the National Health Service (Performers Lists) Regulations 2004(18) (performers lists);

“medical practice premises” means—

- (a) in relation to a provider of primary medical services, premises which are identified in the provider’s arrangements with a Primary Care Trust 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
- (b) in relation to a person on a dispensing doctor list who is not a provider of primary medical services—
 - (i) in the case of a general practitioner 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, or
 - (ii) in the case of a general practitioner who performs services on behalf of a PCTMS practice, the practice premises that the Primary Care Trust has nominated as the practice premises for that practice;

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

- (a) a 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(19) (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 2005 Regulations;

“National Health Service Commissioning Board” means, until the end of 30th September 2012, the NHS Commissioning Board Authority established by the NHS Commissioning Board Authority (Establishment and Constitution) Order 2011(20);

“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(21);

“NHS Care Record” means the component of the EPS which is accessed for the purposes of nominating an NHS chemist or dispensing doctor to dispense electronic prescriptions;

(17) [S.I. 2006/552](#).

(18) [S.I. 2004/585](#); regulation 3 has been amended by [S.I. 2008/1187](#).

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

(20) [S.I. 2011/2237](#).

(21) [S.I. 2005/2414](#).

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

“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;

“nominated dispensing contractor” means an NHS chemist or dispensing doctor who has been nominated in the NHS Care Record to dispense the electronic prescriptions of a particular patient;

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

- (a) provided by a Health Board, the Regional Health and Social Care Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust for use by a prescriber;
- (b) issued by a prescriber; and
- (c) does not indicate that the drug or appliance ordered may be provided more than once;

“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 (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⁽²²⁾ and which has not been superseded;

“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⁽²³⁾ (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⁽²⁴⁾ (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; and

⁽²²⁾ The British Pharmacopoeia Commission was originally established by [S.I. 1970/1256](#) and is at 151 Buckingham Palace Road, London SW1 9SZ.

⁽²³⁾ [S.I. 2002/253](#); amended by [S.I. 2009/1182](#).

⁽²⁴⁾ [1989 c.44](#); amended by [S.I. 2005/848](#).

- (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;
- “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 2005 Regulations;
- “outstanding pharmacy application” has the meaning given in regulation 53(8);
- “partner PCT” has the meaning given in section 116(9) of the Local Government and Public Involvement in Health Act 2007⁽²⁵⁾ (health and social care: joint strategic needs assessments);
- “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⁽²⁶⁾;
- “PCTMS practice” means a medical practice established by a Primary Care Trust in order to provide primary medical services under section 83(2)(a) of the 2006 Act;
- “pharmaceutical needs assessment” is to be construed in accordance with regulation 3(1);
- “pharmaceutical needs assessment map” means the map which a Primary Care Trust 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⁽²⁷⁾ (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—
 - (i) is an NHS pharmacist with whom, or is employed or engaged by an NHS pharmacist with which, a Primary Care Trust has made an arrangement for the provision of an Independent Prescribing Service,
 - (ii) is (where it is possible to be) or who is employed or engaged by, an APMS contractor, a GMS contractor, an LPS chemist or a PMS contractor, and in the course of being so P provides services under arrangements that have been made with a Primary Care Trust that are equivalent to those provided under an Independent Prescribing Service, or
 - (iii) is employed or engaged by a Primary Care Trust, an NHS trust or NHS foundation trust to perform NHS services and is prescribing in that capacity;
- “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⁽²⁸⁾ (the responsible pharmacist);
- “PMS contractor” means—

⁽²⁵⁾ 2007 c.28.

⁽²⁶⁾ S.I. 2004/906. See regulation 2(2) of those Regulations.

⁽²⁷⁾ S.I. 1976/1213 (N.I. 22).

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

- (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 National Health Service (Personal Medical Services Agreements) Regulations 2004(29), but in the context of Schedule 7 means those Regulations as in force immediately before the appointed day;

“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 2005 Regulations;

“prescriber”, unless the context otherwise requires, means a medical practitioner, a dental practitioner, a pharmacist independent prescriber, a supplementary 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(30);

“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(31) (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations(32) (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(33) (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;

(29) S.I. 2004/627.

(30) S.I. 2004/629.

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

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

(33) 2010 c. 15.

“provisional date” is to be construed in accordance with regulation 53(9)(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⁽³⁴⁾ (Regional Health and Social Care Board);

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

“relevant list” means—

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

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

“relevant local authority”, in relation to a Primary Care Trust, means a local authority whose area falls wholly or partly in the area of the Primary Care Trust;

“relevant local involvement network” means a person who in pursuance of arrangements made by a relevant local authority under section 221(1) of the Local Government and Public Involvement in Health Act 2007 (health services and social services: local involvement networks) is to carry on activities specified in section 221(2) of that Act;

“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⁽³⁵⁾;

“repeatable prescriber” means—

- (a) a pharmacist independent prescriber who is issuing or creating repeatable prescriptions as part of an arrangement with a Primary Care Trust for the provision of an Independent Prescribing Service;
- (b) a pharmacist independent prescriber who—
 - (i) is, or who is employed or engaged by, an LPS chemist, and
 - (ii) is issuing repeatable prescriptions as part of an arrangement with a Primary Care Trust under which services are provided that are equivalent to those provided under an Independent Prescribing Service; or
- (c) a prescriber—
 - (i) who is (where it is possible for them to be so), or who is employed or engaged by, a provider of primary medical services or a PMS practice, and
 - (ii) who is issuing repeatable prescriptions under arrangements for the provision of repeatable prescribing services that are part of the practice’s or the provider’s GMS contract, section 92 arrangements or arrangements under section 83(2) of the 2006 Act;

“repeatable prescription” means—

- (a) a form for ordering drugs or appliances which is—

⁽³⁴⁾ 2009 c. 1 (N.I.).

⁽³⁵⁾ S.I. 2003/2382.

- (i) provided by a Health Board, the Regional Health and Social Care Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust for use by a prescriber,
 - (ii) issued by a prescriber,
 - (iii) indicates that the drugs or appliances ordered may be provided more than once, and
 - (iv) specifies the number of occasions on which they may be provided; or
- (b) an electronic repeatable prescription;

“reserved location” means, except in the context of making a determination that an area is a reserved location under these Regulations, an area determined as such under—

- (a) regulation 41(2) or 42(1); or
- (b) regulation 35 of the 2005 Regulations⁽³⁶⁾ (pharmaceutical services in 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⁽³⁷⁾, as in force immediately before the appointed day;

“Scheduled drug” means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations⁽³⁸⁾ (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);

“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⁽³⁹⁾ (bodies corporate);

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

⁽³⁶⁾ Prior to its repeal, regulation 35 was amended by [S.I. 2005/1501](#).

⁽³⁷⁾ [S.I. 1992/664](#). These Regulations, together with the amendments to them, are revoked by paragraph 1 of Schedule 8.

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

⁽³⁹⁾ 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](#).

“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—

- (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⁽⁴⁰⁾ (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.
- (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 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.

⁽⁴⁰⁾ 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).

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(4) Where reference is made in these Regulations to a decision of a Primary Care Trust 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) Where a word or expression used in Schedule 7 has a different meaning in the 2005 Regulations from that given in paragraphs (1) to (3), that word or expression bears the meaning that it bears in the 2005 Regulations, or is given in paragraphs (1) to (3), as the context requires.