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 [M1];

"the 1992 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992 [M2], as in force on 31st March 2005;

"the 2005 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005 [M3], 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 [M4], as in force immediately before the appointed day;

"the 2007 Act" means the Local Government and Public Involvement in Health Act 2007 [M5];

"the 2012 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2012 [M6], 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;

[[F1]"advanced electronic signature" 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;**]**

"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 [M7] (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 [M8] (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 [M9] (definitions applying for the purposes of whole Act).

"arrangements for recharging" means arrangements under paragraph 3 of Schedule 12A to the 2006 Act [M10] (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 [M11] (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);

"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);

[F2]...

"change of ownership application" means an application pursuant to regulation 26;

[F3"Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2015;**]**

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

"chiropodist or podiatrist independent prescriber" means a chiropodist or podiatrist who is registered in Part 2 of the register maintained under article 5 of the **[**F4Health Professions Order 2001**]** (establishment and maintenance of register), and against whose name in that register is recorded an annotation signifying that the chiropodist or podiatrist is qualified to order drugs and appliances as a chiropodist or podiatrist independent prescriber;

[F5"consolidation application" means an application pursuant to regulation 26A(1);**]**

"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;

[F6"coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020 (meaning of "coronavirus" and related terminology);**]**

"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 [M12] (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

(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 **[**F7or via an information hub**]** 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 **[**F8or via an information hub**]** 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;

[F9"electronic signature" 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;**]**

"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;

[F10"EPS token" means a form (which may be an electronic form), approved by the Secretary of State, which—

(a) is issued by a prescriber at the same time as an electronic prescription is created; and

(b) has a barcode that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispensing contractor;**]**

"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 **[**F11NHS England**]**;

"excepted application" means an application to which section 129(2A) of the 2006 Act M13 (regulations as to pharmaceutical services) does not apply by virtue of any provision of Part 4 **[**F12or a consolidation application to which regulation 26A(2) does not apply**]**;

[F13"financial year" means the 12 months ending with 31st March;**]**

"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;

[F14"GMS Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2015;**]**

"GPhC register" means the register maintained under article 19 of the Pharmacy Order 2010 M14 (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 M15 (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 [M16] (the Professional Standards Authority for Health and Social Care);

[F15]...

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

"HWB" means a Health and Wellbeing Board [M17];

"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;

[F16]...

[[F17]"integrated care board" means an integrated care board established under Chapter A3 of Part 2 of the National Health Service Act 2006;**]**

"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);

[[F18]"listed HRT prescription item" is to be construed in accordance with regulation 17A(1)(a) of the Charges Regulations (HRT only pre-payment certificates), read with regulation 17A(7) of those Regulations;**]**

[[F19]"listed prescription items voucher" means a form which—

(a) is provided or approved by the NHSCB for the purposes of ordering a prescription item mentioned in regulation 13(1) of the Charges Regulations (exemption from charges: risks to public health); and

(b) may be an electronic form sent or to be sent via a secure service approved for this purpose by the NHSCB;**]**

[[F19]"LPIV" means a listed prescription items voucher;**]**

"Local Healthwatch organisation" is to be construed in accordance with section 222(2A) of the 2007 Act [M18] (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 [M19] (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 [M20] (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

(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 [M21] (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 [M22];

"NHS chemist" means an NHS appliance contractor or an NHS pharmacist;

[F16]...

[[F20]"NHS England directory of services" means the directory of services, maintained by NHS England, which is accessed by NHS urgent and emergency care services if a patient is in need of urgent assistance from a health care professional or urgent access to health care advice;**]**

"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 [M23];

[[F13]"NHSmail" means the secure e-mail service of that name for the sharing of patient identifiable and patient sensitive information, for which **[**[F21]NHS England**]** is responsible;**]**

"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

(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) **[**[F22]an integrated care board**]**, 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 (INNM);

(c) a British Approved Name (BAN);

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

(e) an approved name,

and for this purpose these names (and their permitted variations) have the same meanings as in a list of names which has been prepared and caused to be published in accordance with regulation 318 of the Human Medicines Regulations 2012 [M24] (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 [M25] (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 [M26] (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);

[[F23]"paramedic independent prescriber" means a person—

(a) who is registered in Part 8 of the register maintained under article 5 of the **[**[F24]Health Professions Order 2001**]**; and

(b) against whose name in that register is recorded an annotation signifying that that person is qualified to order drugs, medicines or appliances as a paramedic independent prescriber;**]**

"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 [M27];

"PDS patient details" means the information held about a patient in the Patient Demographics Service managed by **[**[F21]NHS England**]**;

"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 [M28] (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—

(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 [M29] (the responsible pharmacist);

"physiotherapist independent prescriber" means a physiotherapist who is registered in Part 9 of the register maintained under article 5 of the **[**[F25]Health 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;

[[F26]"PMS Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2015;**]**

"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 **[**[F27], an optometrist independent prescriber**[**[F28], a paramedic independent prescriber**]** or a therapeutic radiographer 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;

[F29"prescription item" means an item available on prescription, whether or not it is supplied in pursuance of a prescription or another basis for supply (for example a serious shortage protocol or a patient group direction);**]**

"Prescription of Drugs Regulations" means the National Health Service (General Medical Services) (Prescription of Drugs etc.) Regulations 2004 M30;

"prescription only medicine" has the same meaning as in the Human Medicines Regulations 2012 M31;

"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 M32 (other contractual terms – restrictions on prescribing by medical practitioners) are satisfied, in Schedule 2 of the Prescription of Drugs Regulations M33 (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 M34 (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);

[F30"PTP" means a pandemic treatment protocol, which is a protocol—

(a) relating to the supply of a prescription only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic; and

(b) approved in accordance with regulation 247 of the Human Medicines Regulations 2012 (exemption for supply in the event or anticipation of pandemic disease);**]**

[F29"PTPGD" means a pandemic treatment patient group direction, which is a patient group direction—

(a) relating to the supply of a prescription only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic; and

(b) which is in accordance with regulation 233 of the Human Medicines Regulations 2012 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business);**]**

"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 M35 (Regional Health and Social Care Board);

"registered pharmacist" means a person who is registered in Part 1 F31... 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 [F32]... 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;

"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 [M36];

"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) **[**F22an integrated care board**]**, 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 M37 (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 M38, as in force on 31st August 2012;

"Scheduled drug" means a drug specified in Schedule 1 or 2 to the Prescription of Drugs Regulations M39 (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);

[F33"serious shortage protocol" 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 (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 Secretary of State in circumstances where England or any part of England is, in the opinion of the Secretary of State, 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 a provider of 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 England (which may be all of England) in which, the protocol is to have effect;**]**

[F34"signatory" means a natural person who creates an electronic signature;**]**

"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;

[F33"SSP" means a serious shortage protocol;**]**

"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 M40 (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—

(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 **[**F35Health Professions Order 2001**]** (establishment and maintenance of register) which relates to chiropodists and podiatrists, **[**F36dietitians,**]** 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;

[[F37]"therapeutic radiographer independent prescriber" means a radiographer—

(a) who is registered in Part 11 of the register maintained under article 5 of the **[**[F38]Health Professions Order 2001**]**; and

(b) against whose name in that register is recorded—

(i) an entitlement to use the title "therapeutic radiographer", and

(ii) an annotation signifying that the radiographer is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent 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.

(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 [M41] (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.

[[F39](8) In these Regulations, where reference is made to an announcement or advice of the NHSCB that relates to a disease being, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially serious risk to human health,

it is to that announcement or advice, which may be withdrawn at any time, as amended from time to time.**]**

F1 Words in reg. 2(1) substituted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 9(a)**

F2 Words in reg. 2(1) omitted (1.7.2022) by virtue of The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **62(2)(a)**

F3 Words in reg. 2(1) substituted (1.4.2015) by The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570), reg. 1, **Sch. 2 para. 5(2)**

F4 Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 31(a)**; S.I. 2019/1436, reg. 2(b)

F5 Words in reg. 2(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **2(a)**

F6 Words in reg. 2(1) inserted (1.10.2022) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022 (S.I. 2022/930), regs. 1(2), **3**

F7 Words in reg. 2(1) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **2(4)**

F8 Words in reg. 2(1) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **2(5)**

F9 Words in reg. 2(1) inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 9(b)**

F10 Words in reg. 2(1) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **2(2)**

F11 Words in reg. 2(1) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 47(2)(a)** (with reg. 3)

F12 Words in reg. 2(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **2(b)**

F13 Words in reg. 2(1) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **2(a)**

F14 Words in reg. 2(1) substituted (7.12.2015) by The National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862), reg. 1(2), **Sch. 4 para. 8** (with reg. 2)

F15 Words in reg. 2(1) omitted (1.4.2023) by virtue of The Health Education England (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/368), reg. 1(2), **Sch. 2 para. 14(2)** (with reg. 7)

F16 Words in reg. 2(1) omitted (1.2.2023) by virtue of The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 47(2)(b)** (with reg. 3)

F17 Words in reg. 2(1) inserted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **62(2)(b)**

F18 Words in reg. 2(1) inserted (1.4.2023) by The National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023 (S.I. 2023/171), regs. 1(1), **2**

F19 Words in reg. 2 inserted (21.12.2021) by The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021 (S.I. 2021/1346), regs. 1(2)(a), **2(2)**

F20 Words in reg. 2(1) inserted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 47(2)(c)** (with reg. 3)

F21 Words in reg. 2(1) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 47(2)(d)** (with reg. 3)

F22 Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), **Sch. para. 1**

F23 Words in reg. 2(1) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **2(3)**

F24 Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 31(b)**; S.I. 2019/1436, reg. 2(b)

F25 Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 31(c)**; S.I. 2019/1436, reg. 2(b)

F26 Words in reg. 2(1) substituted (7.12.2015) by The National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879), reg. 1(2), **Sch. 3 para. 4** (with regs. 2, 88)

F27 Words in reg. 2(1) substituted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **21(a)**

F28 Words in reg. 2(1) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **2(6)**

F29 Words in reg. 2(1) inserted (1.3.2021) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021 (S.I. 2021/169), regs. 1(2), **2**

F30 Words in reg. 2(1) inserted (9.11.2020) by The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (S.I. 2020/1126), regs. 1(2), **2(b)**

F31 Words in reg. 2(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2**

para. 43(a) (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in reg. 2(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 43(b)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in reg. 2(1) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **2(2)**

F34 Words in reg. 2(1) inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 9(c)**

F35 Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 31(d)**; S.I. 2019/1436, reg. 2(b)

F36 Word in reg. 2(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **21(b)**

F37 Words in reg. 2(1) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **21(c)**

F38 Words in reg. 2(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 31(e)**; S.I. 2019/1436, reg. 2(b)

F39 Reg. 2(8) inserted (27.3.2020) by The National Health Service (Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/351), regs. 1(2), **5**

Marginal Citations

M1 1968 c. 67.

M2 1992/662
; these Regulations were revoked by S.I. 2005/641.

M3 2005/641
; these Regulations were revoked by S.I. 2012/1909.

M4 S.I. 2006/552; these Regulations are revoked by Schedule 10.

M5 2007 c. 28.

M6 S.I. 2012/1909; these Regulations are revoked by Schedule 10.

M7 Section 127 has been amended by the Health and Social Care Act 2012 (c. 7), **Schedule 4**, paragraph 64.

M8 *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.

M9 2006 c. 52.

M10 Schedule 12A was inserted by the Health and Social Care Act 2012, Schedule 3.

M11 1971 c.80.

M12 2000 c.7. The definition of "electronic communication" has been amended by the Communications Act 2003 (c. 21), **Schedule 17**, paragraph 158.

M13 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).

M14 S.I. 2010/231.

M15 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)**.

M16 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.

M17 *See* section 194 of the Health and Social Care Act 2012 (c. 7).

M18 Section 222(2A) was inserted by the Health and Social Care Act 2012, section 183(2).
M19 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).
M20 Section 91 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 35.
M21 Section 159 has been amended by S.I. 2010/22.
M22 S.I. 2005/2414.
M23 S.I. 1995/2800; amended by S.I. 2002/2621, 2005/503 and 1445, 2012/1641 and 2013/235.
M24 S.I. 2012/1916.
M25 S.I. 2002/253; amended by S.I. 2009/1182.
M26 1989 c.44; amended by S.I. 2005/848.
M27 S.I. 2004/906. *See* regulation 2(2) of those Regulations.
M28 S.I. 1976/1213 (N.I. 22).
M29 Section 72A was inserted by the Health Act 2006 (c. 28), **section 30**, and has been amended by S.I. 2006/2407.
M30 S.I. 2004/629.
M31 *See* regulation 5(3) of those Regulations.
M32 Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.
M33 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
M34 2010 c. 15.
M35 2009 c. 1 (N.I.).
M36 S.I. 2003/2382.
M37 Prior to its revocation, regulation 35 was amended by S.I. 2005/1501.
M38 S.I. 1992/664; these Regulations were revoked by S.I. 2012/1909.
M39 Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680.
M40 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.
M41 Section 168A was inserted by the Health and Social Care Act 2012 (c. 7), **section 49(4)**.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– blanket amendment words substituted by S.I. 2023/1071 Sch. para. 1