STATUTORY INSTRUMENTS

2015 No. 570

The National Health Service (Charges for Drugs and Appliances) Regulations 2015

Citation and commencement

1. These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) Regulations 2015 and come into force on 1st April 2015.

Interpretation

2.—(1) In these Regulations—

"the 2000 Act" means the Electronic Communications Act 2000 [M1];

"the 2006 Act" means the National Health Service Act 2006;

"accepted disablement" means physical or mental injury or disease which is accepted by the Secretary of State as attributable to, or aggravated by, service in the armed forces of the Crown or such other service as the Secretary of State may determine;

"advanced electronic signature" means an electronic signature which is—

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) **[**[F1]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) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"another primary care organisation" means—

(a) as regards Wales, a Local Health Board;

(b) as regards Scotland, a Health Board constituted under section 2 of the National Health (Scotland) Act 1978 [M2] (Health Boards);

(c) as regards Northern Ireland, the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M3] (Regional Health and Social Care Board); and

(d) as regards England, in relation to any time prior to 1st April 2013, a Primary Care Trust;

[F2]...

"appliance", unless the context otherwise requires, means an appliance included in a list approved by the Secretary of State for the purposes of section 126 of the 2006 Act [M4] (arrangements for pharmaceutical services), but does not include a contraceptive appliance;

"approved", in relation to forms, means approved by the Secretary of State;

"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 [M5] (definitions applying for the purposes of the whole Act);

"arrangements for recharging" means arrangements under paragraph 3 of Schedule 12A to the 2006 Act [M6] (pharmaceutical remuneration – other pharmaceutical remuneration) under which the Board 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 [M7] (which relate to bank holidays), a bank holiday in England;

"batch issue" means an approved form, in the format required by the Board (or person exercising its functions), which—

(a) is issued by a prescriber at the same time as a non-electronic repeatable prescription to enable a 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);

"CCG" means a clinical commissioning group;

"chemist" means an LPS chemist or a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a) or (b) of the Pharmaceutical and Local Pharmaceutical Services Regulations (pharmaceutical lists and EPS lists);

"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 **[**[F3]Health 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;

"community treatment order" means an order under section 17A(1) of the Mental Health Act 1983 [M8] (community treatment orders);

"directed services" means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act [M9] (arrangements for additional pharmaceutical services);

"dispensing doctor" is to be construed in accordance with regulation 46(1) of the Pharmaceutical and Local Pharmaceutical Services Regulations (dispensing doctor lists);

"dispensing services" means the provision of drugs or appliances that may be provided as pharmaceutical services by a medical practitioner in accordance with arrangements made under sections 126 and 132 of the 2006 Act [M10] (arrangements for pharmaceutical services, and persons authorised to provide pharmaceutical services);

"doctor" means a registered medical practitioner;

"drugs" includes medicines, but does not include contraceptive substances;

"elastic hosiery" means anklet, legging, knee-cap, below-knee or thigh stocking;

"electronic communication" has the same meaning as in section 15(1) of the 2000 Act [M11] (general interpretation);

"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 Board (or a person exercising its functions) for—

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

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

unless the chemist or dispensing doctor 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 **[**F4or 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 **[**F5or via an information hub**]** by the Electronic Prescription Service;

(c) indicates that the drug or appliance ordered may be provided more than once; and

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

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

"electronic signature" has the same meaning as in section 7 of the 2000 Act (electronic signatures and related certificates);

[F6"electronic signature creation data" means unique data which is used by the signatory to create an electronic signature;**]**

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

"exemption certificate", unless the context otherwise requires, has the meaning assigned to it by regulation 15(1);

"GMS contract" means a general medical services contract, and "GMS contractor" is to be construed accordingly;

"independent nurse prescriber" means a person—

(a) who is registered in the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 M12 (establishment and maintenance of 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 M13 (the Health and Social Care Information Centre);

[F7"integrated care provider contract" has the meaning given in Schedule 3A to the National Health Service (General Medical Services Contracts) Regulations 2015;**]**

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

"mental disorder" has the same meaning as in section 1 of the Mental Health Act 1983 [M14] (application of Act: "mental disorder");

[[F8]"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;**]**

"NHS services" means services provided as part of the health service (including 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 a 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 an approved form for ordering a drug or appliance which—

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

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

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

unless the chemist or dispensing doctor 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 Board,

(ii) another primary care organisation,

(iii) a local authority, under arrangements for providing NHS services which include, with the consent of the Board, 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 Board, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(vi) an NHS trust, or

(vii) an NHS foundation trust;

(c) has been issued by a prescriber; and

(d) 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;

"optometrist independent prescriber" means a person—

(a) who is registered in the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989 [M15] (register of opticians); and

(b) against whose name in that register is recorded an annotation that the person is qualified to order drugs and appliances as an optometrist independent prescriber;

"out of hours period" means—

(a) the period beginning at 6.30pm on any day from Monday to Thursday and ending at 8am on the following day;

(b) the period beginning at 6.30pm on Friday and ending at 8am on the following Monday; and

(c) Good Friday, Christmas Day and bank holidays;

"out of hours services" means the services commissioned in respect of all, or part of, the out of hours period to enable the registered patients of a GMS, PMS or **[**F9section 83(2)**]** contractor to receive primary medical services outside core hours, and in this definition—

(a) "core hours" means the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday except Good Friday, Christmas Day and bank holidays; and

(b) "part" of an out of hours period means any part of one or more of the periods described in paragraphs (a) to (c) of the definition of "out of hours period";

[F10"paramedic independent prescriber" means a person—

(a) who is registered in Part 8 of the register maintained under article 5 of the **[**F11Health Professions Order 2001**]** (establishment and maintenance of register); 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;**]**

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

"the Pharmaceutical and Local Pharmaceutical Services Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 **M16**;

"pharmacist independent prescriber" means a registered pharmacist—

(a) against whose name in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010 **M17** (establishment, maintenance of and access to the register) or in the register maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 **M18** (which relates to the registers and the registrar) is recorded an annotation signifying that the pharmacist 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, but for these purposes those arrangements must not be arrangements for the provision of—

(i) pharmaceutical services, unless they are arrangements for the provision of enhanced services, or

(ii) local pharmaceutical services, unless they are arrangements that have been made by the Board with an LPS chemist for the provision of services that are equivalent to services provided as enhanced services;

"physiotherapist independent prescriber" means a physiotherapist who is registered in Part 9 of the register maintained under article 5 of the **[**F12Health 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 agreement" means an agreement made under section 92 of the 2006 Act **M19** (arrangements by the Board for the provision of primary medical services);

"PMS contractor" means a contractor within the meaning of **[**F13the National Health Service (Personal Medical Services Agreements) Regulations 2015**]**;

"pre-payment certificate", unless the context otherwise requires, is to be construed in accordance with regulation 16;

"prescriber" means a doctor, a dental practitioner, a pharmacist independent prescriber, a supplementary prescriber, a chiropodist or podiatrist independent prescriber, a physiotherapist independent prescriber, an independent nurse prescriber **[**F14, an optometrist independent prescriber **[**F15, 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;

"provider of NHS services" means a person or a body which provides services under the 2006 Act pursuant to arrangements made with—

(a) the Board;

(aa) **[**F16a person responsible for providing services under an integrated care provider contract;**]**

(b) a CCG;

(c) an NHS trust;

(d) an NHS foundation trust;

(e) a local authority in the exercise of its public health functions—

(i) under section 2B of the 2006 Act M20 (functions of local authorities and Secretary of State as to improvement of public health),

(ii) under section 111 of the 2006 Act M21 (dental public health),

(iii) under paragraphs 1 to 7B and 13 of Schedule 1 to the 2006 Act M22 (further provision about the Secretary of State and services under the Act), or

(iv) pursuant to regulations made under section 6C of the 2006 Act M23 (regulations as to the exercise by local authorities of certain public health functions); or

(f) the Secretary of State when exercising the public health functions of the Secretary of State (as defined in section 1H(5)(a) of the 2006 Act M24 (the Board and its commissioning functions));

"provider of out of hours services" means—

(a) **[**F17a section 83(2)**]** contractor or a PMS contractor which provides out of hours services under **[**F17its section 83(2)**]** contract or PMS agreement;

(b) a GMS contractor which provides out of hours services under its GMS contract; or

(c) an out of hours services sub-contractor of a GMS contractor, PMS contractor or **[**F18section 83(2)**]** contractor;

"registered pharmacist" means a person who is registered in Part 1 or 4 of the register maintained under article 19 of the Pharmacy Order 2010 or in the register maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

[F19"relevant body" means—

(a) a health service body or local authority, pursuant to arrangements with which a provider of NHS services provides NHS services; or

(b) the NHS BSA;**]**

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

"repeatable prescription" means an electronic repeatable prescription or an approved form for ordering drugs or appliances which—

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

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

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

unless the chemist or dispensing doctor 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 Board,

(ii) another primary care organisation,

(iii) a local authority, under arrangements for providing NHS services which include, with the consent of the Board, 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 Board, the dispensing of prescriptions as part of pharmaceutical or local pharmaceutical services,

(vi) an NHS trust, or

(vii) an NHS foundation trust;

(c) has been issued by a prescriber;

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

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

[[F7]"section 83(2) contractor" means a person that provides primary medical services under contractual arrangements under section 83(2) of the 2006 Act (primary medical services), including in circumstances where those contractual arrangements are part of wider contractual arrangements for the provision of NHS services, and "section 83(2) contract" is to be construed accordingly;**]**

[[F20]"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;**]**

[F21"signatory" means a natural person who creates an electronic signature;**]**

[F20"SSP" means a serious shortage protocol;**]**

"the Standing Rules Regulations" means the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 M25;

"supplementary prescriber" means—

(a) a registered pharmacist against whose name in the register ("register" has the same meaning here as in the definition of "registered pharmacist"), 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 under article 5 of the **[**F22Health Professions Order 2001**]** which relates to chiropodists and podiatrists, **[**F23dietitians,**]** 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;

"the Board" means the National Health Service Commissioning Board M26;

[F24"therapeutic radiographer independent prescriber" means a radiographer—

(a) who is registered in Part 11 of the register maintained under article 5 of the **[**F25Health 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;**]**

"the Travel Expenses and Remission of Charges Regulations" means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 M27;

"treatment" includes examination and diagnosis; and

"walk-in centre" means a centre at which information and treatment for minor conditions is provided to the public under arrangements made by the Board or a CCG.

(2) For the purposes of these Regulations, the supply against an order on one prescription form, or on one repeatable prescription (but only where the supply is against one batch issue relating to that repeatable prescription)—

(a) of quantities of the same drug in more than one container is to be treated as the supply of only one quantity of a drug;

(b) of more than one appliance of the same type, except in the case of elastic hosiery and tights, or of two or more component parts of the same appliance, is to be treated as the supply of only one appliance.

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. 14(a)**

F2 Words in reg. 2(1) omitted (1.4.2019) by virtue of The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), 26(3)

F3 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. 34(a)**; S.I. 2019/1436, reg. 2(b)

F4 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), **11(2)**

F5 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), **11(3)**

F6 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. 14(b)**

F7 Words in reg. 2(1) inserted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), 26(2)

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), **11(4)**

F9 Words in reg. 2(1) substituted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **26(4)**

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), **11(5)**

F11 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. 34(b)**; S.I. 2019/1436, reg. 2(b)

F12 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. 34(c)**; S.I. 2019/1436, reg. 2(b)

F13 Words in reg. 2 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. 7** (with regs. 2, 88)

F14 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), **22(a)**

F15 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), **11(6)**

F16 Words in reg. 2(1) inserted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **26(5)**

F17 Words in reg. 2(1) substituted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **26(6)(a)**

F18 Words in reg. 2(1) substituted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **26(6)(b)**

F19 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), **11(7)**

F20 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, **8(2)**

F21 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. 14(c)**

F22 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. 34(d)**; S.I. 2019/1436, reg. 2(b)

F23 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), **22(b)**

F24 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), **22(c)**

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. 34(e)**; S.I. 2019/1436, reg. 2(b)

Marginal Citations

M1 2000 c. 7.

M2 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).

M3 2009 c. 1.

M4 Section 126 has been amended by the Health and Social Care Act 2012, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63. *See* section 126(9), which provides a definition of "listed" that includes the power for the Secretary of State to approve lists for the purposes of section 126.

M5 2006 c. 52.

M6 Schedule 12A was inserted by the Health and Social Care Act 2012 (c. 7), Schedule 3.

M7 1971 c. 80.

M8 1983 c. 20. Section 17A(1) was inserted by the Mental Health Act 2007 (c. 12), section 32(1) and (2).

M9 Section 127 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 65.

M10 Section 132 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 69, the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraphs 120 and 122, and by S.I. 2007/289 and 2010/22 and 231.

M11 The definition of "electronic communication" has been amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

M12 S.I. 2002/253. Article 5 was amended by S.I. 2009/1182.

M13 2012 c. 7.

M14 Section 1 has been amended by the Mental Health Act 2007 (c. 12), sections 1, 2 and 3, and Schedule 11, Part 1.

M15 1989 c. 44. Section 7 has been amended by S.I. 2005/484.

M16 S.I. 2013/349; amended by S.I. 2014/417 and 2015/58.

M17 S.I. 2010/231.

M18 S.I. 1976/1213 (N.I. 22).

M19 Section 92 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 36.

M20 Section 2B was inserted by the Health and Social Care Act 2012 (c. 7), section 12.

M21 Section 111 has been amended by the Health and Social Care Act 2012, section 29.

M22 Relevant amendments have been made to Schedule 1 by the Health and Social Care Act 2012, sections 17 and 143(1), and Schedule 14, paragraph 6, and by S.I. 2010/1158.

M23 Section 6C was inserted by the Health and Social Care Act 2012, section 18(1).

M24 Section 1H was inserted by the Health and Social Care Act 2012, section 9(1).

M25 S.I. 2012/2996.

M26 The National Health Service Commissioning Board is established by section 1H of the National Health Service Act 2006. Section 1H is inserted by section 9 of the Health and Social Care Act 2012 (c. 7).

M27 S.I. 2003/2382.

Supply of drugs and appliances by chemists

3.—(1) Except as provided in paragraph (2), a chemist who provides pharmaceutical services or local pharmaceutical services to a patient must, subject to paragraphs (5) to (7), make and recover from that patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**F26£9.15**]** or **[**F27£18.30**]** per pair;

(b) each other appliance, a charge of **[**F28£9.15**]**;

(c) each quantity of a drug, a charge of **[**F29£9.15**]**.

(2) A chemist who provides repeat dispensing services to a patient must, subject to paragraphs (5) to (7), make and recover from that patient in respect of each batch issue and each electronic prescription form for the supply of—

(a) an item of elastic hosiery, a charge of **[**F30£9.15**]** or **[**F31£18.30**]** per pair;

(b) each other appliance, a charge of **[**F32£9.15**]**;

(c) each quantity of a drug, a charge of **[**F33£9.15**]**.

(3) Where a charge is paid under paragraph (1), the person paying the charge must on doing so F34...—

(a) where a non-electronic prescription form has been issued, sign a declaration in writing on the non-electronic prescription form that the relevant charge has been paid; F35...

(b) where an electronic prescription form has been created, provide a declaration that the relevant charge has been paid on an approved form provided by the Board for recording patient declarations in respect of electronic prescription forms and issued by a chemist **[**F36or the prescriber**]****[**F37; or**]**

[F38(c) where the person has been supplied with a drug—

(i) in accordance with regulation 225 of the Human Medicines Regulations 2012 (emergency sale etc by pharmacist: at patient's request), and

(ii) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act (arrangements for additional pharmaceutical services) or, if the drug is supplied under arrangements for the provision of local pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions,

provide a declaration that the relevant charge has been paid on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012 and issued by a chemist.**]**

(4) Where a charge is paid under paragraph (2), the person paying the charge must on doing so either—

(a) in respect of a batch issue, sign a declaration in writing on the batch issue that the relevant charge has been paid; or

(b) in respect of an electronic repeatable prescription, provide a declaration that the relevant charge has been paid on an approved form provided by the Board for recording patient declarations in respect of electronic repeatable prescriptions and issued by a chemist **[**F39or the prescriber**]**.

(5) No charge is to be made and recovered under paragraph (1) or paragraph (2) where—

F40(a) . . . . . .

F40(b) . . . . . .

(c) the patient is resident in a school or institution, the name of which is inserted on the non-electronic prescription form by a prescriber under the term of an arrangement to provide primary medical services under section 83(2) of the 2006 Act [M28] (primary medical services).

[F41](5A) In cases involving an non-electronic prescription form other than one to which paragraph (5) applies, or a non-electronic repeatable prescription, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations (entitlement to full remission and payment); and

(b) subject to regulation 10(5)(b), a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on the non-electronic prescription form or the batch issue.

(5B) In cases involving an electronic prescription form or an electronic repeatable prescription, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations; and

(b) subject to regulation 10(5)(a), entitlement to that exemption or remission has been declared to the chemist by or on behalf of the patient and the chemist has duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service a record of that entitlement (if that entitlement is not already recorded in those records).

(5C) Where a declaration is made under paragraph (5B)(b), subject to paragraph (5D), the patient or a person acting on the patient's behalf must duly complete a record of that declaration on an approved form provided by the Board for recording such declarations and issued by the chemist or the prescriber.

(5D) The record referred to in paragraph (5C) is not required where a check, known as a real time exemption check, by the chemist of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations has confirmed that no charge is to be made and recovered under paragraph (1) or (2).

(5E) In cases involving a relevant emergency supply of a drug, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations; and

(b) a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012 (emergency sale etc. by pharmacist: at patient's request) and issued by a chemist.

(5F) For the purposes of paragraph (5E), a supply of a drug is a relevant emergency supply of a drug if it is made—

(a) in accordance with regulation 225 of the Human Medicines Regulations 2012; and

(b) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act (arrangements for additional pharmaceutical services) or, if the drug is supplied under arrangements for the provision of local

pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions.**]**

(6) No charge is to be made and recovered under paragraph (1) or (2) where there is an exemption by virtue of section 173(1)(d) of the 2006 Act [M29] (exemptions from general charging) or regulation 10(2), 11, 12, 13 **[**[F42], 13A**]** or 14.

(7) For the purposes of this regulation, where a drug ordered on a single prescription form is supplied by instalments, the charge of **[**[F43]£9.15**]** payable for that drug is payable on the supply of the first instalment.

(8) A chemist is under no obligation to supply drugs or appliances in the course of providing pharmaceutical services or local pharmaceutical services where a charge is required to be made and recovered under paragraphs (1) or (2) unless the patient first pays that charge (notwithstanding any provisions in the chemist's terms of service).

(9) Where a patient requests a receipt for a charge made and recovered under paragraph (1) or (2), the chemist must give the patient a receipt for the amount received on the relevant approved form.

(10) Any sum which would otherwise be payable by the Board to a chemist in respect of the provision by that chemist of pharmaceutical services or local pharmaceutical services is to be reduced by the amount of any charges which must be made and recovered under paragraph (1) or (2).

(11) In paragraph (8), "terms of service" means the terms on which pharmaceutical services or local pharmaceutical services are provided under the 2006 Act.

[[F44](12) Where, instead of supplying a drug or appliance in accordance with a prescription form or an associated batch issue, a chemist provides a drug or appliance in accordance with a SSP, for the purposes of this regulation, the relevant form for recording an exemption or entitlement to remission of a charge is treated as being the prescription for product reimbursement purposes, as mentioned in (as the case may be)—

(a) paragraph 5A(4)(a) of Schedule 4 to the Pharmaceutical and Local Pharmaceutical Services Regulations (terms of service of NHS pharmacists – supply in accordance with a SSP);

(b) paragraph 4A(4)(a) of Schedule 5 to those Regulations (terms of service of NHS appliance contractors – supply in accordance with a SSP); or

(c) paragraph 3A(4)(a) of Schedule 7 to those Regulations (mandatory terms of LPS schemes – supply in accordance with a SSP),

but for these purposes, those provisions are to be read with regulation 119A(2)(a) of those Regulations (transitional provisions in respect of drugs and appliances supplied in accordance with SSPs), so the relevant form may instead be a dispensing token that records the supply of the product ("dispensing token" having the meaning given in regulation 119A(1)(b) of those Regulations).**]**

F26 Sum in reg. 3(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)

F27 Sum in reg. 3(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(a)** (with reg. 6)

F28 Sum in reg. 3(1)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)

F29 Sum in reg. 3(1)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)

F30 Sum in reg. 3(2)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)

F31 Sum in reg. 3(2)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(a)** (with reg. 6)

F32 Sum in reg. 3(2)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)
F33 Sum in reg. 3(2)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)
F34 Word in reg. 3(3) omitted (5.12.2016) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **26(a)(i)**
F35 Word in reg. 3(3)(a) omitted (5.12.2016) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **26(a)(ii)**
F36 Words in reg. 3(3)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **12(2)**
F37 Word in reg. 3(3)(b) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **26(a)(iii)**
F38 Reg. 3(3)(c) inserted (5.12.2016) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (S.I. 2016/1077), regs. 1(1), **26(a)(iv)**
F39 Words in reg. 3(4)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **12(3)**
F40 Reg. 3(5)(a)(b) omitted (26.11.2018) by virtue of The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **12(4)**
F41 Reg. 3(5A)-(5F) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **12(5)**
F42 Word in reg. 3(6) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **9(2)**
F43 Sum in reg. 3(7) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(a)** (with reg. 6)
F44 Reg. 3(12) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **9(3)**

Marginal Citations

M28 Subsection (2) was substituted by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 30.
M29 Subsection (1) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).

Supply of drugs and appliances by doctors

4.—(1) A doctor who provides dispensing services to a patient must, subject to paragraphs (3), (4) and (8), make and recover from that patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**[F45]£9.15**]** or **[**[F46]£18.30**]** per pair;

(b) each other appliance, a charge of **[**[F47]£9.15**]**;

(c) each quantity of a drug, a charge of **[**[F48]£9.15**]**.

(2) Where a charge is paid under paragraph (1), the person paying the charge must on doing so either—

(a) where a non-electronic prescription form has been issued, sign a declaration in writing on the non-electronic prescription form that the relevant charge has been paid; or

(b) where an electronic prescription form has been created, provide a declaration that the relevant charge has been paid on an approved form provided by the Board for recording patient declarations in respect of electronic prescription forms and issued by a doctor **[**[F49]or the prescriber**]**.

(3) No charge is to be made and recovered under paragraph (1) where—

[F50(a) in cases involving a non-electronic prescription form, there is—

(i) an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations (entitlement to full remission and payment), and

(ii) subject to regulation 10(5)(b), a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on the non-electronic prescription form;

(b) in cases involving an electronic prescription form, there is—

(i) an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations, and

(ii) subject to regulation 10(5)(a), entitlement to that exemption or remission has been declared to the doctor by or on behalf of the patient and the doctor has duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service a record of that entitlement (if that entitlement is not already recorded in those records);**]**

(c) the drugs or appliances are supplied in respect of two or more persons in a school or institution in which 20 persons are normally resident, of whom at least 10 are that doctor's patients; or

(d) there is an exemption by virtue of section 173(1)(d) of the 2006 Act M30 (exemptions from general charging) or regulation 10(2), 11(1), 12, **[**F51, 13 or 13A**]**.

[F52(3A) Where a declaration is made under paragraph (3)(b)(ii), subject to paragraph (3B), the patient or a person acting on the patient's behalf must duly complete a record of that declaration on an approved form provided by the Board for recording such declarations and issued by the doctor or the prescriber.

(3B) The record referred to in paragraph (3A) is not required where a check, known as a real time exemption check, by the doctor of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations has confirmed that no charge is to be made and recovered under paragraph (1).**]**

(4) For the purposes of this regulation, where a drug ordered on a single prescription form is supplied by instalments, the charge of **[**F53£9.15**]** payable for that drug is payable on the supply of the first instalment.

(5) A doctor is under no obligation to supply drugs or appliances in the course of providing dispensing services where a charge is required to be made and recovered under paragraph (1) unless the patient first pays that charge (notwithstanding any provisions in the relevant GMS contract, PMS agreement or **[**F54section 83(2)**]** contract).

(6) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the doctor must give the patient a receipt for the amount received on the relevant approved form.

(7) Any sum which would otherwise be payable by the Board to a contractor under a GMS contract, a PMS agreement or **[**F55a section 83(2)**]** contract that includes terms of service by virtue of regulation 47 of the Pharmaceutical Services and Local Pharmaceutical Services Regulations (terms of service of dispensing doctors: general) is to be reduced by the amount of any charges which must be made and recovered under paragraph (1).

(8) Nothing in this regulation authorises the payment of a charge where the drug or appliance supplied is either—

(a) needed for immediate treatment and no order for the drug or appliance is made on a prescription form; or

(b) administered or applied to the patient by the doctor personally.

[F56(9) Where, instead of supplying a drug or appliance in accordance with a prescription form or an associated batch issue, a doctor provides a drug or appliance in accordance with a SSP, for the purposes of this regulation, the relevant form for recording an exemption or entitlement to remission of a charge is treated as being the prescription for product reimbursement purposes, as mentioned in paragraph 3A(2)(b) of Schedule 6 to the Pharmaceutical and Local Pharmaceutical Services Regulations (terms of service of dispensing doctors – supply in accordance with a SSP).

(10) For these purposes, paragraph 3A(2)(b) of Schedule 6 to the Pharmaceutical and Local Pharmaceutical Services Regulations is to be read with regulation 119A(2)(a) of those Regulations (transitional provisions in respect of drugs and appliances supplied in accordance with SSPs), so the relevant form may instead be a dispensing token that records the supply of the product ("dispensing token" having the meaning given in regulation 119A(1)(b) of those Regulations).**]**

F45 Sum in reg. 4(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(b)** (with reg. 6)
F46 Sum in reg. 4(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(b)** (with reg. 6)
F47 Sum in reg. 4(1)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(b)** (with reg. 6)
F48 Sum in reg. 4(1)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(b)** (with reg. 6)
F49 Words in reg. 4(2)(b) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **13(2)**
F50 Reg. 4(3)(a)(b) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), 13(3)
F51 Words in reg. 4(3)(d) substituted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **10(2)**
F52 Reg. 4(3A)(3B) inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **13(4)**
F53 Sum in reg. 4(4) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(b)** (with reg. 6)
F54 Words in reg. 4(5) substituted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **27(2)**
F55 Words in reg. 4(7) substituted (1.4.2019) by The Amendments Relating to the Provision of Integrated Care Regulations 2019 (S.I. 2019/248), regs. 1(1), **27(3)**
F56 Reg. 4(9)(10) inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **10(3)**

Marginal Citations
M30 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).

Out of hours supply of drugs and appliances by providers of out of hours services

5.—(1) A provider of out of hours services which are not dispensing services who supplies drugs or appliances to a patient in the course of providing out of hours services must, subject to paragraphs (3), (4) and (8), make and recover from that patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**F57£9.15**]** or **[**F58£18.30**]** per pair;

(b) each other appliance, a charge of **[**F59£9.15**]**;

(c) each quantity of a drug, a charge of **[**F60£9.15**]**.

(2) Any person paying a charge under paragraph (1) must on doing so sign a declaration in writing on the approved form that the relevant charge has been paid.

(3) No charge is to be made and recovered under paragraph (1) where—

(a) there is an exemption by virtue of regulation 10(1) and a declaration of entitlement to an exemption is duly completed by or on behalf of the patient on the approved form;

(b) there is entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations M31 (entitlement to full remission and payment) and a declaration of entitlement to remission is duly completed by or on behalf of the patient on the approved form;

(c) the drugs or appliances are supplied in respect of two or more persons in a school or institution in which at least 20 persons are normally resident provided that the name of the school or institution is inserted on the approved form; and

(d) in the cases described in sub-paragraphs (a) and (b), such evidence of entitlement to an exemption or remission is provided as the provider of out of hours services may reasonably require.

(4) No charge is to be made and recovered under paragraph (1) where there is an exemption by virtue of section 173(1)(d) of the 2006 Act M32 (exemptions from general charging) or regulation 10(2), 11(1), 12 or 13.

(5) A provider of out of hours services is under no obligation to supply drugs or appliances in the course of providing out of hours services where a charge is required to be made and recovered under paragraph (1) unless the patient first pays that charge (notwithstanding any provisions in the relevant agreement to provide out of hours services).

(6) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the provider of out of hours services must give the patient a receipt for the amount received on the relevant approved form.

(7) Any sum which would otherwise be payable by the Board to a provider of out of hours services in respect of the provision of primary medical services is to be reduced by the amount of any charges which must be made and recovered under paragraph (1).

(8) Nothing in this regulation authorises the payment of a charge where the drug or appliance supplied is either—

(a) needed for immediate treatment and no order for the drug or appliance is made on an approved form; or

(b) administered or applied to the patient by the provider of out of hours services personally.

F57 Sum in reg. 5(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(c)** (with reg. 6)

F58 Sum in reg. 5(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(c)** (with reg. 6)

F59 Sum in reg. 5(1)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(c)** (with reg. 6)

F60 Sum in reg. 5(1)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(c)** (with reg. 6)

Marginal Citations

M31 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

M32 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).

Supply of drugs and appliances by NHS trusts and NHS foundation trusts

6.—(1) Where an NHS trust or an NHS foundation trust supplies a drug or appliance to a patient for the purpose of treatment, the NHS trust or the NHS foundation trust (as the case may be) must, subject to paragraphs (3) to (6), make and recover from the patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**F61£9.15**]** or **[**F62£18.30**]** per pair;

(b) an item specified in column (1) of Schedule 1 (which has effect), the charge specified in relation to it in column (2) of that Schedule;

(c) tights, a charge of **[**F63£18.30**]**;

(d) each other appliance, a charge of **[**F64£9.15**]**;

(e) each quantity of a drug, a charge of **[**F65£9.15**]**.

(2) Any person paying a charge under paragraph (1) must on doing so sign a declaration in writing that the relevant charge has been paid.

(3) No charge is to be made and recovered under this regulation for the supply of drugs administered or appliances fitted or put into service at the hospital or other establishment or facility which forms part of the NHS trust or NHS foundation trust which supplies the drugs or appliances.

(4) No charge is to be made and recovered under this regulation from a patient who is exempt—

(a) by virtue of section 173(1)(a), (c) or (d) of the 2006 Act M33 (exemptions from general charging) or regulation 10(2), 11(1), 12 or 13;

(b) by virtue of regulation 10(3); or

(c) by reason of being entitled to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations M34 (entitlement to full remission and payment),

and who, in the case described in section 173(1)(c) of the 2006 Act (aged under 16 or aged under 19 and in full-time education) and in the cases described in sub-paragraph (b) and (c), completes a declaration of entitlement to such exemption or remission and provides any other evidence of entitlement as the NHS trust or NHS foundation trust may reasonably require.

(5) No charge is to be made and recovered under this regulation from a patient who is accepted by the person supplying the drug as—

(a) suffering from tuberculosis, in respect of any drug supplied to that patient for the treatment of tuberculosis; or

(b) being subject to a community treatment order, in respect of any drug supplied to that patient for the treatment of a mental disorder.

(6) A partially remitted charge must be made and recovered under this regulation from a patient who is entitled to partial remission by virtue of regulation 10(6) if a declaration in writing is provided that the relevant part of the charge has been paid and a declaration of entitlement, and any other evidence of entitlement to partial remission, as may be required, is provided.

(7) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the NHS trust or an NHS foundation trust must give the patient a receipt for the amount received on the relevant approved form.

F61 Sum in reg. 6(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(d)** (with reg. 6)

F62 Sum in reg. 6(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(d)** (with reg. 6)
F63 Sum in reg. 6(1)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(d)** (with reg. 6)
F64 Sum in reg. 6(1)(d) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(d)** (with reg. 6)
F65 Sum in reg. 6(1)(e) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(d)** (with reg. 6)

Marginal Citations

M33 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).
M34 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

Supply of drugs and appliances at walk-in centres

7.—(1) Where drugs or appliances are supplied to a patient, including during the out of hours period, for the purpose of treating that patient, by a prescriber at a walk-in centre, the NHS trust, NHS foundation trust or other person responsible for the management of the centre, must, subject to paragraphs (3) to (5), make and recover from that patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**F66£9.15**]** or **[**F67£18.30**]** per pair;

(b) each other appliance, a charge of **[**F68£9.15**]**;

(c) each quantity of a drug, a charge of **[**F69£9.15**]**.

(2) Any person paying a charge under paragraph (1), must on doing so, sign a declaration in writing that the relevant charge has been paid.

(3) No charge is to be made and recovered under this regulation for the supply of drugs administered or appliances fitted or put into service at the walk-in centre.

(4) No charge is to be made and recovered under this regulation from a patient who is exempt—

(a) by virtue of section 173(1)(d) of the 2006 Act M35 (exemptions from general charging) or regulation 10(2), 11(1), 12 or 13;

(b) by virtue of regulation 10(1); or

(c) by reason of being entitled to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations M36 (entitlement to full remission and payment),

and in the cases described in sub-paragraphs (b) and (c), completes a declaration of entitlement to such exemption or remission and provides any other evidence of entitlement as the NHS trust, NHS foundation trust or other person responsible for the management of the walk-in centre supplying the drug or appliance may reasonably require.

(5) For the purpose of this regulation, where a drug ordered is supplied by instalments, the charge of **[**F70£9.15**]** payable for that drug is payable on the supply of the first instalment.

(6) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the person making and recovering the charge must give the patient a receipt for the amount received on the relevant approved form.

F66 Sum in reg. 7(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(e)** (with reg. 6)

F67 Sum in reg. 7(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(e)** (with reg. 6)
F68 Sum in reg. 7(1)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(e)** (with reg. 6)
F69 Sum in reg. 7(1)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(e)** (with reg. 6)
F70 Sum in reg. 7(5) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(e)** (with reg. 6)

Marginal Citations

M35 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).
M36 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

Supply of drugs under Patient Group Directions

8.—(1) Where, in the course of providing NHS services, drugs are supplied to a patient in accordance with a Patient Group Direction, including during the out of hours period, the person supplying the drugs must, subject to paragraphs (3) to (5), make and recover from the patient for the supply of each quantity of a drug, a charge of **[**[F71]£9.15**]**.

(2) Any person paying a charge under paragraph (1) must on doing so sign a declaration in writing that the relevant charge has been paid.

(3) No charge is to be made and recovered under this regulation from a patient who is exempt—

(a) by virtue of section 173(1)(a) of the 2006 Act [M37] (exemptions from general charging) or regulation 10(2), 11(1), 12 or 13;

(b) by virtue of regulation 10(1); or

(c) by reason of being entitled to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations [M38] (entitlement to full remission and payment),

and who, in the cases described in sub-paragraphs (b) and (c), completes a declaration of entitlement to such exemption or remission and provides any other evidence of entitlement as the person supplying the drug may reasonably require.

(4) No charge is to be made and recovered under this regulation from a patient who is accepted by the person supplying the drug as—

(a) suffering from tuberculosis, in respect of any drug supplied to that patient for the treatment of tuberculosis; or

(b) being subject to a community treatment order, in respect of any drug supplied to that patient for the treatment of a mental disorder.

(5) No charge is to be made and recovered under this regulation where the drug is supplied for personal administration by the person making the supply in accordance with the Patient Group Direction.

(6) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the person making that charge must give the patient a receipt for the amount received on the relevant approved form.

(7) For the purpose of this regulation, the reference to the supply of a drug in accordance with a Patient Group Direction is a reference to the supply of a drug for that purpose as provided for in the Human Medicines Regulations 2012 [M39].

F71 Sum in reg. 8(1) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(f)** (with reg. 6)

Marginal Citations

M37 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).

M38 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

M39 S.I. 2012/1916. *See* regulations 229 to 235 of those Regulations, which provide for the exemptions relating to Patient Group Directions from the general restrictions on the sale and supply of prescription only and pharmacy medicines.

Supply of drugs and appliances by other providers of NHS services

9.—(1) A provider of NHS services who, otherwise than as mentioned in regulations 3 to 8, supplies drugs or appliances to a patient for the purpose of treatment must, subject to paragraphs (3) to (8), make and recover from the patient for the supply of—

(a) an item of elastic hosiery, a charge of **[**F72£9.15**]** or **[**F73£18.30**]** per pair;

(b) tights, a charge of **[**F74£18.30**]**;

(c) an item specified in column (1) of Schedule 1, the charge specified in relation to it in column (2) of that Schedule;

(d) each other appliance, a charge of **[**F75£9.15**]**;

(e) each quantity of a drug, a charge of **[**F76£9.15**]**.

(2) Any person paying a charge under paragraph (1) must on doing so sign a declaration in writing that the relevant charge has been paid.

(3) No charge is to be made and recovered under this regulation from a patient who is exempt—

(a) by virtue of section 173(1)(a), (c) or (d) of the 2006 Act M40 (exemptions from general charging) or regulation 10(2), 11(1), 12 or 13;

(b) by virtue of regulation 10(3); or

(c) by reason of being entitled to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations M41 (entitlement to full remission and payment),

and who, in the cases described in section 173(1)(c) of the 2006 Act and in the cases described in sub-paragraphs (b) and (c), completes a declaration of entitlement to such exemption or remission and provides any other evidence of entitlement as the provider of NHS services may reasonably require.

(4) No charge is to be made and recovered under this regulation from a patient where the drugs supplied to the patient are administered, or the appliances supplied to the patient are fitted or put into service, at the hospital or other establishment or facility from which the provider of NHS services provides such services.

(5) No charge is to be made and recovered under this regulation where the drug or appliance supplied is administered or applied to the patient personally by a person employed by, or contracted to provide services for, a provider of NHS services.

(6) No charge is to be made and recovered under this regulation from a patient who is accepted by the person supplying the drug as—

(a) suffering from tuberculosis, in respect of any drug supplied to that patient for the treatment of tuberculosis; or

(b) being subject to a community treatment order, in respect of any drug supplied to that patient for the treatment of a mental disorder.

(7) A partially remitted charge must be made and recovered under this regulation from a patient who is entitled to partial remission by virtue of regulation 10(6) if a declaration in writing is provided that the relevant part of the charge has been paid and a declaration of entitlement, and any other evidence of entitlement to partial remission, as may be required, is provided.

(8) For the purpose of this regulation, where a drug ordered on a single written direction is supplied by instalments, the charge of **[**F77£9.15**]** is payable for that drug on the supply of the first instalment.

(9) Where a patient requests a receipt for a charge made and recovered under paragraph (1), the provider of NHS services must give the patient a receipt for the amount received on the relevant approved form.

F72 Sum in reg. 9(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(g)** (with reg. 6)
F73 Sum in reg. 9(1)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(f)** (with reg. 6)
F74 Sum in reg. 9(1)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(2)(f)** (with reg. 6)
F75 Sum in reg. 9(1)(d) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(g)** (with reg. 6)
F76 Sum in reg. 9(1)(e) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(g)** (with reg. 6)
F77 Sum in reg. 9(8) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **3(1)(g)** (with reg. 6)

Marginal Citations

M40 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).
M41 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

Exemptions: general

10.—(1) Subject to paragraph (4), no charge is payable under regulations 3, 4, 5, 7 or 8 by a person who—

(a) is under 16 years of age;

(b) is under 19 years of age and is receiving qualifying full-time education within the meaning of section 173(2) and (3) of the 2006 Act (exemptions from general charging);

(c) is 60 years of age or older;

(d) has a valid exemption certificate on the grounds that they—

(i) are expecting a child, or

(ii) have within the last twelve months given birth to a child (including a child whose death was registrable under the special provisions as to the registration of still-births in the Births and Deaths Registration Act 1953 [M42]),

or has a valid exemption certificate issued under equivalent arrangements (to regulation 15) having effect in Scotland, Wales or Northern Ireland;

(e) has a valid exemption certificate on the grounds that they are suffering from one or more of the following conditions—

(i) permanent fistula (including caecostomy, colostomy, laryngostomy or ileostomy) requiring continuous surgical dressing or an appliance,

(ii) the following disorders—

forms of hypoadrenalism (including Addison's disease) for which specific substitution therapy is essential,

diabetes insipidus and other forms of hypopituitarism,

diabetes mellitus – except where treatment is by diet alone,

hypoparathyroidism,

myasthenia gravis, or

myxoedema,

(iii) epilepsy requiring continuous anti-convulsive therapy, or

(iv) a continuing physical disability which prevents the person from leaving the person's residence without the help of another person;

(f) has a valid exemption certificate on the grounds that the person is undergoing treatment for—

(i) cancer,

(ii) the effects of cancer, or

(iii) the effects of cancer treatment;

(g) has a valid exemption certificate issued on any of the grounds in sub-paragraph (e) or (f) under equivalent arrangements which have effect in Scotland, Wales or Northern Ireland;

(h) has a valid exemption certificate in respect of the supply of drugs and appliances for the treatment of accepted disablement, but in either case only in respect of those supplies to which the certificate relates; or

(i) has a valid pre-payment certificate granted under regulation 16 or a valid pre-payment certificate granted under equivalent arrangements (to regulation 16) having effect in Scotland, Wales or Northern Ireland.

(2) No charge is payable under these Regulations in respect of the supply of any drug for the treatment of a sexually transmitted disease within the meaning of section 173(1)(b) of the 2006 Act [M43].

(3) Subject to paragraph (4), no charge is payable under regulation 6 or 9—

(a) by a person of a description specified in paragraph (1)(h) in respect of the supply of an item specified in column (1) of Schedule 1; or

(b) by a person of any description specified in paragraph (1) in respect of the supply of an appliance not specified in column (1) of Schedule 1, or of tights or of drugs.

(4) Subject to paragraph (5), a person who wishes to claim entitlement to exemption by virtue of paragraph (1) or (3) must provide any declaration of entitlement required under regulation 3(5) **[**[F78]to (5E) or 4(3) to (3B),**]** or any declaration and evidence of entitlement required under regulation 5(3), 6(4), 7(4), 8(3) or 9(3).

(5) A person of a description specified in paragraph (1)(a) or (c) is not required to provide any declaration of entitlement required under regulations 3(5) **[**[F79]to (5E) and 4(3) to (3B)**]** where—

(a) an electronic prescription form or an electronic repeatable prescription is created and the person's date of birth is recorded on the person's PDS patient details and is set out on the electronic prescription form or electronic repeatable prescription; or

(b) a non-electronic prescription form or a non-electronic repeatable prescription is issued and the person's date of birth is printed by means of a computer on the non-electronic prescription form or non-electronic repeatable prescription.

(6) A charge referred to in column (2) of Schedule (1) must, in the case of a person referred to in regulation 6 of the Travel Expenses and Remission of Charges Regulations [M44] (entitlement to partial remission and payment), be remitted to the extent specified in that regulation.

(7) Where a charge is remitted in part under paragraph (6), the person making the part payment must, on doing so, sign a declaration in writing that the relevant part of the charge has been paid, complete a declaration of entitlement and provide such other evidence of entitlement to partial remission as may be required by the person supplying the drug or appliance.

(8) An exemption by reference to age or the validity of an exemption certificate must be determined by reference to the age or validity on the day on which—

(a) in the case of pharmaceutical services or local pharmaceutical services provided by a chemist, the order for drugs or appliances is presented for dispensing; and

(b) in any other case, the drugs or appliances are supplied.

(9) Where a claim to an exemption has been made but is not substantiated, and in consequence of the claim a charge has not been recovered, if—

(a) the drugs or appliances were supplied by a chemist as mentioned in regulation 3 or by a doctor as mentioned in regulation 4, then the Board must recover that charge from the person concerned;

(b) the drugs or appliances were supplied by an NHS trust or an NHS foundation trust as mentioned in regulation 6, then that NHS trust or NHS foundation trust must recover that charge from the person concerned; or

(c) the drugs or appliances were supplied as mentioned in regulations 5, 7, 8 or 9, then the body which made the arrangements for the provision of NHS services with the person or body that supplied the drugs or appliances must recover that charge from the person concerned.

F78 Words in reg. 10(4) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **14(2)**

F79 Words in reg. 10(5) substituted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **14(3)**

Marginal Citations

M42 1953 c. 20. *See* in particular section 11 of that Act.

M43 Subsection (1) was amended by the Health Act 2009 (c. 21), Schedule 1, paragraphs 6 and 7(c).

M44 Regulation 6 has been amended by S.I. 2006/562 and 675.

[F80Declarations, signatures and evidence of entitlement or of payment during a pandemic etc.

10A.—(1) Where, by virtue of these Regulations, a person is required to make, provide, complete or sign any declaration, or provide any evidence (including by way of completing a form or providing a certificate), but as a consequence of a disease being, or in anticipation of a disease being imminently—

(a) pandemic; and

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

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified

in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

(2) Modifications under paragraph (1) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to make, provide, complete or sign any declaration, or provide any evidence.

(3) An announcement under paragraph (1) may be withdrawn or amended at any time.**]**

F80 Reg. 10A inserted (14.9.2020) by The National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020 (S.I. 2020/885), regs. 1(2), **2(2)**

Exemption from charges for prisoners and persons detained in other secure accommodation

11.—(1) A prisoner or person detained in other secure accommodation is not liable to pay any charge under these Regulations.

(2) No charge is payable under regulation 3(1), 3(2), or 4 by a person where the charge is for drugs or appliances ordered on a non-electronic prescription form, and—

(a) that person was a prisoner or a person detained in other secure accommodation at the time that the non-electronic prescription form was issued; and

(b) that non-electronic prescription form has printed upon it—

(i) the letters "HMP", and

(ii) the name and address of the prison or other secure accommodation in which the person was detained at the time the non-electronic prescription form was issued.

(3) In this regulation—

"other secure accommodation" means—

(a) a court in which criminal proceedings against a person are heard;

(b) secure training centre accommodation in which offenders in respect of whom detention and training orders have been made under section 100 of the Powers of Criminal Courts (Sentencing) Act 2000 [M45] (offenders under 18: detentions and training orders) may be detained and given training and education and prepared for their release and in which children who have been remanded to youth detention accommodation under section 91(4) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 [M46] (remands of children otherwise than on bail) may be detained; [F81]...

(c) a secure children's home in which accommodation is provided within the meaning of the Care Standards Act 2000 [M47], which provides accommodation for the purposes of restricting liberty and in respect of which a person is registered under Part 2 of that Act (establishments and agencies); **[**[F82]or

(d) premises at which a secure accommodation service, within the meaning of Part 1 of the Regulation and Inspection of Social Care (Wales) Act 2016, is provided;**]**

"person detained in other secure accommodation" means a person who is detained in other secure accommodation in which medical, dental, ophthalmic, pharmaceutical or nursing services are provided under the 2006 Act under arrangements made by the Board pursuant to Parts 4 to 7 of the 2006 Act or regulation 10 of the Standing Rules Regulations [M48] (services for prisoners and other detainees);

"prison" includes a young offenders institution but not a naval, military or air force prison; and

"prisoner" means a person who is detained in a prison in which medical, dental, ophthalmic, pharmaceutical or nursing services are provided under the 2006 Act under arrangements made by the Board pursuant to Parts 4 to 7 of the 2006 Act or regulation 10 of the Standing Rules Regulations.

F81 Word in reg. 11(3) omitted (2.4.2018) by virtue of The Regulation and Inspection of Social Care (Wales) Act 2016 (Consequential Amendments to Secondary Legislation) Regulations 2018 (S.I. 2018/48), reg. 1(2), **Sch. 1 para. 32(2)(a)**

F82 Words in reg. 11(3) inserted (2.4.2018) by The Regulation and Inspection of Social Care (Wales) Act 2016 (Consequential Amendments to Secondary Legislation) Regulations 2018 (S.I. 2018/48), reg. 1(2), **Sch. 1 para. 32(2)(b)**

Marginal Citations

M45 2000 c. 6. Section 100 has been amended by: the Criminal Justice and Court Services Act 2000 (c. 6), Schedule 7, paragraphs 160 and 184; the Criminal Justice Act 2003 (c. 44), Schedule 32, paragraphs 90 and 111, and Schedule 37, Part 7; and the Legal Aid, Sentencing and Punishment of Offenders Act 2012 (c. 10), Schedule 21, paragraphs 7 and 13, and Schedule 26, paragraphs 9 and 11.

M46 2012 c. 10.

M47 2000 c. 14.

M48 S.I. 2012/2996. Regulation 10 has been amended by S.I. 2013/261 and 2014/452.

Exemption from charges for detainees

12.—(1) A detainee is not liable to pay any charge under these Regulations.

(2) In this regulation—

"detainee" means a person who is detained—

(a) under the Immigration Act 1971 [M49] or section 62 of the Nationality, Immigration and Asylum Act 2002 [M50](detention by the Secretary of State); and

(b) in a removal centre in which medical, dental, ophthalmic, pharmaceutical or nursing services are provided under the 2006 Act under arrangements made by the Board pursuant to Parts 4 to 7 of the 2006 Act or regulation 10 of the Standing Rules Regulations [M51] (services for prisoners and other detainees); and

"removal centre" has the same meaning as in section 147 of the Immigration and Asylum Act 1999 [M52] (interpretation of Part 8).

Marginal Citations

M49 1971 c. 77.

M50 2002 c. 41. Section 62 has been amended by the Prevention of Terrorism Act 2005 (c. 2), section 16(2)(c), and the Immigration Act 2014 (c. 22), Schedule 9, paragraphs 3 and 13.

M51 S.I. 2012/2996. Regulation 10 has been amended by S.I. 2013/261 and 2014/452.

M52 1999 c. 33. Section 147 has been amended by section 66 of the Nationality, Immigration and Asylum Act 2002 (c. 41).

Exemption from charges: risks to public health

13.—(1) In the circumstances set out in paragraph (2), the following drugs are exempt from any charge under these Regulations—

(a) drugs for the prevention or treatment of a condition or disease arising from an emergency that threatens, is causing or has caused serious damage or risk to public health in England or any part of England; and

(b) drugs, the supply of which is for, or is in anticipation of, a pandemic disease where the supply is in accordance with protocols relating to that disease as provided for in regulation 247 of the Human Medicines Regulations 2012 [M53] (exemption for supply in the event or anticipation of pandemic disease).

(2) Those circumstances are where—

(a) the Secretary of State has made arrangements for supplying the drug to patients free of charge; or

(b) the NHS body [M54] that is responsible for the arrangements under which the drug is supplied has made arrangements, with the approval of the Secretary of State, for supplying the drug to patients free of charge,

and the patient is supplied with the drug under those arrangements.

Marginal Citations

M53 S.I. 2012/1916. Regulation 247 has been amended by S.I. 2013/235.

M54 "NHS body" is defined in section 275(1) of the National Health Service Act 2006 (c. 41).

[F83Exemption from charges: supply of a smaller quantity of product in accordance with a SSP

13A. No charge is payable under regulation 3(1) or (2) or 4(1) in respect of the supply of any drug or appliance in accordance with a SSP if, as a consequence of the supply being in accordance with a SSP instead of being in accordance with a prescription form or an associated batch issue, the patient receives a smaller quantity of the drug or fewer appliances than the quantity originally ordered.**]**

F83 Reg. 13A inserted (1.7.2019) by The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 (S.I. 2019/990), regs. 1, **11**

[F84Coronavirus and influenza vaccinations and immunisations

13B.—(1) No charge is payable under these Regulations in respect of the supply or administration to an eligible person of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus.

(2) In this regulation—

"coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020; and

"eligible person" means a person who is of a class or description that means they would be entitled to be supplied with the medicinal product, or have it administered to them, in accordance with—

(a) a national patient group direction under regulation 233 of the Human Medicines Regulations 2012 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business), signed on behalf of the Board in accordance with paragraph (5)(a) of that regulation; or

(b) a national protocol under regulation 247A of the Human Medicines Regulations 2012 (protocols relating to coronavirus and influenza vaccinations and immunisations) approved by the Secretary of State,

whether or not the medicinal product is supplied or administered to that person in accordance with such a patient group direction or protocol.**]**

F84 Reg. 13B 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), **29**

Exemption for prescriptions provided or issued in Northern Ireland

14. No charge is payable under regulation 3 in respect of any pharmaceutical services or local pharmaceutical services which are obtained on the presentation of a prescription form which was provided or issued in Northern Ireland.

Certificates of exemption: application and issue

15.—(1) A person who wishes to claim exemption from charges payable under these Regulations by virtue of regulation 10(1)(d), (e), (f), or (h) must apply for a certificate conferring exemption (in these Regulations referred to as an "exemption certificate") as follows—

(a) a claim for an exemption by virtue of regulation 10(1)(d) must be made on an approved form provided by the Secretary of State;

(b) a claim for an exemption by virtue of regulation 10(1)(e) or (f) must be made on the approved form, "FP92A—1 January 2009", provided by the Secretary of State; and

(c) a claim for an exemption by virtue of regulation 10(1)(h) must be made to an office of the Ministry of Defence on a form provided by the Secretary of State.

(2) The Secretary of State, on being satisfied that an applicant is entitled to exemption by virtue of regulation 10(1)(d), must issue an exemption certificate which is to be valid from the date which is one month before the date on which the Secretary of State received the application made under paragraph (1) until, in the case of an expectant mother, the end of that mother's pregnancy, and in the case of a mother who gives birth—

(a) to a child whose death is registrable under the special provisions as to the registration of still-births in the Births and Deaths Registration Act 1953 [M55], thereafter until the end of the period of twelve months beginning with the expected date of confinement; or

(b) to a live child (who is not registrable as still-born), thereafter until the end of the period of twelve months beginning with the date of birth of that child.

(3) The Secretary of State, on being satisfied that an applicant, not being a person entitled to exemption by virtue of regulation 10(1)(a), (b) or (c), is entitled to exemption by virtue of regulation 10(1)(e), must issue to the applicant an exemption certificate which is to be valid—

(a) from the date one month prior to the date on which the Secretary of State received the application made under paragraph (1); and

(b) for such period as the Secretary of State may determine.

(4) The Secretary of State, on being satisfied that an applicant, not being a person entitled to exemption by virtue of regulation 10(1)(a), (b), (c), or (e) is entitled to exemption by virtue of regulation 10(1)(f), must issue to the applicant an exemption certificate which is to be valid—

(a) from the date one month prior to the date on which the Secretary of State received the application under paragraph (1); and

(b) for such period as the Secretary of State may determine.

(5) The Secretary of State, on being satisfied that an applicant is entitled to exemption by virtue of regulation 10(1)(h), must issue to the applicant an exemption certificate which is to be valid for such period as the Secretary of State may determine.

Marginal Citations

M55 1953 c. 20. *See* in particular section 11 of that Act.

Pre-payment certificates: application and grant

16.—(1) A person applying to the Secretary of State for a pre-payment certificate (referred to in this regulation as "the applicant") must—

(a) pay, or undertake to pay by means of a direct debit in ten monthly instalments, to the Secretary of State, the sum payable for the pre-payment certificate as set out in paragraph (3); and

(b) provide the Secretary of State with the information required to determine that application by—

(i) duly completing and submitting an application for the pre-payment certificate on an approved form provided for the purpose, or

(ii) providing the Secretary of State with that information in a manner that is acceptable to the Secretary of State.

(2) A pre-payment certificate is valid for a period of either 3 months or 12 months and an application for such a certificate must indicate the period for which it is required to be valid.

(3) The applicant must pay to the Secretary of State—

(a) in the case of a 3 month pre-payment certificate, **[**F85£29.65**]**;

(b) in the case of a 12 month pre-payment certificate payable by means of a single instalment, **[**F86£105.90**]**; or

(c) in the case of a 12 month pre-payment certificate payable by means of a direct debit in ten monthly instalments, instalments amounting to **[**F87£10.59**]**,

and the payment amount referred to for each type of pre-payment certificate is referred to in this regulation and regulation 17 as "the issuing amount".

(4) Subject to paragraph (6), the Secretary of State must grant a pre-payment certificate to the applicant as soon as reasonably practicable after the applicant has fulfilled the requirements set out in paragraph (1).

(5) The Secretary of State may refuse to accept payment for a pre-payment certificate valid for 12 months by means of direct debit in ten monthly instalments, and refuse to grant such a certificate to an applicant, where the applicant has—

(a) previously been granted a pre-payment certificate valid for 12 months payable by direct debit in ten monthly instalments;

(b) failed to pay in full the amount payable for that previously granted prepayment certificate without good reason; and

(c) failed to return without good reason that previously granted pre-payment certificate to the Secretary of State within 28 days of the date on which it was requested to be returned.

(6) A pre-payment certificate is valid—

(a) from a date before the application is made, where that date—

(i) was specified by the applicant when making the application, and

(ii) is no more than one month prior to the date when the application was made under paragraph (1); or

(b) from a date after the application is made, where that date—

(i) was specified by the applicant when making the application, and

(ii) is not more than one month after the date when the application was made under paragraph (1); or

(c) if the applicant does not specify a date in accordance with sub-paragraphs (a)(i) or (b)(i), from the date when the application is received.

(7) Pre-payment certificates granted under this regulation are not valid in respect of the items specified in column (1) of Schedule 1.

F85 Sum in reg. 16(3)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **4(a)** (with reg. 6)

F86 Sum in reg. 16(3)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **4(b)** (with reg. 6)

F87 Sum in reg. 16(3)(c) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **4(c)** (with reg. 6)

Pre-payment certificates: repayment

17.—(1) Where the issuing amount in respect of a pre-payment certificate has been paid and, not more than one month after the date when the pre-payment certificate became valid, the relevant person—

(a) dies; or

(b) becomes resident in a hospital and thereafter dies while resident in hospital before the expiry of the pre-payment certificate,

an application for repayment of the entirety of the issuing amount which has already been paid may be made on behalf of that person's estate in accordance with paragraph (6) and (7).

(2) Where the issuing amount in respect of a pre-payment certificate valid for 12 months has been paid and during the period beginning on the date when the pre-payment certificate became valid and ending on the date of its expiry, the relevant person becomes—

(a) entitled to exemption by virtue of regulation 10(1)(b) to (h);

(b) entitled to remission by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations [M56] (entitlement to full remission and payment); or

(c) resident in hospital and thereafter remains in hospital until the expiry of the pre-payment certificate,

an application for a refund may be made, by or on behalf of that person or that person's estate, in accordance with paragraph (6) and (7), and is to be calculated in accordance with paragraph (4), in respect of each complete month following the date on which one of the events listed in sub-paragraph (a) to (c) occurred.

(3) Where the issuing amount in respect of a pre-payment certificate has been paid and during the period beginning one month after the date when the pre-payment certificate became valid and ending with the date of its expiry, the relevant person—

(a) dies; or

(b) becomes resident in hospital and thereafter dies while resident in hospital before the expiry of the pre-payment certificate,

an application for a refund may be made on behalf of that person's estate in accordance with paragraph (6) and (7), and is to be calculated in accordance with paragraph (4), in respect of each complete month following the date when the person died or became resident in hospital.

(4) The refund referred to in paragraph (2) and (3) is to be calculated as follows—

(a) in the case of a pre-payment certificate valid for 3 months, one third of **[**F88£29.65**]** for each complete month during which the pre-payment certificate is or was valid following the relevant date;

(b) in the case of a pre-payment certificate valid for 12 months where a person has paid for the pre-payment certificate by means of a single payment, one twelfth of **[**F89£105.90**]** for each complete month during which the pre-payment certificate is or was valid following the relevant date; or

(c) in the case of a pre-payment certificate valid for 12 months where a person is or was paying for the pre-payment certificate in ten monthly instalments by means of direct debit either—

(i) where the sum payable for the pre-payment certificate has been paid in full, one twelfth of **[**F90£105.90**]** for each complete month during which the pre-payment certificate is or was valid following the relevant date, or

(ii) where the sum payable for the pre-payment certificate has not been paid in full, the amount paid for the pre-payment certificate at the point of refund, minus £104.00, plus one twelfth of **[**F91£105.90**]** for each complete month during which the pre-payment certificate is or was valid following the relevant date,

and for the purposes of these calculations, a "complete month" is a month beginning on the monthly anniversary of the date on which the pre-payment certificate became valid and ending on the date immediately preceding that date in the following month, "the relevant date" is the date on which one of the events listed in paragraph (2) or (3) occurred, and if a calculation produces a minus figure for the refund, no refund is payable.

(5) Where the issuing amount in respect of a pre-payment certificate valid for 3 months has been paid and not more than one month after the date on which the pre-payment certificate became valid, the relevant person becomes—

(a) entitled to exemption by virtue of regulation 10(1)(b) to (h);

(b) entitled to remission by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations; or

(c) resident in a hospital and remains there until expiry of the pre-payment certificate,

an application for a refund of two thirds of **[**F92£29.65**]** may be made by or on behalf of that person in accordance with paragraph (6) and (7).

(6) An application for a refund under this regulation is to be made to the Secretary of State and must be accompanied by the pre-payment certificate (where granted) and a declaration in support of the claim.

(7) An application for a refund under this regulation is to be made—

(a) where the relevant person dies or becomes resident in hospital and thereafter dies, within 24 months of the date of that death;

(b) where the relevant person becomes—

(i) entitled to exemption by virtue of regulation 10(1)(b) to (h), or

(ii) entitled to remission by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations,

within 3 months of the date on which the event specified in paragraph (i) or (ii) occurred; or

(c) where the relevant person becomes resident in hospital and remains there until the expiry of the pre-payment certificate, within 3 months of the date of expiry.

(8) Any repayment is to be made in such manner and subject to such conditions as the Secretary of State may determine.

(9) Where the calculation of an amount under this regulation produces a sum which is not a whole number, the amount must be rounded up to the nearest penny.

(10) In this regulation, "the relevant person" means the person in respect of whom an issuing amount was paid.

F88 Sum in reg. 17(4)(a) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **5(a)(i)** (with reg. 6)

F89 Sum in reg. 17(4)(b) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **5(a)(ii)** (with reg. 6)

F90 Sum in reg. 17(4)(c)(i) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **5(a)(ii)** (with reg. 6)

F91 Sum in reg. 17(4)(c)(ii) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **5(a)(ii)** (with reg. 6)

F92 Sum in reg. 17(5) substituted (1.4.2020) by The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2020 (S.I. 2020/201), regs. 1(1), **5(b)** (with reg. 6)

Marginal Citations

M56 Relevant amendments were made to regulation 5 by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475 and 2014/2667.

Repayment of charges

18.—(1) Where a charge has been paid under these Regulations by or on behalf of a person who was at the time of payment exempt from the requirement to pay that charge, an application for repayment may be made in accordance with paragraph (2) by or on behalf of that person.

(2) An application for repayment must be—

(a) made to the person or body specified in the receipt which is given under regulation 3(9), 4(6), 5(6), 6(7), 7(6), 8(6) or 9(9) as being the person or body to whom application for repayment of charges may be made;

(b) made in such form and manner as the Secretary of State may determine for the applicant, any class of applicant or applicants generally;

(c) made within 3 months from the date on which the drug or appliance was supplied to the applicant or within such longer period as the Secretary of State may allow; and

(d) accompanied by the receipt which is given pursuant to regulation 3(9), 4(6), 5(6), 6(7), 7(6), 8(6) or 9(9) for the charge paid and a declaration as to the grounds of exemption.

(3) In the case of a charge under regulation 6 or 9 in respect of an item specified in column (1) of Schedule 1, the application must be accompanied by the exemption certificate referred to in regulation 10(1)(h) and, if the patient was referred by a doctor to the NHS trust, NHS foundation trust or other provider of NHS services for treatment—

(a) a certificate from the doctor certifying that the treatment was for an accepted disablement; or

(b) a statement that such a certificate was surrendered to the NHS trust, NHS foundation trust or other provider of NHS services before the supply of the item.

(4) The Secretary of State must make arrangements for the repayment of any charge paid under these Regulations by a person who is entitled to exemption.

[F93Sharing of prescription and charging data

18A.—(1) As regards any order for a drug or an appliance in respect of which—

(a) a charge is payable under these Regulations (whether or not it is partially remitted); or

(b) a charge would be payable under these Regulations, but for an exemption by virtue of these Regulations,

paragraph (3) applies to the data relating to that order which is described in paragraph (2) (which may be electronic data).

(2) The data relating to that order described in this paragraph is—

(a) data used for ordering the drug or appliance (which may be in the form of a prescription form), if the data, in the form in which it is used for ordering the drug or appliance, is also used for the purposes of claiming a payment by way of—

(i) reimbursement for the cost of the supply of the drug or appliance, or

(ii) remuneration for the service provided in the course of which the drug or appliance was supplied;

(b) data derived from the data used for ordering the drug or appliance (which may have been in the form of a prescription form), which is to be or has been provided to a health service body by a provider of NHS services for the purposes of claiming a payment by way of—

(i) reimbursement for the cost of the supply of the drug or appliance, or

(ii) remuneration for the service provided in the course of which the drug or appliance was supplied; and

(c) data relating to whether a charge is payable by a patient under these Regulations in respect of the order.

(3) The processing of data which relates to a patient and which is or is part of data described in paragraph (2) is—

(a) necessary for the performance of a task carried out in the public interest;

(b) the exercise of a function conferred on a person by an enactment (whether or not it would be so but for this sub-paragraph); and

(c) if the data is personal data concerning health, necessary for the management of health care systems or services,

where the processing is by or on behalf of a relevant body or a provider of NHS services (including by another body on behalf of the relevant body or the provider of NHS services) and is for the purposes of performing, or facilitating the performance of, the functions listed in paragraph (4).

(4) Those functions are—

(a) reimbursement for the cost of the supply of that drug or appliance (taking account, as appropriate, of any charge payable under these Regulations);

(b) remuneration for providing the service in the course of which that drug or appliance was supplied (taking account, as appropriate, of any charge payable under these Regulations);

(c) ascertaining whether a charge is payable under these Regulations;

(d) providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations;

(e) recovery of unpaid charges payable under these Regulations, and the making and recovery of penalty charges;

(f) repayment or partial repayment of amounts paid as a charge under these Regulations where no amount or only part of the amount was payable; and

(g) management functions of a relevant body relating to ensuring that the functions mentioned in sub-paragraphs (a) to (f) are performed effectively, efficiently and economically.

(5) A person who—

(a) is employed or engaged by a relevant body or provider of NHS services, or by a body processing data on their behalf as mentioned in paragraph (3); and

(b) in the course of being so employed or engaged is required, for the purposes mentioned in paragraph (3), to undertake the processing of data described in paragraph (2),

owes a duty of confidentiality in respect of that data (whether or not that person would do so but for this paragraph), but that duty is such that, if the processing is for the purposes mentioned in paragraph (3), that person is able, lawfully, to process that data by virtue of this regulation.

(6) Words and expressions used in both—

(a) paragraphs (3) and (5); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraph 2(2)(f) of Schedule 1 (special categories of personal data and criminal convictions etc data) to, the Data Protection Act 2018,

bear the meanings they bear in those provisions of the Data Protection Act 2018.**]**

F93 Reg. 18A inserted (26.11.2018) by The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 (S.I. 2018/1114), regs. 1(1), **15**

Transitional provision

19. Where, on or after 1st April 2015, an item specified in column (1) of the table in Schedule 1 is supplied pursuant to an order made before that date, the National Health Service (Charges for Drugs and Appliances) Regulations 2000 [M57] are to have effect in relation to the supply of that appliance as if these Regulations had not come into force (and so those Regulations had not been revoked).

Marginal Citations

M57 S.I. 2000/620. The relevant amendments to this instrument are listed in Schedule 3 as a consequence of being revoked by these Regulations.

Consequential amendments

20. The amendments set out in Schedule 2 have effect.

Revocations

21. The Regulations and Orders specified in column (1) of Schedule 3 are hereby revoked in relation to England to the extent specified in column (3) of that Schedule.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Charges for Drugs and Appliances) Regulations 2015. 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 :

- Sch. 1 sum substituted by S.I. 2021/178 reg. 3(3)(a)
- Sch. 1 sum substituted by S.I. 2021/178 reg. 3(3)(b)
- Sch. 1 sum substituted by S.I. 2021/178 reg. 3(3)(c)
- Sch. 1 sum substituted by S.I. 2021/178 reg. 3(3)(d)
- Sch. 1 sum substituted by S.I. 2021/178 reg. 3(3)(e)
- Sch. 1 sum substituted by S.I. 2023/300 reg. 3(3)(a)
- Sch. 1 sum substituted by S.I. 2023/300 reg. 3(3)(b)
- Sch. 1 sum substituted by S.I. 2023/300 reg. 3(3)(c)
- Sch. 1 sum substituted by S.I. 2023/300 reg. 3(3)(d)
- Sch. 1 sum substituted by S.I. 2023/300 reg. 3(3)(e)
- Regulations words substituted by S.I. 2022/634 Sch. para. 1(1)(3)
- reg. 2 words inserted by S.I. 2023/171 reg. 6
- reg. 2 words omitted by S.I. 2023/98 Sch. para. 49(2)(b)
- reg. 2 words substituted by S.I. 2023/98 Sch. para. 49(2)(a)
- reg. 2(1) words inserted by S.I. 2021/1346 reg. 11(2)
- reg. 2(1) words inserted by S.I. 2022/634 reg. 83(2)(b)
- reg. 2(1) words inserted by S.I. 2023/1071 reg. 81(2)(b)
- reg. 2(1) words omitted by S.I. 2022/634 reg. 83(2)(a)
- reg. 2(1) words omitted by S.I. 2023/1071 reg. 81(2)(a)
- reg. 3(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(a)
- reg. 3(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(a)
- reg. 3(1)(b) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(1)(b) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(1)(c) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(1)(c) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(2)(a) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(2)(a) sum substituted by S.I. 2021/178 reg. 3(2)(a)
- reg. 3(2)(a) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(2)(a) sum substituted by S.I. 2023/300 reg. 3(2)(a)
- reg. 3(2)(b) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(2)(b) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(2)(c) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(2)(c) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 3(5B)(b) words substituted by S.I. 2023/98 Sch. para. 49(3)
- reg. 3(7) sum substituted by S.I. 2021/178 reg. 3(1)(a)
- reg. 3(7) sum substituted by S.I. 2023/300 reg. 3(1)(a)
- reg. 4(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(b)
- reg. 4(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(b)
- reg. 4(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(b)
- reg. 4(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(b)
- reg. 4(1)(b) sum substituted by S.I. 2021/178 reg. 3(1)(b)
- reg. 4(1)(b) sum substituted by S.I. 2023/300 reg. 3(1)(b)
- reg. 4(1)(c) sum substituted by S.I. 2021/178 reg. 3(1)(b)
- reg. 4(1)(c) sum substituted by S.I. 2023/300 reg. 3(1)(b)
- reg. 4(3)(b)(ii) words substituted by S.I. 2023/98 Sch. para. 49(4)
- reg. 4(4) sum substituted by S.I. 2021/178 reg. 3(1)(b)
- reg. 4(4) sum substituted by S.I. 2023/300 reg. 3(1)(b)
- reg. 5(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(c)

- reg. 5(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(c)
- reg. 5(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(c)
- reg. 5(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(c)
- reg. 5(1)(b) sum substituted by S.I. 2021/178 reg. 3(1)(c)
- reg. 5(1)(b) sum substituted by S.I. 2023/300 reg. 3(1)(c)
- reg. 5(1)(c) sum substituted by S.I. 2021/178 reg. 3(1)(c)
- reg. 5(1)(c) sum substituted by S.I. 2023/300 reg. 3(1)(c)
- reg. 6(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(d)
- reg. 6(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(d)
- reg. 6(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(d)
- reg. 6(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(d)
- reg. 6(1)(c) sum substituted by S.I. 2021/178 reg. 3(2)(d)
- reg. 6(1)(c) sum substituted by S.I. 2023/300 reg. 3(2)(d)
- reg. 6(1)(d) sum substituted by S.I. 2021/178 reg. 3(1)(d)
- reg. 6(1)(d) sum substituted by S.I. 2023/300 reg. 3(1)(d)
- reg. 6(1)(e) sum substituted by S.I. 2021/178 reg. 3(1)(d)
- reg. 6(1)(e) sum substituted by S.I. 2023/300 reg. 3(1)(d)
- reg. 7(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(e)
- reg. 7(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(e)
- reg. 7(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(e)
- reg. 7(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(e)
- reg. 7(1)(b) sum substituted by S.I. 2021/178 reg. 3(1)(e)
- reg. 7(1)(b) sum substituted by S.I. 2023/300 reg. 3(1)(e)
- reg. 7(1)(c) sum substituted by S.I. 2021/178 reg. 3(1)(e)
- reg. 7(1)(c) sum substituted by S.I. 2023/300 reg. 3(1)(e)
- reg. 7(5) sum substituted by S.I. 2021/178 reg. 3(1)(e)
- reg. 7(5) sum substituted by S.I. 2023/300 reg. 3(1)(e)
- reg. 8(1) sum substituted by S.I. 2021/178 reg. 3(1)(f)
- reg. 8(1) sum substituted by S.I. 2023/300 reg. 3(1)(f)
- reg. 9(1)(a) sum substituted by S.I. 2021/178 reg. 3(1)(g)
- reg. 9(1)(a) sum substituted by S.I. 2021/178 reg. 3(2)(f)
- reg. 9(1)(a) sum substituted by S.I. 2023/300 reg. 3(1)(g)
- reg. 9(1)(a) sum substituted by S.I. 2023/300 reg. 3(2)(f)
- reg. 9(1)(b) sum substituted by S.I. 2021/178 reg. 3(2)(f)
- reg. 9(1)(b) sum substituted by S.I. 2023/300 reg. 3(2)(f)
- reg. 9(1)(d) sum substituted by S.I. 2021/178 reg. 3(1)(g)
- reg. 9(1)(d) sum substituted by S.I. 2023/300 reg. 3(1)(g)
- reg. 9(1)(e) sum substituted by S.I. 2021/178 reg. 3(1)(g)
- reg. 9(1)(e) sum substituted by S.I. 2023/300 reg. 3(1)(g)
- reg. 9(8) sum substituted by S.I. 2021/178 reg. 3(1)(g)
- reg. 9(8) sum substituted by S.I. 2023/300 reg. 3(1)(g)
- reg. 10(1)(h) word omitted by S.I. 2023/171 reg. 7(a)
- reg. 10(1)(i) word inserted by S.I. 2023/171 reg. 7(b)
- reg. 11(3) words substituted by 2020 c. 17 Sch. 24 para. 428
- reg. 13(1)(b) word omitted by S.I. 2021/1346 reg. 12(2)
- reg. 13A substituted by S.I. 2023/171 reg. 8
- reg. 15(1) substituted by S.I. 2021/1346 reg. 13(2)
- reg. 15(2) words substituted by S.I. 2021/1346 reg. 13(3)(a)
- reg. 15(2)(a) words inserted by S.I. 2021/1346 reg. 13(3)(b)
- reg. 16(3)(a) sum substituted by S.I. 2021/178 reg. 4(a)
- reg. 16(3)(a) sum substituted by S.I. 2023/300 reg. 4(a)
- reg. 16(3)(b) sum substituted by S.I. 2021/178 reg. 4(b)
- reg. 16(3)(b) sum substituted by S.I. 2023/300 reg. 4(b)
- reg. 16(3)(c) sum substituted by S.I. 2021/178 reg. 4(c)
- reg. 16(3)(c) sum substituted by S.I. 2023/300 reg. 4(c)
- reg. 17(4)(a) sum substituted by S.I. 2021/178 reg. 5(a)(i)
- reg. 17(4)(a) sum substituted by S.I. 2023/300 reg. 5(a)(i)
- reg. 17(4)(b) sum substituted by S.I. 2021/178 reg. 5(a)(ii)

- reg. 17(4)(b) sum substituted by S.I. 2023/300 reg. 5(a)(ii)
- reg. 17(4)(c)(i) sum substituted by S.I. 2021/178 reg. 5(a)(ii)
- reg. 17(4)(c)(i) sum substituted by S.I. 2023/300 reg. 5(a)(ii)
- reg. 17(4)(c)(ii) sum substituted by S.I. 2021/178 reg. 5(a)(ii)
- reg. 17(4)(c)(ii) sum substituted by S.I. 2023/300 reg. 5(a)(ii)
- reg. 17(5) sum substituted by S.I. 2021/178 reg. 5(b)
- reg. 17(5) sum substituted by S.I. 2023/300 reg. 5(b)

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

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 10(h)(j) inserted by S.I. 2023/171 reg. 7(c)
- reg. 15(2A) inserted by S.I. 2021/1346 reg. 13(4)
- reg. 15A inserted by S.I. 2021/1346 reg. 14
- reg. 17(11) inserted by S.I. 2023/171 reg. 9
- reg. 17A inserted by S.I. 2023/171 reg. 10
- reg. 17A substituted by S.I. 2023/300 reg. 6