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. (See end of Document for details) View outstanding changes*

STATUTORY INSTRUMENTS

2015 No. 570

NATIONAL HEALTH SERVICE, ENGLAND

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

Made - - - -	*4th March 2015*
Laid before Parliament	*11th March 2015*
Coming into force - -	*1st April 2015*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 172(1) and (2), 174, 178, 182, 184(1) and 272(7) and (8) of the National Health Service Act 2006 [F1].

F1 2006 c. 41. *See* section 275(1) of the National Health Service Act 2006 ("the 2006 Act") which contains definitions of "prescribed" and "regulations" that are relevant to the powers being exercised. By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.

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 [F2];

"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) **[**F3created 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 F4 (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 F5 (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;

F6…

"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 F7 (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 F8 (definitions applying for the purposes of the whole Act);

"arrangements for recharging" means arrangements under paragraph 3 of Schedule 12A to the 2006 Act F9 (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 F10 (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 **[**F11Health 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 F12 (community treatment orders);

"directed services" means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act F13 (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 F14 (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 F15 (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 **[**F16or 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 **[**F17or 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);

[[F18]"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 [F19] (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 [F20] (the Health and Social Care Information Centre);

[[F21]"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 [F22] (application of Act: "mental disorder");

[[F23]"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 [F24] (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 **[**[F25]section 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";

[[F26]"paramedic independent prescriber" means a person—

(a) who is registered in Part 8 of the register maintained under article 5 of the **[**[F27]Health 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 [F28];