STATUTORY INSTRUMENTS

2018 No. 1114

The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018

PART 3

Amendments to the Charges Regulations

Amendment of regulation 2 of the Charges Regulations

11.—(1) Regulation 2(1) of the Charges Regulations(1) (interpretation) is amended as follows.

(2) In sub-paragraph (c) of the definition of "electronic prescription form", after "nominated dispensing contractor" insert "or via an information hub".

(3) In sub-paragraph (b) of the definition of "electronic repeatable prescription", after "nominated dispensing contractor" insert "or via an information hub".

(4) At the appropriate place in the alphabetical order insert—

""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(2);".

(5) At the appropriate place in the alphabetical order insert—

"paramedic independent prescriber" means a person-

- (a) who is registered in Part 8 of the register maintained under article 5 of the Health and Social Work Professions Order 2001(3) (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;".

(6) In the definition of "prescriber", after "optometrist independent prescriber" insert ", a paramedic independent prescriber".

(7) At the appropriate place in the alphabetical order insert—

""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;".

⁽¹⁾ Regulation 2 has been amended by S.I. 2015/1879 and 2016/696 and 1077.

⁽²⁾ S.I. 2005/2414; amended by S.I. 2006/632, 2007/1201, 2013/235, 2015/1862, 2017/959 and 2018/378.

⁽³⁾ S.I. 2002/254; amended by S.I. 2009/1182. The Health and Social Work Professions Order 2001 is to be renamed the Health Professions Order 2001 by virtue of the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraph 45, on a date to be appointed.

Amendment of regulation 3 of the Charges Regulations

12.—(1) Regulation 3 of the Charges Regulations(4) (supply of drugs and appliances by chemists) is amended as follows.

- (2) In paragraph (3)(b), after "by a chemist" insert "or the prescriber".
- (3) In paragraph (4)(b), after "by a chemist" insert "or the prescriber".
- (4) In paragraph (5), omit sub-paragraphs (a) and (b).
- (5) After paragraph (5), insert the following paragraphs—

"(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(5) (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

⁽⁴⁾ Relevant amendments have been made to regulation 3 by S.I. 2016/1077 and 2018/201.

 ⁽⁵⁾ S.I. 2003/2382; amended by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475, 2015/643, 993 and 1776, and 2016/1045.

the Human Medicines Regulations 2012(6) (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.".

Amendment of Regulation 4 of the Charges Regulations

13.—(1) Regulation 4 of the Charges Regulations(7) (supply of drugs and appliances by doctors) is amended as follows.

- (2) In paragraph (2)(b), after "by a doctor" insert "or the prescriber".
- (3) In paragraph (3), for sub-paragraphs (a) and (b) substitute—
 - "(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);".
- (4) After paragraph (3) insert the following paragraphs—

"(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).".

⁽⁶⁾ S.I. 2012/1916; amended by S.I. 2014/490.

⁽⁷⁾ Relevant amendments have been made to regulation 4 by S.I. 2018/201.

Amendment of regulation 10 of the Charges Regulations

14.—(1) Regulation 10 of the Charges Regulations (exemptions: general) is amended as follows.

- (2) In paragraph (4), for "or 4(3)," substitute "to (5E) or 4(3) to (3B),".
- (3) In paragraph (5), for "and 4(3)" substitute "to (5E) and 4(3) to (3B)".

New regulation 18A of the Charges Regulations

15. After regulation 18 of the Charges Regulations (repayment of charges), insert the following regulation—

"Sharing 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(8),

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