STATUTORY INSTRUMENTS

2018 No. 1114

NATIONAL HEALTH SERVICE, ENGLAND

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

Made - - - -	*24th October 2018*
Laid before Parliament	*29th October 2018*
Coming into force - -	*26th November 2018*

CONTENTS

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7(1C), 85(1), 89(1) and (2)(a) and (c), 94(1), 126(2), 129(6), 130(1), 132(1), 150A, 172(1), 178, 182, 184(1) and 272(7) and (8) of, and paragraph 3(1) and (3)(c) and (d) of Schedule 12 to, the National Health Service Act 2006(**a**).

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 and come into force on 26th November 2018.

(2) In these Regulations—

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

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

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

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(**a**) 2006 c.41. Section 7(1C) was inserted by Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), section 21(1) and (2). Section 89 has been amended by the 2012 Act, sections 28(1) and 202(2), and Schedule 4, paragraph 34. Section 94 has been amended by the 2012 Act, section 28(2), and Schedule 4, paragraph 38, and by the Crime and County Courts Act 2013 (2013 c. 22), Schedule 9, paragraph 52(1) and (2). Section 126 has been amended by the 2012 Act, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63. Section 129(6) has been amended by: the Health Act 2009 (c. 21) ("the 2009 Act"), sections 26 and 27, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Section 130 has been amended by the 2012 Act, section 207(10), and Schedule 4, paragraph 67, and by S.I. 2010/22. Section 132 has been amended by the 2012 Act, Schedule 4, paragraph 69, by the Protection of Freedoms Act 2012, Schedule 9, paragraph 122, and by S.I. 2007/289 and 2010/22 and 231. Section 150A was inserted by the 2009 Act, section 28, and has been amended by the 2012 Act, Schedule 4, paragraph 78. Paragraph 3 of Schedule 12 has been amended by the 2009 Act, section 29(13) to (15), and by the 2012 Act, Schedule 4, paragraph 93(4). *See* section 275(1) of the 2006 Act for the meanings given to "prescribed" and "regulations". 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.

(**b**) S.I. 2015/570.

(**c**) S.I. 2015/1862.

(**d**) S.I. 2013/349.

"the PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2015(**a**).

PART 2

Amendments to the PLPS Regulations

Amendment of regulation 2 of the PLPS Regulations

2.—(1) Regulation 2(1) of the PLPS Regulations(**b**) (interpretation) is amended as follows.

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

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

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

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

(3) 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(**c**); 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;".

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

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

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

Amendment of regulation 69 of the PLPS Regulations

3.—(1) Regulation 69 of the PLPS Regulations (local dispute resolution before serving remedial notices or breach notices) is amended as follows.

(2) In paragraph (3)(b)(i), after "good cause" insert ", the NHSCB having made reasonable efforts to communicate with C with a view to establishing what the cause was".

Amendment of regulation 70 of the PLPS Regulations

4.—(1) Regulation 70 of the PLPS Regulations (breaches of terms of service: remedial notices) is amended as follows.

(2) After paragraph (7), insert the following paragraph—

"(8) The NHSCB may rescind a remedial notice at any time.".

(**a**) S.I. 2015/1879.
(**b**) Regulation 2 has been amended by S.I. 2015/137, 570, 1862 and 1879, and 2016/696 and 1077.
(**c**) 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 71 of the PLPS Regulations

5.—(1) Regulation 71 of the PLPS Regulations (breaches of terms of service: breach notices) is amended as follows.

(2) After paragraph (4), insert the following paragraph—

"(5) The NHSCB may rescind a breach notice at any time.".

Amendment of Schedule 3 to the PLPS Regulations

6.—(1) Schedule 3 to the PLPS Regulations(**a**) (appeals to the Secretary of State) is amended as follows.

(2) In paragraph 8 (oral hearings), in sub-paragraph (2)(a), omit from ", which—" to "at the oral hearing".

Amendment of Schedule 4 to the PLPS Regulations

7.—(1) Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists) is amended as follows.

(2) In paragraph 5(**b**) (dispensing of drugs and appliances)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "P receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "P receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 7(**c**) (preliminary matters before providing ordered drugs or appliances)—

(a) in sub-paragraph (3), for "a declaration" substitute "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription";

(b) after sub-paragraph (3), insert the following sub-paragraph—

"(3ZA) For the purposes of sub-paragraph (3), satisfactory evidence includes evidence derived from a check, known as a real time exemption check, of electronic records that are

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(**a**) There are no relevant amendments to Schedule 3.
(**b**) Paragraph 5 has been amended by S.I. 2015/915.
(**c**) Paragraph 7 has been amended by S.I. 2015/570 and 2016/296.

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 the Charges Regulations."; and

(c) in sub-paragraph (5), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (3))".

(4) In paragraph 9 (refusal to provide drugs or appliances ordered), after sub-paragraph (2) insert the following sub-paragraph—

"(2A) P may refuse to provide a drug or appliance ordered on an electronic prescription if the access that P has to the Electronic Prescription Service is not such as to enable P to dispense that prescription promptly (or at all).".

(5) In paragraph 11 (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (5), insert the following sub-paragraph—

"(6) If P dispenses an electronic prescription or makes an urgent supply without a prescription, P must send the form duly completed by or on behalf of the patient, if one is required under regulation 3(3)(b) or (c), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.".

Amendment of Schedule 5 to the PLPS Regulations

8.—(1) Schedule 5 to the PLPS Regulations (terms of service of NHS appliance contractors) is amended as follows.

(2) In paragraph 4 (dispensing of appliances)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) or (ii), and

(ii) requests the provision of an appliance in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) or (ii), and

(ii) requests the provision of appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 6(**a**) (preliminary matters before providing appliances)—

(a) in sub-paragraph (3)(a), for "a declaration" substitute "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription";

(b) in sub-paragraph (3)(c), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (a))"; and

(c) after sub-paragraph (3), insert the following sub-paragraph—

"(3A) For the purposes of sub-paragraph (3), satisfactory evidence includes evidence derived from a check, known as a real time exemption check, 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 the Charges Regulations.".

(4) In paragraph 8 (refusal to provide appliances ordered), after sub-paragraph (1) insert the following sub-paragraph—

"(1A) C may refuse to provide an appliance ordered on an electronic prescription if the access that C has to the Electronic Prescription Service is not such as to enable C to dispense that prescription promptly (or at all).".

(5) In paragraph 10 (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (5), insert the following sub-paragraph—

"(6) If C dispenses an electronic prescription or makes an urgent supply without a prescription, C must send the form duly completed by or on behalf of the patient, if one is required under regulation 3(3)(b), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.".

Amendment of Schedule 6 to the PLPS Regulations

9.—(1) Schedule 6 to the PLPS Regulations (terms of service of dispensing doctors) is amended as follows.

(2) In paragraph 2(**b**) (dispensing of drugs and appliances ordered by another prescriber)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "D receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents D with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(**a**) Paragraph 6 has been amended by S.I. 2015/570.
(**b**) Paragraph 2 has been amended by S.I. 2015/915.

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "D receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents D with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 4(**a**) (preliminary matters before providing ordered drugs or appliances)—

(a) in sub-paragraph (a), for "a declaration" substitute "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription"; and

(b) in sub-paragraph (c), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (a))".

(4) After paragraph 4, insert the following paragraph—

"**Charge exemption and remission of charges: declarations and checks**

4A.—(1) For the purposes of paragraph 4, satisfactory evidence includes evidence derived from a check, known as a real time exemption check, 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 the Charges Regulations.

(2) If D dispenses an electronic prescription, D must send the form duly completed by or on behalf of the patient, if one is required under regulation 4(2)(b) or (3A) of the Charges Regulations in respect of that electronic prescription (which may be the associated EPS token), to the NHS BSA.".

(5) In paragraph 6 (refusal to provide drugs or appliances ordered), after sub-paragraph (1) insert the following sub-paragraph—

"(1A) D may refuse to provide a drug or appliance ordered on an electronic prescription if the access that D has to the Electronic Prescription Service is not such as to enable D to dispense that prescription promptly (or at all).".

Amendment of Schedule 7 to the PLPS Regulations

10.—(1) Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 3(**b**) (dispensing)—

(a) in sub-paragraph (1)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) in paragraph (b)(i), after "a drug" insert "or appliance",

(iv) insert "; or" at the end of paragraph (b), and

(**a**) Paragraph 4 has been amended by S.I. 2015/570.
(**b**) Paragraph 3 has been amended by S.I. 2015/915.

(v) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of a drug or appliance in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

(ii) requests the provision of a drug or appliance in accordance with the related electronic repeatable prescription,".

(3) In paragraph 5(**a**) (preliminary matters before providing ordered drugs or appliances)—

(a) in sub-paragraph (3), for "a declaration" substitute "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription";

(b) after sub-paragraph (3), insert the following sub-paragraph—

"(3ZA) For the purposes of sub-paragraph (3), satisfactory evidence includes evidence derived from a check, known as a real time exemption check, 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 the Charges Regulations."; and

(c) in sub-paragraph (5), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (3))".

(4) In paragraph 7 (refusal to provide drugs or appliances ordered), after sub-paragraph (2) insert the following sub-paragraph—

"(2A) C may refuse to provide a drug or appliance ordered on an electronic prescription if the access that C has to the Electronic Prescription Service is not such as to enable C to dispense that prescription promptly (or at all).".

(5) In paragraph 9 (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (4), insert the following sub-paragraph—

"(5) If C dispenses an electronic prescription or makes an urgent supply without a prescription, C must send the form duly completed by or on behalf of the patient, if one is required under regulation 3(3)(b) or (c), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.".

(**a**) Paragraph 5 has been amended by S.I. 2015/570 and 2016/296.

PART 3

Amendments to the Charges Regulations

Amendment of regulation 2 of the Charges Regulations

11.—(1) Regulation 2(1) of the Charges Regulations(**a**) (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(**b**);".

(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(**c**) (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;".

Amendment of regulation 3 of the Charges Regulations

12.—(1) Regulation 3 of the Charges Regulations(**d**) (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**) Regulation 2 has been amended by S.I. 2015/1879 and 2016/696 and 1077.
(**b**) S.I. 2005/2414; amended by S.I. 2006/632, 2007/1201, 2013/235, 2015/1862, 2017/959 and 2018/378.
(**c**) 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.
(**d**) Relevant amendments have been made to regulation 3 by S.I. 2016/1077 and 2018/201.

(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(**a**) (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(**b**) (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.".

(**a**) 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.

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

Amendment of Regulation 4 of the Charges Regulations

13.—(1) Regulation 4 of the Charges Regulations(**a**) (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). ".

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

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

(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(**a**),

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

PART 4

Amendments to the GMS Contracts Regulations

Amendment of regulation 3 of the GMS Contracts Regulations

16.—(1) Regulation 3 of the GMS Contracts Regulations(**b**) (interpretation) is amended as follows.

(2) In paragraph (b)(ii) of the definition of "prescription form", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(3) In paragraph (c)(ii) of the definition of "repeatable prescription", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

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

""authorised person", in relation to a patient, is a person who is entitled to make an application for pharmaceutical services on behalf of the patient by virtue of regulation 116(a) to (c) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (authorised persons to apply for services);".

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

""contractor's EPS phase 4 date" means the date, encoded within the Electronic Prescription Service software, which is the date that a contractor has agreed is to be the date on and after which the contractor's prescribers are to use the Electronic Prescription Service for all eligible prescriptions;".

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

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

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

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

(**a**) 2018 c. 12.
(**b**) Regulation 3 has been amended by S.I. 2016/696 and 1077 and 2018/844.

Amendment of regulation 56 of the GMS Contracts Regulations

17.—(1) Regulation 56 of the GMS Contracts Regulations (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (1), for "paragraphs (2) and (3)" substitute "paragraphs (1A), (2) and (3)".

(3) After paragraph (1), insert the following paragraphs—

"(1A) If, on a particular occasion when a drug, medicine or appliance is needed as mentioned in paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription;

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser; and

(c) none of the reasons for issuing a non-electronic prescription form or a non-electronic repeatable prescription given in paragraph (1B) apply,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(1B) The reasons given in this paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that the prescriber has to the Electronic Prescription Service is reliable, or

(ii) the Electronic Prescription Service is functioning reliably;

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in England;

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or a non-electronic repeatable prescription for a particular prescription and in the professional judgment of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued;

(d) the prescription is to be issued before the contractor's EPS phase 4 date or the contractor has no such date.".

Amendment of regulation 57 of the GMS Contracts Regulations

18.—(1) Regulation 57 of the GMS Contracts Regulations (electronic prescriptions) is amended as follows.

(2) In paragraph (1), omit sub-paragraphs (a) and (b).

(3) After paragraph (1), insert the following paragraphs—

"(1A) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to paragraph (1C), an EPS token; and

(b) if the patient, or where appropriate an authorised person, so requests, a written record of the prescription that has been created.

(1B) On and after the contractor's EPS phase 4 date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

(1C) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.".

(4) Omit paragraphs (3) and (4).

Amendment of regulation 58 of the GMS Contracts Regulations

19.—(1) Regulation 58 of the GMS Contracts Regulations (nomination of dispensers for the purposes of electronic prescriptions) is amended as follows.

(2) In paragraph (1)—

(a) in the opening words, after "its patients must", insert ", if a patient, or where appropriate the patient's authorised person, so requests,"; and

(b) in sub-paragraph (a), after "chosen by the patient", insert ", or where appropriate the patient's authorised person".

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) in sub-paragraph (a), after "a patient" insert "or a patient's authorised person"; and

(b) in sub-paragraph (b)—

(i) after "by a patient", insert "or a patient's authorised person",

(ii) after "whom the patient", insert "or the patient's authorised person", and

(iii) after "provide the patient", insert "or, as the case may be, the patient's authorised person".

PART 5

Amendments to the PMS Agreements Regulations

Amendment of regulation 3 of the PMS Agreements Regulations

20.—(1) Regulation 3 of the PMS Agreements Regulations(**a**) (interpretation) is amended as follows.

(2) In paragraph (b)(ii) of the definition of "prescription form", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(3) In paragraph (b)(ii) of the definition of "repeatable prescription", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

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

""authorised person", in relation to a patient, is a person who is entitled to make an application for pharmaceutical services on behalf of the patient by virtue of regulation 116(a) to (c) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (authorised persons to apply for services);".

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

""contractor's EPS phase 4 date" means the date, encoded within the Electronic Prescription Service software, which is the date that a contractor has agreed is to be the date on and after which the contractor's prescribers are to use the Electronic Prescription Service for all eligible prescriptions;".

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

(**a**) Regulation 3 has been amended by S.I. 2016/696 and 1077 and 2018/844.

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

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

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

Amendment of regulation 49 of the PMS Agreements Regulations

21.—(1) Regulation 49 of the PMS Agreements Regulations (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (1), for "paragraphs (2) and (3)" substitute "paragraphs (1A), (2) and (3)".

(3) After paragraph (1), insert the following paragraphs—

"(1A) If, on a particular occasion when a drug, medicine or appliance is needed as mentioned in paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription;

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser; and

(c) none of the reasons for issuing a non-electronic prescription form or a non-electronic repeatable prescription given in paragraph (1B) apply,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(1B) The reasons given in this paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that the prescriber has to the Electronic Prescription Service is reliable, or

(ii) the Electronic Prescription Service is functioning reliably;

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in England;

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or a non-electronic repeatable prescription for a particular prescription and in the professional judgment of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued;

(d) the prescription is to be issued before the contractor's EPS phase 4 date or the contractor has no such date.".

Amendment of regulation 50 of the PMS Agreements Regulations

22.—(1) Regulation 50 of the PMS Agreements Regulations (electronic prescriptions) is amended as follows.

(2) In paragraph (1), omit sub-paragraphs (a) and (b).

(3) After paragraph (1), insert the following paragraphs—

"(1A) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to paragraph (1C), an EPS token; and

(b) if the patient, or where appropriate an authorised person, so requests, a written record of the prescription that has been created.

(1B) On and after the contractor's EPS phase 4 date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

(1C) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.".

(4) Omit paragraphs (3) and (4).

Amendment of regulation 51 of the PMS Agreements Regulations

23.—(1) Regulation 51 of the PMS Agreements Regulations (nomination of dispensers for the purposes of electronic prescriptions) is amended as follows.

(2) In paragraph (1)—

(a) in the opening words, after "its patients must", insert ", if a patient, or where appropriate the patient's authorised person, so requests,"; and

(b) in sub-paragraph (a), after "chosen by the patient", insert "or where appropriate the patient's authorised person".

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) in sub-paragraph (a), after "the patient" insert "or the patient's authorised person"; and

(b) in sub-paragraph (b)—

(i) after "by the patient", insert "or the patient's authorised person",

(ii) after "whom the patient", insert "or the patient's authorised person", and

(iii) after "provide the patient", insert "or, as the case may be, the patient's authorised person".

Signed by authority of the Secretary of State for Health and Social Care.

Steve Brine
Parliamentary Under-Secretary of State,
Department of Health and Social Care

24th October 2018

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations"), which govern the arrangements in England under Part 7 of the National Health Service Act 2006 ("the 2006 Act") for the provision of pharmaceutical services and local pharmaceutical services. These Regulations also amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015 ("the Charges Regulations"), which provide for the making and recovery of charges for drugs and appliances supplied in England, most often on prescription, under the 2006 Act. These Regulations also amend the National Health Service (General Medical Services Contracts) Regulations 2015 ("the GMS Contracts Regulations") and the National Health Service (Personal Medical Services Agreements) Regulations 2015 ("the PMS Agreements Regulations"), which make provision in

respect of the services provided in England under a general medical services contract and a personal medical services agreement made pursuant to Part 4 of the 2006 Act.

Part 1 contains general provisions. Part 2 contains the amendments to the PLPS Regulations – and principally these amendments relate to electronic prescribing. Prior to these Regulations, an NHS patient wishing to have an electronic prescription dispensed by a provider of pharmaceutical or local pharmaceutical services needed have a nominated dispensing contractor who was recorded as such in the Electronic Prescription Service (EPS). However, new arrangements known as EPS phase 4 will allow for the NHS patient to have a prescription dispensed by a dispensing contractor who is not the patient's nominated dispensing contractor but to whom the patient presents an EPS token which has the appropriate barcode – as well as allowing for dispensing by a nominated dispensing contractor (regulations 2(2) and (4) to (6), 7(2) and (5)(a), 8(2) and (5)(a), 9(2) and 10(2) and (5)(a)). Not all dispensing contractors will have the facility to dispense against such a token, and these Regulations also ensure that dispensing contractors are not under an obligation to dispense if they do not have the necessary access to the EPS (regulations 7(4), 8(4), 9(5) and 10(4)). All patients who are claiming exemption from prescription charges, apart from those who are exempt by reason of their age, are obliged to make a declaration to the dispensing contractor that they are exempt, and amendments are made to dispensing contractors' terms of service both in relation to the recording of these declarations and for allowing real time exemption checks of electronic database records managed by the NHS Business Services Authority to be considered by the dispensing contractor as satisfactory evidence of exemption entitlement (regulations 7(3), 8(3), 9(3) and (4), and 10(3)). Forms recording patient declarations, where these have to be completed, have to be sent on by the dispensing contractor to the NHS Business Services Authority (regulations 7(5)(b), 8(5)(b), 9(4) and 10(5)(b)).

Some other amendments are also made to the PLPS Regulations. Provision is made so that prescriptions written by paramedic independent prescribers will be dispensed as part of pharmaceutical and local pharmaceutical services (regulation 2(3)). Providers of such services who are known as NHS chemists are subject to an enforcement scheme that provides for the service of breach and remedial notices by the NHS Commissioning Board (now known as NHS England), and amendments are made to provide for the rescission of such notices (regulations 4 and 5). Also, if NHS England are minded to serve a breach notice relating to an NHS chemist not being open for business at its notified hours without good cause, they are now required to make a reasonable effort to communicate with the NHS chemist to find out what the cause was (regulation 3). A number of decisions by NHS England under the PLPS Regulations are appealable to the NHS Litigation Authority, and there is a simplification of the arrangements under which certain third parties may attend oral hearings, removing a requirement that they need to indicate, when they make their written representations, that they also wish to make oral representations (regulation 6).

Under the Charges Regulations, entitlement to some exemptions from paying prescription charges is based on the patient both having a valid exemption certificate (recording for example a relevant medical exemption) and duly declaring the exemption. The obligations on NHS chemists and doctors in general practice to levy prescription charges are amended so that, if the prescription is an electronic prescription, the obligation not to levy a charge is predicated on the record of that declaration being duly entered into the EPS. In the case of a paper prescription, it is predicated on the paper declaration by or on behalf of the patient. In the case of an electronic prescription, the patient or someone acting on their behalf is nevertheless required to produce a separate declaration of entitlement, unless the dispensing contractor has been able to undertake a check known as a real time exemption check of electronic database records managed by the NHS Business Services Authority, which has confirmed the entitlement to an exemption declared by the patient (regulations 11(2) and (3) and 12 to 14).

Provision is also made in the Charges Regulations so that prescriptions charges can be levied in respect of prescriptions written by paramedic independent prescribers (regulation 11(4) and (5)), and to provide for a statutory gateway to enable information on or derived from both electronic and paper prescriptions to be used for the purposes of paying providers of NHS services (such as NHS chemists and doctors in general practice) and for matters relating to prescription charge enforcement. That statutory gateway also ensures that a duty of confidentiality is owed by the

persons using the data for the specified purposes, whether or not they would otherwise owe such a duty (regulation 15).

The terms of service in the GMS Contracts Regulations and the PMS Agreements Regulations in respect of electronic prescribing are also amended to take account of the new EPS phase 4 arrangements, described above, under which patients will be able to have an electronic prescription dispensed by a dispensing contractor who is not the patient's nominated dispensing contractor. Prior to these Regulations, prescribers prescribing under a general medical services contract or a personal medical services agreement (most commonly doctors in general practice) had the option of issuing either a paper prescription or an electronic prescription. If the prescriber's practice is participating in EPS phase 4, the prescriber will be under an obligation to issue an electronic rather than a paper prescription, subject to various exceptions. If the NHS patient has a nominated dispensing contractor, he or she will be asked if they wish to use that dispensing contractor, and if they do, the prescriber will not issue an EPS token (making the prescribing process potentially paperless) (regulation 16(2), (3), (5) and (6), 17, 18, 20(2), (3), (5) and (6), 21 and 22). In some instances, prescription items are requested on behalf rather than by patients, and arrangements for nominating dispensing contractors in the PLPS, GMS Contracts and PMS Agreements Regulations are aligned so the same categories of authorised representatives can act on behalf of patients under all these sets of Regulations (regulation 16(4), 19, 20(4) and 23).

An impact assessment has not been prepared for this instrument. It does not create or impose significant costs on business, charities or voluntary bodies. There is also no significant impact on the public sector.

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