STATUTORY INSTRUMENTS

2019 No. 990

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019

Made - - - -	*5th June 2019*
Laid before Parliament	*7th June 2019*
Coming into force - -	*1st July 2019*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126(2), 129(6), 132, 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(**1**).

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019 and come into force on 1st July 2019.

(2) In these Regulations—

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2015(**2**); and

"the PLPS Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**3**).

(**1**) 2006 c.41. Section 126 has been amended by the Health and Social Care Act 2012 (c. 7) ("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 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. 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 National Health Service Act 2006 ("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.

(**2**) S.I. 2015/570, as amended.

(**3**) S.I. 2013/349, as amended.

PART 2

Amendments to the PLPS Regulations

Amendment of regulation 2 of the PLPS Regulations

2.—(1) Regulation 2(1) of the PLPS Regulations(**4**) (interpretation) is amended as follows.

(2) At the appropriate places insert—

""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(**5**) (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;"; and

""SSP" means a serious shortage protocol;".

New regulation 119A of the PLPS Regulations

3. After regulation 119 of the PLPS Regulations (transitional provisions) insert—

"**Transitional provisions in respect of drugs or appliances supplied in accordance with SSPs**

119A.—(1) This paragraph applies where—

(a) pursuant to paragraph 5A(4)(a) of Schedule 4, paragraph 4A(4)(a) of Schedule 5, paragraph 3A(2)(a) of Schedule 6 or paragraph 3A(4)(a) of Schedule 7, an NHS chemist, an LPS chemist or a dispensing doctor is required to endorse a prescription or an associated batch issue; and

(b) the Secretary of State (or the NHS BSA acting on the Secretary of State's behalf) is only able, or is also able, to process a claim for pharmaceutical reimbursement in respect of the product being provided if the claim is made using a separate token

(**4**) Regulation 2 has been amended by S.I. 2015/137, 570, 1862 and 1879, 2016/696 and 1077 and 2018/1114.
(**5**) S.I. 2012/1916; regulation 226A was inserted by S.I. 2019/62.

("a dispensing token"), which is in a form approved by the Secretary of State for the purposes of making such claims (and for prescription charge purposes).

(2) Where paragraph (1) applies—

(a) to the extent required or permitted by the Drug Tariff, a dispensing token recording the provision of the product is treated as being, as regards that product, the prescription for product reimbursement purposes;

(b) if the manner for recording the provision of the product in the dispensing token is provided for in the Drug Tariff, the recording of the provision of the product in the dispensing token must be in the manner provided for in the Drug Tariff; and

(c) the manner of the endorsement of the original prescription or associated batch issue (where provided for in the Drug Tariff) may vary, depending on whether or not it is to be used for product reimbursement purposes.

(3) Where, by virtue of paragraph (2)(a), a dispensing token is treated as being the prescription for product reimbursement purposes—

(a) paragraph 7(6) of Schedule 4 applies as if the reference to paragraph 5A(4)(a) of that Schedule included a reference, in the alternative, to paragraph (2)(a);

(b) paragraph 6(3B) of Schedule 5 applies as if the reference to paragraph 4A(4)(a) of that Schedule included a reference, in the alternative, to paragraph (2)(a);

(c) paragraph 4B of Schedule 6 applies as if the reference to paragraph 3A(2)(b) of that Schedule included a reference, in the alternative, to paragraph (2)(a); and

(d) paragraph 5(6) of Schedule 7 applies as if the reference to paragraph 3A(4)(a) of that Schedule included a reference, in the alternative, to paragraph (2)(a).

(4) For the purposes of this regulation, "pharmaceutical reimbursement" has the meaning given in paragraph 19(3) of Schedule 7.".

Amendment of Schedule 4 to the PLPS Regulations

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

(2) After paragraph 5 (dispensing of drugs and appliances) insert—

"**Supply in accordance with a SSP**

5A.—(1) This sub-paragraph applies where—

(a) any person requests a drug or appliance from an NHS pharmacist (P) in accordance with a prescription form or repeatable prescription; and

(b) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, P must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, P may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

(a) P is able to do so with reasonable promptness;

(b) to do so is in accordance with the SSP; and

(c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a registered pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where P, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

(a) the registered pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription); and

(b) if the patient to or for whom the product is provided is on a patient list, and the supply—

(i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012(**6**) (sale etc. by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or

(ii) is of any other type, and the Secretary of State and the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on its patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

P must notify the provider of primary medical services on whose patient list the patient is of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(5) Where—

(a) sub-paragraph (1) applies;

(b) a registered pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) P is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 5(2) and (3) are to be read as requirements to act within a reasonable timescale.".

(3) In paragraph 7(**7**) (preliminary matters before providing ordered drugs or appliances), after sub-paragraph (5) insert—

"(6) Sub-paragraphs (3) to (5) apply to the provision of a drug or appliance in accordance with a SSP as they apply to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these

(**6**) Inserted by S.I. 2019/62.
(**7**) Amended by S.I. 2015/570, 2016/296 and 2018/1114.

purposes, the prescription for product reimbursement purposes, as mentioned in paragraph 5A(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).".

(4) In paragraph 8 (providing ordered drugs or appliances)—

(a) in sub-paragraph (4), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,";

(b) in sub-paragraph (5), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,";

(c) in sub-paragraph (10), after "or a repeatable prescription" insert ", or is to be provided in accordance with a SSP,";

(d) in sub-paragraph (15), after "under paragraph 5" insert ", or provides under paragraph 5A,"; and

(e) after sub-paragraph (15) insert—

"(16) Where P provides a drug or appliance under paragraph 5A, P must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.".

(5) In paragraph 9(**8**) (refusal to provide drugs or appliances ordered), after sub-paragraph (2A) insert—

"(2B) P must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description; and

(b) alternative provision has already taken place in accordance with the SSP.

(2C) P may refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description;

(b) a registered pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) P is unable to provide the drug or appliance within a reasonable timescale,

but if P does refuse to do so, P must provide the patient or the person requesting the drug or appliance on behalf of a patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.".

(6) In paragraph 10(2)(**9**) (further activities to be carried out in connection with the provision of dispensing services), after "4, P is unable" insert "(having regard to any relevant SSP)".

(**8**) Amended by S.I. 2018/1114.
(**9**) Amended by S.I. 2015/58.

Amendment of Schedule 5 to the PLPS Regulations

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

(2) After paragraph 4 (dispensing of appliances) insert—

"**Supply in accordance with a SSP**

4A.—(1) This sub-paragraph applies where—

(a) any person requests an appliance from an NHS appliance contractor (C) in accordance with a prescription form or repeatable prescription; and

(b) a SSP has effect in respect of—

(i) the requested appliance, or

(ii) appliances of a specified description, and the requested appliance is of that description.

(2) Where sub-paragraph (1) applies, C must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, C may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

(a) C is able to do so with reasonable promptness;

(b) to do so is in accordance with the SSP; and

(c) C is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where C, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

(a) C must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription); and

(b) if—

(i) the patient to or for whom the product is provided is on a patient list, and

(ii) the supply is of a type in relation to which the Secretary of State and the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS appliance contractors, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on its patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

C must notify the provider of primary medical services on whose patient list the patient is of the supply in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription.

(5) Where—

(a) sub-paragraph (1) applies;

(b) C is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) C is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 4(2) and (3) are to be read as requirements to act within a reasonable timescale.".

(3) In paragraph 6(**10**) (preliminary matters before providing appliances), after sub-paragraph (3A) insert—

"(3B) Sub-paragraphs (3) and (3A) apply to the provision of an appliance in accordance with a SSP as they apply to the provision of an appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes the prescription for product reimbursement purposes, as mentioned in paragraph 4A(4)(a), is treated as being the prescription in accordance with which the appliance is provided (even though the supply is not in pursuance of that prescription).".

(4) In paragraph 7 (providing appliances)—

(a) in sub-paragraph (2), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,";

(b) in sub-paragraph (3), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,"; and

(c) after sub-paragraph (3), insert—

"(4) Where C provides an appliance under paragraph 4A, C must include with it in a written note, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.".

(5) In paragraph 8(**11**) (refusal to provide appliances ordered), after sub-paragraph (1A) insert—

"(1B) C must refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested appliance; or

(ii) appliances of a specified description, and the requested appliance is of that description; and

(b) alternative provision has already taken place in accordance with the SSP.

(1C) C may refuse to provide an appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested appliance, or

(ii) appliances of a specified description, and the requested appliance is of that description;

(b) C is of the opinion that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) C is unable to provide the appliance within a reasonable timescale,

but if C does refuse to do so, C must provide the patient or the person requesting the appliance on behalf of a patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.".

(**10**) Amended by S.I. 2015/570 and 2018/1114.
(**11**) Amended by S.I. 2018/1114.

Amendment of Schedule 6 to the PLPS Regulations

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

(2) After paragraph 3 (dispensing of drugs and appliances ordered by a dispensing doctor), insert the following paragraph—

"**Supply in accordance with a SSP**

3A.—(1) This sub-paragraph applies where, in relation to an order for a drug or an appliance on a prescription form or a repeatable prescription—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug appliance is of that description.

(2) Where sub-paragraph (1) applies and D provides a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, in accordance with the SSP—

(a) D must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff); and

(b) the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription).

(3) Where D provides a drug or appliance under this paragraph, D must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.".

(3) In paragraph 4 (preliminary matters before providing ordered drugs or appliances), after "in accordance with paragraph 3" insert "or 3A".

(4) After paragraph 4A(**12**) (charge exemption and remission of charges: declarations and checks) insert—

"**Checks and records in the case of supply in accordance with a SSP**

4B. In a case involving providing drugs or appliances in accordance with paragraph 3A, the references in paragraph 4 to a prescription form or repeatable prescription are to be construed as references to the prescription for product reimbursement purposes, as mentioned in paragraph 3A(2)(b).".

(5) In paragraph 6 (refusal to provide drugs or appliances ordered), after sub-paragraph (3) insert —

"(4) D must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance; or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description; and

(**12**) Inserted by S.I. 2018/1114.

(b) alternative provision has already taken place in accordance with the SSP.".

Amendment of Schedule 7 to the PLPS Regulations

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

(2) After paragraph 3 (dispensing) insert—

"**Supply in accordance with a SSP**

3A.—(1) This sub-paragraph applies where—

(a) any person requests a drug or appliance from an LPS contractor (C) in accordance with a prescription form or repeatable prescription; and

(b) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description.

(2) Where sub-paragraph (1) applies, C must consider whether it is reasonable and appropriate to supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.

(3) Where sub-paragraph (1) applies, C may provide a different product or quantity of product to the product or quantity of product ordered on the prescription form or repeatable prescription, where—

(a) C is able to do so with reasonable promptness;

(b) to do so is in accordance with the SSP; and

(c) the supply of a different product or quantity of product to that ordered by the prescriber is by or under the direct supervision of a registered pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is reasonable and appropriate.

(4) Where C, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

(a) the registered pharmacist mentioned in sub-paragraph (3)(c) must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription); and

(b) if the patient to or for whom the product is provided is on a patient list, and the supply—

(i) by virtue of regulation 226A(5)(c)(iii) of the Human Medicines Regulations 2012(**13**) (sale etc. by a pharmacist in accordance with a serious shortage protocol), is of a prescription only medicine that is different to but has a similar therapeutic effect to the product ordered by the prescriber, or

(ii) is of any other type, and the Secretary of State and the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act in

(**13**) Inserted by S.I. 2019/62.

respect of pharmaceutical remuneration of LPS chemists, acting jointly, have issued and publicised in such manner as they see fit a recommendation to the effect that, for clinical reasons, in the case of supplies of that type, providers of primary medical services should be notified of a supply to a patient on its patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

C must notify the provider of primary medical services on whose patient list the patient is of the supply in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription.

(5) Where—

(a) sub-paragraph (1) applies;

(b) a registered pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) C is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirements to act with reasonable promptness in paragraph 3(1) and (2) are to be read as requirements to act within a reasonable timescale.".

(3) In paragraph 5(**14**) (preliminary matters before providing ordered drugs or appliances), after sub-paragraph (5) insert—

"(6) Sub-paragraphs (3) to (5) apply to the provision of a drug or appliance in accordance with a SSP as they apply to the provision of a drug or appliance in accordance with a prescription form or a repeatable prescription (or an associated batch issue), and for these purposes the prescription for product reimbursement purposes, as mentioned in paragraph 3A(4)(a), is treated as being the prescription in accordance with which the drug or appliance is provided (even though the supply is not in pursuance of that prescription).".

(4) In paragraph 6 (providing ordered drugs or appliances)—

(a) in sub-paragraph (2), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,";

(b) in sub-paragraph (3), after "If the order is for" insert ", or a product to be provided in accordance with a SSP is,";

(c) in sub-paragraph (8), after "or repeatable prescription" insert ", or is to be provided in accordance with a SSP,";

(d) in sub-paragraph (13), after "under paragraph 3" insert ", or provides under paragraph 3A,"; and

(e) after sub-paragraph (13) insert—

"(14) Where C provides a drug or appliance under paragraph 3A, C must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a SSP, identifying the particular SSP.".

(5) In paragraph 7(**15**) (refusal to provide drugs or appliances ordered), after sub-paragraph (2A) insert—

"(2B) C must refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

(**14**) Amended by S.I. 2015/570, 2016/296 and 2018/1114.
(**15**) Amended by S.I. 2018/1114.

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description; and

(b) alternative provision has already taken place in accordance with the SSP.

(2C) C may refuse to provide a drug or appliance ordered on a prescription form or a repeatable prescription where—

(a) a SSP has effect in respect of—

(i) the requested drug or appliance, or

(ii) drugs or appliances of a specified description, and the requested drug or appliance is of that description;

(b) a registered pharmacist is of the opinion, in the exercise of his or her professional skill and judgement, that supplying a different product or quantity of product to that ordered by the prescriber is unreasonable or inappropriate; and

(c) C is unable to provide the drug or appliance within a reasonable timescale,

but if C does refuse to do so, C must provide the patient or the person requesting the drug or appliance on behalf of a patient with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.".

PART 3

Amendments to the Charges Regulations

Amendment of regulation 2 of the Charges Regulations

8.—(1) Regulation 2(1) of the Charges Regulations(**16**) (interpretation) is amended as follows.

(2) At the appropriate places insert—

""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(**17**) (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,

(**16**) Regulation 2 has been amended by S.I. 2015/1879, 2016/696 and 1077 and 2018/1114.
(**17**) S.I. 2012/1916. Regulation 226A was inserted by S.I. 2019/62.

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;"; and

""SSP" means a serious shortage protocol;".

Amendment of regulation 3 of the Charges Regulations

9.—(1) Regulation 3 of the Charges Regulations(**18**) (supply of drugs and appliances by chemists) is amended as follows.

(2) In paragraph (6), after "13" insert ", 13A".

(3) After paragraph (11) insert—

"(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).".

Amendment of regulation 4 of the Charges Regulations

10.—(1) Regulation 4 of the Charges Regulations(**19**) (supply of drugs and appliances by doctors) is amended as follows.

(2) In paragraph (3)(d), for "or 13" substitute ", 13 or 13A".

(3) After paragraph (8) insert—

"(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

(**18**) Relevant amendments have been made to regulation 3 by S.I. 2016/1077, 2018/1114 and 2019/287.
(**19**) Relevant amendments have been made to regulation 4 by S.I. 2016/1077, 2018/1114 and 2019/287.

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).".

New regulation 13A of the Charges Regulations

11. After regulation 13 of the Charges Regulations (exemption from charges: risks to public health) insert—

"**Exemption 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.".

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

Seema Kennedy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

5th June 2019

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"). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006 ("the 2006 Act"), for the provision of pharmaceutical and local pharmaceutical services. Dispensing services are provided as part of these services by retail pharmacy businesses, dispensing appliance contractors (which are only allowed to dispense appliances, not drugs) and, in some rural areas, dispensing doctors.

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 make provision in relation to serious shortage protocols (SSPs). SSPs allow the Secretary of State to put in place alternative arrangements for supply where a drug or appliance is ordered on prescription but there is, or may in the future be, a serious shortage of the drug or appliance.

SSPs under the Human Medicines Regulations 2012 ("the 2012 Regulations") allow pharmacists at retail pharmacy businesses to supply a different prescription only medicine, or a different quantity of a prescription only medicine, to that ordered by a prescriber, without breaching the restrictions on the sale or supply of prescription only medicines in Part 12 of the 2012 Regulations. These Regulations extend the potential scope of SSPs to all drugs and appliances that may be dispensed as part of the provision of pharmaceutical and local pharmaceutical services in England – not just prescription only medicines (regulations 2 and 8).

Where a SSP is in place for a particular product, a retail pharmacy business or a dispensing appliance contractor must consider supplying in accordance with the SSP rather than fulfilling an NHS prescription for that product. It may, instead of fulfilling the NHS prescription, supply a different product, or a different quantity of the ordered product, in the circumstances and subject to the conditions set out in the SSP. If the retail pharmacy business or dispensing appliance contractor – or a dispensing doctor – does supply in accordance with the SSP (rather than, in the case of a dispensing doctor, issuing a new prescription), the original NHS prescription must be endorsed accordingly (regulations 4(2), 5(2), 6(2) and 7(2)).

If a product supplied by a retail pharmacy business in accordance with a SSP is a prescription only medicine that is different to but has a similar therapeutic effect to the product originally ordered, it must notify the patient's NHS GP practice of the substitution (if the patient has one). A retail pharmacy business or dispensing appliance contractor must also notify a patient's NHS GP practice in other cases of a supply in accordance with a SSP, if a requirement to notify has been agreed between the Secretary of State and the relevant representative body for consultation in relation to pharmaceutical remuneration (regulations 4(2), 5(2) and 7(2)).

When a pharmacy retail pharmacy business, dispensing appliance contractor or dispensing doctor supplies a product in accordance with a SSP instead of fulfilling a prescription, a notification that the supply is in accordance with the SSP must be included in the dispensing label on the packaging of the product supplied or, in the case of a supply by a dispensing appliance contractor, in a separate note for the patient (regulation 4(4)(e), 5(4)(c), 6(2) and 7(4)(e)).

A number of consequential changes are made to the NHS terms of service for retail pharmacy businesses, dispensing appliance contractors and dispensing doctors in Schedules 4 to 7 of the PLPS Regulations. In particular, if a retail pharmacy business, a dispensing appliance contractor or a dispensing doctor makes a supply in accordance with a SSP, the original NHS prescription can no longer be fulfilled – and the original prescription from, in an endorsed form, is repurposed as the record of the SSP supply for payment and prescription charges purposes. If a retail pharmacy business or dispensing appliance contractor does not think it reasonable or appropriate to supply in accordance with protocol, but is unable to fulfil the original prescription with reasonable promptness (the normal timescale required for fulfilling prescriptions), it does not breach its NHS terms of service if it nevertheless fulfils the original prescription within a reasonable timescale. However, if it does not think it reasonable or appropriate to supply in accordance with the SSP but cannot fulfil the original prescription within a reasonable timescale, it may simply refuse to dispense the product in question. If it does refuse to do so, it must provide the patient or the patient's representative with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment (regulations 4(2), (3), (4)(a) to (d), (5) and (6), 5(2), (3), (4)(a) and (b) and (5), 6 and 7(2), (3), (4)(a) to (d) and (5)).

Consequential changes are also made to the provisions of the Charges Regulations that apply where retail pharmacy businesses, dispensing appliance contractors or dispensing doctors provide pharmaceutical or local pharmaceutical services.

In parallel with the changes to the PLPS Regulations, if a retail pharmacy business, a dispensing appliance contractor or a dispensing doctor makes a supply in accordance with a SSP, the original prescription from, in an endorsed form, is repurposed as the record of the SSP supply for prescription charge exemption and remission of charges purposes. Additionally if, as a consequence of a supply being in accordance with a SSP instead of being in accordance with the original prescription, a patient who would otherwise pay a prescription charge is supplied with a smaller quantity of a drug or fewer appliances, no prescription charge is payable (regulations 9 to 11).

There is a transitional provision that allows for the issuing of tokens ("dispensing tokens") that can function, instead of the endorsed original prescription, as the record of the supply in accordance with an SSP for prescription charge, prescription charge exemption and remission of charges purposes – and for the purposes of reimbursing the dispenser. These transitional arrangements are to apply while reimbursement systems are not able to process payments to dispensers on the basis of the endorsed original prescriptions, or while reimbursement systems permit the use of both forms (regulations 3, 9(3) and 10(3)).