STATUTORY INSTRUMENTS

2019 No. 990

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

PART 2

Amendments to the PLPS Regulations

Amendment of regulation 2 of the PLPS Regulations

2.—(1) Regulation 2(1) of the PLPS Regulations(**1**) (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(**2**) (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—

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

"**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 ("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(**3**) (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

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

(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(**4**) (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 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(**5**) (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;

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

(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)(**6**) (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)".

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

(**6**) Amended by S.I. 2015/58.

(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(**7**) (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(**8**) (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

(**7**) Amended by S.I. 2015/570 and 2018/1114.
(**8**) Amended by S.I. 2018/1114.

(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.".

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(**9**) (charge exemption and remission of charges: declarations and checks) insert—

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

"**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

(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(**10**) (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 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(**11**) (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,";

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

(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(**12**) (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—

(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.".

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