STATUTORY INSTRUMENTS

2019 No. 990

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

PART 3

Amendments to the Charges Regulations

Amendment of regulation 2 of the Charges Regulations

- **8.**—(1) Regulation 2(1) of the Charges 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

Amendment of regulation 3 of the Charges Regulations

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

[&]quot;"SSP" means a serious shortage protocol;".

⁽¹⁾ Regulation 2 has been amended by S.I. 2015/1879, 2016/696 and 1077 and 2018/1114.

⁽²⁾ S.I. 2012/1916. Regulation 226A was inserted by S.I. 2019/62.

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

- (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(**4**) (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 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."