
WELSH STATUTORY INSTRUMENTS

2019 No. 1330

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

Amendment of Schedule 4 to the Pharmaceutical Services Regulations

3.—(1) Schedule 4 to the Pharmaceutical Services Regulations⁽¹⁾ (terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provision of drugs) 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) a person requests a drug or appliance from an NHS pharmacist 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, the NHS pharmacist 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, the NHS pharmacist 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) the NHS pharmacist 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 their 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 an NHS pharmacist, 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 so endorsed is

⁽¹⁾ Schedule 4 has been amended by [S.I. 2019/917 \(W. 162\)](#).

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 (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 Welsh Ministers and the person who is, for the time being, the person consulted under section 89(1)(a) of the 2006 Act⁽²⁾ 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 their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS pharmacist 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 their 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) the NHS pharmacist 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(1) and (2) are to be read as requirements to act within a reasonable timescale.”

(3) In paragraph 7 (preliminary matters before providing ordered drugs or appliances), after sub-paragraph (2) insert—

“(3) Sub-paragraph (2) applies to the provision of a drug or appliance in accordance with a SSP as it does 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 “Where a drug is ordered by a prescriber” insert “, or is to be provided in accordance with a SSP,”,

(d) in sub-paragraph (14), for “this paragraph” substitute “paragraph 5, or provides under paragraph 5A”, and

(2) See the definition of “the 2006 Act” in regulation 2(1) of the Pharmaceutical Services Regulations.

(e) after sub-paragraph (14) insert—

“(15) Where an NHS pharmacist provides a drug or appliance under paragraph 5A, the NHS pharmacist 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 (refusal to provide drugs or appliances ordered), after sub-paragraph (2) insert—

“(2A) An NHS pharmacist 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.

(2B) An NHS pharmacist 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 their 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) the NHS pharmacist is unable to provide the drug or appliance within a reasonable timescale,

but if the NHS pharmacist does refuse to do so, they must provide the patient or the person requesting the drug or appliance on behalf of the 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) (further activities to be carried out in connection with the provision of dispensing services), after “under paragraph 4, an NHS pharmacist is unable” insert “(having regard to any relevant SSP)”.