
W E L S H S T A T U T O R Y
I N S T R U M E N T S

2019 No. 1330 (W. 229)

**NATIONAL HEALTH
SERVICE, WALES**

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I. 2013/898 (W. 102)) (“the Pharmaceutical Services Regulations”). The Pharmaceutical Services Regulations govern the arrangements for the provision of pharmaceutical and local pharmaceutical services in Wales, under Part 7 of the National Health Service (Wales) Act 2006 (c. 42).

As a result of amendments made to the Human Medicines Regulations 2012 (S.I. 2012/1916) (“the 2012 Regulations”) by the Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), Serious Shortage Protocols (“SSPs”) may be issued by the Secretary of State and/or the Minister for Health, Social Services and Public Safety in Northern Ireland (either of them acting alone or both of them acting jointly), in circumstances where the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage of a prescription only medicine. SSPs issued under the 2012 Regulations allow pharmacists at retail pharmacy businesses to supply a different prescription only medicine, or a different strength, form or quantity of the prescription only medicine, to that ordered by the prescriber, in the circumstances and subject to the conditions specified within the SSP, without breaching the restrictions on the sale or supply of prescription only medicines in Part 12 of the 2012 Regulations.

These Regulations make a number of consequential changes to the NHS terms of service for NHS pharmacists and NHS appliance contractors in Schedules 4 and 5 to the Pharmaceutical Services Regulations, and make provision in relation to SSPs.

Regulation 2 of these Regulations amends the Pharmaceutical Services Regulations to extend the scope of SSPs. The amendments enable the Welsh Ministers to issue SSPs relating to health care products (drugs and appliances) that are not prescription only. Where the Welsh Ministers are of the opinion that Wales (or a part of Wales) is experiencing, or may experience, a serious shortage of the healthcare product concerned, they may issue a SSP to enable NHS pharmacists and NHS appliance contractors providing pharmaceutical or local pharmaceutical services in Wales, to supply a different product or quantity of product to that ordered on a prescription form. The supply must be in accordance with any conditions contained with the applicable SSP, and only in the circumstances specified.

Where a SSP is in place, the NHS pharmacist or NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP rather than fulfilling the NHS prescription for that product. Where an NHS pharmacist or NHS appliance contractor does supply in accordance with the SSP, the original NHS prescription must be endorsed accordingly. The original NHS prescription can no longer be fulfilled, and the original prescription form, in its endorsed form, is repurposed as the record of the SSP supply for payment purposes. An NHS pharmacist must include information to the effect that the product is being supplied in accordance with a SSP in the dispensing label on the packaging of the product supplied. An NHS appliance contractor must provide information to the effect that the product is being supplied in accordance with a SSP, in a written note for the patient's benefit (regulations 3(2), (3) and (4)(e) and 4(2), (3) and (4)(c)).

If a product supplied by (or under the supervision of) an NHS pharmacist 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, the NHS pharmacist must notify the patient's NHS GP practice of the substitution (if the patient has one). An NHS pharmacist or NHS 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 Welsh Ministers and the relevant representative body for consultation in relation to pharmaceutical remuneration (regulations 3(2) and 4(2)).

If an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP, but is unable to fulfil the original prescription with reasonable promptness (the normal timescale required for fulfilling prescriptions), they will not breach the NHS terms of service if the original prescription is nevertheless fulfilled within a reasonable timescale (regulations 3(2) and 4(2)).

Where an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP but cannot fulfil the original prescription within a reasonable timescale, they may refuse to dispense the product in question. If they do refuse to do so, they 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 3(5) and 4(5)).

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.

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2019 No. 1330 (W. 229)

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

Made 8 October 2019

Laid before the National Assembly for Wales
10 October 2019

Coming into force 31 October 2019

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 80(2), 83(6), and 203(9) and (10) of the National Health Service (Wales) Act 2006⁽¹⁾.

Title, commencement and interpretation

1.—(1) The title of these Regulations is the National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019.

(2) These Regulations come into force on 31 October 2019.

(3) In these Regulations, “the Pharmaceutical Services Regulations” means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013⁽²⁾.

⁽¹⁾ 2006 c. 42.

⁽²⁾ S.I. 2013/898 (W. 102), amended by S.I. 2014/2291 (W. 226), S.I. 2016/696, S.I. 2016/1221 (W. 292), S.I. 2019/149 (W. 34) and S.I. 2019/917 (W. 162). It is prospectively amended by S.I. 2019/1094.

Amendment of regulation 2 of the Pharmaceutical Services Regulations

2.—(1) Regulation 2(1) of the Pharmaceutical Services Regulations⁽¹⁾ (interpretation) is amended as follows.

(2) At the appropriate places insert—

““serious shortage protocol” (*“protocol prinder difrifol”*) 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 Welsh Ministers in circumstances where Wales or any part of Wales is, in the opinion of the Welsh Ministers, 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 an NHS pharmacist or an NHS appliance contractor providing 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 Wales (which may be

(1) Regulation 2 has been amended by S.I. 2014/2291 (W. 226), S.I. 2016/696, S.I. 2016/1221 (W. 292) and S.I. 2019/149 (W. 34). It is prospectively amended by S.I. 2019/1094.

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

all of Wales) in which, the protocol is to have effect;”, and
““SSP” (“PPD”) means a serious shortage protocol;”.

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

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

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 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⁽¹⁾ 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

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

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
- (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)”.

Amendment of Schedule 5 to the Pharmaceutical Services Regulations

4.—(1) Schedule 5 to the Pharmaceutical Services Regulations⁽¹⁾ (terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances) 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) a person requests an appliance from an NHS appliance contractor 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, an NHS appliance contractor 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, an NHS appliance contractor 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 appliance contractor is able to do so with reasonable promptness;
- (b) to do so is in accordance with the SSP; and
- (c) the NHS appliance contractor 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 an NHS appliance contractor, in accordance with sub-paragraph (3), provides a different product or quantity of product to that ordered by the prescriber—

- (a) the NHS appliance contractor must endorse the prescription or the associated batch issue accordingly (if the manner for making the endorsement is provided for in the

⁽¹⁾ Schedule 5 has been amended by S.I. 2019/917 (W. 162).

Drug Tariff, in the manner provided for in the Drug Tariff), and the prescription or associated batch issue as so 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 Welsh Ministers and the person who is, for the time being, the person consulted under section 89(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 their patient list that is in accordance with a SSP instead of in accordance with a prescription form or repeatable prescription,

the NHS appliance contractor 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) an NHS appliance contractor 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) the NHS appliance contractor is able to supply the product or quantity of product ordered by the prescriber within a reasonable timescale but not with reasonable promptness,

the requirement to act with reasonable promptness in paragraph 4(2) is to be read as a requirement to act within a reasonable timescale.”

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

“(3A) Sub-paragraph (3) applies to the provision of an appliance in accordance with a SSP as it applies 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 an NHS appliance contractor provides an appliance under paragraph 4A, the NHS appliance contractor 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 (refusal to provide appliances ordered), after sub-paragraph (1) insert—

“(1A) An NHS appliance contractor 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.

(1B) An NHS appliance contractor 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) the NHS appliance contractor 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) the NHS appliance contractor is unable to provide the appliance within a reasonable timescale,

but if the NHS appliance contractor does refuse to do so, they must provide the patient or the person requesting the 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.”

Vaughan Gething

Minister for Health and Social Services, one of the
Welsh Ministers

8 October 2019