

SL(6)551 – The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2024

Background and Purpose

These Regulations make amendments to secondary legislation relating to Pharmaceutical Services in Wales to:

- Amend the current terms of service for NHS Community Pharmacy Contractors;
- Extend the existing regulations for the dispensing, supply and provision of medicines and appliances by community pharmacists to include signed orders issued by optometrists working in the NHS in Wales as part of the Wales General Ophthalmic Services (WGOS) introduced in 2023;
- Introduce regulations to allow the implementation of original pack dispensing by NHS pharmacies and dispensing doctors in Wales.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

The following 15 points are identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

Regulation 1(3) of these Regulations states that "*Regulation 8*" comes into force on 1 January 2025. However, these Regulations only contain 4 regulations and a Schedule. Regulation 1(3) therefore appears to be an error.

Likewise, regulation 1(4) states that "*All other regulations*" come into force at a later date, namely 1 April 2025. Because of the provision set out in regulation 1(3), this would have the consequence of provisions concerning the title and territorial application of these Regulations, and the coming into force provision in regulation 1(3), coming into force on 1 April 2025. This is unworkable as these provisions would need to be brought into force at the same time or prior to the regulation set out (albeit in error) in regulation 1(3).



2. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 2(2) of these Regulations, it should be stated that definitions are to be inserted into regulation 2(1) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (emphasis added), rather than generically referring to “*regulation 2*”, for clarity of drafting.

3. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 2(2) of these Regulations, a definition of “*Electronic Prescription Service*” is inserted into regulation 2 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. However, the definition is not used elsewhere in either these Regulations or the existing text of the 2020 Regulations and, as such, it is not clear why the insertion of this definition has been considered necessary.

4. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 2(2) of these Regulations, definitions for the terms “*ophthalmic listed medicine*” and “*ophthalmic listed appliance*” are inserted into regulation 2 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. However, rather than these defined terms, the terms “*listed medicine*” and “*listed appliance*”, which have not been defined for the purposes of the 2020 Regulations, are used in the text to be inserted into Schedule 5 of the 2020 Regulations by regulation 3 of these Regulations.

The Welsh Government is asked to clarify the drafting intention behind the use of these different terms, as it appears that it would have been clearer to have used the defined terms in the amendments to Schedule 5 of the 2020 Regulations.

5. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

In regulation 2(2) of these Regulations, the definition of the “*Ophthalmic Combined List*” makes reference to “***the list*** required to be prepared by Local Health Boards by virtue of regulation 10 of the National Health Service (Ophthalmic Services) (Wales) Regulations 2023” (emphasis added).

The Welsh Government is asked to clarify whether “*the list*” is a reference to “*the combined list*” provided for in regulation 10 of the 2023 Regulations, given that regulation 10 also refers to “*the ophthalmic list*” and “*the supplementary list*”, which together make up the “*combined list*”.

6. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 3(3) of these Regulations, in the new paragraph 5A(3)(a) of Schedule 5 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, there is an



incorrect reference to “*paragraph (4)*”, which should instead be described as “*sub-paragraph (4)*”. The same error occurs in the new paragraph 5A(5) of Schedule 5 to the 2020 Regulations, where the reference to “*paragraph (4)*” should be described as “*sub-paragraph (4)*”.

This is potentially confusing for the reader because provisions such as sub-paragraphs (6), (7) and (8) in the new paragraph 5A of Schedule 5 to the 2020 Regulations state “*to which this paragraph applies*”, “*In this paragraph*” and “*under this paragraph*” respectively when appearing to refer to the new paragraph 5A of Schedule 5, rather than only to sub-paragraphs (6), (7) and (8).

7. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 3(3) of these Regulations, in the new paragraph 5A of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, there are several references to “*drugs*” and “*appliances*”. “*Drugs*” is an existing defined term in regulation 2(1) of the 2020 Regulations, as is “*appliance*”.

However, if the undefined terms “*listed appliance*” and “*listed medicine*”, which are also used in several places in the new paragraph 5A of Schedule 5 to the 2020 Regulations, are intended to have a narrower meaning than “*appliance*” and “*drug*”, clarity is required as to whether it was intended that “*listed appliance*” and “*listed medicine*” be used consistently throughout the new paragraph 5A. Alternatively, it may have been helpful to have defined the terms “*listed appliance*” and “*listed medicine*” for the purposes of the 2020 Regulations (or part of it) to differentiate their meaning more clearly in contrast to the defined terms “*appliance*” and “*drugs*”.

8. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 3(5) of these Regulations, in the new sub-paragraphs (8B) and (8C) that are inserted into paragraph 9 of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, the term “*prescription only medicine*” is used. Although it is acknowledged that the 2020 Regulations already refer to this term in several instances, it is not defined for the purposes of the 2020 Regulations and these Regulations may have been an opportune mechanism to have defined that term for clarity.

9. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

In regulation 3(5) of these Regulations, in the new sub-paragraph (8C)(b) that is inserted into paragraph 9 of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, it refers to “*the registered pharmacist carrying out or **directly** supervising the provision...*” (emphasis added). However, in regulation 3(4) of these Regulations, the phrase “*direct*” is omitted from the phrase “*...the **direct** supervision of a registered*”



pharmacist” (emphasis added) in a similar context in paragraph 9(2) of Schedule 5 to the 2020 Regulations.

The Welsh Government is asked to clarify whether it was intended that these provisions, which appear in a similar context, carry a different meaning through the use or otherwise of the terms “*direct*” or “*directly*”.

10. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 3(14)(a) of these Regulations, in the new text that is inserted into paragraph 23(6)(a) of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, it refers to “*sub-paragraph (6)(c)*”. However, this cross-reference is incorrect because there is no sub-paragraph (6)(c) in paragraph 23 of Schedule 5 to the 2020 Regulations, nor is that provision inserted by these Regulations.

11. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 3(16) of these Regulations, in the new sub-paragraph (6B) that is inserted into paragraph 23 of Schedule 5 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, the reference at the end to “*paragraph (6)*” should read “*sub-paragraph (6)*”. This is potentially confusing to the reader as the same provision makes an earlier correct reference to “*sub-paragraph (2)*”, which is at the same division level as “*paragraph (6)*”.

12. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

In regulation 3(18) of these Regulations, in the new paragraph 28(3)(a)(iv) of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, the word “*should*” is used when referring to a requirement.

Whilst it is acknowledged that the word “*should*” is used in several places in the existing text of the 2020 Regulations (such as in paragraph 28(3)(a)(i) and (iv) of Schedule 5, and paragraph 17(3)(a)(i) and (iv) of Schedule 6), the Welsh Government is asked to clarify whether the word “*must*” should have been used in relation to the requirement.

13. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In paragraph 2 of the Schedule to these Regulations, in the new definition of “*qualifying optometrist*” to be inserted into regulation 2 of the National Health Service (Ophthalmic Services) (Wales) Regulations 2023, reference is made to a Local Health Board’s “*Ophthalmic Combined List*”. However, this term is not defined for the purposes of the 2023 Regulations.

The term “*combined list*” is defined for the purposes of the 2023 Regulations by regulation 2 of the 2023 Regulations. Therefore, it appears that the term “*combined list*” should have been



used in the new definition of “*qualifying optometrist*” in paragraph 2 of the Schedule to these Regulations.

14. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In paragraph 3 of the Schedule to these Regulations, in the new regulation 4A(1) of the National Health Service (Ophthalmic Services) (Wales) Regulations 2023, it states that “A *qualifying optometrist* **will** order...” (emphasis added). However, the use of “*will*” is inconsistent with the following new regulation 4B of the 2023 Regulations, which is also inserted by paragraph 3 of the Schedule to these Regulations, which states that “A *qualifying optometrist* **must** not order...”.

Therefore, it is not clear whether the use of different terms is designed to convey a different meaning.

15. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In paragraph 3 of the Schedule to these Regulations, in the new regulation 4B of the National Health Service (Ophthalmic Services) (Wales) Regulations 2023 as inserted, it states that a qualifying optometrist must not order “*drugs*” or “*appliances*”. However, unlike for the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, those terms are not defined for the purposes of the 2023 Regulations.

The new regulation 4A of the 2023 Regulations, which is also inserted by paragraph 3 of the Schedule to these Regulations, refers to a qualifying optometrist ordering “*ophthalmic listed medicines*” or “*ophthalmic listed appliances*”, which are new defined terms inserted into regulation 2 of the 2023 Regulations by paragraph 2 of the Schedule to these Regulations.

It is therefore unclear whether the new regulation 4B of the 2023 Regulations should also use the new defined terms, rather than the words “*drugs*” or “*appliances*”, which are not defined for the purposes of the 2023 Regulations.

Merits Scrutiny

No points are identified for reporting under Standing Order 21.3 in respect of this instrument.

Welsh Government response

A Welsh Government response is required.

Committee Consideration

The Committee considered the instrument at its meeting on 9 December 2024 and reports to the Senedd in line with the reporting points above.

