SL(6)542 – <u>The National Health Service (General</u> <u>Medical Services Contracts) (Prescription of Drugs</u> <u>Etc.) (Wales) (Amendment) (No. 2) Regulations 2024</u>

Background and Purpose

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 (the "principal Regulations"), which make provisions as to the drugs, medicines or other substances that may be ordered under certain circumstances for patients in the provision of medical services under a general medical services contract ("GMS contract") within the meaning of section 42 of the National Health Service (Wales) Act 2006.

The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2024 (the "2024 Regulations") made in July 2024 amended the principal Regulations. They placed restrictions on the prescribing of gonadotrophin releasing hormone (GnRH) analogues by general medical practitioners in Wales when used to suppress puberty as part of treating gender incongruence or gender dysphoria in children and young people under 18 years of age.

These Regulations extend these restrictions beyond treatment provided by a general medical practitioner to treatment provided under a GMS contract. This will capture prescribers such as an independent nurse prescriber or an independent pharmacist prescriber who is prescribing under a GMS contract. The Explanatory Note explains that this "change recognises the increase in the use of independent prescribers (including medical and non-medical prescribers) in GMS settings and makes clear that the restrictions apply to any person prescribing under a general medical services contract including prescribing by independent prescribers."

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 point is identified for reporting under Standing Order 21.2 in respect of this instrument.



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

Regulation 2(3)(b) of these Regulations omits the definition of a "general medical practitioner", which was previously inserted by the 2024 Regulations, from Schedule 2 to the principal Regulations. This follows on from the amendment to column 2, paragraph (2), in the entry for "GnRH analogue", by regulation 2(3)(a) of these Regulations, which removes the reference to a "general medical practitioner" in that entry.

However, it is noted that the table in Schedule 2 to the principal Regulations makes several other references to "general medical practitioners" in the entries relating to "Oseltamivir (Tamiflu)" and "Zanamivir (Relenza)". As a result of the amendment made by regulation 2(3)(b), those references will no longer have a defined meaning.

The Welsh Government is asked to clarify the interpretation of "general medical practitioners" in Schedule 2 to the principal Regulations, following the amendment made by regulation 2(3)(b).

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument.

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

The 2024 Regulations adopted a definition of a "general medical practitioner" as a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council under section 2 of the Medical Act 1983 (the "1983 Act"). This definition was inserted into Schedule 2 to the principal Regulations.

The Committee considered and <u>reported</u> on the 2024 Regulations on 16 July 2024. It reported on a lack of clarity concerning that definition by noting that the General Practitioner Register was maintained under section 34C, rather than section 2, of the 1983 Act. The Welsh Government's <u>response</u> to the Committee's report accepted the lack of clarity and explained that the provision would be made clearer "at the next available opportunity, and within the next 12 months". In a <u>letter</u> to the Cabinet Secretary for Health and Social Care on 24 September 2024, the Committee expressed disappointment that this lack of clarity would remain on the statute book for up to another 12 months.

The policy intention behind these Regulations is to extend the restrictions on the prescription of puberty blockers beyond general medical practitioners. This policy change was set out in the Cabinet Secretary's <u>response</u> to the Committee on 7 October 2024 and further detail is provided in the Explanatory Memorandum to these Regulations.

As a consequence, the definition of a "general medical practitioner" that was inserted into Schedule 2 to the principal Regulations by the 2024 Regulations is omitted by regulation 2(3)(b) of these Regulations.

Welsh Government response

A Welsh Government response is required in relation to reporting point 1.

Committee Consideration

The Committee considered the instrument at its meeting on 11 November 2024 and reports to the Senedd in line with the reporting points above.