

Explanatory Memorandum to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) (No.2) Regulations 2024

This Explanatory Memorandum has been prepared by Directorate of Primary Care and Health Science; Health, Social Care and Early Years Group and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Cabinet Secretary's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) (No.2) Regulations 2024. I am satisfied that the benefits justify the likely costs.

Jeremy Miles MS
Cabinet Secretary for Health and Social Care

25th October 2024

PART 1

1. Description

- 1.1 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 National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 (“the principal Regulations”) placing restrictions on the prescribing of gonadotrophin releasing hormone (GnRH) analogues by NHS general practitioners (GPs) 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.
- 1.2 Following the making of the 2024 Regulations, the Legislation, Justice and Constitution Committee sought clarity on the definition of General Medical Practitioner.
- 1.3 The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) (No.2) Regulations 2024 (“the No.2 Regulations”) make clear that the restrictions on prescribing GnRH analogues apply to all prescriptions made under a general services medical contract.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

- 2.1 The 2024 Regulations came into force on 19 July 2024. The 2024 Regulations imposed restrictions on the prescribing of GnRH analogues to patients under 18 years of age by General Medical Practitioners.
- 2.2 In preparing the 2024 Regulations officials adopted a definition of “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 Legislation, Justice and Constitution committee subsequently requested clarification of this definition because the Medical Act 1983 provides for two registers that could potentially apply to the definition. The registers in question are:
 - section 2 of the Medical Act 1983 which provides for a “register of medical practitioners”; and
 - section 34C of the Medical Act 1983 which provides for a “register of general practitioners, known as the General Practitioner Register”.
- 2.3 The policy intention was to refer to the register made under Section 2 of the Act. This definition would include both registered GPs (who are also included in the register made under section 34C) and other medical practitioners who could potentially prescribe, for example, GP registrars, trainees, or non-GPs who work under a general medical services contract.

- 2.4 The policy intention was to ensure that general practitioners were restricted from prescribing puberty blockers unless permitted by the Regulations. That legal effect is achieved because either register includes qualified general practitioners as per the original policy intention. Further amendments are now required to clarify this point and to take account of the increasing number of non-medical prescribers working in general practice in Wales.
- 2.5 In recent years the general practice workforce has diversified, with other professionals such as nurses, pharmacists, physiotherapists and paramedics now routinely working in primary care. Whilst the 2024 regulations impose restrictions on prescribing of GnRH analogues by medical prescribers it could be interpreted that they do not place the same restrictions on non-medical prescribers.
- 2.6 The No. 2 amendment regulations make clear the restrictions apply to any prescriber working under a GMS contract.

3 Legislative background

- 3.1 The 2024 Regulations amended the principal Regulations which make provision as to the drugs, medicines or other substances that may be ordered for patients in the provision of medical services under a general medical services contract within the meaning of section 42 of the National Health Service (Wales) Act 2006.
- 3.2 The 2024 Regulations ensured the prescribing of puberty blockers are prescribed in accordance with the NHS' clinical policy for children and young people. They prevent the inappropriate prescribing of puberty blockers to children and young people outside holistic gender identity services, improving effectiveness and safety and preventing unnecessary medical interventions taking place.
- 3.3 The No.2 Regulations further amend the principal Regulations so as to clarify who the restrictions on prescribing GnRH analogue products applies to.
- 3.4 The Welsh Ministers have power to make the Regulations under sections 46(2), 203(9) and (10), and 204(1)(b) of the National Health Service (Wales) Act 2006.
- 3.5 These Regulations follow the negative resolution procedure.

4 Purpose and intended effect of the legislation

- 4.1 On 29 May 2024, the UK Government introduced emergency restrictions on the sale and supply of GnRH analogues when used to suppress puberty as part of treating gender incongruence or gender dysphoria in children and young people under 18 years of age. The restrictions which impact on private prescribing by UK and non-UK registered prescribers came into effect on 3 June 2024.
- 4.2 Alongside the restrictions on private prescribing by UK and non-UK registered prescribers, Regulations were introduced in England which place restrictions on the prescribing of GnRH analogues by NHS GPs in England which prohibit them from initiating new prescriptions for puberty suppressing hormones in children and young people. In July 2024 the Welsh Government made Regulations which place similar restrictions on NHS GPs in Wales.
- 4.3 The Regulations improved safety by ensuring puberty blockers are prescribed in accordance with the NHS England's clinical policy for children and young people. They prevent the inappropriate prescribing of puberty blockers to children and young people outside holistic gender identity services, improving the effectiveness of health services.
- 4.4 Those Regulations also ensure patients in Wales are treated in the same way regardless of the health board area in which they live. They are also treated in the same way as patients in England, promoting equity.
- 4.5 The 2024 Regulations were developed following discussions with the General Practitioner Committee Wales and Community Pharmacy Wales (who represent pharmacies dispensing these medicines) who are most likely to be affected by these changes. The proposals also took account of guidance published by the RCGP and the General Pharmaceutical Council. The No.2 Regulations further amend the principal Regulations to extend the restriction on prescribing GnRH to all prescribers under a general medical services contract.

Impact

- 4.6 The No.2 Regulations proposals are needed to ensure the prescribing of puberty blockers are prescribed in accordance with the NHS' clinical policy for children and young people.
- 4.7 The restrictions in the principal Regulations which were introduced by the 2024 Regulations limit the prescribing by a General Practitioner of GnRH analogues in certain circumstances. The No.2 Regulations extend the restrictions further so that they also apply to non-medical prescribers working in general practice who could prescribe puberty blockers but are not included on a register under those provisions (for example an independent nurse prescriber or an independent pharmacist prescriber who is prescribing under a general medical services "GMS" contract). The restrictions under the No.2 Regulations will apply to any prescribing under a GMS contract.

Duty of Quality

- 4.8 The No.2 Regulations will ensure patients in Wales are treated in the same way regardless of the health board area in which they live.
- 4.9 The Welsh Government's obligations in respect of the Welsh Language Standards, the United Nations Convention on the Rights of the Child (UNCRC), the Equality Act 2010 and the Wellbeing of Future Generations (Wales) Act 2015 have been considered. Making these Regulations does not change any child or young person's right to access treatment. Officials are therefore content there are no issues which need to be addressed in making these Regulations.

5 Consultation

- 5.1 The proposal affects any prescriber working under a GMS contract working in Wales by restricting their prescribing and dispensing of medicines known as gonadotropin releasing hormone (GnRH) analogues which have been used to suppress puberty in children and young people with gender dysphoria or gender incongruence.
- 5.2 Representatives of general practitioners (General Practitioners' Committee Wales) and community pharmacists (Community Pharmacy Wales) were consulted on the intention to place restrictions on prescribing and dispensing of these medicines in primary care. No concerns were raised during the consultation, and both contractors' representatives had no objection to the proposals.
- 5.3. These Regulations clarify a technical point; they clarify who the restrictions in prescribing relate to and make clear that the restrictions apply to any prescribers under a general medical services contract.
- 5.4 No consultation is taking place with persons to represent the interests of those who may require puberty blockers for gender dysphoria.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Options

- 6.1 The No.2 Regulations amend the principal Regulations to clarify that the restrictions on prescribing puberty blockers apply to all prescribers under a general medical services contract. The amendments support the recommendations of the Cass Review. The No.2 Regulations will prevent treatment being initiated inappropriately or unsafely outside specialist services providing the type of holistic care required by this patient cohort as recommended by the Cass Review.
- 6.2 The option not to make regulations restricting prescribing of puberty suppressing hormones by prescribers under a general medical services contract has been considered and discounted on the basis that it is considered the UK wide restrictions on private prescribing may increase the number of children and young people seeking prescriptions from their GP. The restrictions will prevent prescribers under general medical services contracts initiating new prescriptions other than where holistic treatment is provided through gender identity services as envisaged by the Cass Review.

7. Costs and benefits

- 7.1 There are no significant costs or savings associated with the proposals.

8. Competition Assessment

- 8.1 This legislation does not affect business, charities and/or the voluntary sector; therefore, a competition assessment has not been completed.

9. Post implementation review

- 9.1 A post implementation review is not required for this legislation.