

Explanatory Memorandum to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) (Amendment) 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) Regulations 2024. I am satisfied that the benefits justify the likely costs.

Eluned Morgan MS
Cabinet Secretary for Health and Social Care

28 June 2024

PART 1

1. Description

1.1 The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) (Amendment) Regulations 2024 place 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 In addition to the changes restricting the prescribing of puberty suppressing hormones, the Regulations make one further change to remove the current restriction on GPs prescribing of vitamin B12 (cyanocobalamin) tablets.

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

2.1 The final report of the independent review of gender identity services for children and young people (“the Cass Review”) was published in April. The Cass Review was commissioned by NHS England and relates to services provided by NHS England. NHS Wales does not provide gender identity services for children and young people and instead commissions them through NHS England. Therefore, the findings of the Cass Review relate to services that are provided in Wales to Welsh NHS patients.

2.2 The Cass Review was commissioned to make recommendations on how to improve NHS gender identity services and ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria receive a high standard of care, that meets their needs, and is safe, holistic, and effective.

2.3 In conjunction with the review, NHS England consulted on and has implemented a clinical policy on the use of puberty suppressing hormones (“puberty blockers”) which makes clear these medicines will no longer routinely be prescribed as part of NHS children and young people’s gender services given the “remarkably weak” evidence supporting their use in those under the age of 18.

2.4 The Cass Review made specific recommendations relating to the prescribing of puberty blockers to children through UK private (i.e. non-NHS) gender services and by overseas prescribers who were not registered with UK regulators and the need to ensure steps were taken by the UK Government and professional regulators to ensure prescribing was appropriate and aligned with the NHS’s updated policy.

2.5 On 29 May 2024 the UK Government introduced emergency restrictions on the sale or supply of puberty suppressing hormones for children and young

people by prescribers working outside the NHS. Restrictions which impact on private prescribing by UK and non-UK registered prescribers came into effect on 3 June 2024

2.6 The UK Government emergency restrictions on private prescribing were implemented using reserved powers and apply to England, Scotland and Wales.

2.7 The restrictions mean it is now a criminal offence for a doctor, pharmacist or any other individual to sell or supply a GnRH analogue to anyone under the age of 18 other than in specified circumstances. The restrictions will affect private prescriptions for GnRH analogues authorised by non-UK registered and UK registered prescribers although the way in which they are affected differs depending on whether or not the prescriber is registered in the UK. The emergency restrictions did not affect NHS prescribing.

2.8 Alongside the emergency restrictions, the UK government laid an amendment to the 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 in England.

2.9 These Regulations came into force in England on 26 June 2024 and will prohibit NHS GPs in England from prescribing puberty blockers to anyone under 18 years of age unless:

- They are for a condition other than gender incongruence or gender dysphoria;
- The patient commenced treatment prior to 3 June 2024; or
- The patient is receiving treatment as part of a National Institute for Health Research (NIHR) clinical trial.

2.10 Introducing similar restrictions on NHS GPs in Wales to those that have been introduced in England will therefore ensure the arrangements for prescribing and dispensing puberty blockers in England and Wales are the same, thereby minimising any confusion amongst GPs, pharmacies and patients.

2.11 It would also allow the continuation of treatment for any child or young person who might be considered at risk of harm and in the longer term, it will provide for potential shared care arrangements between NHS GPs and specialist gender services whilst preventing NHS GPs from initiating treatment inappropriately, outside specialist services.

2.12 The removal of restrictions on prescribing cyanocobalamin tablets for vitamin B12 deficiency are unrelated to the treatment of gender dysphoria or gender incongruence. Traditionally, vitamin B12 deficiency has been treated using vitamin B12 (hydroxocobalamin) injections, with oral treatment only available on the NHS for vegans and people with vitamin B12 deficiency of dietary origin. Changes to practice now mean oral treatment is considered of

similar efficacy to injectable treatment and is more suitable for some patients. As such the restriction on GPs prescribing oral treatment is being removed.

3. Legislative background

3.1 These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Wales) Regulations 2004 (“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 Regulation 2 makes amendments to the table in Schedule 2 to the principal Regulations (drugs or medicines to be ordered only in certain circumstances) which restricts the circumstances in which drugs and medicines specified in column 1 of the table that consist of or contain gonadotrophin-releasing hormone (GnRH) analogues may be ordered by authorised prescribers at GP practices that hold GMS contracts for patients who are under the age of 18, if they are prescribed for the purpose of puberty suppression in respect of gender dysphoria, gender incongruence or a combination of both.

3.3 Regulation 2(2)(d) removes the restriction on ordering Cyanocobalamin Tablets for the treatment or prevention of vitamin B12 deficiency.

3.4 The Welsh Ministers have power to make the Regulations under sections 46(2), 203(9) and (10) 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 Gender dysphoria is a term that describes a sense of unease that a person may have because of a mismatch between their biological sex and their gender identity. This sense of unease or dissatisfaction may be so intense it can lead to depression and anxiety and have a harmful impact on daily life.

4.2 Some people with gender dysphoria, but not all, may want to use hormones and sometimes surgery to express their gender identity. Prior to March 2024, NHS gender identity services may have prescribed some children and young people with persistent gender dysphoria, medicines known as gonadotrophin releasing hormone (GnRH) analogues. These medicines which are sometimes referred to as puberty blockers were prescribed after a certain stage of pubertal development, alongside psychosocial and psychological support, to arrest the progress of puberty and delay the development of secondary sexual characteristics.

4.3 Gender identity services for children and young people in Wales are commissioned by the NHS Wales Joint Commissioning Committee and provided by NHS England. The Joint Commissioning Committee only provides gender identity services for children and young people through NHS England with services for Welsh patients aligned to those of NHS England.

4.4 In response to the weakness of the evidence underpinning and the long-term implications of use of puberty blockers, in January 2020 NHS England began an independent review of the published evidence on the use of puberty blockers and masculinising/ feminising hormones in children and young people with gender dysphoria to inform a policy position on their future use. Dr Hilary Cass led the review.

4.5 The Cass Review was published in April 2024.

4.6 The Cass Review made recommendations on how to improve NHS gender identity services and ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria receive a high standard of care, that meets their needs, is safe, holistic, and effective.

4.7 On publication of the Cass Review's interim report, NHS England consulted on and subsequently implemented a clinical policy on the use of puberty blockers which makes clear these medicines will no longer routinely be prescribed as part of NHS children and young people's gender services. Whilst NHS England's policy does not allow the routine prescribing of puberty blockers, they may be prescribed in individual circumstances following an individual funding request (IFR).

4.8 In addition to the implementation of the updated NHS policy in England the review made specific recommendations relating to the prescribing of puberty blockers to children through UK private (i.e. non-NHS) gender services and by overseas prescribers who were not registered with UK regulators, and the need to ensure steps were taken by the UK Government and professional regulators to ensure prescribing was appropriate and aligned with the NHS's updated policy.

4.9 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.

4.10 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. The Welsh Government's intention is to make Regulations which place similar restrictions on NHS GPs in Wales.

4.11 The Regulations will improve safety by ensuring puberty blockers are prescribed in accordance with the NHS England's clinical policy for children and young people. They will prevent the inappropriate prescribing of puberty blockers to children and young people outside holistic gender identity services, improving the effectiveness of health services.

4.12 These Regulations will also ensure patients in Wales are treated in the same way regardless of the health board area in which they live. They will also be treated in the same way as patients in England, promoting equity.

4.13 Officials have considered the likely effect of the emergency restriction on demand for GP prescriptions. The Royal College of General Practitioners (RCGP) advise GPs they should not routinely prescribe puberty blockers for gender incongruence or gender dysphoria in children and young people. Officials expect the vast majority of GPs will follow the RCGP advice already however consider it is likely that some GPs will come under increasing pressure from some patients and their families to prescribe following the UK wide restrictions coming into force that restrict private and non-UK prescriptions and may as result, do so.

4.14 The Cass Review found there to be very weak evidence supporting the prescribing of puberty blockers for gender dysphoria and gender incongruence children and young people and also stressed the importance of providing holistic care including psychosocial and psychological support. Such specialist support is unlikely to be available from GPs meaning puberty blockers would be being prescribed in a way which could potentially be unsafe.

4.15 The continuation of a prescription may in some cases be appropriate, for example when treatment was initiated before the UK wide restrictions came into force and there is an agreed clinical need to continue treatment including where a GP is prescribing in accordance with a shared care agreement made with an NHS gender identity service. GP prescribing may also be appropriate where it is in the context of a clinical trial as recommended by the Cass Review.

4.16 The proposal to restrict GP prescribing of GnRH analogues will ensure when they are prescribed in the treatment of children and young people with gender dysphoria or gender incongruence this is done safely as part of their holistic care. Where care is provided in this way it is more likely to identify whether following a medical pathway rather than taking a social or psychosocial approach, is in a child's or young person's best interests. It is also more likely to identify difficulties the child or young person may have been through, such as loss of a parent, traumatic illness, diagnosis of neurodiversity and isolation or bullying in school, and be able to address these with long term benefits for individuals.

4.17 The proposal helps to prevent potentially unnecessary and irreversible medical intervention whilst continuing to provide holistic, supportive care for all those who need it.

4.18 The proposals prevent medicalising children and young people whose multiple other difficulties may be manifesting through gender confusion and gender-related distress.

4.19 The proposals relate only to whether and if so in which circumstances puberty blockers should be provided by NHS GPs. The proposals do not restrict access to puberty blockers for gender dysphoria or gender incongruence where they are initiated as part of a treatment plan overseen by specialist NHS gender identity services or where the child or young person started treatment before the UK wide restriction on private prescribing came into force. They have therefore been 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 take account of guidance published by the RCGP and the General Pharmaceutical Council.

4.20 No consultation has taken place with persons to represent the interests of those who may require puberty blockers for gender dysphoria. However, the proposals reflect accepted good practice and are not an outright restriction or ban on puberty blockers, but a restriction on NHS GP's prescribing them with specialist gender services still able to do so where it is clinically appropriate. The restrictions on GP prescribing align with the recommendations of the Cass Review which was the subject of extensive public consultation.

Impact

4.21 The proposals are needed to ensure the prescribing of puberty blockers are prescribed in accordance with the NHS' clinical policy for children and young people. They will 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.

4.22 The proposals are supported by the evidence gathered through the Cass Review.

4.23 The proposals will have limited impacts on GPs and pharmacies prescribing and dispensing GnRH analogues for conditions other than gender incongruence. This is because GPs will have to annotate their prescriptions to indicate they are for a reason other than gender dysphoria or gender incongruence in a child or young person. Where prescriptions are not annotated in this way there may be small delays to prescriptions being dispensed. We expect any impact of this type will be short-lived as GPs become familiar with the new requirements.

4.24 These Regulations will also ensure patients in Wales are treated in the same way regardless of the health board area in which they live. They will also be treated in the same way as patients in England, promoting equity.

Duty of Quality

4.25 The Cass Review highlighted significant concerns regarding the quality of care provided to children and young people with gender dysphoria or gender incongruence. In part those concerns related to the absence of a holistic approach to care where puberty blockers were prescribed without the appropriate psychological and psychosocial support services being in place.

4.26 These Regulations will improve quality by restricting prescribing outside the mechanisms recommended by the Cass Review which are intended to improve the quality of care.

4.27 The proposals will ensure care is effective by ensuring unnecessary medical interventions are avoided which may in future need to be reversed. The proposals may also reduce the incidence of irreversible harms which may result from treatment.

4.28 The proposals specifically support the recommendations relating to the need for research into the benefits and harms of the use of puberty blockers in children and young people.

4.29 These Regulations will improve **safety** by ensuring puberty blockers are prescribed in accordance with the NHS's clinical policy for children and young people.

4.30 These Regulations will prevent the inappropriate prescribing of puberty blockers to children and young people outside holistic gender identity services who are better placed than GPs to provide specialist care and support with the prescribing of puberty blockers, improving the **effectiveness** of health services.

4.31 These Regulations will ensure patients in Wales are treated in the same way regardless of the health board area in which they live. They will also be treated in the same way as patients in England, promoting **equity**.

4.32 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. They will prevent treatment being initiated inappropriately or unsafely by NHS GPs outside specialist services providing the type of holistic care required by this patient cohort as recommended by the Cass Review. Officials are therefore content there are no issues which need to be addressed in making these Regulations.

5. Consultation

5.1 The proposal most affects general practitioners and community pharmacists 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) have been 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 have no objection to the proposals.

5.3 No consultation is taking place with persons to represent the interests of those who may require puberty blockers for gender dysphoria. The proposals are not an outright restriction or ban on puberty blockers, but a restriction on NHS GP's prescribing them with specialist gender services still able to do so.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Options

6.1 The restrictions which impact on private prescribing by UK and non-UK registered prescribers which came into effect on 3 June 2024 are a reserved matter.

6.2 Following the Cass Review, 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. To achieve parity of services between NHS England and NHS Wales it is appropriate to introduce similar legislation in Wales to place restrictions on the prescribing of GnRH analogues.

6.3 These Regulations support the recommendations of the Cass Review. The Regulations will prevent treatment being initiated inappropriately or unsafely by NHS GPs outside specialist services providing the type of holistic care required by this patient cohort as recommended by the Cass Review.

6.4 The option not to make Regulations restricting prescribing of puberty suppressing hormones by GPs 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 GPs 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.