

## **Explanatory Memorandum to The National Health Service (Pharmaceutical Services) (Wales) (Miscellaneous Amendments) Regulations 2026**

This Explanatory Memorandum has been prepared by the Primary Care and Mental Health Division within the Health, Social Services and Early Years Group of the Welsh Government 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 (Pharmaceutical Services) (Wales) (Miscellaneous Amendments) Regulations 2026. I am satisfied that the benefits justify the likely costs.

**Jeremy Miles MS**  
**Cabinet Secretary for Health and Social Care**  
**26 March 2026**

## **Part 1**

### **1. Description**

1.1 The National Health Service (Pharmaceutical Services) (Wales) (Miscellaneous Amendments) Regulations 2026 will amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (“the 2020 Regulations”) which govern the provision of pharmaceutical services as part of the National Health Service in Wales.

1.2 The amendments:

- Correct drafting defects identified by the Legislation Justice and Constitution Committee in regard of previous amendments to the 2020 Regulations.
- Clarify the definition of ‘electronic prescription service’.
- Introduce new provisions to require NHS pharmacists to provide information relating to their workforce to the relevant Local Health Board.
- Clarify the provisions in regard of supervision of specified activities taking place in the pharmacy by NHS pharmacists, to align with UK legislation.

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

2.1 These Regulations correct drafting defects identified by the Legislation, Justice and Constitution Committee in consideration of the National Health Service (Pharmaceutical Services) (Wales) (Miscellaneous Amendments) Regulations 2025, SL(6)598<sup>1</sup>.

### **3. Legislative background**

3.1 This instrument amends the 2020 Regulations which govern the provision of pharmaceutical services as part of the National Health Service in Wales under Part 7 of the National Health Service (Wales) Act 2006 (“2006 Act”).

3.2 The relevant powers for Welsh Ministers to amend the 2020 Regulations are contained within sections 15, 80, 203(9) and (10) of the 2006 Act.

3.3 These Regulations are made under the Senedd annulment procedure.

### **4. Purpose and intended effect of the legislation.**

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<sup>1</sup> <https://business.senedd.wales/mglssueHistoryHome.aspx?Ild=45352>

- 4.1 The purpose of this legislation is to ensure that in the undertaking of NHS contractual obligations to provide pharmaceutical services, NHS pharmacists:
- can utilise changes to the Human Medicines Regulations 2012 and Medicines Act 1968 which enable pharmacists to authorise pharmacy technicians to supervise the preparation, assembly or dispensing of medicines in the pharmacy,
  - provide information about the pharmacy workforce to local health board in whose list the NHS pharmacist is included, and
  - participate in the electronic prescription service.
- 4.2 These Regulations will provide more certainty and flexibility to pharmacy professionals and NHS pharmacists, clarifying their responsibilities and reducing bureaucracy which will allow them to invest in the delivery of health services that are more responsive to the needs of local communities and the wider NHS.
- 4.3 The intention is to increase the capacity and improve the capability of NHS pharmacists and the professionals working in pharmacies to provide patient centred services, impacting positively on public health and reducing pressures on other NHS services.
- 4.4 These Regulations also address the Legislation Justice and Constitution Committee reporting points in relation to the 2025 Amendment Regulations.
- 4.5 In summary, these Regulations contain provisions relating to:

#### Workforce reporting

- 4.6 The Regulations will enable Local Health Boards (“LHBs”) to access data about the individuals engaged to provide pharmaceutical services by the NHS pharmacist, which is critical to enabling evidence-based decision making and workforce planning at national, health board and cluster levels.
- 4.7 Through the 2025/26 Community Pharmacy Contractual Framework agreement the Welsh Government reaffirmed the importance of NHS pharmacists providing workforce intelligence data through a nationally approved system (currently the Primary Care Workforce Information System) as a contractual obligation from April 2026.
- 4.8 This imposes similar arrangements for NHS pharmacists as those already in place for General Medical Services, Dental and Optometry contractors as each set of the relevant regulations contain specific provision regarding the provision of workforce information.
- 4.9 Whilst there are existing provisions in the 2020 Regulations requiring NHS pharmacists to allow access to information, the requirement is not specific to workforce data. There is therefore some uncertainty and doubt about the

extent to which these can be relied upon to facilitate workforce reporting by pharmacies.

- 4.10 These Regulations amend the 2020 Regulations to incorporate a specific provision explicitly requiring NHS pharmacists to provide, or allow access to, workforce information. This approach will make clear the lawful basis for the processing of workforce data.

### Supervision

- 4.11 In 2024, the UK Government consulted on changes to the Medicines Act 1968 and the Human Medicines Regulations 2012 to ensure the legislation governing the requirements for a pharmacist to supervise specified activities in a pharmacy or pharmacy service meets the changing nature of pharmacy practice.
- 4.12 Subsequently [the Human Medicines \(Authorisation by Pharmacists and Supervision by Pharmacy Technicians\) Order 2025](#) (“the Order”) was laid in Parliament on 17 July and approved on 30 October 2025.
- 4.13 The Order makes provisions which will enable pharmacy technicians to supervise the assembly, dispensing and supply of medicines when authorised to do so by a pharmacist, and for pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities, will come into force on 10 December 2026.
- 4.14 The Order removes the requirement (in section 220 of the Human Medicines Regulations) that a medicine other than a general sales list medicine, can only be sold or supplied by or under the supervision of a pharmacist, replacing it with an exemption which allows such a sale or supply to take place by or under the supervision of a pharmacy technician where the pharmacy technician has been authorised to do so by a pharmacist.
- 4.15 The terms of service for NHS pharmacists in Wales, in Schedule 5, Part 2, paragraph 9 of the 2020 Regulations, requires that “Drugs or appliances so ordered must be provided either by or under the supervision of a registered pharmacist.”
- 4.16 The 2020 Regulations, whilst reflecting the current legal position, will therefore impose a higher bar on the dispensing of prescriptions than the overarching UK legislation providing the framework for such supplies, when the Order comes into force in December 2026. This will prevent NHS pharmacists in Wales from utilising the flexibilities introduced by the change to UK legislation and will compromise their ability to deliver patient facing, clinical services commissioned by health boards.
- 4.17 These Regulations remove specific references to supervision from the 2020 Regulations and instead rely on the overarching requirements in UK legislation which regulate pharmacy practice, which will apply in any case.

### Previous drafting corrections

- 4.18 These Regulations address minor drafting defects as identified by the Legislation Justice and Constitution Committee (LJCC) in regard of previous amendments to the 2020 Regulations made by the National Health Service (Pharmaceutical Services) (Wales) (Miscellaneous Amendments) Regulations 2025, SL(6)598 (“the 2025 Amendment Regulations”).
- 4.19 The LJCC reporting points in relation to the 2025 Amendment Regulations highlighted the omission of the definition of “ETP service” from regulation 2(1) of the 2020 Regulations. However, references to “ETP service” remain in paragraph 7(2)(b)(ii) of Schedule 5 and paragraphs 4(2)(b), 6(2)(b) and 7(3)(c) of Schedule 6 to the 2020 Regulations. Therefore, the term “ETP service” no longer has any meaning.
- 4.20 These Regulations will ensure all remaining instances of the abbreviation ETP are deleted and replaced with “electronic prescription service”.
- 4.21 The LJCC reporting points also identified a disparity in the Welsh text between paragraph 5A of Schedule 5 to the 2020 Regulations and the definitions found in regulation 2(1) of the 2020 Regulations (as amended by regulation 2(2) of the National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2024). The same error also occurs in the Welsh text of the amendments made by regulation 3(3)(a). These Regulations will correct these drafting defects.

### Definition of electronic prescription service

- 4.22 The electronic prescription service being deployed in Wales is managed by NHS England (NHSE) and administered by Digital Health Care Wales (DHCW) in Wales. The current definition of ‘electronic prescription service’ contained in the 2020 Regulations describes the service as being “managed by DHCW” and differs from the definition in the National Health Service (General Medical Services Contracts) (Wales) Regulations 2023 (“the GMS Regulations”).
- 4.23 The electronic prescription service (EPS) is currently being rolled out in Wales with more than 80% of pharmacies and 40% of GP practices using EPS.
- 4.24 The Misuse of Drugs Regulations 2001 require that the electronic transfer of prescriptions for controlled drugs is only through the EPS, by reference to the pharmaceutical services regulations in force in England, which define EPS as the system “managed by NHSE”. These Regulations will amend the definition of EPS contained in the 2020 Regulations, so as to make clear that the EPS in Wales is the same system as the EPS in England and that it is managed by NHSE. This will put beyond doubt that controlled drug prescriptions can be transferred using the EPS being rolled out in Wales. This change will also ensure that the definition within the 2020 Regulations is consistent with the definition in the GMS Regulations.

## **5. Consultation**

- 5.1 There is no statutory requirement to consult prior to making these Regulations, however stakeholder engagement has been undertaken with Community Pharmacy Wales and LHB representatives in regard of the provisions relating to workforce reporting.
- 5.2 The Welsh Government has also engaged NHS Wales Shared Services Partnership (NWSSP) to procure and implement the Wales National Workforce System capturing the workforce for primary and community care sector.
- 5.3 The changes to UK legislation in respect of supervision requirements were subject to a full public consultation by UK Government. These Regulations make technical changes to the 2020 Regulations which give effect to the policy intention and therefore have not been consulted on.

## **6. Outcome of consultation with the Information Commissioner's Office**

- 6.1 Under Article 36(4) of the UK GDPR, the government is required to consult the Information Commissioner's Office (ICO) on any proposals for legislative or statutory measures they are developing which involve the processing of personal data. The government duly consulted the ICO on the development of this instrument.

## Part 2 - Regulatory Impact Assessment

### 7. Options

- Option 1: Do nothing, retain the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 as currently in force.
- Option 2: Amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 to:
- Correct drafting defects identified by the Legislation Justice and Constitution Committee in regard of previous amendments to the 2020 Regulations.
  - Clarify the definition of ‘electronic prescription service’.
  - Introduce new provisions to specifically require contractors to provide information relating to the workforce to Local Health Boards.
  - Clarify the provisions in regard of supervision of specified activities by pharmacists, to align with UK legislation.

#### Option 1: Do Nothing

- 7.1 Changes to the role of community pharmacies in Wales described in [‘Presgripsiwn Newydd - A New Prescription \(gov.wales\)’](https://gov.wales/presgripsiwn-newydd), which came into effect from April 2022, introduced substantial reforms to the Community Pharmacy Contractual Framework for NHS pharmacists.
- 7.2 ‘Presgripsiwn Newydd – A new Prescription’ committed the Welsh Government to review the current terms of service for community pharmacy contractors with a view to reducing unnecessary bureaucracy and administrative burden and releasing pharmacist time for the provision of direct patient care.
- 7.3 Retention of the current terms of service as set out in the 2020 Regulations, as they relate to supervision and workforce; does not support the intended effect of Presgripsiwn Newydd and therefore, is not an option.
- 7.4 Doing nothing will prevent NHS pharmacists in Wales from utilising the flexibilities introduced by the change to UK legislation and will compromise their ability to deliver the provision of clinical services commissioned by health boards.

#### Option 2: Amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

- 7.5 The amendments to the terms of service in the 2020 Regulations for NHS pharmacists in regard of supervision update and clarify the existing subordinate legislation and align with UK legislation and therefore do not involve significant new policy changes.

- 7.6 The amendments have been developed following discussions with Community Pharmacy Wales and LHB representatives. Responses received showed there was clear majority support for the changes.
- 7.7 The amendments in regard of workforce reporting will enable the collection of workforce data and consequently improve workforce planning at national, health board and cluster levels.
- 7.8 This option will ensure identified minor drafting defects are corrected.
- 7.9 This option supports the changing way in which the pharmacy healthcare professionals are providing pharmaceutical services. This is the preferred option.

## **8. Costs and Benefits**

### Costs

- 8.1 Additional administrative costs for NHS pharmacists associated with completing workforce reporting requirements have been recognised through a £1.2m uplift (£2,000 per annum per NHS pharmacist) to the establishment payment allocation of the Community Pharmacy contractual Framework (CPCF). This uplift has been agreed with Community Pharmacy Wales and met through redistribution of monies from the overall CPCF quantum available to pharmacies (£182m).
- 8.2 Whilst the benefits of workforce reporting have not been quantified, implementing the workforce requirements will reduce time and costs for NHS pharmacists associated in providing workforce data and enables:
- Health Boards to understand capacity, risks and skill-mix within community pharmacy, supporting evidence-based workforce planning, targeted investment and sustainable service delivery.
  - standardised workforce reporting for NHS pharmacists, which reduces duplication and improves visibility of workforce pressures,
  - the Welsh Government to make informed decisions in relation to workforce, supporting the Programme for Government goal: 'Provide effective, high quality and sustainable healthcare'.
- These benefits are likely to outweigh the small costs associated with implementation which have been met through the existing CPCF allocation.
- 8.3 The changes on supervision enable NHS pharmacists to benefit from changes to the regulatory framework governing the whole of the UK and which are the subject of a UK Government regulatory impact assessment published

alongside the Order approved on 30 October 2025 (paragraph 4.12 above). The impact assessment concluded there would be significant benefits resulting from changes to supervision in pharmacies with the monetised benefits arising from the release of pharmacist time with net labour savings estimated to be between £15m and £75m per year for the UK (i.e. £0.75m to £3.75m for Wales).

- 8.4 Unmonetised benefits included increased availability of services from pharmacies, improved career development opportunities for pharmacy technicians and improved consistency and convenience for people using pharmacies. Small costs may arise from additional training for pharmacy staff estimated by the UK government to be £500 per pharmacy (i.e. £350,000 for Wales). Overall, the changes result in a net benefit for Wales of at least £0.45m per year.

## Benefits

- 8.5 The changes to the terms of service in the 2020 Regulations reflect developing service models for delivery of care as set out in the Primary Care Model for Wales. They aim to provide health professionals with greater clarity on responsibilities for the provision of services, reduce administrative bureaucracy, free up time and resource for service delivery, and encourage more effective evaluation of activities to help better plan resources and delivery of services.
- 8.6 The principal impact of these Regulations is likely to be on access to services. It will enable easier access to services that support healthier lifestyles and enable pharmacies to deliver primary care services in a way that better reflects the needs of the population and the NHS in Wales.
- 8.7 They also allow a reconfiguration of work practice within a pharmacy to improve efficient delivery of services to patients, allowing pharmacists to deliver more clinical services.
- 8.8 The gathering of workforce information will improve official statistics, workforce planning, policy development, and, in some cases, validating additional capacity payments.
- 8.9 Amending the definition of 'electronic prescription service' will provide clarity and put beyond doubt that controlled drug prescriptions can be transferred using the EPS being rolled out in Wales. This change will also ensure the definition used in the 2020 Regulations is consistent with the definition in the GMS Regulations.
- 8.10 Correcting drafting defects identified by the LJCC in regard of previous amendments to the 2020 Regulations will ensure clear understanding and interpretation of the 2020 Regulations.

## 9. Competition Assessment

9.1 These Regulations are not expected to impact on competition in Wales or the competitiveness of Welsh firms.

**10. Post implementation review**

10.1 No formal review timescale is proposed. Regulations will be reviewed as part of regular ongoing discussions with community pharmacy stakeholders.