

Explanatory Memorandum to The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2024

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) (Amendment) Regulations 2024. I am satisfied that the benefits justify the likely costs.

Jeremy Miles MS
Cabinet Secretary for Health and Social Care
22 November 2024

Part 1

1. Description

1.1 The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2024 will amend Schedule 5 (as applicable) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 which govern the provision of pharmaceutical services as part of the National Health Service in Wales.

1.2 The amendments:

- update and clarify the terms of service for community pharmacy contractors providing NHS pharmaceutical services in Wales.
- 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.

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

2.1 None.

3. Legislative background

3.1 This instrument amends the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 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, 104 and 203(9) and (10) of the 2006 Act.

3.3 These Regulations follow the negative resolution procedure.

4. Purpose and intended effect of the legislation.

4.1 The wide-ranging contractual reforms introduced in April 2022 through [Presgripsiwn Newydd - A New Prescription \(gov.wales\)](#) mean a wider than ever range of clinical services are being offered by community pharmacists in Wales. Streamlining and focusing activities on patient outcomes and the things that are more valuable to the NHS will support pharmacies to utilise

more effectively the clinical skills and expertise of pharmacists and pharmacy technicians in line with the objectives of [Pharmacy: Delivering a Healthier Wales \(rpharms.com\)](https://www.rpharms.com).

- 4.2 The purpose of this legislation is to ensure that activities carried out in the undertaking of NHS contractual obligations for pharmaceutical services:
- remain fit for purpose and support the strategic aims of the Programme for Government's commitment to reform primary care services to be more accessible and sustainable in line with the Primary Care Model for Wales.
 - align with the Human Medicines Regulations 2012 and Medicines Act 1968.
 - take account of the changing way in which healthcare services are provided by pharmacies and wider primary care (GPs, dentists and optometrists) and the way medicines are supplied; and
 - reduce the administrative burden for community pharmacies.
- 4.3 Amending the regulations will provide more certainty and flexibility to pharmacy professionals and contractors, 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.
- 4.4 The intention is to increase the capacity of community pharmacy to focus on patient centred services, impacting positively on public health and reducing pressures on other NHS services.
- 4.5 In summary, The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2024 contain provisions to:

Essential Services

- Allow pharmacies to process signed prescriptions from optometrists providing [Wales General Ophthalmic Services \(WGOS\)](#) for urgent eye problems.
- Clarify requirements for supervision arrangements for pharmacists in line with primary legislation.
- Extend the requirement to provide advice on healthy living to anyone as appropriate not just people with certain health conditions.
- Require a record of the advice given only where it is clinically significant.
- Reduce the requirement for a specific number of public health campaigns each year to allow a more targeted approach.
- Require pharmacists to participate in the evaluation of health promotion campaigns in place of recording the numbers of individuals provided with information.

Pharmacy Opening Hours

- Require a period of 3 months before an NHS pharmacy can amend its supplementary opening hours where there is a reduction in the overall number of hours pharmaceutical services are provided to allow time to inform the public.
- Allow flexibility to change the core opening hours of the pharmacy to include a rest break of up to one hour per day provided this does not result in an overall decrease to the number of core hours at which services are provided on that day.
- Introduce flexibility on how pharmacies engage with service users to assess satisfaction with services offered.
- Amend specific audit requirements and introduce a more flexible approach requiring pharmacies to engage with local partners to improve health services.
- Require the reporting of patient safety incidents to the national system approved by the Welsh Government instead of a local system.
- Clarify local clinical governance requirements.
- Update the requirements relating to child protection procedures in line with [Cysur | Wales Safeguarding Procedures](#) to include adults as well as children.

Original Pack Dispensing

- Following UK legislation in 2023, introduce regulations to allow flexibility to dispense up to 10% more or less than the quantity of medicine prescribed (with specified exceptions) so that a manufacturer's original full pack can be dispensed instead of splitting the pack. This will benefit patient safety by ensuring patients are more often supplied medicines which contain the safety information included in or on a medicine's original packaging.

5. Consultation

- 5.1 There is no statutory requirement to consult prior to making these regulations.
- 5.2 A targeted, shortened consultation was undertaken in early 2024 with relevant stakeholders. Details of the proposals were sent to a range of organisations who would have direct interest. This included all community pharmacies in Wales, representatives of dispensing doctors, Community Pharmacy Wales, representative organisations for the pharmacy profession and other professions including GPs and Optometry, Llais/Citizen's Voice Body for a patient perspective and all local health boards. Stakeholders had a period of eight weeks to consider and respond to the proposals.
- 5.3 Twelve responses were received. These indicated there was majority support in principle across all proposals. Where concerns were raised, officials considered these matters and minor amendments have been made to relevant proposals as appropriate.

Part 2 - Regulatory Impact Assessment

6. 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 update the terms of service for NHS pharmacists providing pharmaceutical services and introduce regulations to implement original pack dispensing flexibility.

Option 1: Do Nothing

- 6.1 [‘Presgripsiwn Newydd - A New Prescription \(gov.wales\)](#), which came into effect from April 2022, introduced substantial reforms to the Community Pharmacy Contractual Framework for NHS community pharmacies.
- 6.2 ‘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.
- 6.3 Retention of the current terms of service regulations, therefore, is not an option.
- 6.4 With regard to original pack dispensing, UK legislation covering Wales was introduced in October 2023 through [The Human Medicines \(Amendment Relating to Original Pack Dispensing\) \(England and Wales and Scotland\) Regulations 2023 \(legislation.gov.uk\)](#). This legislation does not give Welsh Ministers discretion to vary the quantity of medicine that can be dispensed from the 10% specified but does require further subordinate legislation for it to be implemented in Wales.

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

- 6.5 The amendments to the terms of service regulations for NHS pharmacists update and clarify the existing subordinate legislation and do not involve significant new policy changes
- 6.6 The amendments have been developed following discussions with Community Pharmacy Wales and local health board representatives and a wider stakeholder group has been consulted. Responses received showed there was clear majority support for the regulatory changes.
- 6.7 Regulatory amendments are also required to take account of the changing way in which healthcare services are provided by other primary care contractors. Specifically, by extending the existing provisions to allow community pharmacists to supply medicines against signed orders issued by

qualified optometrists in line with the [Wales General Ophthalmic Services \(WGOS\)](#) introduced in 2023. (The existing regulations allow only signed orders from doctors and dentists). Including optometrists will ensure patients accessing WGOS care for urgent eye problems can receive appropriate NHS treatment, including prescription only medicines, without the need to obtain a GP prescription or have a further Common Ailment Service consultation at the pharmacy benefitting both the patient and the NHS.

- 6.8 To enable introduction of original pack dispensing as described under paragraph 4.5 above, further subordinate legislation is required. These provisions will come into force on 1 January 2025.

7. Costs and Benefits

Costs

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

Benefits

- 7.2 The intention of the amendments is to enable pharmacies to be more responsive to the needs of the populations they serve. By updating regulations to meet changes in the way healthcare services are delivered and removing outdated and ineffective activities, community pharmacies' capacity to focus on patient centred services should be increased, impacting positively on public health.
- 7.3 The regulatory changes to the terms of service 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.
- 7.4 The principal impact of the 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.
- 7.5 Introducing regulations to allow NHS pharmacists the flexibility to dispense a quantity of up to 10% more or 10% less of a medicine than the quantity prescribed if it means the medicine can be dispensed in its original manufacturer's packaging will have benefits for patient safety by ensuring patients are more often supplied medicines which contain the safety information included in or on a medicine's original packaging.

8. Competition Assessment

- 8.1 The Regulations are not expected to impact on competition in Wales or the competitiveness of Welsh firms.

9. Post implementation review

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