EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (MISCELLANEOUS AMENDMENTS) REGULATIONS 2025

2025 No. 989

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Stephen Kinnock, Minister of State for Care, at DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 Alette Addison, Deputy Director for Pharmacy, Eye Care and Controlled Drugs, at DHSC confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Inna Kochetkova at the DHSC email: CommunityPharmacyTeam@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the PLPS Regulations) (S.I. 2013/349, as amended). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of NHS pharmaceutical and local pharmaceutical services, such as the dispensing of NHS prescriptions.

4.2 Most pharmaceutical services provision in England is by community pharmacies that are on lists, known as pharmaceutical lists. The arrangements made with GP practices, known as NHS dispensing doctors, are solely for patients in some rural areas, and usually for patients who live more than a certain distance from a pharmacy.

4.3 Applications for entry onto pharmaceutical lists, which is the basis upon which most community pharmacies provide NHS pharmaceutical services, are determined by NHS England (NHSE) who now delegate this function to integrated care boards (ICBs), but the functions remain in NHSE's name. The decisions by NHSE are based, with some exceptions, on the local plans outlining the needs and availability of pharmaceutical and local pharmaceutical services in an area. Known as the Pharmaceutical Needs Assessments (PNAs), these are developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs). A relatively small number of community pharmacies provide NHS services on the basis of a local pharmaceutical services (LPS) contracts, rather than on the basis of being on

pharmaceutical lists. LPS contracts are a model of provision under which fewer terms of service are set centrally.

Regarding hub and spoke dispensing

4.4 The changes in this instrument follow on to the amendments to the Human Medicines Regulations 2012 (HMRs) and the Medicines Act 1968 (MA), made by the Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025 (S.I. 2025/758), that are coming into force on 1 October 2025. The amendments to the HMRs will enable the use of hub and spoke arrangements between different retail pharmacy businesses and between a hub pharmacy and NHS dispensing doctors (who can only act as a spoke in hub and spoke arrangements). Hub and spoke arrangements are what happens when a "spoke" community pharmacy or GP practice sends a "hub" pharmacy the details of a prescription, and the "hub" pharmacy dispenses and sends the prescribed item back to the "spoke" for the "spoke" to supply it to or for the patient. This instrument enables more orders to be processed through hub and spoke arrangements and sets additional requirements for NHS contractors entering into the arrangements with a hub.

Regarding Zero or nominal reimbursement of human papilloma virus (HPV) vaccines

4.5 This instrument provides that, where the Government has centrally purchased HPV vaccines that are made available to community pharmacies at no cost for supply or administration to NHS patients, the Secretary of State or in some instances NHSE may determine that the amount to be paid by way of NHS reimbursement for product costs to community pharmacies for supplying or administering those vaccines may be set at zero or a nominal amount, if certain conditions are met. This only affects the reimbursement for the product costs. It does not affect the amount that the community pharmacy will be paid for the service cost of supplying or administering the vaccine as part of NHS pharmaceutical services.

4.6 The change makes it possible for community pharmacy contractors to access centrally procured HPV immunisation products as they already do for several other immunisation products.

Regarding other changes

4.7 This instrument makes small changes to the terms of service for community pharmacies, as agreed with Community Pharmacy England (CPE). These include no longer requiring pharmacies to create a practice leaflet and removing the requirement that all staff providing NHS services must have references.

4.8 The instrument also brings the legislation up to date with the current practice and operational structure by ensuring the PLPS Regulations contain references to correct organisations (NHS BSA replaces NHS CFA in some contexts) and operational tools (NHS.net Connect replaces NHS Mail).

4.9 The instrument aligns wording in regard to where pharmaceutical services can be delivered with the wording in the HMRs and MA, i.e. 'at or from' pharmacy premises replaces 'at' or 'on'. This clarifies that activities starting at pharmacy premises may be completed elsewhere.

4.10 Finally, it clarifies the requirements about the information that can be included in supplementary statements that HWBs can publish to update their PNAs, specifically that supplementary statements cannot make a new assessment of improvements or needs (that needs to await a new PNA).

Where does the legislation extend to, and apply?

4.11 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.12 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

Regarding hub and spoke dispensing

5.1 This instrument enables a wider range of orders for prescription items to be processed through valid hub and spoke arrangements than permitted by the amendments made to the HMRs by S.I. 2025/758, which only affected what are "medicinal products" for the purposes of the HMRs. This will help NHS community pharmacies and dispensing doctors to maximise the benefits of hub and spoke arrangements.

5.2 It also puts additional requirements for all hub and spoke arrangements, kept to a reasonable minimum, where NHS contractors are acting as spokes. Specifically, the requirements include prior notification to the commissioners about contractors' intention to enter into hub and spoke arrangements, the preparation of business continuity plans by the contractors to cover any interruptions to the arrangements and for all NHS contractors to be compliant with an information governance framework for sharing patient data for all orders. The instrument also enables commissioners to object to the arrangements, if they do not have the required features or to protect patient safety and NHS financial interests, to request additional information from the spokes regarding these objections and provides a local dispute resolution process in the event of any disagreement. These additional requirements aim to ensure commissioners have visibility over NHS dispensing to ensure dispensing remains safe for patients. The arrangements are slightly different for dispensing doctors in order to fit in with the contractual framework for NHS GPs.

Regarding Zero or nominal reimbursement of HPV vaccines or children

5.3 The policy context is a desire to enable community pharmacies to use centrally procured HPV vaccines in specially commissioned services (known as enhanced services) to support NHSE's immunisation programmes. This will increase patient access to these vaccines, therefore improving patient health and reducing the pressure on health services.

Regarding other changes

5.4 The clinical governance requirements for pharmacies, set out in paragraph 28(2)(a)(i) of Schedule 4, Part 4, of the PLPS Regulations include that the community pharmacy on a pharmaceutical list produces in an approved manner, and makes available in an appropriate manner, a practice leaflet containing approved particulars in respect of pharmacy premise. The practice leaflet must be made available for patients in the printed format. However, all information included in the practice leaflet is usually made available on the pharmacy premises on the posters, which is a more impactful format for the patients presenting at the pharmacy, and is also available online, so the requirement to prepare the practice leaflet has become disproportionate and is removed. Another requirement is that all pharmacy owners must have arrangements for the checking of qualifications and references of all staff engaged in the provision

of NHS services. The requirement for references is removed as this is now considered unnecessary.

5.5 The amendments made to the HMRs by S.I. 2025/758 included amendments to regulations 220, 221 and 274 to change references to the sale or supply of products "at" or "on" premises to sale or supply "at or from" premises. These amendments bring the HMRs into line with the MA in clarifying that transactions may take place from pharmacy premises, and therefore the transaction being completed elsewhere. This instrument amends the PLPS Regulations to bring the provisions in line with the MA and the HMRs.

5.6 Finally, the requirements for the content of supplementary statements that HWBs can publish to update PNAs is clarified. Specifically, such statements must not include a new analysis of needs or improvements to pharmaceutical services provision (rather than simply stating facts). A new analysis would require a new PNA and importantly, consultation with stakeholders as part of that.

What was the previous policy, how is this different?

Regarding hub and spoke dispensing

5.7 HMRs include minimal requirements for the parties entering into hub and spoke arrangements, including having a written agreement in place, providing a notice for patients, complying with the information gateway requirements and only including the spoke's details on the medicines label. These requirements only apply to prescription orders for medicinal products.

5.8 This instrument extends these requirements and thus widens the scope of hub and spoke arrangements for NHS contractors to prescription items that are not medicinal products (e.g. foods, cosmetics and appliances) and to orders other than usual prescription forms (prescription vouchers or pandemic orders).

5.9 The changes to the PLPS Regulations enable NHS contractors to process more orders through hub and spoke arrangements and provide a clear regulatory framework for the NHS community pharmacy contractors and dispensing doctors who choose to act as a spoke and enter into hub and spoke arrangements with a hub owned by a different legal entity.

Regarding Zero or nominal reimbursement of HPV vaccines

5.10 The expectation under the ordinary reimbursement arrangements for NHS pharmaceutical services is that pharmacy contractors are reimbursed an amount which is in respect of (but ordinarily slightly more than) the price that they paid when they purchased a prescription item that they go on to supply or administer. However, there are powers in Part 7 of the NHS Act 2006 to make regulations to enable alternatives to these ordinary remuneration arrangements in some circumstances. That option is being exercised here.

Regarding other changes

5.11 The other changes are part of the ordinary process of updating the arrangements for the provision of pharmaceutical services that take place following discussions with the relevant representative bodies. Keeping the legislation up to date and continually trying to improve the service is a standard part of how the framework operates.

6. Legislative and Legal Context

How has the law changed?

6.1 These Regulations amend the PLPS Regulations, which govern the arrangements in England, under Part 7 of the 2006 Act, for the provision of NHS pharmaceutical and local pharmaceutical services, such as the dispensing of NHS prescriptions.

Regarding hub and spoke dispensing

6.2 The new Regulations prohibit sub-contracting of core dispensing services by community pharmacies and dispensing doctors other than by valid hub and spoke arrangements, and some other standard exceptions that relate to ordinary commercial practice. For example, this prohibition will not apply to home delivery services (which are outside the definition of core dispensing functions) and contracts with a different legal entity to provide pharmacy staff (e.g. locums). Subcontracting by a sub-contractor (a hub) is also prohibited.

6.3 The Regulations set three sets of conditions for valid hub and spoke arrangements, with some variation between community pharmacy contractors and dispensing doctors, reflecting the fact that there are already some sub-contracting requirements within the GP contractual framework.

6.4 The conditions include pre-conditions to entering into these arrangements. For community pharmacies a 28 day advance notice to the NHS commissioner is required, however a commissioner could agree for the arrangements to begin sooner. For dispensing doctors, the requirement is to give reasonable advance notice. A community pharmacy's notice must be in according with NHS approved particulars. A dispensing doctors notice requirements are included in the regulations to align with other subcontracting requirements for general practice.

6.5 The conditions also include a second set of conditions applying to both community pharmacies and dispensing doctors. These are the ongoing features that hub and spoke arrangements must have. These are kept to a reasonable minimum, but one of the key concepts is that the same hub and spoke conditions will apply to of all types of items (e.g. medicines, as well as foods, cosmetics or appliances) that are ordered by a health professional on any of the legal order forms and not limited to the routine FP10 (prescription) order forms.

6.6 The Regulations also provide for two sorts of "objection" arrangements by the NHS commissioner. The first set, for community pharmacies, are for prior objection – in the 28-day notice period from the date of the notification. If there is prior objection by the NHS commissioner, no valid arrangements can be put in place unless or until the objections are resolved under dispute resolution.

6.7 The second set of objection arrangements, for both community pharmacies and dispensing doctors, become relevant once the hub and spoke arrangements are up and running, and again they fall into two categories.

6.8 The first category sets out the grounds on which the NHS commissioner can issue an objection notice, and the spoke must end the arrangements promptly, without the parties first going to dispute resolution. In this category are patient safety risks and material financial loss to the NHS, as well as historic problems with the arrangements about which there has already been dispute resolution (for example where the prescriptions are not being dispensed properly, the parties go to dispute resolution, the spoke gives undertakings on the basis of which the arrangements are allowed to continue, but nothing improves). If this "urgency" procedure is followed, the dispute

resolution, if needed, comes after the issuing of the notice. The second category of objections in the course of the arrangements are the grounds for objection about which the parties must go to dispute resolution before the NHS commissioner can issue a notice ending the arrangements. So, for example, the notice that should be up on the spoke's premises, or on its website, about the hub and spoke arrangements, persistently not being there.

6.9 For community pharmacies, the dispute resolution arrangements are the local dispute resolution arrangements based on regulation 69 of the PLPS Regulations (i.e. the pharmacy can bring in the Local Pharmaceutical Committee if it wants to). For dispensing doctors, they will need to follow their dispute resolution arrangements in their main contract.

6.10 There is a new information gateway for all contractors. The information gateway in the new regulation 222B of the HMRs will apply in the case of medicines on FP10 order forms (regulation 222A orders), and the new gateway in the PLPS Regulations will apply to non-regulation 222A orders (all other orders), but both gateways will apply in exactly the same way.

6.11 If the hub and spoke arrangements do break down – either because the NHS commissioner ends the arrangements or because of a commercial break clause in the contract or there is service disruption, dispensing doctors and community pharmacies must have business continuity arrangements in place and action these arrangements when necessary.

Regarding Zero or nominal reimbursement of HPV vaccines

6.12 The scheme for payment for pharmaceutical and local pharmaceutical services in Part 7 of the 2006 Act is predicated on the basis that the determining authorities for pharmaceutical remuneration (that is, the Secretary of State and, for some purposes, NHSE) will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients.

6.13 However, section 164 of the 2006 Act allows for the creation, by regulations, of some statutory exceptions to this principle. The exceptions are to allow for the use of some centrally purchased medicines in the NHS services provided by community pharmacies – and where the medicines are supplied free of charge to the pharmacies, the remuneration for the pharmacies then does not need to include anything for those medicines when the pharmacies go on to supply or administer those medicines for NHS patients. The powers have previously been exercised to support the supply of coronavirus, MMR, RSV, childhood flu and pertussis vaccines and coronavirus antivirals, and now a new statutory exception is being created for HPV vaccines in the same terms as the existing vaccines exceptions.

Regarding other changes

6.14 As a result of amendments introduced to the HMRs by S.I. 2025/758, consequential amendments are made to the PLPS Regulations so that references to "on" or "at" premises are now to be read as "at or from" premises. This brings the PLPS Regulations in line with the MA and the HMRs on this issue. This clarifies that transactions starting at pharmacy premises may be completed elsewhere.

6.15 Community pharmacies on pharmaceutical lists will no longer be required to produce practice leaflet and seek references for all staff involved in the provision of pharmaceutical services.

Why was this approach taken to change the law?

6.16 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 Customarily, the Department seeks the views of the CPE, the representative body for all community pharmacies, on changes to the PLPS Regulations relating to the market entry process and changes to community pharmacies' NHS terms of service. The Department has been able to discuss the policy changes in these areas with CPE and responded to their comments, making changes to the Regulations where appropriate.

7.2 The Department has consulted with the British Medical Association regarding additional requirements for dispensing doctors who participate in hub and spoke arrangements and they have approved the changes made in this instrument.

8. Applicable Guidance

8.1 Departmental guidance is not required for changes to the PLPS Regulations. Pharmacy contractors and dispensing doctors will be supported with guidance in the usual way by the representastive trade bodies.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 An assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate, so one has not been prepared for this instrument. These Regulations are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.

Impact on businesses, charities and voluntary bodies

9.2 Simplifying clinical governance requirements and enabling pharmacy contractors to access centrally procured stock of HPV immunisation products impact positively on businesses, including small or micro businesses.

9.3 The changes to hub and spoke regulations enable small and micro businesses process more orders through the hub and spoke arrangements and thus free up more time to deliver clinical services for patients.

9.4 There is no significant impact on the public sector.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The Department monitors the implementation of the PLPS Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The instrument is being laid on 3rd September 2025, allowing more than 21 days before it comes into force on 1st October, which is the next Common Commencement date. Due to the common commencement date being a set date, some of the parliamentary scrutiny period falls during the recess period on this occasion.

12. European Convention on Human Rights

12.1 The instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (“relevant European Union Acts”).