EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) (NO. 2) REGULATIONS 2026

2026 No. 961

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 and the Secondary Legislation Scrutiny Committee.

2. Declaration

2.1 Diana Johnson, Minister of State for Public Health and Patient Safety, at DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 Peter Lilford, 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 can be contacted by email at the following address with any queries regarding the instrument: CommunityPharmacyTeam@dhsc.gov.uk. Alternatively, the department can be contacted by telephone: 0300 790 4007.

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 undertaken by community pharmacies that are on lists, known as pharmaceutical lists. Applications for entry onto these lists are determined by NHS England (who delegate this function to integrated care boards, but the functions remain in NHS England's name). Arrangements with retail pharmacy businesses are made either on the basis of entry on these approved pharmaceutical lists or, much less often, on the basis of a contract for local pharmaceutical services (LPS). Businesses that are party to these arrangements are known respectively as, "pharmacy contractors" and "LPS contractors".

4.3 Once contractors are accepted on the NHS pharmaceutical list and begin delivering services to patients, they are required to deliver the same core hours as were included in their application to join the pharmaceutical list. The PLPS Regulations, however, allow contractors to apply to NHS England if they wish to reduce the total number of core hours or change when they deliver these core hours. There is a "needs" test,

which applies to all applications to NHS England requesting a change in core opening hours except for when applying to introduce a rest break.

4.4 Pharmacy contractors and LPS contractors are required to comply with the NHS terms of service requirements outlined, respectively, in Schedule 4 and Schedule 7 of the PLPS Regulations.

4.5 Arrangements with dispensing appliance contractors (DACs) are made on the basis of separate pharmaceutical lists, but they share with pharmacy contractors common arrangements for market entry, market exit and dispute resolution. Arrangements are also made with dispensing doctors and are solely for patients in some rural areas, and usually for patients who live more than a certain distance from a pharmacy.

Independent prescribing & changes to requirements for providing directed services

4.6 The Government is expanding the role of pharmacist independent prescribers in community pharmacy as part of its wider ambition to improve access to NHS care, to make better use of the skills of the pharmacy workforce and support the shift of care into community settings. While service specifications, directions and professional guidance can set out the operational and clinical requirements for these services, legislation is required to establish a clear legal framework governing the exercise of prescribing functions within NHS pharmaceutical services.

4.7 Community pharmacies are increasingly delivering clinically focused NHS services that involve direct patient assessment, diagnosis and treatment. It is therefore important that there is a consistent and proportionate approach to safeguarding across all providers delivering these services. The amendments to Schedules 4 and 7 of the PLPS Regulations are to ensure that staff involved in the provision of pharmaceutical services are subject to the same Disclosure and Barring Service (DBS) requirements regardless of the contractual route through which services are commissioned. This creates a uniform national baseline for patient safety and public assurance, supports consistency across the community pharmacy sector, and reduces variation in safeguarding arrangements between providers. The DBS requirements apply equally to all community pharmacies, including those with LPS contracts, ensuring that patients can expect equivalent safeguarding standards irrespective of the type of NHS community pharmacy provider delivering their care.

Changes regarding NHS pharmacies terms of service: closures for learning and development

4.8 Changes to Schedule 4 to the PLPS Regulations will allow NHS pharmacy contractors to temporarily close their premises for learning and development activities without being treated as breaching their opening hours requirement, provided specified conditions are met, including advance notification to NHS England and limits on the duration and timing of the closure.

4.9 NHS England will be able to object to the closure if it will lead to avoidable disruption to the provision of pharmaceutical service in the area.

Changes to other terms of service of NHS pharmacies and LPS contractors

4.10 Amendments to Schedules 4 and 7 to the PLPS Regulations strengthen protections for patients' choice of NHS provider by making clear that an NHS pharmacy contractor cannot change an electronic entry about a patient's nominated pharmacy without the explicit consent of the patient or, where appropriate, their authorised representative. This is intended to ensure that patients remain in control of where their prescriptions are sent and dispensed.

Changes regarding applications to provide pharmaceutical services and the procedures to be followed

4.11 Several changes to the arrangements governing NHS pharmaceutical lists and dispensing doctor lists in England will reduce outdated administrative requirements, streamline application processes and support the delivery of NHS pharmaceutical services.

4.12 Changes to regulation 31 of the PLPS Regulations exempt change of ownership without relocation applications from the application of mandatory grounds of refusal specified in this regulation. The purpose of the regulation is to prevent a contractor from applying for multiple inclusions in a pharmaceutical list at the same address with no benefit to patients. A change of ownership with no relocation of premises does not fall within that remit which is why it is being specifically excluded.

4.13 The requirement for NHS England to notify interested parties and invite representations on certain applications made by doctors for dispensing rights is removed where NHS England is required to refuse the application. Instead, interested parties will be notified of the refusal decision. This avoids undertaking a consultation exercise where representations cannot affect the outcome because the application must be refused under the PLPS Regulations, reducing administrative burden and speeding up decision making

4.14 When applying to open a new pharmacy, the applicant is required to provide information about their sex, whether they are applying as an individual or as a partnership. This requirement is removed as this information is not material to making a decision on the application. This change will also apply to potential DACs.

4.15 Similarly, outdated requirements to provide some details regarding future provision of directed services, are removed. This includes information about accreditation for the provision of directed services and premises floor plan, indicating where these services will be provided. This information is not required to make decisions on new applications.

Changes to local dispute resolution process regarding issue of breach notices

4.16 Changes to the local dispute resolution process for NHS pharmacy contractors and DACs in regard to breach notices clarify what is meant by cooperation during the dispute resolution process and allow NHS England to suspend its obligation to engage in this process where a contractor is not cooperating. These changes are intended to support the effective and efficient resolution of disputes by ensuring that all parties participate appropriately in the process.

Where does the legislation extend to, and apply?

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

4.18 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 Independent prescribing & changes to requirements for providing directed services

5.1 New regulation 66A of the PLPS Regulations provides for restrictions on the ability of pharmacist independent prescribers delivering NHS pharmaceutical services to make changes to or initiate prescriptions for a patient's medication only in accordance with specified legal and governance requirements. Where prescribing activity results in the initiation, amendment, discontinuation or optimisation of treatment originally prescribed elsewhere within the NHS, appropriate processes must be followed to ensure continuity of care, clear clinical accountability and effective communication with the patient's existing care team. This supports safe medicines use, reduces the risk of fragmented care and ensures that prescribing decisions form part of the patient's wider clinical record.

5.2 These legislative provisions distinguish between essential services (the core of which is activity relating to dispensing of prescriptions) and directed services (the additional services that pharmacies may provide). The directed services requirements complement, rather than replace, the detailed requirements that will be set out through service directions, clinical specifications and professional guidance. In relation to the delivery of essential services, the requirements on the face of the legislation are more detailed, but at their core, currently, is a restriction that pharmacies will not be able to change prescriptions from GP practices unless the GP practice has either agreed that specific change or there is an agreement in place between the pharmacy and the GP practice that covers such changes. The pharmacist who changes the prescription must also be someone who is entitled to prescribe as part of a directed service, establishing consistency in relation to who may prescribe.

5.3 Together, these arrangements establish an appropriate framework of legal, clinical and operational governance for pharmacist prescribing within NHS pharmaceutical services. This approach is consistent with existing arrangements whereby legislation provides the enabling framework, while more detailed service requirements are contained within directions and supporting guidance.

5.4 An additional requirement is introduced to the terms of service for all pharmacy contractors providing NHS pharmaceutical services; to have arrangements in place to ensure professional staff involved in the delivery of these services have a valid enhanced DBS certificate or evidence which demonstrates that an enhanced DBS status check has been undertaken using the DBS Update Service.

Changes regarding NHS pharmacies terms of service: closures for learning and development

5.5 Currently pharmacy contractors are required to deliver a certain number of core hours, which means a pharmacy must be open and able to provide pharmaceutical services during these hours.

5.6 Community pharmacies are increasingly delivering a wider range of clinical services, extending their role beyond dispensing medicines and putting more pressure on pharmacy owners to ensure pharmacy teams are appropriately trained. The amendments enable pharmacy owners to close the pharmacy for learning and development purposes, subject to meeting certain requirements. These requirements aim to minimise the disruption for patients and prescribers and ensure continuity of services.

Changes to other terms of service of NHS pharmacies and LPS contractors

5.7 People in England can choose to receive pharmaceutical services from any pharmacy included in an NHS pharmaceutical list or with an LPS contract. The Electronic Dispensing System enables a prescriber to send prescriptions to any pharmacy of a patient's choice electronically and patients are free to change nominations at any time via the NHS app or by asking their GP or a pharmacy to do this. The instrument does not introduce a new requirement in relation to pharmacy nominations. It does however make it clear that changing a patient's nomination without consent from a patient or patient representative is a breach of the NHS terms of service.

Changes regarding applications to provide pharmaceutical services and the procedures to be followed

5.8 These amendments make a number of administrative improvements to the arrangements governing approvals for the provision of NHS pharmaceutical services in England. The changes remove outdated information requirements, streamline application and decision-making processes, and reduce unnecessary administrative burden for applicants and NHS England. Collectively, they support the more efficient administration of NHS pharmaceutical services while maintaining existing policy intent and decision-making criteria.

Changes to local dispute resolution process regarding issue of breach notices

5.9 In case of any potential breaches of the NHS terms of service, the commissioner is required to seek to resolve the dispute through the local dispute resolution process before proceeding to issue a breach notice. Both the contractor and the commissioner are required to engage in the local dispute resolution process. Currently, the requirements for the two parties are covered by separate regulations 68 and 69 and in a situation where a contractor is not engaging it is not clear if the commissioner must continue trying to engage or if they can proceed to issue a breach notice. It is also not clear what engagement and cooperation is expected from the contractor.

5.10 The amendments to regulation 68 clarify contractors' responsibilities regarding cooperation with the dispute resolution process. Correspondingly, the amendments to regulation 69 provide that commissioners are not required to undertake engagement where a contractor has failed to comply with its engagement obligations.

What was the previous policy, how is this different?

Independent prescribing & changes to requirements for providing directed services

5.11 Previously, nationally commissioned community pharmacy services were delivered through a combination of service directions, clinical specifications and professional standards, with no specific legislative framework governing the exercise of pharmacist independent prescribing within NHS pharmaceutical services. Although pharmacist independent prescribing has been established in other parts of the NHS, including hospital and general practice settings, prescribing activity has not previously formed part of a nationally commissioned community pharmacy service. This instrument introduces a consistent national legal framework to support the safe delivery of prescribing activity within NHS pharmaceutical services, including requirements relating to clinical accountability, communication and continuity of care when changes are made to a patient's treatment. This instrument complements the detailed requirements that will continue to be set out in service directions and

guidance, ensuring an appropriate balance between legal certainty and operational flexibility. It also provides a scalable framework that can accommodate the expansion of prescribing services over time, while allowing local commissioners to develop additional services and governance arrangements that reflect local population needs.

5.12 Previously, requirements relating to DBS checks were not set out in the PLPS Regulations and were instead supported through contractual arrangements, service requirements and wider professional and regulatory frameworks. These amendments introduce a requirement for pharmacy contractors to ensure that all pharmacy staff, including locums, involved in the provision of pharmaceutical services hold a current enhanced DBS certificate, or are subject to an enhanced DBS status check through the DBS Update Service, as part of the contractor's clinical governance arrangements. The requirement was initially introduced through the Pharmacy Quality Scheme as a mechanism to support the adoption of consistent safeguarding standards across the sector. These amendments build on that approach by embedding the requirement within the regulatory framework governing NHS pharmaceutical services, ensuring that the same baseline safeguarding requirements apply to all pharmacies providing directed services, including LPS contractors, and provide a consistent foundation for the continued expansion of clinical services delivered through community pharmacy.

Changes regarding NHS pharmacies terms of service: closures for learning and development

5.13 Previously, contractors were required to be open and provide services during the full number of their core hours and were not able to organise training involving all staff during these hours.

5.14 Changes to the NHS terms of service permit pharmacies to close for up to 4 hours in each calendar month for staff training, subject to giving 30 days advance notice to NHS England, informing GP practices that usually refer patients for urgent services about the dates and times of closure and ensuring patients are informed via a notice on the premises (does not apply to distance selling pharmacies (DSPs)) or on the website (applies to DSPs only). In addition, closure for training cannot be scheduled during the first three hours of opening or the last three hours before closing Monday to Friday and cannot take place on a weekend. Pharmacies subject to 100 hours condition are not permitted to close for training between 5 and 9pm on any weekday.

5.15 Upon receipt of notice from pharmacies, NHS England is able to object to the proposed closure if, when taken with other pharmacy closures in the area, it is likely to cause local access issues.

Other changes

5.16 The other changes in this instrument are part of the ordinary process of updating the arrangements for the provision of pharmaceutical services and the administration of pharmaceutical lists that take place following discussions with the relevant representative bodies. Keeping the legislation up to date and continually improving the service is a standard part of how the framework operates.

6. Legislative and Legal Context

How has the law changed?

Regarding Independent prescribing & changes to requirements for providing directed services

6.1 New regulation 66A of the PLPS Regulations outlines the conditions for the provision of services including prescribing by pharmacy staff at the pharmacy premises. This

restricts pharmacists from prescribing and dispensing their own prescriptions except in specified circumstances.

6.2 The exceptions include supplies that form part of a directed service where the service specification expressly allows a pharmacy to dispense prescriptions issued by its own prescribing pharmacist, provided all applicable service requirements are met.

6.3 This is also permitted as part of an essential service, but only where all the following conditions are satisfied:
- The pharmacy provides a directed service under which the pharmacist is authorised to prescribe.
- Appropriate standard operating procedures are in place for prescribing and dispensing on the same premises and best-interests assessments are carried out before prescribing at those premises.
-The prescription replaces one that would otherwise have been issued by a primary medical services provider, with that provider's agreement (either individually or through a pre-agreed arrangement).
-The prescription is issued electronically.
-The prescription is for a prescription-only medicine that the pharmacist is legally authorised to prescribe.
-The pharmacist completes a best interests assessment which concludes that the pharmacist is satisfied that the prescription is clinically appropriate, represents value for money for the NHS and is professionally appropriate.

Changes regarding NHS pharmacies terms of service: closures for learning and development

6.4 New paragraph 23B in Schedule 4 to the PLPS Regulations permits contractors to close their pharmacy for learning and development purposes without this closure being considered a breach of the core opening hours requirement, subject to meeting conditions regarding the total duration of closures and notification to commissioners, pharmacy users and primary care providers.

Changes to other terms of service of NHS pharmacies and LPS contractors

6.5 Changes to Schedule 7, paragraph 9, sub paragraph (5) and to Schedule 4, paragraph 11, sub-paragraph (6) of the PLPS Regulations explicitly forbid contractors from changing a patient's nominated pharmacy without explicit consent given by either the patient or their authorised representative.

Changes regarding applications in respect of pharmaceutical lists and the procedures to be followed

6.6 Regulation 31 of the PLPS Regulations is amended so that the mandatory grounds for refusal do not apply to applications for a change of ownership without relocation, of a pharmaceutical service provider.

6.7 Regulation 52 of the PLPS Regulations is amended by inserting a new paragraph (12). The amendment removes the requirement for NHS England to notify interested parties and invite representations in relation to certain applications by doctor practices for outline consent or premises approval (preliminaries to having a right to dispense) where the PLPS Regulations require the application to be refused. This includes applications where the proposed dispensing premises are within 1.6 kilometres of a community pharmacy (other than a distance-selling pharmacy) or where the premises are not situated in a controlled locality.

6.8 Regulation 53 of the PLPS Regulations is amended to require notification to interested parties of the NHS England decision including where the application was not notified under new paragraph (12) in regulation 52. This is to preserve transparency and awareness for interested parties, even though the earlier consultation step is being removed.

6.9 Removal of sub-paragraph (b) from paragraph 2(2) in Schedule 2 to the PLPS Regulations removes the requirement for applicants seeking inclusion in a pharmaceutical list to provide information about their sex irrespective of whether the applicant is an individual or in a partnership.

6.10 Removal of sub paragraphs (b) to (d) of paragraph 1(8) of Schedule 2 to the PLPS Regulations removes requirements relating to the future provision of directed services. Applicants will no longer be required to provide details of accreditation for directed services, accreditation of premises for directed services, or submit floor plans showing where directed services will be provided.

Changes to local dispute resolution process regarding issue of breach notices

6.11 Changes to regulation 68 and 69 of the PLPS Regulations affect the local dispute resolution process regarding breach notices. New paragraph (3) in regulation 68 introduces a definition of cooperation that contractors must follow. Changes to regulation 69 release NHS England from the requirement to engage and cooperate with contractors during the local dispute resolution process if the contractor is not cooperating.

Why was this approach taken to change the law?

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

7. Consultation

Summary of consultation outcome and methodology

7.1 Customarily, DHSC seeks the views of Community Pharmacy England (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. DHSC has been able to discuss the policy changes in these areas with CPE and has responded to their comments, making changes to the instrument where appropriate.

7.2 The Department has consulted with the British Medical Association regarding changes to notification requirement for dispensing doctors' applications and they did not raise any concerns.

7.3 In line with the requirement to consult under Article 36(4) of the UK GDPR, an enquiry form was submitted to the Information Commissioner's Office (ICO) notifying them of the changes referenced in paragraphs 6.1, 6.5 and 6.9 above. Having considered the submission, the ICO confirmed they do not wish to engage further at this time.

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 representative 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 There is no or no significant impact on charities or voluntary bodies because they are not involved in the provision of NHS pharmaceutical services.

9.3 There is a small positive impact on businesses, including small or micro businesses. Permitting pharmacy contractors to close for up to 4 hours in each calendar month will enable training for the whole pharmacy team without the need to bring in additional temporary staff to keep a pharmacy open. The regulatory requirements preceding such closures are minimal and seek to prevent detrimental impact on local access to pharmaceutical services.

9.4 The requirement for all pharmacy professionals to have a valid enhanced DBS certificate has been incentivised via the Pharmacy Quality Scheme in previous years and the majority of pharmacies already comply with this requirement. As a result, the additional impact of these Regulations is expected to be limited, although some costs may continue to arise for contractors employing new staff or engaging professionals who do not already hold a current enhanced DBS certificate. It was not possible to exempt small or micro businesses (employing up to 50 people), from the DBS requirement as this is essential for patient safety.

9.5 There is no significant impact on the public sector because the instrument does not introduce new onerous requirements on NHS commissioners.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is through regular discussions with interested parties including NHS England and contractors' representatives on any problems identified in their operation.

10.2 The instrument does not include a statutory review clause.

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 2026, allowing more than 21 days before it comes into force on 1st October 2026, 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 As the instrument is subject to negative 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").