EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CHARGES, REMISSION OF CHARGES AND PHARMACEUTICAL SERVICES ETC.) (AMENDMENT AND TRANSITIONAL PROVISIONS) REGULATIONS 2025

2025 No. 636

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.

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?

Regarding distance selling premises (DSPs)

4.1 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 now delegate this function to integrated care boards, but the functions remain in NHS England's name).

4.2 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 as, respectively, "pharmacy contractors" and "LPS contractors".

4.3 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 and market exit. The arrangements made with dispensing doctors are solely for patients in some rural areas, and usually for patients who live more than a certain distance from a pharmacy. Those arrangements are not affected by the National Health Service (Charges, Remission of Charges, Pharmaceutical Services etc.) (Amendment and Transitional Provisions) Regulations 2025 (the Regulations).

4.4 Decisions by NHS England on new market entry by pharmacy contractors or DACs are based on the local plans outlining the needs and availability of pharmaceutical and

local pharmaceutical services in an area. Known as the Pharmaceutical Needs Assessments, these are developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs).

4.5 In 2005 The National Health Service (Pharmaceutical Services) Regulations (2005 S.I. 3005/ 641) exempted certain categories of contractors from NHS market entry tests. In 2013 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the PLPS Regulations) (S.I. 2013/349), most of these exemptions were removed, however the DSP exemption was retained. This is because, at the time, these pharmacies operated like any mail order company in that they received and fulfilled orders for medicines "remotely" from a patient or customer anywhere in the country rather than face to face as in a traditional pharmacy.

4.6 This instrument implements changes to the NHS market entry conditions and terms of service of DSPs, agreed with Community Pharmacy England through the Community Pharmacy Contractual Framework 2024/25 and 2025/26 consultation. Following the regulatory change, contractors focusing on remote selling will be required to satisfy the same market entry tests as any other potential NHS pharmacy contractor and will need to provide services at as well as from those premises in the ordinary way. They will not benefit from the easements in the Regulations for DSPs. In effect, the instrument removes the exemption from the market entry test that permitted an easier route to the market for DSPs, however DSP contractors already on the pharmaceutical list will be able to apply to relocate or change ownership of their premises as they do now.

4.7 DSP contractors will also not be able to deliver directed pharmaceutical services face to face at the pharmacy premises from 1 October 2025, but will be able to continue delivering influenza and COVID-19 vaccinations at the premises until 31 March 2026. The requirement for DSP contractors to deliver all essential services remotely will be retained and they will also be able to continue delivering directed services remotely.

Regarding applications by contractors to redistribute core opening hours

4.8 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 on their application to join the pharmaceutical list. The 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 introducing a rest break.

4.9 In 2023, the PLPS Regulations were amended to make the needs test less onerous (S.I. 2023/479). An applicant who wanted to reduce or redistribute their core opening hours was required to demonstrate either that they are able to maintain as necessary the existing level of service provision in that area or, if maintaining the existing level of service provision is neither a necessary nor a realistically achievable outcome, that they are able to maintain a sustainable level of adequate service provision.

4.10 This instrument retains this needs test for applications to reduce core opening hours and for applications to redistribute core opening hours, and introduces an additional needs test for the latter type of applications. The additional needs test requires contractors to evidence that the people accustomed to using the pharmacy will be more likely to do so during the proposed new hours rather than during the current hours.

4.11 From 23 June 2025, a contractor that wants to change but not reduce their hours can rely on the old needs test or the new needs test. They just have to say in their application which test they want to apply. The retention of the old test ensures that contractors who previously applied do not have to present any new evidence because an addition of the new test. Likewise, appeals can carry on as they are now.

Regarding Zero or nominal reimbursement of flu vaccines for children

4.12 This instrument provides that, where the Government has centrally purchased influenza 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.

4.13 The instrument makes it possible for community pharmacy contractors to access centrally procured influenza immunisation products for children as they already do for adults.

Regarding changes to prescription charges

4.14 The instrument also amends the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570) ("the Charges Regulations") to allow the automatic cancellation and refund of a prescription payment certificate (PPC) when a person becomes exempt because they have a valid medical or maternity exemption certificate.

4.15 The amendments to the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 ("the TERC Regulations") amendments remove the NHS charge and NHS travel expense exemption for those in receipt of HMRC Tax Credits where the individual (including their partner and dependent children) is in receipt of Child Tax Credit, Working Tax Credit and Child Tax Credit paid together or Working Tax Credit including a disability or severe disability element. This is because Working Tax Credit and Child Tax Credit ended at the end of 5 April 2025 and no more payments will be made after that. Claimants previously in receipt of this benefit are invited to apply for the DWP's Universal Credit benefit, however not all people who qualified for Tax Credits will be eligible for Universal Credit.

Where does the legislation extend to, and apply?

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

4.17 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 distance selling premises (DSPs)

5.1 DSPs or internet-based pharmacy are defined in the PLPS Regulations as registered pharmacy businesses that provide essential services to patients otherwise than at the

registered premises[1]. They receive and fulfil orders for medicines (as well as provide other NHS essential services) "remotely" from a patient or customer rather than face to face as in a traditional pharmacy and must deliver medicines on an England wide footprint where requested to do so by patients. Under current regulations, to qualify as an excepted application, a DSP must not provide NHS essential services direct to patients at the premises. It may, however, sell or supply goods that are not NHS-related and also provide advanced or enhanced services from its premises where these services can be provided wholly separately from the provision of essential services at the premises.

5.2 Since 2013, NHS pharmacies have been commissioned to deliver an increasing range of clinical services alongside their core dispensing function. However, DSP market entry conditions and terms of service have not been updated to reflect the changes in the current operating environment, leading to uncertainty as to what activities can be undertaken by contractors both on and off the registered pharmacy premises and potentially undermining local service planning. Continuation of DSP exemption created a situation, where a traditional pharmacy is not able to open due to market entry tests, a satisfactory application from a DSP offering to provide the same services (albeit remotely) has to be accepted and once open, the pharmacy can also provide the same directed services as a traditional pharmacy face to face on its premises.

5.3 This instrument will remove the exemption from the market entry tests for a contractor wanting to provide NHS pharmaceutical services remotely, resulting with an even playing field for all potential pharmacy contractors. The Department will continue monitoring the market closely and may consider reintroducing the exemption, potentially with the revised market entry criteria, if patient choice of pharmaceutical service providers is impaired. This instrument will also align the requirements for the delivery of directed services from the DSP premises with that of the essential services requirement, so that all NHS services can only be delivered remotely by DSPs already included on the NHS pharmaceutical list. This will provide clarity and consistency for patients and commissioners regarding mode of service delivery by a DSP versus a traditional pharmacy. Two different in-force dates (31 March 2026 for flu and COVID-19 vaccinations and 1 October 2025 for all other directed services) will provide sufficient notice for contractors and commissioners affected by these changes.

Regarding applications by contractors to redistribute core opening hours

5.4 As explained in para 4.11, pharmacy contractors who want to apply to redistribute when they deliver their core hours during the week, will be able to choose if they want to base their application on the previous or the new test. The change aims to support contractors with keeping opening hours flexible and better respond to patients needs.

Regarding Zero or nominal reimbursement of flu vaccines or children

5.5 The policy context is a desire to enable community pharmacies to use centrally procured pertussis vaccines in specially commissioned services (known as enhanced services) to support NHSE's immunisation programmes.

5.6 Influenza (flu) is a respiratory disease that is vaccine preventable. Immunisation is the most effective way to protect against flu. NHSE has proposed to commission community pharmacies to provide additional capacity and increased access to flu vaccine for children. This will increase patient access to vaccines, therefore improving

[1] The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 https://www.legislation.gov.uk/uksi/2013/349/regulation/64

patient health and reducing the pressure on health services in responding to the increasing outbreaks of flu before the Winter months.

Regarding changes to prescription charges

5.7 The Charges Regulations provide the amount of the charge for an NHS prescription item and certain other appliances supplied by the NHS, the circumstances in which the charge must, or must not, be made and the patients who are exempt from prescription charges. The amendment will remove the NHS charge and NHS travel expenses exemption for those in receipt of HMRC Tax Credits where the individual (including their partner and dependent children) is in receipt of Child Tax Credit, Working Tax Credit and Child Tax Credit paid together or Working Tax Credit including a disability or severe disability element. This is because Working Tax Credit and Child Tax Credit ended at the end of 5 April 2025 and no more payments will be made after that. Claimants previously in receipt of this benefit are invited to apply for the DWP's Universal Credit benefit, however not all people who qualified for Tax Credits will be eligible for Universal Credit.

What was the previous policy, how is this different?

Regarding distance selling premises

5.8 Until 22 June 2025, potential pharmacy contractors did not need to meet market entry tests if they wanted to open a DSP pharmacy. They were only required to evidence that they would deliver essential services remotely to anyone in England. Once open, DSP pharmacies could deliver directed services face to face at the pharmacy premises. From 23 June 2025 onwards, the exemption from market entry tests for DSPs is removed, with a transitional provision for applications already in the system. Existing DSP's terms of service for the delivery of directed services is aligned with the requirement for essential services, so that all directed services can only be delivered remotely without face to face contact with the patient at the pharmacy premises (from 31 March 2026 for flu and COVID-19 vaccinations and from 1 October 2025 for all other services)

Regarding applications by contractors to redistribute core opening hours

5.9 As explained in para 4.8, the same test applied to pharmacy contractors who wanted to reduce or redistribute their core hours. Going forward, contractors wanting to redistribute when they deliver their core hours are able to choose if they want their application to be subject to the old test or the new test.

Regarding Zero or nominal reimbursement of flu vaccines or children

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 (2006 Act) to make regulations to enable alternatives to these ordinary remuneration arrangements in some circumstances. That option is being exercised here.

Regarding changes to prescription charges

5.11 The previous regulations included receipt of certain HMRC Tax Credits as a valid exemption from NHS charges and NHS travel expenses, and they did not allow the NHS Business Services Authority (NHS BSA) to automatically refund a PPC when

the person became exempt on maternity or medical grounds because they had obtained a valid exemption certificate.

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 distance selling premises

6.2 From 23 June 2025, potential pharmacy contractors focusing on remote selling will be required to satisfy the same market entry tests as apply to any other pharmacy contractor. Applications submitted on or before 22 June will be processed according to the current rules.

6.3 From 1 October 2025 DSP contractors will be required to cease face to face provision of directed pharmaceutical services, although they will be able to deliver flu and COVID-19 vaccinations until 31 March 2026.

Regarding applications by contractors to redistribute core opening hours

6.4 From 23 June 2025, contractors will be able to rely on the old or the new test when applying to NHS England to redistribute when they deliver their core opening hours.

Regarding Zero or nominal reimbursement of flu vaccines or children

6.5 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.

6.6 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, and pertussis vaccines and antivirals, and now a new statutory exception is being created for influenza vaccines for children in the same terms as the existing vaccines exceptions.

Regarding changes to prescription charges

6.7 In relation to the TERC Regulations, HMRC Tax Credits ceased to exist at the end of 5 April 2025. This change will remove these benefits from the listed NHS charge and NHS travel expenses exemptions.

6.8 The NHS BSA do not currently have authority to automatically cancel and refund a PPC when a person becomes exempt on maternity or medical grounds because they hold a valid exemption certificate. At present the person is required to make contact with the NHS BSA to request a refund.

Why was this approach taken to change the law?

6.9 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 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. 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 CPE has also been consulted on the amendment to the PLPS Regulations with regards to the addition of influenza vaccines for children. CPE have agreed to the proposed amendment

7.3 DHSC is not required to consult on the Charges Regulations and the TERC Regulations.

8. Applicable Guidance

8.1 Departmental guidance is not required for changes to the PLPS Regulations. Pharmacy contractors will be supported with guidance in the usual way by NHS England.

8.2 In relation to the TERC Regulations, NHS BSA and HMRC have notified patients that the last Tax Credit charge exemptions were issued with an end date of 5 April 2025. The exemption will be removed from the FP10 prescription form and token over the coming months as old stocks are used up.

8.3 NHS BSA issue PPCs, maternity and medical exemption certificates, so they will correspond with patients who become exempt during the validity of their PPC to refund them a pro-rata amount on their annual PPC.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because not many businesses are affected. On 30 April 2025 there were 410 active DSP contractors (4% of the total number of active NHS contractors). Over 90% of DSPs are within a mile distance from a traditional pharmacy, so patients accustomed to receiving directed services face to face from DSP premises will be able to access these services through the alternative pharmacy location or remotely through any DSP pharmacy. Other changes in this instrument are enabling and do not have direct impact on businesses.

Impact on businesses, charities and voluntary bodies

9.2 The changes to DSP market entry conditions and terms of service impact on businesses, including small or micro businesses. Potential pharmacy contractors focusing on remote selling will be required to satisfy the same market entry tests as any other potential NHS pharmacy contractor. Existing DSP contractors will be required to deliver all directed services remotely.

9.3 To minimise the impact of the requirement to cease face to face provision of directed services at the premises on small or micro businesses (employing up to 50 people) the implementation of the change is delayed until 31 March 2026 for flu and COVID-19 vaccinations and until 1 October 2025 for all other directed services.

9.4 The requirements that aim to provide contractors with flexibilities to amend their opening hours are not delayed as they aim to support contractors to better respond to patient needs. The provisions that remove the exemption from the market entry tests for DSP applications include transitional provisions so that businesses that have already submitted applications on or before 22 June are not impacted by this change and their applications are processed according to previous rules.

9.5 The amendments on PPC and removal of the Tax Credit exemption box place no new requirements on small or micro businesses. Both will both save time in pharmacies as changes align with revised services.

9.6 There is no, or 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. No review is required for the amendments being made to the TERC Regulations.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None

12. European Convention on Human Rights

12.1 As 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").