



June 2025

Briefing 013/25: Regulatory Changes in June 2025 – DSPs, Opening Hours, etc.

The Department of Health and Social Care (DHSC) laid new regulations in June 2025, which include important regulatory changes to the community pharmacy sector, including those on distance selling premises (DSP) pharmacies and core opening hours.

The <u>amendment regulations</u> made changes to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the PLPS regulations), which were agreed in the 2024/25 and 2025/26 negotiations between the Department of Health and Social Care (DHSC), NHS England (NHSE), and Community Pharmacy England.

Overview

In this briefing, we cover:

- DSP changes;
- Core opening hours changes; and
- Other regulatory changes announced in June 2025.

Details of the regulatory changes agreed in the settlement on the CPCF for 2024/25 and 2025/26, including FAQs, are available on <u>our website</u>.

DSP changes

DSP market entry exemption closing

From 23 June 2025, no new applications for DSP pharmacies can be accepted/are permitted under the PLPS regulations. Similar to the previous 100-hour pharmacy exemption, the DSP route to establish a new pharmacy will now be closed.

Any new DSP applications submitted on or before 22 June 2025 will be determined in accordance with the current market entry test, i.e. the test that was in effect on and before 22 June 2025.





DSP pharmacies already on a pharmaceutical list will continue to be on the list and be able to continue to deliver pharmaceutical services in accordance with their Terms of Service in the PLPS regulations (which are also changing – see below). DSP pharmacy owners will continue to be able to apply to relocate or change the ownership of the pharmacy.

DSPs to deliver Directed Services remotely

From 1 October 2025, with one exception, DSP pharmacies will no longer be permitted to deliver Directed services (Advanced, National Enhanced, and Enhanced services) in person, onsite at the distance selling premises (i.e., no longer permitted to provide Directed services onsite, face-to-face with a patient).

Where a service specification allows, DSP pharmacies will continue to be permitted to provide:

- remote consultations (from the distance selling premises) or
- off-site delivery of a Directed service face-to-face with a patient (i.e. not on the distance selling premises) with ICB approval, if required.

The one exception to this is that DSP pharmacies may continue to deliver the COVID-19 and Influenza vaccination services onsite, face-to-face, at the distance selling premises, until 31 March 2026. This is to ensure adequate provision of these services for winter 2025/26 and to protect those who have already placed orders for their vaccination stock.

We have created an <u>FAQs page</u>, which addresses some key DSP related questions of the regulatory changes.

Core Opening Hours

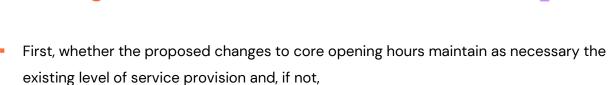
Pharmacy owners who want to change their core contractual hours (core opening hours) must apply to the ICB.

Existing application route

The existing application route is defined in para 24(1) of Schedule 4 of the PLPS regulations, which applies to applications to reduce the total number of core opening hours, or to rearrange the existing number.

This route is a 2-part regulatory test, which is:





 Second, whether they will maintain a sustainable level of adequate provision in circumstances where this is unnecessary or unrealistically achievable.

This application route considers the needs of people in the area, and the opening hours and provision of pharmacy services by the applicant's pharmacy and other pharmacies in the area.

New application route

The new application route is defined in para 26(2ZB) of Schedule 4 of the PLPS regulations, which applies to applications to rearrange the existing number of core opening hours (the total number of weekly hours must remain the same).

This route has a single regulatory test, which states that NHSE (in practice, the ICB) must:

'... seek to ensure that the people who are accustomed to accessing pharmaceutical services at the pharmacy premises are likely to benefit from the changes because, overall, they would be more likely to access those services at those premises during the proposed core opening hours than during the existing core opening hours.'

This application route considers the needs of people who are accustomed to accessing pharmacy services at the applicant's pharmacy, and the opening hours and provision of pharmacy services by the applicant's pharmacy.

What to include with applications

With both the new and existing application routes, pharmacy owner applicants will need to:

- Specify which application route applies, otherwise, the application will be invalid.
- Provide the ICB with such information as may reasonably be requested (i.e., provide all relevant information when the application is made).
- Consider what evidence is relevant to their application, and depending on the application route, this could include, for example:
 - Any changes to local GP practice hours and the opening hours of nearby pharmacies.
 - Information about the demand for and use of the pharmacy's services patient surveys, levels of use – for prescriptions/requests for advice/OTC medicines sales



- for the relevant days/times. (e.g. the proposed core opening hours and the existing core opening hours and other relevant hours if Saturday afternoon is quiet with few patients, as well as showing another time in the week better meets the needs of patients, you may need to show that some of the small number of patients in the afternoon could have come in the morning).
- The distance from the applicant's pharmacy to nearby pharmacies, including any 100 (72) - hour pharmacies, or other pharmacies, their opening days and times, the services they offer, and how patients can travel to them.
- Evidence of the economic viability of the current opening hours, which can be considered alongside evidence of patient demand for the pharmacy's services during these hours (the Pharmacy Manual will be amended to state this or something similar).
- Other evidence relevant to the <u>regulatory test</u>.

Note: for an application under the new application route to be granted, people accustomed to using the pharmacy must be likely to benefit from the changes because, overall, they are more likely to access pharmacy services at the premises during the proposed hours than during the existing hours. An application could be about moving a set number of core hours or a broader change to core opening hours.

It is understood that in due course, NHSE will revise its application form for changing core opening hours.

We have provided an <u>information page</u>, which addresses some key information relating to the changes to opening hours applications as part of the CPCF settlement.

Other regulatory changes

The amendment regulations make two other relevant changes:

First, provision for the central supply of Flu vaccinations for children to pharmacies from national stocks, without purchase by the pharmacy (and with zero or nominal reimbursement). Provision for central supply was introduced for COVID-19 vaccines (and antivirals) and now applies to other vaccines including the MMR, RSV, and Pertussis vaccines. Flu vaccinations for children will join this list. Central supply of these vaccines enables community



pharmacies to play a vital role in future public health vaccination programmes, according to local patient needs. (The change is made to Reg 91A of the PLPS regulations).

Second, a change to the 'Charges Regulations' to enable the automatic cancellation and refund of a pre-payment certificate to a person who becomes entitled to a maternity or medical exemption certificate.

Further information

After reading this briefing information and resources on our website, if you have further queries or require more information, please contact the <u>Regulations Team</u>.