Briefing: 025/24: New Pharmacy Regulations: What you need to know

Revised January 2025

The community pharmacy landscape is changing. Several important regulatory changes are now underway to help make dispensing more efficient and support capacity for providing clinical services.

Below Community Pharmacy England's Director, Legal, Gordon Hockey, outlines the current plans for introducing a series of changes two of which were originally agreed by the Department of Health and Social Care (DHSC) and NHS England back in 2019 – namely, Original Pack Dispensing and Hub & Spoke. Proposals to change Supervision are more recent and follow the sector's Pharmacy Supervision Report in 2023.

Original Pack Dispensing (OPD) +/- 10%

Status: Coming into effect from 1st January 2025.

Overview: Pharmacists must consider if it is reasonable and appropriate to dispense up to 10% more or less than the prescribed quantity stated on a prescription if it would mean that as a result the medicine can be supplied as a complete/original pack.

Community Pharmacy England view: We have been battling to get the details right and ensure it is an enabling provision and not mandatory, meaning pharmacists can make a professional decision to use the provision or not, and some products (such as schedule 2-4 Controlled Drugs) will be exempt – the exact quantity on the prescription must be supplied.

The Human Medicines Regulations were updated to enable OPD +/- 10% in Autumn 2023, but this currently only applies to private prescriptions[1]. Changes to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations will allow pharmacies to

[1]The only exception is NHS prescriptions for sodium valproate which, for safety reasons, must be dispensed in its original pack unless there are exceptional circumstances.

use OPD +/-10% rules from 1st January 2025 for NHS prescriptions. Reimbursement for any additional (or reduced) dispensing applies to EPS prescriptions only.

Scope of OPD +/- 10%

Product Type	Eligible for OPD?
POMs	Yes
Non-POMs including P, GSL and non-medicines (i.e. ACBS products, food supplements, cosmetics, toiletries etc)	Yes
Controlled drugs in Schedule 5	Yes
Controlled drugs in Schedules 2 - 4	No
Part IX Appliances	No
Unlicensed specials	No
Special Containers (see below)	No
Products supplied in accordance with SSPs	No
Products supplied in accordance with PGDs	No

The NHS terms of service will say that pharmacies may supply up to 10% more or less than the quantity prescribed if:

- an original pack will be supplied;
- the supervising pharmacist considers the patient can still follow the prescriber's directions (medication regimen); and
- otherwise, the prescription requirements are complied with.

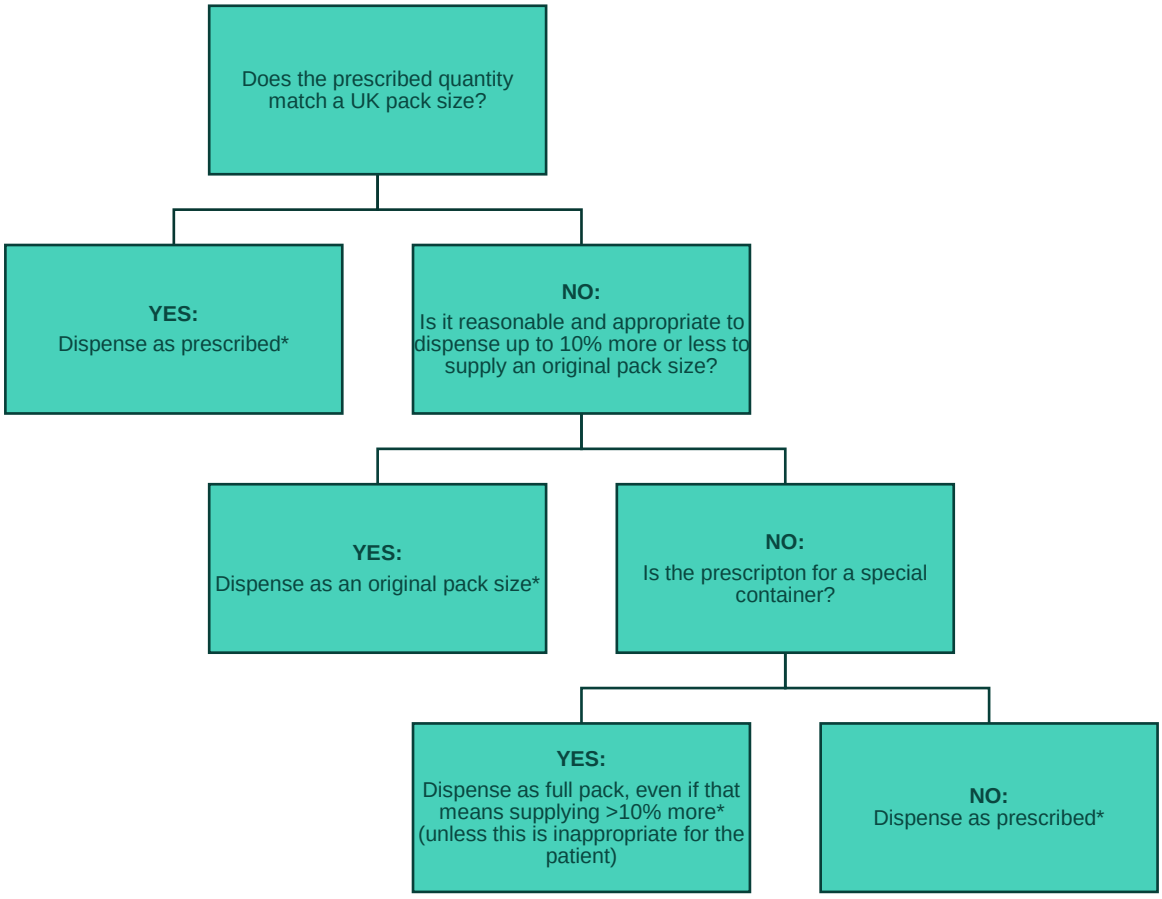
However, if the product is classed as a 'special container' in NHS dictionary of medicines and devices (dm+d) pharmacies may (as before) supply more than 10% (or more than 10% less) to dispense the full pack (i.e. in the special container). This would be outside of the OPD +/-10% rules and payment would be made in accordance with the nearest full pack or sub-pack.

The terms of service also say the supervising pharmacist must consider, using their professional judgement, whether it is reasonable and appropriate to dispense +/-10% of the prescribed amount, having regard to the benefits to patients where they are provided with drugs in the manufacturer's original outer packaging.

Arguably there may be a professional imperative to dispense an original pack for safety reasons (as the patient information leaflet will be supplied), but along with ensuring the patient can follow

the prescriber's directions, there are other considerations including, for example, whether the patient is generally prescribed 28 or 30 each month for any other medicines, if the patient wants the full prescribed amount (30) if they are paying for their prescription (and the pack size is 28) and the availability of stock. You should use your professional judgment to determine the best course of action in each case.

OPD Decision-making



**Exceptions – if it is not possible to obtain and supply with reasonable promptness, or not practicable to supply (e.g. patient needs). This is an existing terms of service requirement.*

Reimbursement and IT

The NHS Business Services Authority (NHSBSA) will reimburse prescriptions as follows:

- where the quantity supplied matches the quantity prescribed, reimbursement will be calculated based on the **quantity prescribed**.
- where the quantity supplied is within +/-10% of the quantity prescribed, reimbursement will be calculated based on the **quantity supplied**.
- where the quantity supplied is less than that prescribed, reimbursement will be calculated based on the **quantity supplied** – this may be much less than prescribed (e.g. 50% less than that prescribed).

- where the quantity supplied is greater than 10% (outside of HMR provisions) of the quantity prescribed, reimbursement will be calculated based on the **quantity prescribed**
- where the product is classed as a special container, reimbursement will continue to be based on the **nearest sub-pack/complete pack size**.

The dispensed quantity field is already included in a prescription's Electronic Reimbursement Endorsement Message (EREM). With OPD, ensuring this is populated correctly now becomes more significant to pharmacy claims and reimbursement as the payment system moves to pay as dispensed model. IT system suppliers are now working to implement the OPD +/-10% reimbursement changes.

It is expected that pharmacy owners will start to introduce the change from 1st January 2025, depending on their IT system readiness. You will not be reimbursed for dispensing up to 10% more or less than the quantity prescribed until your IT system is ready (and able to communicate the dispensed quantity information to the NHSBSA in the EREM)

Find out more

Watch **our on-demand Webinar:** Original Pack Dispensing (OPD) Webinar - Community Pharmacy England

Read our OPD webpage

Read our FAQ briefing

Hub and Spoke Dispensing

Status: Pending.

Overview: Dispensing process could be shared between different retail pharmacy businesses (DHSC has proposed two models of hub and spoke).

Community Pharmacy England view: We support model 1 but have concerns about patient safety and market entry issues with model 2.

Hub and spoke dispensing – essentially sharing the dispensing process between two pharmacies – is currently permitted within the same retail pharmacy business (i.e. the same legal entity), but planned regulatory changes will permit it between different retail pharmacy businesses (i.e.

different legal entities). DHSC has suggested that dispensing error rates could be reduced with the appropriate use of automation and the right arrangements in place. The legal requirements for hub and spoke dispensing may be as follows:

- **Shared dispensing:** 'Hubs' must be registered pharmacies, whilst 'Spokes' must be either a registered pharmacy or a dispensing doctor. Both Hub and Spoke pharmacies must have a Responsible Pharmacist. There may be two models as described below.
- **Written arrangements between Spoke and Hub:** A comprehensive agreement of the responsibilities of each for the shared dispensing process and the labelling of the dispensed medicine (Hub or Spoke, not both).
- **Notice in the Spoke:** A clearly displayed notice of any Hub and Spoke model used, including the name and address of the Hub.
- **GDPR/data protection:** An information gateway involving the professional confidentiality of those working for a hub, the professional responsibilities of healthcare professionals and pharmacy staff, and (the above mentioned) written arrangements (which may be in a contract) between the Hub and Spoke.

The necessary changes to the Human Medicines Regulations were due to be introduced from 1st January 2025 but progress has recently been paused. NHS Pharmaceutical regulations (which include the terms of service) should be introduced at the same time and, for example, should ensure that the Spoke must have an NHS contract.

Hub and Spoke models

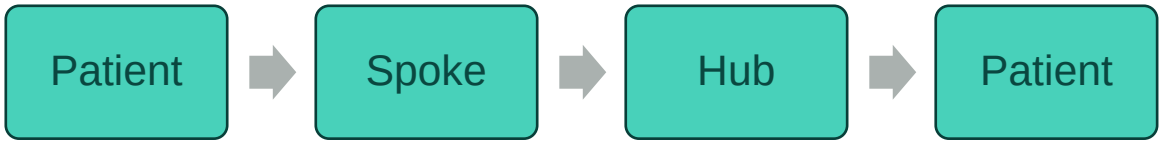
Model 1 would involve patients only interacting with the Spoke pharmacy, whilst Model 2 would permit the Hub to supply medicines directly to the patient on behalf of the Spoke.

Model 1

Community Pharmacy England accepts this model but did suggest some clarity on what the above written arrangements should include, specifically: the processes for induction and ongoing audits for the shared dispensing process, the ability for either hub or spoke to cease the

dispensing process/contract at any point for safety reasons, and clear procedures agreed for patient complaints.

Model 2



Community Pharmacy England has concerns about this model. There is, for example, a lack of clarity around where responsibility for the dispensing process lies, which is a patient safety concern. Additionally, under this model, the potential proliferation of Hub pharmacies could cause issues with the market entry controls in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations.

Find out more

The introduction of Hub and Spoke is delayed for now, we will update pharmacy owners once DHSC has given more clarity on timescales.

Read our Hub & Spoke webpage

Supervision and Pharmacy Technicians

Status: Awaiting DHSC's response to its consultation. No change is imminent.
Overview: Reduced direct pharmacist involvement in the supervision of activities around the dispensing process, making better use of the pharmacy team skill mix. Pharmacists to be able to authorise pharmacy technicians to dispense and supervise dispensing.
Community Pharmacy England view: We broadly support the consultation's proposals and are seeking to ensure the new provisions can be used in practice.

DHSC is currently undertaking a consultation process to update relevant legislation around the supervision of activities by a pharmacist in a pharmacy. Within the consultation, there are two proposals that, if implemented, would bring significant changes to supervision of the dispensing process. These are set out below.

Current guidance on Supervision

Before considering these proposals, it's helpful to consider the current meaning of/guidance on supervision and to note that RPS guidance on supervision may be updated.

The process of …

- preparing, assembling or dispensing a medicine and
- supplying or handing it over to the patient

… must both be carried out or supervised by a pharmacist, but in practice, the two supervision requirements are merged into one.

Currently, pharmacists assess whether a prescription is clinically appropriate for the patient (**a clinical check**). They or an appropriate pharmacy team member will also perform an **accuracy check** of the dispensed medicine. This may be carried out by an Accuracy Checking Technician (ACT). With robust procedures or protocols, the final supply of the dispensed medicine can go ahead (and be supervised) when the pharmacist is in the pharmacy's consultation room, so long as the pharmacist is interruptible (and interrupted if further intervention is required of them).

The RPS guidance on 'supervision' is based on old case law as well as good pharmacy practice. The last time the RPS considered the issues formally was in 2005. However, pharmacy practice has changed since then, for example, through automated dispensing in High Street pharmacies and large, remote Hub pharmacies. The Royal Pharmaceutical Society (RPS) has committed to reviewing its guidance on supervision to take into account these developments.

The RPS guidance on supervision is likely to be updated after planned GPhC standards/rules for responsible pharmacists and standards for superintendent pharmacists have been issued.

In terms of the DHSC consultation on supervision, the current meaning of, or guidance on supervision is stated as:

> *What this means, when compared to the terms of the original Roberts definition of 'supervision' [1943 case law based on the Pharmacy and Poisons Act 1933] is as follows:*
>
> *in the case of a POM or P supply of a dispensed medicine:*
>
> *as regards the 'awareness' requirement, the pharmacist will be aware of the supply (having done the earlier checks), but will not be aware of the actual supply at the moment to supply*

the 'in a position to intervene' requirement is met by the pharmacist being on the premises and interruptible, and procedures or protocols ensuring that the supply will not ahead if the threshold for a pharmacist's intervention is met but the pharmacist was not interrupted

in the case of a P sale:

the 'awareness' requirement no longer applied because it was not considered professionally necessary

the 'in a position to intervene' requirement was again met by the pharmacist being on the premises and interruptible, and procedures or protocols ensuring that the supply will not go ahead if the threshold for a pharmacist's intervention was met but the pharmacist was not interrupted

This clearly put most strain on the Roberts position in the case of supply of P medicines - because of the difficulty in arguing that a pharmacist was aware, in any but the most general terms, of the transactions in question. However, DHSC and the devolved administrations have supported the RPS approach, recognising that the approach taken by the Court of Appeal in Summers [1992 case law] does allow for a body such as RPS or PSNI to provide what amounts to a determination of what good practice in the profession would regard as necessary - and the 2005 guidance amounts to a reasonable determination, updating Roberts, in this case.

That said, there are presumed limits to how far a professional body could go with issuing this sort of guidance, even though there are no legal bright lines to say when these limits would be reached. It is not thought that the proposals covered in this consultation document could not simply be achieved by RPS or PSNI simply issuing even more flexible guidance on the meaning of 'supervision', for example. Some consistency with the courts' historic approach is necessary, even if the updating of that approach that has happened to date properly uses tools that the courts' themselves have given to provide such an update.

That said, it is important to emphasise that the proposed changes to legislation will not, in themselves, redefine 'supervision' - and supervision by a pharmacist will continue as before as one route to lawful preparation, assembly, dispensing and final sale or supply. New routes to the lawful undertaking of these activities are being established, which add

to what is there at the moment, but conventional supply by or under the supervision of a pharmacist will remain an option.

What is important is that pharmacy owners and the pharmacy team are aware of the current RPS guidance on supervision and that the RPS is intending to update its guidance in the context of modern pharmacy practice.

DHSC Consultation proposals

Proposal 1

This proposal would see pharmacy technicians dispense or supervise dispensing if given prior authorisation to do so by the pharmacist. The proposal is that the authorisation must state the pharmacy to which it applies and have due regard for safety. However, it could be:

- General or specific;
- Given orally or in writing;
- Subject to conditions or restrictions; or
- For future prescriptions.

Authorisation may also be varied or withdrawn by the pharmacist at any time.

Proposal 2

This proposal would see pharmacy staff handing out pre-checked and bagged medicines (which have already had a clinical and accuracy check) in the absence of a pharmacist. The proposal is that any member of the pharmacy team could be authorised by the pharmacist to hand out bagged and dispensed medicines.

Note

Note for both proposals, practice related requirements (e.g. record keeping of authorisations) are unlikely to be set out in legislation. These may become professional standard requirements or guidance from the General Pharmaceutical Council (GPhC) or good practice from the RPS.

The DHSC consultation on Supervision can be found at https://www.gov.uk/government/consultations/pharmacy-supervision

Other pharmacy team skill mix changes

Pharmacy technicians have been included in the classes of individuals able to supply and administer medicines under PGDs since 26th June 2024. As with all individuals, they must be specifically included in a PGD to be able to supply or administer under that particular PGD. For Autumn/Winter 2024/25, pharmacy technicians have been included in the NHS seasonal vaccination programme.

The way is also being paved for wider use of the pharmacy team, with a VAT exemption for services carried out by supervised pharmacy staff (in May 2023) and expanding the Hypertension Case-Finding Service (HCFS) to include suitably trained and competent pharmacy staff (in December 2023).

Find out more

Read our Supervision webpage

HCFS: Maximising the use of my team