One of the ways we protect the public is by setting standards. These describe what safe and effective pharmacy care looks like.

We have asked patients and members of the public, and the pharmacy profession, what these arrangements should look like, whether someone uses a pharmacy close to home, in a supermarket or online. We recognise that there are different ways that pharmacies and pharmacy services are arranged and delivered. Using all that information, we have developed the standards for registered pharmacies.

Pharmacies can only register with us and remain on that register if they are eligible and meet these standards.

Everyone who works in a pharmacy should make themselves aware of these standards. All staff are responsible for keeping patients safe and helping to improve their health and wellbeing.

When we come to check how well the standards are being achieved, it is pharmacy owners and superintendents of company-owned pharmacies who we will be holding to account.

We want to use the standards to:

- improve the quality of pharmacy practice
- share examples of good practice, as well as highlight poor practice, when necessary

Five principles

The standards are set out under five principles which describe arrangements for safe and effective pharmacy practice.

principle 1 – looks at how you identify and manage risks in your pharmacy

principle 2 – looks at staffing issues

principle 3 – is about your pharmacy premises

principle 4 – is about how you deliver pharmacy services

principle 5 – is about equipment and facilities

When we talk about pharmacy services we mean: all pharmacy-related services provided by a registered pharmacy including the management of medicines, advice and referral services, clinical services such as vaccinations, and services provided to care homes.

All the principles are important. You might notice that there are a number of themes that run across more than one principle, like confidentiality and managing risk.

Under each principle there is a list of standards which must be achieved if a pharmacy is to continue to be registered.
What is different?

It will be up to owners and superintendents to provide us with evidence about how well the standards are being achieved. A pharmacy can demonstrate that they are achieving the standards any way they like.

Our inspectors will gather and record evidence in a number of ways, including:

- looking at written or documentary evidence
- observing what is going on
- posing scenarios to staff
- by testing systems

To illustrate further, it will not be enough to point us to standard operating procedures (SOPs). Owners and superintendents will need to provide evidence that staff are aware of the SOPs in use in the pharmacy and that those SOPs reflect how the pharmacy operates.

The principles

We have set out what we think each principle means, including some questions which you might find helpful to consider.

This is not an exhaustive list and neither do these questions replace the standards themselves. We encourage all members of the pharmacy team to read and become familiar with the standards, which can be found at: www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf

Principle 1: How you identify and manage risks in your pharmacy

When we talk about risk we mean managing risks to patient safety. This principle is about having the right governance systems and processes in place to keep patients safe. Not all pharmacies provide the same services. They need to be able to demonstrate that services are delivered safely, and can be done safely every day.

Questions to consider:

- have I got systems and processes in place to manage risks associated with the services I am providing?
- have I got arrangements in place to regularly review my systems and processes to make sure they remain safe and fit for purpose, and reflect current practice? And how can I demonstrate this?
- how have I made sure that staff are clear about what they can and cannot do within their roles?
- do I keep records of near misses, errors and incidents and have any changes been made to how the pharmacy operates following an incident or near miss?
- are patients asked for feedback?
- how can I demonstrate that staff are acting on concerns/complaints/feedback from patients? And can I show what has improved as a result?
- have I got appropriate and up-to-date insurance?
- are my records up to date and legally compliant? Can I assure myself that confidential information is not shared intentionally or unintentionally without patient consent?
- do my team know what to do to safeguard potentially vulnerable children and adults?
- when I have locums working for me, if asked, are they clear about the skills and qualifications of other members of the pharmacy team? Are there clear lines of accountability written down and signed? Have they received training?

It might also help to have information about what services you provide and whether you conducted a risk assessment before you started a new service.
Principle 2: Empowered and competent staff

In this principle, the bottom line is that all members of the pharmacy team are able to meet their professional and legal obligations to put the interests of patients first, and without being hindered by improper influences or targets.

Each member of the pharmacy team needs to be trained to the appropriate level for their role, and the right mix of skills should be in place to deliver the range and volume of services the pharmacy offers.

A culture of openness and honesty should be encouraged and fostered. This means encouraging staff to report and record errors and incidents, and to learn from them. Staff should feel able to make suggestions about how to improve services and expect those suggestions to be listened to and acted on.

Questions to consider:

- can I demonstrate that there are enough suitably qualified/trained pharmacy staff to deliver the range and volume of services I am providing?
- have I changed staff numbers or the mix of skills when a new service has been introduced?
- do staff have 1-2-1s/team meetings/appraisals?
- how can I demonstrate that staff are appropriately supervised, particularly trainees?
- how can I demonstrate that staff are encouraged and required to report and record errors/incidents/near misses, and learn from them?
- how can I demonstrate that staff views/feedback have been used to improve services for patients?
- do I set targets or offer incentives for staff and can I assure myself that they don’t impact on patient care?
- do staff know what to do should they have concerns about the poor professional practice of others or if the standards are not being achieved?

Principle 3: How you manage the pharmacy premises

This is about the management of the actual premises—being able to show that the space we register as the pharmacy is clean, hygienic, secure and properly maintained, and appropriate for providing the services on offer, including the protection of privacy, dignity and confidentiality of patients.

Questions to consider:

- how do I use the workspace? Can I demonstrate that the size, design and layout of the pharmacy supports safe practice?
- do I have a consultation room or can I demonstrate that there is a quiet area where patients can have confidential conversations with pharmacy staff?
- can I demonstrate that the pharmacy has appropriate heating, lighting and ventilation controls?
- can the pharmacy be closed when the rest of the store is open? Who holds the keys?
- where do I store excess stock?
Principle 4: How you deliver pharmacy services

This is about managing the services offered by the pharmacy - and we don’t just mean supplying medicines. It is also about making sure the pharmacy is accessible, including making information available about the services on offer, and in formats and languages that meet the needs of the local community.

Questions to consider:

• how can I demonstrate that the services I offer are accessible and that I have made reasonable efforts to make them accessible?
• do I signpost patients to other service providers?
• do I tailor services to the local population?
• how can I demonstrate that patients are given the right advice about how to take their medicines?
• can I demonstrate that I have robust stock management arrangements – including for ordering, storing, date checking and rotating stock?
• do I have a dispensing audit trail?
• what do I do with patient returns?
• do I provide a delivery service and if so, do I have an audit trail for deliveries?
• if providing internet services - how do I manage the sale of OTC medicines?

Principle 5: Equipment and facilities you have and use to deliver pharmacy services

This is about having the right equipment and facilities for the services the pharmacy provides.

Questions to consider:

• do I have all the equipment I need to provide the services I offer?
• how can I demonstrate that the equipment is clean, working and properly calibrated?
• how can I demonstrate that the pharmacy has up-to-date reference sources?
• can I assure myself that equipment is stored safely and securely?
• how do I store paper records? Are PMR passwords protected?