

Standards for registered pharmacies

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plain English
approved
by the word centre



About the GPhC

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain.

We work to assure and improve standards of care for people using pharmacy services.

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

We set standards for pharmacy professionals and pharmacies to enter and remain on our register.

We ask pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies.

We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

Through our work we help to promote professionalism, support continuous improvement and assure the quality and safety of pharmacy.

Introduction

The purpose of these standards is to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy. The standards apply to all pharmacies registered with the General Pharmaceutical Council.

We recognise that for anyone operating a registered pharmacy there will always be competing demands. These may be professional, managerial, legal or commercial. However, medicines are not ordinary items of commerce. Along with pharmacy services, the supply of medicines is a fundamental healthcare service. Pharmacy owners must take account of this when applying these standards.

Pharmacy owners are responsible for ensuring the safe and effective provision of pharmacy services at or from a registered pharmacy. They are accountable for making sure that the standards for registered pharmacies are met. If the pharmacy is owned by a 'body corporate', the directors must assure themselves that the standards for registered pharmacies are being met.

Although registered pharmacies may have different ownership structures, it is important that the culture and processes within the pharmacy deliver safe and effective care to patients and the public.

In a limited, or public limited company, the board of directors has a significant role in making sure people receive safe and effective care from

registered pharmacies. The Companies Act, and other relevant legislation, sets out the legal responsibilities for directors. In a pharmacy where healthcare is being delivered to the public, there is further guidance¹ for directors about their extra responsibilities in delivering a public service. This applies whether they are in a private or a voluntary organisation.

As a pharmacy owner you should consider the context of each individual pharmacy. This includes:

- the range of services provided
- the skill mix and number of staff in the pharmacy team
- most importantly, the needs of patients and people who use pharmacy services

As well as meeting our standards, the pharmacy owner must make sure they comply with all legal requirements including those covering medicines legislation, health and safety, employment, data protection and equalities legislation.

Pharmacy owners must make sure that all staff, including non-pharmacists, involved in the management of pharmacy services are familiar with the standards and understand the importance of their being met. We also expect them to be familiar with all relevant guidance.

All registered professionals working in a registered pharmacy should also be familiar with these standards; and pharmacists and pharmacy technicians must understand that they have a professional responsibility to raise concerns if they believe the standards are not being met.

The standards can also be used by patients and the public so that they know what they should expect when they receive pharmacy services from registered pharmacies.

Throughout this document we use the term 'pharmacy services'. This covers all pharmacy-related services provided at or from a registered pharmacy including the management of medicines, provision of advice and referral, clinical services such as vaccination services, and services provided to care homes.

Throughout this document we use the term 'staff'. This includes agency and contract workers, as well as employees and other people who are involved in the provision of pharmacy services by a registered pharmacy. Where we use the term 'you,' this means the pharmacy owner.

In some limited circumstances (for example following death or bankruptcy), a representative can take the role of the pharmacy owner. In these cases, the appointed representative will be responsible for making sure these standards are met.

¹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/481535/6.1291_CO_LAL_Ethical_standards_of_public_life_report_Interactive_2_.pdf



Standards for registered pharmacies

We have grouped the standards under five principles. The principles are the backbone of our regulatory approach and are all equally important.

The principles:

Principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients and the public.

Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

Principle 3: The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

Principle 4: The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.

Principle 5: The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

The standards

The standards under each principle are requirements that must be met when you operate a registered pharmacy.

Responsibility for meeting the standards lies with the pharmacy owner. If the registered pharmacy is owned by a 'body corporate' the directors must assure themselves that the standards for registered pharmacies are being met.



Applying the standards

The principles for registered pharmacies, and the standards that must be met, are all equally important.

Therefore, you should read all the standards in their entirety. Pharmacy owners and other pharmacy professionals should also be familiar with the standards for pharmacy professionals.

We know that a pharmacy owner may be accountable for one, a few or a large number of registered pharmacies. We expect the pharmacy owner to make sure that these standards are met whatever the number of pharmacies they are accountable for.



Principle 1:

The governance arrangements safeguard the health, safety and wellbeing of patients and the public.

'Governance arrangements' includes having clear definitions of the roles and accountabilities of the people involved in providing and managing pharmacy services. It also includes the arrangements for managing risks, and the way the registered pharmacy is managed and operated.

Standards

- 1.1 The risks associated with providing pharmacy services are identified and managed
- 1.2 The safety and quality of pharmacy services are reviewed and monitored
- 1.3 Pharmacy services are provided by staff with clearly defined roles and clear lines of accountability
- 1.4 Feedback and concerns about the pharmacy, services and staff can be raised by individuals and organisations, and these are taken into account and action taken where appropriate
- 1.5 Appropriate indemnity or insurance arrangements are in place for the pharmacy services provided
- 1.6 All necessary records for the safe provision of pharmacy services are kept and maintained
- 1.7 Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- 1.8 Children and vulnerable adults are safeguarded.

Principle 2:

Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

The staff you employ and the people you work with are key to the safe and effective practice of pharmacy. Staff members, and anyone involved in providing pharmacy services, must be competent and empowered to safeguard the health, safety and wellbeing of patients and the public in all that they do.

Standards

- 2.1 There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided
- 2.2 Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training
- 2.3 Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public
- 2.4 There is a culture of openness, honesty and learning
- 2.5 Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services
- 2.6 Incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff.



Principle 3:

The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

It is important that patients and the public receive pharmacy services from premises that are suitable for the services being provided and which protect and maintain their health, safety and wellbeing. To achieve this you must make sure that all premises where pharmacy services are provided are safe and suitable. Any associated premises, for example non-registered premises used to store medicines, must also comply with these standards where applicable.

Standards

- 3.1 Premises are safe, clean, properly maintained and suitable for the pharmacy services provided
- 3.2 Premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- 3.3 Premises are maintained to a level of hygiene appropriate to the pharmacy services provided
- 3.4 Premises are secure and safeguarded from unauthorised access
- 3.5 Pharmacy services are provided in an environment that is appropriate for the provision of healthcare.

Principle 4:

The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.

'Pharmacy services' covers all pharmacy-related services provided by a registered pharmacy including the management of medicines, advice and referral, and the wide range of clinical services pharmacies provide. The management of medicines includes arrangements for obtaining, keeping, handling, using and supplying medicinal products and medical devices, as well as security and waste management. Medicines and medical devices are not ordinary commercial items. The way they are managed is fundamental to ensuring the health, safety and wellbeing of patients and the public who receive pharmacy services.

Standards

- 4.1 The pharmacy services provided are accessible to patients and the public
- 4.2 Pharmacy services are managed and delivered safely and effectively
- 4.3 Medicines and medical devices are:
 - obtained from a reputable source
 - safe and fit for purpose
 - stored securely
 - safeguarded from unauthorised access
 - supplied to the patient safely
 - disposed of safely and securely
- 4.4 Concerns are raised when it is suspected that medicines or medical devices are not fit for purpose.



Principle 5:

The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

The availability of safe and suitable equipment and facilities is fundamental to the provision of pharmacy services and is essential if staff are to safeguard the health, safety and wellbeing of patients and the public when providing effective pharmacy services.

Standards

- 5.1 Equipment and facilities needed to provide pharmacy services are readily available
- 5.2 Equipment and facilities are:
 - obtained from a reputable source
 - safe to use and fit for purpose
 - stored securely
 - safeguarded from unauthorised access
 - appropriately maintained
- 5.3 Equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services.

More information

If you have any questions or comments about the content of the standards, please contact our Standards Team:

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We have also produced guidance on topics that you may find useful: **www.pharmacyregulation.org/standards/guidance**



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