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About the GPhC

Who we are

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

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

What we do

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.
Overview

Background
Following recent legislation, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) are working to strengthen pharmacy governance.

The GPhC now has powers that allow us to:

- develop rules setting out the essential roles and responsibilities of Responsible Pharmacists, and
- set professional standards for Chief Pharmacists, Superintendent Pharmacists and Responsible Pharmacists

The first part of this work is to develop the Chief Pharmacist standards. The second stage, to produce rules and standards for Responsible Pharmacists and standards for Superintendent Pharmacists, will start in 2024/25.

The legislation

The Pharmacy (Preparation and Dispensing Errors - Hospital and Other Pharmacy Services) Order 2022 came into force on 1 December 2022. The purpose of this Order is to remove the threat of criminal penalties for accidental or unintentional preparation and dispensing errors by pharmacy staff working in hospitals and similar settings.

Under the 1968 Medicines Act, there are already ‘defences’ pharmacy professionals can use if they are responsible for an inadvertent preparation or dispensing error.

Since 2018, pharmacy staff working in registered pharmacies have been able to use these defences. The Order now includes pharmacy staff working in certain other pharmacy settings, such as hospitals, care homes, Integrated Care Boards, mental health trusts, prisons, and places where people are lawfully detained. This will:

- lead to consistency across the pharmacy sector
- encourage people to report preparation and dispensing errors, and
- mean that there is more ‘shared learning’ from errors, which will improve patient safety

To benefit from the defences in the Order, the hospital (or other pharmacy setting listed in the Order) must have a Chief Pharmacist (or equivalent) in post. This must be a registered pharmacist with the appropriate skills, training and experience. Under the Order, the GPhC can set professional standards for Chief Pharmacists. If an organisation chooses to have a Chief Pharmacist (or equivalent) in post, the postholder must meet the standards set out in this document.

1 There is a list of eligible settings in section 67F of the Medicines Act 1968.
The standards

The draft standards (please see Appendix 1 below) set out the professional responsibilities of a Chief Pharmacist. They also describe the knowledge a Chief Pharmacist must have, and the conduct and performance expected of them if they are to support the organisation and its staff to deliver safe and effective pharmacy services, including preparing and dispensing medicines.

In developing these standards, we worked with a broad range of stakeholders from across the pharmacy sector in England, Scotland, and Wales. We analysed and used the feedback to develop these standards for Chief Pharmacists. The standards set out what Chief Pharmacists must do if pharmacy staff are to benefit from the defences. Each standard includes examples of how it can be met in practice. The four standards are:

1. **Provide strategic and professional leadership.**
2. **Develop a workforce with the right skills, knowledge, and experience.**
3. **Delegate responsibly and make sure there are clear lines of accountability.**
4. **Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services.**

The aim of this consultation is to get the views of our stakeholders on the proposed standards, and to find out if there are any issues, or if there is anything else we should have included. To read the draft standards for Chief Pharmacists, please see Appendix 1.
The consultation process

The consultation will run for 12 weeks and will close on 16 April 2024.

During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including Chief Pharmacists, pharmacy professionals, pharmacy owners, patients’ representative bodies, and other people and organisations with an interest in this area.

After the consultation, we will publish a report summarising what we heard.

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive and consider any changes that are needed.

Our governing Council will receive the analysis at a meeting in Summer 2024 and will consider the responses when approving the final standards for Chief Pharmacists.

We will publish our analysis of the responses and an explanation of the decisions we take. You will be able to see this on our website www.pharmacyregulation.org.

Why we consult

Under the Pharmacy Order 2010, we have to consult before we set any standards or requirements. We will also consult, when we need to, to make sure we are carrying out our statutory duties effectively and proportionately to meet our main objective of protecting the public.

How to respond

You can respond to this consultation by going to pharmacyregulation.org/consultation-draft-standards-chief-pharmacists and filling in the online questionnaire there.

We encourage everyone to use the online questionnaire. However, if you want to send a response by email, please write your response to the consultation questions and send it to us at consultations@pharmacyregulation.org.

Other formats

Please contact us at communications@pharmacyregulation.org if you would like a copy of the consultation survey in another format (for example, in larger type or in a different language).

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to:

feedback@pharmacyregulation.org

or post them to us at:

Governance Team
General Pharmaceutical Council
Level 14, One Cabot Square
London
E14 4QJ

Please do not send consultation responses to this address.
Responding to the consultation

How we use your information

We will use your response to help us develop our work. We ask you to give us some background information about you and, if you respond on behalf of an organisation, your organisation. We use this to help us analyse the possible impact of our plans on different groups. We are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties. There is an equality monitoring form at the end of the survey. You do not have to fill it in, but if you do, it will give us useful information to check that this happens.

How we share your information

If you respond as a private individual, we will not use your name or publish your individual response. If you respond on behalf of an organisation, we will list your organisation’s name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it. But we cannot guarantee that confidentiality can be maintained in all circumstances.

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

Your rights

Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you. You may also ask us to delete your response. For more information about your rights and who to contact please read our privacy policy on our website.
Consultation questions

The standards

1. We have set out four standards for Chief Pharmacists. Do you think the standards will:
   a. strengthen and maintain pharmacy governance in the interests of patient safety?
      Yes
      No
      Don’t know
   b. provide a governance framework which will support staff to:
      i. report preparation and dispensing errors?
         Yes
         No
         Don’t know
      ii. learn from those errors?
          Yes
          No
          Don’t know
   c. Please explain your answers.
      Free text

2. The Chief Pharmacist has a key role in making sure that pharmacy staff can benefit from the defences for ‘inadvertent’ (accidental or unintentional) preparation and dispensing errors. Thinking about this role, are there any other standards for Chief Pharmacists that you think are missing?
   Yes
   No
   Don’t know
   If ‘yes’, what are the standards you think should be included?
   Free text

3. We have developed the standards to apply to Chief Pharmacists, whatever setting they work in. Are there any settings where you think these standards could not be applied or met?
   Yes
   No
   Don’t know
   If ‘yes’, please say which setting and why the standards could not be applied or met
   Free text

Impact of the proposals

Impact on people sharing protected characteristics

We want to understand whether our proposals may have a positive or negative impact on any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. These are:

Age
Disability
Gender reassignment
Marriage and civil partnership
Pregnancy and maternity
Race
4. Do you think our proposals will have a positive or negative impact on individuals or groups who share any of the protected characteristics?

   - Positive impact
   - Negative impact
   - Positive and negative impact
   - No impact
   - Don't know

   Please describe the impact you think our proposals will have and the protected characteristic(s) concerned.

   Free text

**Impact on other groups**

We also want to know if our proposals will have an impact on other individuals or groups (not related to protected characteristics) specifically, patients and the public, Chief Pharmacists, pharmacy owners or employers, pharmacy staff, other healthcare professionals, and pharmacist and pharmacy technician students and trainees.

5. Do you think our proposals will have a positive or negative impact on any of these groups?

   - patients and the public
   - Chief Pharmacists
   - pharmacy owners/employers
   - pharmacy staff
   - other healthcare professionals
   - pharmacist and pharmacy technician students and trainees

   - Positive impact
   - Negative impact
   - Positive and negative impact
   - No impact
   - Don't know

   Please describe the impact you think our proposals will have and the individuals or groups concerned.

   Free text

**Any other comments**

6. Is there anything else related to the Chief Pharmacist standards that you would like to raise?

   Free text

**Responding to the consultation**

If you can, please use the online survey at pharmacyregulation.org/consultation-draft-standards-chief-pharmacists

If you want to send a response by email, please make sure you:

   - give your response to all six questions
   - when answering the ‘impact’ questions (numbers four and five), say what you think the impact will be for each group or characteristic we’ve listed. You can say ‘no impact’ or ‘don’t know’ if you need to

This will help us to take account of your views in the same way as the ones we collect from our online survey.
Appendix 1: Draft standards for Chief Pharmacists

Introduction

The aim of this Order is to remove the threat of criminal penalties for inadvertent (accidental or unintentional) preparation and dispensing errors by pharmacy staff working in hospitals and similar settings.

Under the 1968 Medicines Act, there are already ‘defences’ pharmacy professionals can use if they are responsible for an accidental or unintentional preparation or dispensing error.

Since 2018, pharmacy staff working in registered pharmacies have been able to use these defences. The Order now includes pharmacy staff working in hospitals and certain other pharmacy settings, such as care homes, some Integrated Care Boards (ICBs), some ambulance trusts, prisons, and other places where people are lawfully detained.

Including these other pharmacy settings will:

- lead to consistency across the pharmacy sector
- encourage people to report preparation and dispensing errors, and
- mean that there is more ‘shared learning’ from errors, which will improve patient safety

If you are not sure whether you or staff within your organisation are able to benefit from the defences, please ask your organisation's legal team for advice.

The Order gives the GPhC various new powers. One of these is the power to set professional standards for Chief Pharmacists, including a description of their professional responsibilities. By producing new standards, we will clarify the role, responsibilities, and accountability of Chief Pharmacists. In turn this will maintain and strengthen pharmacy governance. Strengthening governance will create a framework where there is a smaller likelihood of preparation and dispensing errors, and a culture where staff feel able to report any errors and learn from them.

To benefit from the defences set out in the Order, the hospital (or other pharmacy setting listed in the Order) must have a Chief Pharmacist (or equivalent) in post. This must be a registered pharmacist with the appropriate skills, training, and experience. If an organisation chooses to have a Chief Pharmacist (or equivalent) in post, the postholder must meet the standards set out in this document.

The legislation is ‘enabling’ in its effects, rather than imposing new rules. This means that an organisation can choose not to benefit from the defences, and if so, they will not need to have a Chief Pharmacist (or their equivalent) in post. If that is the case, our standards for Chief Pharmacists will not apply. However, we encourage organisations to acknowledge and
follow the standards as part of good practice and to strengthen pharmacy governance.

Developing these Chief Pharmacist standards is the first part of a programme of work to strengthen pharmacy governance. The programme also includes producing rules and professional standards for Responsible Pharmacists, and professional standards for Superintendent Pharmacists.

The Chief Pharmacist role

Under the 2022 Order, organisations in any of the listed pharmacy settings must have a Chief Pharmacist (or equivalent) in place if they want to benefit from the defences against criminal prosecution in case of an accidental or unintentional preparation or dispensing error. The new standards describe the role and responsibilities of Chief Pharmacists as well as setting standards of conduct and performance. The postholder must meet our standards for pharmacy professionals as well as the new standards for Chief Pharmacists.

Chief Pharmacists are senior healthcare professionals responsible for providing leadership, expertise, and oversight and management of pharmacy services within an organisation. The role includes:

- planning and allocating resources
- improving productivity
- providing value for money, and
- making sure that pharmacy services meet the needs of the communities they serve and improve health outcomes

The work of a Chief Pharmacist contributes to the safe, high-quality, and effective provision of services in these settings.

It is not necessary to use the title ‘Chief Pharmacist’. Other titles, such as Director of Pharmacy, are often used. If a title other than Chief Pharmacist is used, for the organisation to benefit from the defences the job description must meet:

- the description of a Chief Pharmacist’s role given in section 67F (4) of the Medicines Act 1968, and
- our requirements in these standards for Chief Pharmacists

Section 67F (4) of The Medicines Act 1968 sets out the role of the Chief Pharmacist (or equivalent) as someone:

Who plays a significant role (irrespective of whether other individuals also do so) in:

I. The making of decisions about how the whole or a substantial part of the activities of the pharmacy service are to be managed or organised, or

II. The actual managing or organising of the whole or a substantial part of those activities

- Has the authority to make decisions that affect the running of the pharmacy service as far as concerns the sale or supply of medicinal products, and
- Is responsible for securing that the pharmacy service is carried on safely and effectively.

The Chief Pharmacist (or equivalent) must meet these requirements if their organisation wants the pharmacy staff to benefit from the defences. We have built upon these requirements in producing the standards for Chief Pharmacists. If a Chief Pharmacist does not meet these standards, we may investigate concerns about their fitness to practise.
The standards for Chief Pharmacists

The standards for Chief Pharmacists set out their professional responsibilities. They also describe the knowledge, conduct and performance required by a Chief Pharmacist to support the organisation and its staff to deliver safe and effective pharmacy services, including preparing and dispensing medicines.

The Chief Pharmacist plays a vital leadership role in making sure pharmacy services are delivered safely and effectively. Chief Pharmacists must meet the following standards:

1. **Provide strategic and professional leadership.**
2. **Develop a workforce with the right skills, knowledge, and experience.**
3. **Delegate responsibly and make sure there are clear lines of accountability.**
4. **Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services.**

The standards are designed to be ‘outcome’ focused in acknowledgement of the differing circumstances of pharmacy settings. We do not set out one way of achieving each outcome, instead, we accept that there may be multiple ways of achieving the same outcome. For example, all Chief Pharmacists must develop a workforce with the right skills, knowledge, and experience. The outcome or goal is to deliver safe and effective pharmacy services, but how each Chief Pharmacist will achieve this will be dependent on multiple factors, including the services they deliver, the skills, knowledge and experience of their existing team, the resources available to them, and so on. Chief Pharmacists should make sure they can show that they are meeting the standards, while considering the requirements of the setting they work in. The standards are also a statement of what patients and other people working with Chief Pharmacists can expect of them.

**How to demonstrate that the standards are being met**

There are several ways a Chief Pharmacist can show that they are meeting the standards:

- **during a regulatory inspection discussion, including ones with the Care Quality Commission**
- **by referring to the requirements of their role as a Chief Pharmacist when carrying out their revalidation work**
- **through investigation, if a concern is raised with the regulator:**
  - by a member of staff, a patient or a member of the public, or
  - through inspections or other regulatory actions carried out by the Care Quality Commission, Healthcare Improvement Scotland, or Healthcare Inspectorate Wales
- **during the regular performance reviews with their line manager**

**Applying the standards**

We have developed the standards to apply to all Chief Pharmacists, whatever setting they work in. Although Chief Pharmacists may not provide care directly to patients and the public, their actions have an impact on the safe and effective care that patients and the public receive, and on
the confidence that members of the public have in pharmacy.

Chief Pharmacists are personally accountable for meeting the standards and must be able to justify their conduct and the decisions they make.

Alongside these standards, Chief Pharmacists must also meet the GPhC’s standards for pharmacy professionals, which need to be met by all pharmacy professionals. Chief Pharmacists should also:

- follow their organisation’s policies and procedures, and
- meet the requirements of, and follow the advice from, other relevant regulatory bodies and inspectorates, such as the Care Quality Commission, Healthcare Improvement Scotland, Healthcare Improvement Wales, and the Medicines and Healthcare products Regulatory Agency, as well as any other relevant legislation

There will be times when Chief Pharmacists are faced with conflicting legal and professional responsibilities. Or they may be faced with complex situations that mean they have to balance competing priorities. The standards for pharmacy professionals and those for Chief Pharmacists provide a framework to help them when making professional judgements. We expect Chief Pharmacists to consider these standards, their legal duties and any relevant guidance when making decisions, including those covering medicines legislation.

Standard 1: Provide strategic and professional leadership

As leaders, Chief Pharmacists play a central role in setting the strategic direction required to deliver safe and effective pharmacy services. It is part of the role of the Chief Pharmacist to empower and guide pharmacy professionals and the wider workforce in delivering improved outcomes for patients.

Chief Pharmacists must:

- have a clear vision and strategy to deliver safe and effective pharmacy services
- lead by example, taking responsibility for their own professional growth and development
- be able to influence and work collaboratively with others, to meet the needs of patients and contribute to shared organisational and system objectives
- embrace research, technology and innovation to enhance safety and improve services

Examples of how to meet this standard

Here are some examples of how Chief Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

- being able to build effective relationships at all levels both inside and outside the organisation, and across organisational boundaries
- building and developing partnership working
• meeting organisational priorities
• making sure staff understand their impact and the wider impact of pharmacy on patients
• being able to solve problems in high-pressure situations
• being able to analyse and interpret complex data and information when making decisions
• demonstrating good decision-making skills that positively affect how pharmacy services are delivered
• being able to adapt and innovate to meet the changing needs of patients and changes to how pharmacy services are delivered
• keeping up to date with developments in the pharmacy sector and applying any relevant learning to their organisation
• developing and supporting a culture of research and innovation (within financial constraints)
• providing clinical leadership in the sourcing and management of medicines
• providing professional support and expert pharmacy advice to colleagues

**Standard 2: Develop a workforce with the right skills, knowledge, and experience**

To deliver high-quality, efficient and safe pharmacy services with positive outcomes for patients, staff must have the right skills, knowledge, and experience. As part of their overall responsibility, Chief Pharmacists must make sure that the pharmacy workforce receives the necessary development and training. They must also put ‘succession planning’ in place, so that team efficiency does not suffer when staff move on.

Chief Pharmacists must:

• be aware of what skills, knowledge and experience are needed to deliver safe and effective pharmacy services in their setting
• make the best use of resources, and get the right skill mix in each team to deliver safe and effective pharmacy services
• support and value staff, and consider their health and wellbeing
• create and maintain a culture of equality, diversity and inclusion where:
  – people (including staff, patients and the public) are treated as equals, with dignity and respect, and
  – staff meet their own legal responsibilities under equality and human rights legislation, while respecting diversity and cultural differences
• make sure staff in their organisation know who the Chief Pharmacist is
• let staff know that they can benefit from the defences, as long as certain conditions are met
• promote a culture where staff feel safe to report errors and near misses, and can learn from them

Examples of how to meet this standard

Here are some examples of how Chief Pharmacists can meet this standard. It is not meant to be a complete list, and should be used as a prompt and not as a checklist:

• being aware of the skill mix of each team, making sure that gaps are identified and the necessary actions taken
• developing recruitment and retention strategies, as well as succession planning, to deal with any workforce or staffing issues
• keeping up-to-date education and training plans that support the workforce in their ongoing development, including when innovation and new technologies are introduced
• encouraging staff to work collaboratively, including as part of integrated and multi-disciplinary teams
• helping to protect the rights of individuals
• promoting equal opportunity for staff, patients and the wider public
• helping to improve the experience and healthcare outcomes of patients and members of the public who use their organisation's pharmacy services
• building organisational policies and procedures into team management practices - for example, around EDI (equality, diversity and inclusion) training, such as that on building ‘cultural competence’
• making sure systems are in place so that the workforce can provide feedback and suggestions, and contribute to the development of and changes in the pharmacy service
• identifying good practice and sharing it with all relevant staff
• making sure staff have regular development reviews and that any development needs are met
• developing a culture where staff feel confident about raising concerns, in line with the duty of candour. This is the professional responsibility to be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress
Standard 3: Delegate responsibly and make sure there are clear lines of accountability

Chief Pharmacists have wide-ranging responsibilities and often need to delegate to make sure services are delivered safely and effectively. To make sure that this happens Chief Pharmacists must delegate responsibly. As senior leaders, when delegating, Chief Pharmacists are responsible and accountable for making sure the lines of accountability are clear. Details of delegation must be recorded, including who is responsible and accountable. This will reduce errors and foster a culture of transparency and accountability. If pharmacy staff are to continue to benefit from the defences, a pharmacy setting must make sure that if a Chief Pharmacist leaves the organisation, a replacement or an interim Chief Pharmacist is in post.

Chief Pharmacists must:

- provide clarity about the roles, responsibilities and accountabilities of the pharmacy workforce
- carry out appropriate risk assessments and only delegate to people who have the relevant skills, knowledge and experience, and who are confident about assuming the extra responsibility
- communicate effectively and record delegation decisions accurately

Examples of how to meet this standard

Here are some examples of how Chief Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- being able to successfully manage and lessen clinical, safety, financial and reputational risk
- making sure risk assessments are carried out and that relevant staff are consulted/involved
- making sure that risk assessments are reviewed when needed for example, if any changes take place
- allowing staff to refuse a delegated task if they have a good reason for example, if they feel the task is outside their scope of practice
- making sure staff are aware of their responsibilities and the reporting structure
Standard 4: Maintain and strengthen governance to ensure safe and effective delivery of pharmacy services

Establishing clear governance, and then maintaining and strengthening it, is a key part of the Chief Pharmacist’s role. It involves several aspects, such as having arrangements for managing risks and overseeing how the pharmacy is managed and run. To demonstrate that they are meeting this standard, Chief Pharmacists must communicate effectively at all levels and take a strategic approach when making decisions that affect how pharmacy services are delivered and organised.

Chief Pharmacists must:

- **have oversight of, and make sure that there is effective management of, all pharmacy services and staff**
- **establish and communicate clear lines of reporting**
- **make sure there is a process to get feedback, which includes feedback about interventions, errors and incidents, and that the process is reviewed regularly and appropriately managed**

Examples of how to meet this standard

Here are some examples of how Chief Pharmacists can meet this standard. It is not meant to be a complete list and should be used as a prompt and not as a checklist:

- reviewing governance procedures regularly, including standard operating procedures (SOPs), and having oversight of how the pharmacy is run and how services are delivered
- making sure necessary records are kept and are up to date and accurate
- making sure that an effective records management system is in place, and that relevant staff are trained in how to use it
- carrying out robust performance measurement and reporting, and making changes when needed
- having oversight of, and contributing to, the development and review of policies
- having systems in place to anticipate, identify and respond to risks
- making sure there are systems in place to identify and report errors, including preparation and dispensing errors, and that errors are reviewed and appropriately managed
- regularly reviewing and acting on internal and external complaints and concerns
- planning and using resources effectively, considering any financial, audit and budgetary requirements