

Consultation on draft Standards for Chief Pharmacists Royal Pharmaceutical Society Response

Background

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 accidental or unintentional preparation or dispensing error. (Both the Act and the Order use the term ‘inadvertent’. The key point is that the defences don't apply if there is an intention to cause harm.)

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 other 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

The Order amends the Medicines Act and introduces the conditions which must be satisfied if pharmacy staff are to benefit from the defences. The first condition is that the pharmacy must serve a facility where certain ‘regulated activities’ are carried on. Examples of these include hospitals, care homes, places where people are lawfully detained (such as prisons and pre-departure accommodation for people facing deportation) and other similar facilities. The Act contains the full list of eligible pharmacy settings. The second condition is that the pharmacy service must have a Chief Pharmacist (or equivalent role) in post.

Some of the requirements of the role of the Chief Pharmacist are set out in the Order. The Chief Pharmacist must:

- be a pharmacist who plays a significant role in making decisions about how the activities of the pharmacy service are managed or organised, or who actually manages or organises those activities
- have the authority to make decisions about the running of the pharmacy service in terms of selling or supplying medicines, and
- be responsible for making sure the pharmacy service is carried on safely and effectively

The Order also made changes to our own legislation - the Pharmacy Order 2010. We now have the power to define the responsibilities of Chief Pharmacists and to set professional standards of conduct and performance for postholders. The standards are intended to strengthen and maintain pharmacy governance in the interests of patient safety. If an organisation chooses to have a Chief Pharmacist (or equivalent) in post, the postholder must meet these standards. If a Chief Pharmacist fails to meet these standards we may investigate concerns about their fitness to practise.

Here are the proposed standards that Chief Pharmacists must meet:

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

We have set out four standards for Chief Pharmacists. Do you think the standards will: *

strengthen and maintain pharmacy governance in the interests of patient safety?	Yes	No	Don't know
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provide a governance framework which will support staff to report preparation and dispensing errors?	Yes	No	Don't know
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provide a governance framework which will support staff to learn from those errors?	Yes	No	Don't know
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Please explain your answers.

The Royal Pharmaceutical Society are pleased to be able to respond to this consultation, setting out the standards expected of Chief Pharmacists to fulfil the requirements set out in the Pharmacy Order 2022. Overall, the standards are concise and clearly articulated. Meeting these standards will strengthen and maintain pharmacy governance, but the standards themselves may or may not provide the framework to support staff to report errors and learn from those errors. The wording within the standards must be strengthened to reflect the vital nature of the principles described. As they are written, they do not provide a governance framework but do provide a set of principles from which a framework may be generated.

We are thoughtful of the purpose of these standards and suggest that consideration be given to a clarification statement at the outset. This clarification would state that the standards described for Chief Pharmacists are those necessary for the defined purpose within the legislation; and not as an exhaustive list of standards which reflect the full scope of a Chief Pharmacist role which will be diverse in the independent and national health systems across the three nations.

The 4 standards represent the necessity for a Chief Pharmacist to demonstrate the skills of self; development of others, establishing delegation structures and creating the conditions for governance within their scope of responsibility. We have made some points for consideration to strengthen the wording of the standards and examples.

Standard 1: we agree that the leadership role of the Chief Pharmacist in an organisation is vital and agree this is a fundamental standard which should be demonstrated by Chief Pharmacists. We believe that a Chief Pharmacist must be able to demonstrate their knowledge and skills in addition to “taking responsibility for their own professional growth and development”. Within Standard 1, the bullet referencing research, technology and innovation should be changed from “embrace” to something which reflects the leading, championing or promoting of these vehicles for improvement. Technology could be amended to read “digital technology” to reference the dynamic nature of digital developments across healthcare. Though it is referenced in the examples, we are thoughtful about how Standard 1 reflects the scope of a Chief Pharmacist role with respect to the collaboration and influence elements. The necessary collaboration and influence may be required within and across integrated, modern health systems and multiple professions including those with extended roles into prescribing.

Standard 2: we agree that developing the workforce is of paramount importance and is crucial for safeguarding patients. Having staff with the necessary skills, knowledge, experience; in the appropriate skill-mix is reflected in the standard. A Chief Pharmacist must do more than “be aware of” the skills and knowledge necessary to deliver safe and effective services, they must demonstrate an up to date understanding and good working knowledge of what is necessary. We would also suggest that ensuring these staff are available at the right time to meet the needs of patients is important, with a system which assures the quality of the service being provided. To illustrate the point we refer to the duties described under the Health and Care (Staffing) (Scotland) Act 2019 which includes the duty to ensure appropriate staffing; duty to have real-time staffing assessment in place; duty to have risk assessment in place and assessment of severe and recurring risk amongst others.

The role of the Chief Pharmacist in setting the tone for the importance of staff wellbeing is crucial, not only when services are performing well but also on occasions when near-misses or incidents are reported. Supporting the wellbeing of staff during investigations is a key responsibility and in order to do that effectively, the Chief Pharmacist themselves will need to have support systems in place for their own wellbeing. Creating and nurturing the safety culture within a pharmacy team is essential to strengthening governance and we suggest changing “maintain a culture” to “cultivate the appropriate safety culture”. The standards should make clear the importance of creating a culture of belonging, making sure that pharmacy teams are in an environment free from bullying and discrimination. The diversity must be celebrated and organisations have a zero tolerance culture. The NHS England Pharmacy Workforce Race Equality Standard (PWRES) data demonstrates that staff are bullied by their managers. This impacts their wellbeing, retention and patient safety.

It is essential that staff within the organisation know who the Chief Pharmacist is, but it is also important that colleagues are aware of the Chief Pharmacist standards and the roles and responsibilities they cover. Merely knowing who the Chief Pharmacist is, is not enough. In addition, making staff aware that they can benefit from the defences is not enough, they also must be assured that the Chief Pharmacist is ensuring the conditions for safe and effective pharmacy services are met so that staff may benefit.

Standard 3: Chief Pharmacists will rely on their teams to deliver safe and effective pharmacy services and clear lines of responsibility and accountability are vital. We suggest that the wording is strengthened to describe the Chief Pharmacist leadership role in the identification, recording, mitigation and monitoring of clinical, medicines, workforce and where appropriate, corporate risk. Following the recent DHSC Pharmacy Supervision consultation, the GPhC Chief Pharmacist standards would benefit from more examples pertaining to the expansion of accountable pharmacy professional roles within aseptic dispensing services, in the event that this is changed. The examples of how to meet this standard should include ‘establish a pharmacy governance and assurance framework which will include the staff roles, accountabilities and responsibilities and reporting structure’.

Standard 4: This standard reflects the governance framework necessary to ensure the safe and effective delivery of services and must describe the governance framework that a Chief Pharmacist must have in place, across the scope of their role. Due to the complex nature of health systems in which Chief Pharmacists operate, they may also influence the development of governance frameworks in integrated systems, and this should be reflected in the standards. The examples given for this standard must give an indication of the comprehensive nature of the governance framework necessary. Chief Pharmacists must ensure effective management of the service; establish, promote and maintain effective lines of communication. In addition, with reference to feedback and learning, the Standards would benefit from inclusion of the importance of having effective means of learning from incidents and sharing the learning effectively to demonstrate improvement. This may be sharing learning internally, externally and across professional disciplines.

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

As described above we have identified that the role of the Chief Pharmacist is made clearer in:

- Identification, mitigation and escalation of risk within a system
- Consider where whistleblowing might fit within the standards
- Emphasise the objective of delivering high quality services (as well as safe).

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

Our assessment is that there would be benefit in providing clarity on those settings where a Chief Pharmacist must be in place. We recognise that these are listed within the statutory instrument but recommend that these are included in the standards to provide clarity e.g. including the regulated activities which a Chief Pharmacist may be responsible for. Of note, interfaces between Chief Pharmacists in Integrated Care Boards and Integrated Care Systems in England may introduce complexity in ascertaining accountabilities with reference to the Pharmacy Order 2022.

The additional benefits of inclusion would be to indicate the significance of the Chief Pharmacist role, not only in providing the defences as described, but also in professional leadership, strengthening governance of pharmacy and medicines across organisations where systems are heterogeneous and complex. We assert that the role of the Chief Pharmacist should not be optional. We also assert that the title Chief Pharmacist should be protected.

Standard 3 describes the requirements for delegating responsibility and accountability and some clarity on the pharmacy commissioner and pharmacy provider line of accountability would be useful here. e.g. if a pharmacy service is commissioned and an incident takes place, which organisation requires to have a Chief Pharmacist in place to allow the staff member to access the necessary defence?

The standards reflect traditional, transactional dispensing environments and there are difficulties with their application in modern health systems where pharmacy staff may be preparing and dispensing medicines (or putting procedures with supportive training in place) in a variety

of environments e.g. out of hours services; emergency departments; peri-operative care; substance use services and homecare. In addition, we suggest that the standards are not yet future-proofed for further advances in medicine and therapeutics, where blended approaches to medicinal blood products, radioisotopes and advanced therapeutic medicinal products may be prepared and dispensed by multi-professional staff groups with shared accountabilities across healthcare professions.

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.

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
Age				X	
Disability				X	
Gender reassignment				X	
Marriage and civil partnership				X	
Pregnancy and maternity				X	
Race				X	

	Positive impact	Negative impact	Positive and negative impact	No impact	Don't know
Religion or belief				X	
Sex				X	
Sexual orientation				X	

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

From GPhC data published in 2023, we know that there is over-representation of concerns which proceed to Fitness to Practice investigation in pharmacists with Black, Asian and Minority Ethnic backgrounds, with a higher representation from South Asian. In the protected characteristic of sex, there is over-representation of male pharmacists where concerns proceed to investigation. Whilst we do not anticipate a specific positive or negative impact on pharmacists or groups who share protected characteristics, the development of a set of standards which Chief Pharmacists are expected to meet, will have a positive impact in strengthening pharmacy governance overall. The inclusivity of these standards must be reinforced in the ways that they are applied. In order for these standards to be used as the basis for Fitness to Practice proceedings, the language and the wording in the standards must be more specific, measurable and less open to subjective interpretation.

Even though the standards do not have specific impacts on individuals with protected characteristics, there is a risk of systemic and institutional discrimination based on the different protected characteristics which may impact on how the standards are applied to individuals. There needs to be an awareness of conscious and unconscious biases that may influence how people are treated based on their protected characteristics. Examples may include based on race as highlighted by the GPhC Fitness to Practice 2023 data and NHS England PWRES data on bullying and discrimination. There is little data collected on disability, but there is anecdotal experience of people with a disability and or neurodiversity that may be treated differently and discriminated against and therefore treated more harshly.

Impact on other groups

We also want to know if our proposals may have a positive or negative 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.

Do you think our proposals will have a *positive* or *negative* impact on each of these groups? *

	Positive impact	Negative impact	Positive and negative impact	No impact	Don't know
Patients and the public	X				
Chief Pharmacists	X				
Pharmacy owners and employers			X		
Pharmacy staff	X				
Other healthcare professionals	X				
Pharmacist and pharmacy technician students and trainees	X				

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

The impact of these standards should be positive as part of the wider impact of measures to strengthen pharmacy governance. The ability for an organisation to choose to have a Chief Pharmacist or not, and the mechanisms for transparency on that decision will be important for patients, the public, pharmacy and other healthcare staff. Our view is that having a Chief Pharmacist is a positive indicator of pharmacy governance in an organisation and we believe the public will feel that way too. If there is a lack of clarity about the circumstances in which a Chief Pharmacist is necessary (or not) then there could be a risk that this undermines the paramount importance of leadership surrounding medicines in an organisation (delivered by a Chief Pharmacist role). There is a risk that introducing standards for a role which is optional will backfire.

Our feedback suggests that the standards provide clarity on the professional leadership role of the Chief Pharmacist and would be especially useful for those pharmacists new to the role or changing role between organisations, therefore we indicated a positive impact on Chief Pharmacists. In the main, current or former Chief Pharmacists are already aware of their responsibilities in this role and the introduction of these standards would have minimal impact on those with established experience of the role.

With reference to pharmacy employers, our opinion is that the impact will be greater on those organisations/employers who choose not to have a Chief Pharmacist. Will potential pharmacy candidates (staff and students) be dissuaded from working within an organisation which does not have a Chief Pharmacist and therefore would not be afforded the protections within the legislation in the event of an unintentional error which meets the relevant criteria?

Alongside the opinion that overall having these defences available to pharmacy staff and students within the defined criteria would have a positive impact on pharmacy staff, we also heard opinion that it might not have any impact on pharmacy staff at all. We received feedback that the impact on pharmacy staff would be somewhat lower than expected as they are already comfortable with reporting errors and near misses as demonstrated in the NHS Staff Survey where pharmacy staff reporting is higher than average.

From strengthening pharmacy governance, we can anticipate that other healthcare professionals would benefit from the governance layer set out in the standards but as they did not specifically benefit from the defences, it was felt that this impact, although positive, would be minimal.

Any other comments

Is there anything else related to the draft Standards for Chief Pharmacists that you would like to raise?

The principle point of feedback in relation to the Chief Pharmacist standards is the opportunity for an organisation to choose whether they have such a role or not. Our view is that having a Chief Pharmacist is a positive indicator of pharmacy governance in an organisation and should not

be optional. Where an organisation chooses not to have a Chief Pharmacist, there must be a transparent declaration available for patients and the public as well as any pharmacy staff employed or seeking employment with the organisation.

We acknowledge that the Chief Pharmacist standards have been created to fulfil the purpose as set out in the Pharmacy Order 2022 and not to describe the Chief Pharmacist role in totality. This clarification should be included in the documentation. We expect that those wider requirements will be set out in job descriptions by the employer.

We recognise that RPS professional standards and guidance will help Chief Pharmacists to meet these new GPhC standards, and also act as a means to demonstrate meeting them. Within the examples for each Standard, we would like to see GPhC encourage the use of pharmacy leadership body standards. The RPS has published a number of resources which would support Chief Pharmacists to meet the standards including Professional Standards for Hospital Pharmacy, Professional Standards for Homecare Services, Interim Professional Standards for Hospital at Home, Professional Standards for Optimising Medicines for people in Secure Environments, RPS/RCN Professional guidance on the administration of medicines in healthcare settings and our anticipated Professional Standards for Patient Safety set to launch in April 2024. Elements of these resources could be mapped across to each of the 4 standards.