

Council meeting 13 September 2012

09.12/C/03

Public business

Standards for Registered Pharmacies

Purpose

This paper seeks the Council's approval of the standards for registered pharmacies.

The Council is asked to agree:

- i. **The standards for registered pharmacies, subject to minor drafting amendments**
- ii. **To delegate approval of any additional required amendments to the Chair**

1.0 Introduction

- 1.1 The Pharmacy Order 2012 sets out a requirement for the GPhC to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies.
- 1.2 The draft standards for registered pharmacies were developed using the principles set out in the Council's regulatory standards policy. These included that our standards:
 - Are outcome focussed
 - Enable pharmacy professionals to exercise their professional judgement
 - Inform patients and the public about the standards they can expect
- 1.3 The development of the standards was informed by extensive pre-consultation engagement during 2011 and a three month formal consultation in 2012. The consultation report forms part of paper 09.12/C/02.

2.0 Draft Standards for Registered Pharmacies

2.1 The standards have been reviewed and re-drafted in light of what we heard through the consultation period. The key changes to note are:

- the merging of some standards so that they are clearer and avoid duplication;
- an amendment to principle 4 to include reference to *pharmacy services*. This is to reflect the GPhC's statutory role in safeguarding the wellbeing of patients and the public and the wide range of pharmacy services provided by registered pharmacies, which are not limited to the management of medicines;
- the movement of the standard relating to accessibility of pharmacy services from principle 3 to principle 4. This is to make clear that accessibility is not limited to physical access to services;
- amendments to principle 3 and 5 to reflect the need to safeguard the health, safety and wellbeing of patients and the public. This introduces a consistent theme across all five principles;
- the movement of the compliance indicators from the standards; these will now form part of the GPhC inspection decision framework. This framework will be used by inspectors to assist them in making consistent decisions about whether our standards are being met.

2.2 A range of additional standards were suggested to either make clear requirements of the law or to include specific information about how the standards could be met.

2.3 The standards do not seek to duplicate or provide an interpretation of the law. The owner and superintendent pharmacist must make sure that they comply with the legal requirements in relation to operating a business, for example employment law, health and safety, equalities and data protection legislation; it is not the GPhC's role to provide professional advice or specific guidance on these matters.

2.4 A consequence of outcome focussed standards is that the GPhC has not prescribed in detail how pharmacy services should be delivered. Pharmacy owners and superintendents, working collaboratively with the staff they employ and others are best placed to make decisions about how to deliver safe and effective services for patients and the public.

- 2.5 Pharmacy owners and superintendents will be required to demonstrate to the GPhC and our inspectors how they have met the outcomes we have set, and the GPhC inspection decision framework will support understanding of how this could be achieved.
- 2.6 The consultation set out two areas where we suggested that additional guidance would be produced. As proposed, we plan to produce guidance to support compliance with our standards relating to internet pharmacy services and the manufacture of medicines enabled by the exemption for registered pharmacies set out in medicines legislation. Subject to Council's feedback, we will also develop guidance in relation to self-selection of P medicines.
- 2.7 Whilst at this stage we do not propose producing any further guidance, beyond those outlined above, we will continually review this decision in line with our regulatory standards policy.
- 2.8 We are also committed to working in partnership with professional and representative organisations and trade unions so that owners, superintendents and pharmacy professionals have the support and guidance that is needed to make professional decisions about meeting our standards.
- 2.9 The draft standards for Council approval are set out in Appendix 1.

3.0 Next Steps

- 3.1 Following Council approval, the standards will be submitted to the Word Centre for plain English approval. Any changes suggested by the Word Centre are likely to be minimal and will not alter the meaning of the standards.
- 3.2 Council is asked to agree that any final changes, suggested by the Word Centre, will be authorised by the Chair.
- 3.3 It is our intention to print and publish the standards once approved. A communications and engagement plan has been developed, which includes a timetable for raising awareness of the standards over the next year.

4.0 Equality and diversity implications

- 4.1 We sought, through the pre-consultation engagement activities and the formal consultation period, to access as wide a range of audiences as possible. Activities included working with patient representative groups as well as deliberative events with the public.

4.2 We are currently drafting an equalities impact assessment consistent with our responsibilities as set out in the Equalities Act 2010.

4.3 We will also be required to draft an equalities impact assessment for the consultation on the Rules.

5.0 Communications implications

5.1 Communication and engagement on the new standards will form a key part of the GPhC's transitional plans, which are set out in paper 09.12/C/04

6.0 Resource implications

6.1 Publication and distribution of the standards for registered pharmacies has been budgeted for in this financial year.

6.2 Additional resource to support communication and understanding of the new standards for registered pharmacies during the transition has also been budgeted for.

7.0 Risk implications

7.1 The risks associated with the standards for registered pharmacies are linked to the way in which we manage the transition following agreement of the standards.

7.2 These risks can be mitigated by thorough and effective communication with owners, pharmacy professionals and others, partnership working with other organisations and the development of a robust and transparent inspection model.

Recommendations

The Council is asked to agree:

- i The standards for registered pharmacies, subject to minor drafting amendments**
- ii To delegate approval of any additional required amendments to the Chair**

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30 August 2012

Appendix 1**Standards for Registered Pharmacies****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, in the NHS or in the independent sector, 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 and superintendent pharmacists must take account of this when applying these standards.

Responsibility for meeting the standards lies with the pharmacy owner. If the registered pharmacy is owned by a 'body corporate' (for example a company or NHS organisation) the superintendent pharmacist also carries responsibility. Pharmacy owners and superintendent pharmacists have the same set of responsibilities; a corporate owner does not avoid responsibility by employing a superintendent. Both are fully responsible for making sure that the standards are met. All those responsible need to take into account the nature of the pharmacy and the services provided and, most importantly, the needs of patients and members of the public. We also expect them to be familiar with all relevant guidance.

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

Pharmacy owners and superintendent pharmacists 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 them being met. 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 includes all pharmacy-related services provided by a registered pharmacy from the management of medicines, provision of advice and referral to 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.

Throughout this document we use the term 'you'. This means:

- the pharmacist who owns a pharmacy as a sole trader, or
- the pharmacist (and non pharmacist in Scotland) who owns a pharmacy as a partner in a partnership, or
- the pharmacist who is the appointed superintendent pharmacist for a body corporate, and
- the body corporate.

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.

Standards for registered pharmacies

We have grouped the standards under five over-arching 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' (for example a company or NHS organisation) the superintendent pharmacist also carries responsibility. Pharmacy owners and superintendent pharmacists have the same set of responsibilities; a corporate owner does not avoid responsibility by employing a superintendent. Both are fully responsible for making sure that the standards are met.

If a registered pharmacy is owned by a body corporate, the superintendent must have the authority to:

- comply with their professional and legal obligations, and
- use their professional judgement in the best interests of patients and the public.

Applying the standards

The principles for registered pharmacies, and the standards that must be met, are all equally important. As a result the standards should be read in their entirety. Pharmacy owners, superintendent pharmacists and other pharmacy professionals should also be familiar with the standards of conduct, ethics and performance.

We know that a pharmacy owner and superintendent pharmacist may be accountable for one, a few or a large number of registered pharmacies. We expect the pharmacy owner and superintendent pharmacist 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.

Appropriate governance arrangements include 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 meet 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 The premises are safe, clean, properly maintained and suitable for the pharmacy services provided
- 3.2 The premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- 3.3 The premises are maintained to a level of hygiene appropriate to the pharmacy service provided
- 3.5 The premises are secure and safeguarded from unauthorised access
- 3.6 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 includes all pharmacy-related services provided by a registered pharmacy, from the management of medicines, advice and referral, to 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 for staff 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.