



Standards for Registered Pharmacy Premises 2018

Approved by Council on
05 June 2018

COMMENCEMENT DATE TO BE CONFIRMED

Contents

| | |
|---|-----------|
| About us | 2 |
| Introduction | 2 |
| The Premises Standards | 3 |
| Compliance | 4 |
| Sanctions..... | 4 |
| The inspection regime | 5 |
| Principle 1: Governance arrangements..... | 6 |
| Principle 2: Working environment | 7 |
| Principle 3: Patient-centred pharmacy services | 8 |
| Principle 4: Equipment and facilities | 9 |
| Principle 5: Staff..... | 10 |
| Glossary – terms and definitions..... | 11 |
| Appendix 1 | 13 |

About us

The Pharmaceutical Society of Northern Ireland is the regulator for pharmacists and registered pharmacies in Northern Ireland.

Introduction

Legislative changes in 2016¹ require the Council of the Pharmaceutical Society NI to set Standards for Pharmacy Premises in connection with the carrying on of retail pharmacy businesses,² at or from a registered pharmacy, by the person(s) carrying on that business and will give new powers to enforce these standards.

These Standards for Pharmacy Premises outline the physical and organisational requirements for a retail pharmacy for the safe and effective practice of pharmacy. These Standards apply to all pharmacies registered with the Pharmaceutical Society NI, including 'the working environment and condition of equipment and facilities at associated premises³.

The accountability for adhering to these Standards rests with the Pharmacy Owners⁴. If the registered pharmacy is owned by a pharmacist or partnership of pharmacists, they carry joint accountability for compliance.

Where a 'body corporate' (for example, a company) owns a pharmacy, then the 'body' is accountable for meeting the Premises Standards, and does not avoid its accountability by employing a Superintendent Pharmacist: both parties are accountable to the regulator for ensuring that these Standards are met. The body corporate is required to appoint a Superintendent Pharmacist, and to manage their performance. All staff,⁵ and those in positions of responsibility and/or authority, must take these Standards into account when operating their pharmacy services, and have a duty to raise concerns if they consider the Standards are not being met.

As well as these Standards the Pharmacy Owner and Superintendent Pharmacist must comply with all regulatory standards and legal and professional requirements, including amongst others:

- health service 'terms of service'
- medicines
- health and safety

¹ Legislation commencement order for these standards still to be commenced, at May 2018

² See glossary

³ See glossary

⁴ See glossary

⁵ See glossary

- employment
- data protection, and
- equality legislation.

In limited circumstances (for example following death or bankruptcy), a representative can take the role of the Pharmacy Owner. In these cases, the appointed representative is accountable for making sure these Standards are met.

In this document we use the term 'pharmacy services'. This covers all pharmacy-related services provided by a registered pharmacy including the management of medicines, provision of advice and referral, clinical services such as vaccination services, involvement with, for example, Building Community Pharmacy Partnership (BCPP), and services provided to care homes.

The Premises Standards

The Premises Standards have been grouped under **five mandatory Principles** of equal importance. The Principles provide a clear regulatory framework for the Pharmacy Owner and Superintendent, which must be met and upheld, to safeguard the health, safety and wellbeing of patients and the public, and to ensure the optimal patient and public experience from a retail pharmacy business at or from registered pharmacy premises.

Principle 1 relates to governance arrangements for registered pharmacies, including arrangements for managing and monitoring the safe and effective provision of pharmacy services at, or from registered pharmacies;

Principle 2 relates to working environment, at, and the condition of, registered pharmacies and associated premises;

Principle 3 relates to patient-centred pharmacy services provided at, or from registered pharmacies;

Principle 4 relates to equipment and facilities used in the provision of pharmacy services at, or from registered pharmacies and associated premises;

Principle 5 relates to staff training, and the arrangements for ensuring staff have the appropriate ability and are properly held to account for the safe and effective provision of pharmacy services at or from registered pharmacies.

All registered pharmacy premises must comply with these Standards, including where applicable associated premises. The Standards describe the outcomes we expect for patients and the public accessing pharmacy services and these must always be met. The Pharmacy Owner and Superintendent Pharmacist are required to assure that these Standards are met whatever number of pharmacies they are accountable for, and that management structures are in place to support this.

Compliance

These Premises Standards will focus on outcomes to patients and continuous improvement to pharmacy services. This approach aims to provide greater autonomy to Pharmacy Owners and Superintendents to evidence the delivery of patient-centred pharmacy services without affecting innovation in pharmacy practice or compromising the health, safety and wellbeing of the patients and the public.

This document sets the minimum standards required of Pharmacy Owners and Superintendents, and articulates to the public what they can expect when accessing a pharmacy service. The inspection process aims to assure that standards are being met and to help Pharmacy Owners meet the Standards. This not only promotes compliance with the Standards but also builds public confidence. Where compliance with the standards is poor, the implementation of action plans by the Pharmacy Owner and Superintendent will contribute to compliance and general improvements in quality and performance, within an agreed timeframe.

Where compliance with the standards is unsatisfactory A Statutory committee may determine that it is necessary for the protection of the public or is otherwise in the public interest that sanctions, as detailed below, may be applied

Our vision for improving pharmacy services is to assure that Pharmacy Owners and Superintendents have robust governance systems in place, safe premises, empowered and competent staff, as well as quality equipment and facilities. Patients will visit well maintained premises and have appropriate interaction with knowledgeable and competent staff

Sanctions

The Order has revised the sanctions that the Statutory Committee of the Pharmaceutical Society NI operate in relation to Pharmacy Owners.

- Firstly, it enables the Statutory Committee to remove entries from the premises part of the register - or to disqualify a Pharmacy Owner for breaches of the Premises Standards.
- Secondly, sanctions may be applied Pharmacy Owners that are bodies corporate, and to Pharmacy Owners that are partnerships or individual pharmacists.
- Thirdly, suspension may be applied in relation to breaches of Premises Standards where the Statutory Committee is satisfied it is necessary for the protection of the public or is otherwise in the public interest.

The Order aligns the disciplinary provisions for Pharmacy Owners in respect to breaches of Premises Standards with those for individual registrants involved in fitness to practise cases.

The inspection regime

The Pharmaceutical Society NI does not employ its own pharmacy inspectorate; however, investigations and inspections are conducted by an arms-length pharmacy inspectorate in the Medicines Regulatory Group (MRG), Department of Health (DoH), Belfast, as defined in the Pharmacy (Northern Ireland) Order 1976, and in keeping with a service level agreement with the DoH Belfast.

The Department of Health NI has enforcement powers and duties under, the Medicines Act 1968, The Misuse of Drugs Act 1971, and the Poisons (Northern Ireland) Order 1976, Regulations made under the Health Act 2006 and the Veterinary Medicines Regulations. These enforcement duties/powers relate to the sale and supply of medicinal products from registered pharmacy premises, and associated premises.

These Premises Standards will maintain and complement the framework for inspections; ensuring that inspection visits are kept proportionate and fair, and that decision-making is consistent.

Principle 1: Governance arrangements

The Pharmacy Owner and Superintendent must have robust governance arrangements in place including, clear definitions of the roles and accountabilities of pharmacy staff, and monitoring and managing any risks which might affect the safe and effective provision of pharmacy services.

Standards

- 1.1 The risks associated with pharmacy services must be identified and managed through appropriate risk assessment
- 1.2 The safety and quality of pharmacy services must be reviewed and monitored
- 1.3 Staff must have clearly defined roles and be clear about their accountabilities
- 1.4 Appropriate indemnity or insurance arrangements must be in place for pharmacy services provided
- 1.5 All necessary records for the safe provision of pharmacy services must be kept and maintained accurately, and be attributable
- 1.6 Information must be managed confidentially to protect the dignity and privacy of patients and the public who receive pharmacy services
- 1.7 Vulnerable individuals, including adults and children must be safeguarded.

Principle 2: Working environment

The Pharmacy Owner and Superintendent must ensure that the working environment of the registered pharmacy, and its associated premises, is suitable to assure the safe and effective provision of pharmacy services to patients and the public.

Standards

- 2.1 Premises must be safe, clean and properly maintained for the provision of pharmacy services
- 2.2 Premises must be maintained to a high level of hygiene, appropriate to pharmacy services provided
- 2.3 Premises must be secure and protected from unauthorised access
- 2.4 Premises must protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services
- 2.5 Premises must be appropriate for the provision of quality patient care.

Principle 3: Patient-centred pharmacy services

The Pharmacy Owner and Superintendent must ensure the delivery of accessible, professional and quality patient-centred pharmacy services to patients and the public from a registered pharmacy. The safe and effective management, and administration (where relevant) of medicines, and arrangements for stocking and supplying medicinal products and medical devices, will be essential to ensuring the health and wellbeing of patients and the public.

Standards

- 3.1 Provide pharmacy services that are accessible to patients and the public
- 3.2 Ensure the management and delivery of safe and effective pharmacy services
- 3.3 Provide appropriate stock of medicines and medical devices to ensure the appropriate provision of patient-centred care
- 3.4 Respond to constructive patient and public feedback on service provision
- 3.5 Respond appropriately and in a timely manner to any complaint about care or service, following your complaint procedure.

Principle 4: Equipment and facilities

The Pharmacy Owner and Superintendent must provide safe and suitable equipment and facilities to safeguard the health, safety and wellbeing of patients and the public, when providing safe and effective pharmacy services.

Standards

4.1 Equipment and facilities must be available to use as appropriate

4.2 Equipment and facilities must be:

- i. obtained from a reputable source
- ii. safe to use and fit for purpose
- iii. stored securely
- iv. protected from unauthorised access
- v. appropriately maintained.

4.3 Equipment and facilities must be used in a manner that protects the privacy and dignity of the patients and the public who receive pharmacy services.

Principle 5: Staff

The Pharmacy Owner and Superintendent must ensure that arrangements are in place so that staff members have the appropriate authority and requisite skills and knowledge to competently provide pharmacy services; and are properly held to account for the health and well-being of patients and the public to whom pharmacy services are provided.

Standards

- 5.1 Staff must have the appropriate skills, qualifications and competence to carry out their role and, where relevant, supervise the work of another person
- 5.2 Staff must act with professionalism and exercise their professional judgement in the best interest of patients
- 5.3 Staff must comply with the laws and regulations that affect their professional practice, and be accountable for any acts and/or omissions
- 5.4 Staff must feel empowered to raise concerns in a way that is consistent with a culture of openness, honesty and learning
- 5.5 Staff must ensure that incentives or targets do not compromise their professional judgement, or the health, safety or wellbeing of patients and the public.

Glossary – terms and definitions

A

Associated pharmacy premises: The traditional perception of pharmacy premises being entirely self-contained operations is no longer valid. These Standards also apply to associated premises, which are integral to the delivery of pharmacy services. Associated premises may include:

- warehouses
- premises where electronic storage may be stored/kept
- “hub and spoke” – where a ‘hub’ pharmacy dispenses medicines on a large scale, often by making use of automation, preparing and assembling the medicines for regular ‘spoke’ pharmacies that supply the medicines to the patient.

B

Body Corporate: a body corporate includes entities and organisations such as limited companies: a Limited (Ltd) company, Public Limited Companies (PLC); a Trust; a Co-operative; and a Limited Liability Partnership (LLP).

O

Outcomes-focused practise: 'outcomes' are defined as the impact, or end-results, of services on a person's life; therefore outcomes-focused practise aims to achieve the priorities that patients and the service users identify as important.

P

Patients and service users: any individuals or groups, patients, customers and clients who use or need pharmacy services, advice or other services provided by pharmacists.

Pharmacist: in the context of these Standards, a healthcare professional registered with the Pharmaceutical Society NI. Only a Registered Pharmacist can act as Superintendent Pharmacist.

Pharmacy Owner: is accountable for ensuring their pharmacy meets the Premises Standards. Where the Pharmacy Owner is a corporate body; the ‘body’ is accountable for the corporate governance of the business, including the appointment and management of a Superintendent Pharmacist.

Pharmacy services: the activities, advice, products, treatment or care that is provided at or from a registered pharmacy.

Pharmacy staff: includes agency and contract workers, as well as employees and other people who are involved in the provision of pharmacy services to registered pharmacy.

R

The Register: the definition can be found in Article 6 of the Pharmacy Order 1976. The Register which is maintained by the Pharmaceutical Society NI consists of a list of:

- (a) a register of pharmaceutical chemists;
- (b) a register of druggists;
- (c) a register of students; and
- (d) a register of visiting pharmaceutical chemists from a relevant European State.

The Register has a public facing search facility and members of the public, and others, can search for registered pharmacy premises and pharmacists on the website at www.psnj.org

Retail pharmacy business means a business (not being a professional carried on by a practitioner) which consists of, or includes, the retail sale of medicinal products other than GSL products (whether such medicinal products are sold in the course of that business or not) (Medicines Act 1968 s.132(1)). Such a business may, subject to certain conditions, lawfully be conducted by a person (s.69) who is:

1. A pharmacist, or partnership where each partner is a pharmacist; or
2. A body corporate where the business so far as concerns the keeping, preparing and dispensing of medicinal products, is under the management of a Superintendent who is a pharmacist and who does not act in a similar capacity for any other body corporate (s.71); or
3. A representative of a pharmacist who is deceased, bankrupt or becomes a person who lacks mental capacity or who judged, via some legislative order⁶
⁷, to be mentally ill, whose name, together with the names and address of the representative, has been notified to the Registrar (s.72(2)).

Registered pharmacy: means a pharmacy premises entered in the Pharmaceutical Society NI register under section 75 of the Medicines Act 1968. In the context of these Standards, a registered pharmacy, serves patients and users of pharmacy services, often on the high street or at the heart of a local community.

S

Superintendent pharmacist: a pharmacist who is a Superintendent of a retail pharmacy business, owned by a body corporate, as detailed in the Medicines Act 1968.

⁶ Mental Health (Northern Ireland) Order SI 1986 No.595 (N.I.4)

Appendix 1

New Article 5A of the 1976 Order, as inserted by Article 13 of the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016

Premises standards

5A.—(1) The Council shall set standards that are to be met in connection with the carrying on of a retail pharmacy business at or from a registered pharmacy by the person carrying on that business.

(2) The standards may, in particular, relate to—

(a) governance arrangements for registered pharmacies, including arrangements for managing and monitoring the safe and effective provision of pharmacy services at or from registered pharmacies;

(b) the working environment at and the condition of registered pharmacies;

(c) the patient and public experience of pharmacy services provided at or from registered pharmacies;

(d) the condition of the equipment and facilities used in the provision of pharmacy services at or from registered pharmacies;

(e) the working environment at and condition of associated premises and the condition of equipment and facilities at associated premises (being premises at which activities are carried on which are integral to the provision of pharmacy services at or from registered pharmacies), but only to the extent appropriate for ensuring the safe and effective provision of pharmacy services at or from registered pharmacies;

(f) training of staff of the retail pharmacy business;

(g) arrangements for ensuring staff of the retail pharmacy business—

(i) have the authority and ability to act to ensure, and

(ii) are properly held accountable for, the health, safety and well-being of patients to whom pharmacy services are provided at or from registered pharmacies, and of other persons at registered pharmacies.

(2) The Council shall publish the standards set under this article, as they exist from time to time, in such manner as it considers appropriate”.