

**Draft Premises Standards for a Retail
Pharmacy Business at or from a Registered
Pharmacy**

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Introduction

The Pharmaceutical Society is the regulator for pharmacists and registered pharmacies in Northern Ireland. Legislative changes in 2016 (yet to be commenced) require the Pharmaceutical Society NI to set standards (“Premises Standards”) in connection with the carrying on of retail pharmacy businesses at or from a registered pharmacy by the person(s) carrying on that business.¹

The Premises Standards are designed to help ensure that every retail pharmacy business or registered pharmacy meets minimum acceptable standards to assure the delivery of safe and effective pharmacy services to patients and the public. This new regulatory framework will support the development and maintenance of a quality systems approach to pharmacy practice and encourage pharmacy professionals to use their own initiative when meeting the regulatory standards.

This document represents the first Premises Standards published by the Council of the Pharmaceutical Society NI since the 2016 legislation². The Premises Standards cover the following matters:

- a. governance arrangements;
- b. working environment at registered pharmacies and associated premises;
- c. patient and public experience of pharmacy services;
- d. condition of the equipment and facilities;
- e. staff, including
 - i. training, and
 - ii. arrangements for ensuring staff have the appropriate authority and ability, and are properly accountable for the health, safety and well-being of patients³.

¹ See Article 5A of the Pharmacy (Northern Ireland) Order 1976 (“the 1976 Order”) which was inserted by Article 13 of the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016. See Appendix 1 for relevant excerpt from the legislation.

² The Council is obliged to publish the standards under Article 5A of the 1976 Order (as amended) as they exist from time to time, in such a manner as it considers appropriate

³ Article 5A(2) of the 1976 Order (as amended)

The Premises Standards

The Premises Standards have been divided into three sections.

Section One: In this section, the 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 a registered pharmacy premises by the person carrying on that business.

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 and public experience 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;

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.

Section Two: In this section the **Standards** relating to the five Principles detail the requirements of the Pharmacy Owner and Superintendent carrying on a retail pharmacy business at or from a registered pharmacy by the person carrying on that business and their staff. All registered pharmacy premises, including any associated premises, must comply with these Standards where applicable. The Standards describe the outcomes we expect for patients and the public accessing pharmacy services and these must be met at all times. It is the responsibility of Pharmacy Owner and Superintendent Pharmacist to make sure that these Standards are met.

Section Three: This section provides examples of **compliance indicators** to help guide the Pharmacy Owner and Superintendent Pharmacist in demonstrating compliance with the Standards. Whilst the Standards are generally well understood and integrated into pharmacy practice, pharmacists will be required to demonstrate evidence of compliance in meeting these Standards during pharmacy inspections. The compliance indicators are not an exhaustive list and should be used primarily as a guide.

The compliance indicators have been included for guidance purposes.

Compliance

There is a wide range of services operating in pharmacy premises; bespoke and traditional pharmacy services. The proposed new Premises Standards will focus on outcomes to patients and continuous improvement to pharmacy services. This new 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.

By setting these standards greater clarity is provided to Pharmacy Owners and Superintendents on what is required, and to the public on what to expect when accessing a pharmacy service. The inspection process aims to assure that standards are being met and to help pharmacies 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.

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, have appropriate interaction with knowledgeable and competent staff, and use technology more effectively across the broad range of pharmacy services. Overall, this will lead to an improved patient experience.

Risk-based inspection

A risk-based approach to the inspection of pharmacy premises will continue to be used. While there will be regular inspection of registered premises, within clear time-frames, pharmacy inspections will be prioritised to those premises considered to be at higher risk to patients and the public; either because of reported concerns or the nature of the pharmacy services they provide.

The new Pharmacy Premises Standards will maintain the existing 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 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 records must be maintained accurately, clearly, and be legibly written and 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.

Examples of Compliance indicators

The following are examples of how Pharmacy Owners and Superintendents can demonstrate compliance with the standards.

- provide details of the services owners and superintendents provide
- have the appropriate skill mix of staff to offer the range of services
- undertake risk assessments for each new service
- have risk management systems in place to manage risk including SOPs, near-miss logs
- review and monitor the safety and quality of the services provided
- have clearly defined roles and responsibilities for staff so staff understand what is expected of them
- keep accurate and up-to-date records
- ensure the confidentiality, security and integrity of data and patient information
- have evidence of appropriate indemnity arrangements for the pharmacy premises and the range of services provided
- ensure all staff have undergone appropriate child protection and vulnerable adults training.

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.

Examples of Compliance indicators

The following are examples of how Pharmacy Owners and Superintendents can demonstrate compliance with the standards.

- have procedures in place to ensure the premises are kept clean and hygienic
- have appropriate security systems in place to prevent unauthorised access to areas of the pharmacy where there medicines are stored in order to safeguard patients, the public and staff
- have a private, quiet area for private and confidential discussions and consultations with patients
- the pharmacy presents a professional image and is conducive to the provision of a quality professional services
- ensure that patients and the public are safeguarded from any building work, repairs or maintenance that may affect their personal safety.

Principle 3: Patient and public experience

The Pharmacy Owner and Superintendent must ensure the delivery of accessible, professional and quality patient-centred services to patients and the public.

Standards

- 3.1 Provide pharmacy services that are accessible to patients and the public
- 3.2 Ensure the safe management and delivery of pharmacy services
- 3.3 Provide an appropriate stock of medicines and medical device
- 3.4 Measure and evaluate patient outcomes to demonstrate commitment to quality service provision, for example, number of Medicines Use Review (MURs), or smoking cessation figures
- 3.5 Respond to constructive patient and public feedback on service provision
- 3.6 Ensure an effective complaint procedure is available
- 3.7 Respond quickly and appropriately to any complaint about care or service, and take appropriate action.

Examples of Compliance indicators

The following are examples of how Pharmacy Owners and Superintendents can demonstrate compliance with the standards.

- consider whether the range of services are appropriate and accessible to the patient population
- record near-misses, dispensing errors and accidents in the pharmacy
- have an effective risk management policy and procedure in place
- have a complaints procedure in place which is openly available to patients and the public
- have an audit trail in place of complaints received and handled in a timely and appropriate manner
- listen to feedback from patients, staff and the public who use the pharmacy.

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:

- obtained from a reputable source
- safe to use and fit for purpose
- stored securely
- protected from unauthorised access
- 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.

Examples of Compliance indicators

The following are examples of how Pharmacy Owners and Superintendents can demonstrate compliance with the standards.

- the equipment and facilities are appropriate for the provision of safe and effective services
- the equipment and facilities have been obtained from reputable sources and it is safe to use and fit for purpose
- the equipment and facilities are properly installed and maintained to make sure they are in proper working order
- the equipment and facilities are used in the pharmacy to uphold the privacy and dignity of patients and to reduce risks to patient safety.

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 be suitably qualified and skilled for the safe and effective provision of pharmacy services provided
- 5.2 Staff must 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
- 5.3 Staff must act with professionalism and in the best interest of patients
- 5.4 Staff must comply with the laws and regulations that affect their professional practice and be accountable for any acts and/or omissions
- 5.5 Staff must feel empowered to raise concerns in a way that is consistent with a culture of openness, honesty and learning
- 5.6 Staff must ensure that incentives or targets do not compromise their professional judgement, in the interests of the health, safety or wellbeing of patients and the public.

Examples of Compliance indicators

The following are suggested examples of how Pharmacy Owners and Superintendents can demonstrate compliance with the standards.

- verify the qualifications of the staff employed
- staff have the training they need to perform the duties required
- staff performance is reviewed and constructive feedback is provided
- staff work in a professional environment in which they feel empowered to exercise their professional judgement in the interests of patients, the public and other staff
- staff understand their professional and legal obligations when providing services
- there is a procedure for staff to raise concerns about poor practice or if the actions of others are compromising patient safety or putting the public at risk, for example a whistle-blowing policy
- incentives or targets have no adverse impact on the safety and quality of services.

Glossary – terms and definitions

C

Community pharmacy: in the context of these standards, a retail pharmacy business or a registered pharmacy, serving patients and users of pharmacy services, often on the high street or at the heart of a local community.

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 pharmacy professionals.

Pharmacist: in the context of these standards, a healthcare professional registered with the Pharmaceutical Society NI to practise in a retail pharmacy in Northern Ireland. Only a Registered Pharmacist can act as a Responsible Pharmacist or Superintendent Pharmacist. (See also: "Responsible Pharmacist", "Superintendent Pharmacist", "Owner").

Pharmacy Owner: may be an individual pharmacist (sole trader); a pharmacist partnership; a body corporate that owns a retail pharmacy business; or a representative of the aforementioned in the event of death or bankruptcy. The Pharmacy Owner is responsible for ensuring their pharmacy meets the Premises Standards.

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

R

Responsible pharmacist: to conduct a retail pharmacy business lawfully, a registered pharmacist must be in charge as the responsible pharmacist, to ensure the safe and effective operation of the pharmacy. The name and registration number of the Responsible Pharmacist is recorded in the pharmacy record and displayed in the registered pharmacy. The Responsible Pharmacist is in charge of a particular pharmacy on a given day.

S

Superintendent pharmacist: a pharmacist who is a Superintendent of a retail pharmacy business owned by a body corporate, with responsibilities detailed in the Medicines Act 1968. A Superintendent is intended to be the professional lead within a company and is responsible for ensuring that all pharmacy staff meets the Premises Standards of the Pharmaceutical Society NI.

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”.