

Australian Standard

AS 85000:2011

Quality Care Pharmacy Standard - quality management system for pharmacies in Australia

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**Quality Care
Pharmacy Program**

An initiative of The Pharmacy Guild of Australia

This Australian Standard[®] was prepared by the Pharmacy Guild of Australia Standards Committee as a requirements document for Quality Management Systems for Pharmacy in Australia. It was approved on behalf of the Council of Standards Australia in March, 2011.

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The following are represented on the Pharmacy Guild of Australia Standards Committee

- API
- Australian Association of Consultant Pharmacy
- Australian College of Pharmacy
- Australian Pharmacy Council
- Australian Self Medication Industry
- Consumer Health Forum
- Department of Health and Ageing
- Johnson and Johnson
- Pharmaceutical Society of Australia
- Pharmacy Board of South Australia
- Pharmacy Guild of Australia
- Sigma Company Ltd
- Society of Hospital Pharmacist of Australia
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as a QCPP Committee Draft

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Forward

This standard was prepared by the Pharmacy Guild of Australia and is published by Standards Australia as an Australian Standard.

It replaces the Quality Care Pharmacy Program Standards that were published by the Pharmacy Guild of Australia and which formed the basis of the accreditation program for the practice of pharmacy in Australia.

The Pharmacy Guild of Australia is an accredited Standards Development Organisation, accredited by the Accreditation Board for Standards Development Organisations and Standards Australia.

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0 Introduction

The Quality Care Pharmacy Program (QCPP) Standards were originally developed by the Pharmacy Guild of Australia in conjunction with a number of key stakeholder associations to be used for a pharmacy accreditation program in Australia. The second edition of the QCPP Standards reduced the complexity of the first edition and re-structured the key issues that impact community pharmacy in Australia into eighteen overarching standards with specific requirements.

This revision of the standards and subsequent publishing as an Australian Standard has retained the structure and essentially maintained the requirements of the second edition. Once published as an Australian Standard, the Quality Care Pharmacy Program Standard will enter a phase of continuous review by the stakeholder committee sponsored by the Pharmacy Guild of Australia.

The Accreditation Board for Standards Development Organisations and Standards Australia have accredited the Pharmacy Guild of Australia as an Accredited Standards Development Organisation. This accreditation allows the Pharmacy Guild to formally introduce the QCPP Standard as an Australian Standard.

1 Scope

This Standard provides guidance for the design and implementation of a pharmacy quality management system. A structured management system will support the provision of consistent and high quality pharmacy health services that in turn will contribute to positive health outcomes for all Australians.

2 Normative References

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, users of this standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below.

For undated references, the latest edition of the normative document referred to applies.

- a) Australian Commission for Safety and Quality in Healthcare, Australian Charter of Healthcare Rights
- b) Australian Commission for Safety and Quality in Healthcare, National Safety and Quality Framework
- c) Commonwealth Government of Australia, National Medicines Policy and National Strategy for Quality Use of Medicines
- d) Pharmaceutical Society of Australia, Competency Standards for Pharmacists in Australia
- e) Pharmaceutical Society of Australia, Professional Practice Standards
- f) Pharmaceutical Society of Australia, Standards for the Provision of Pharmacy and Pharmacist Only Medicines

3 Definitions

3.1 Contracted or Staff Pharmacist

Pharmacist that has completed the registration requirements of the Pharmacy Board of Australia and is engaged to provide service within the pharmacy.

3.2 Dispensary Assistant

A suitably trained person who assists a pharmacist in the dispensing of medicines, in the dispensing area of a pharmacy business or pharmacy department, in accordance with procedures and guidelines.

3.3 Medical Devices

A medical device is any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended to be used for human beings for the purpose of one or more of the following:

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
- b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- c) investigation, replacement or modification of the anatomy or of a physiological process;
- d) control of conception;
- and
- e) that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means;
- but
- f) that may be assisted in its function by such means;
- or
- g) an accessory to such an instrument, apparatus, appliance, material or other article.

3.4 Professional Services

For the purpose of this standard, Professional Services means the provision of services within a pharmacy, which require the specific supervision and active involvement of the pharmacist. Professional Pharmacy Services may be offered outside of the pharmacy but are outside the scope of this standard.

3.5 Professional Service Area

An area established within a pharmacy where only health related products and services are provided. The Professional Services Area is a continuous section within the pharmacy and includes the dispensary, a counselling area, and a place for the receipt of prescriptions and supply of prescription medicines as well as the storage of non-prescription therapeutic goods. The Professional Services Area should enable general supervision by the duty pharmacist and the opportunity for pharmacy assistants to efficiently interact with customers. The Professional Services Area should not contain any non-health related products or services.

3.6 Supply of medicines

The provision of medicines within a pharmacy environment and includes prescriptions from a health professional or by request from a consumer and covers the assessment of the consumer's requirements and the provision of professional advice.

3.7 System

When “system” is used in the context of a requirement in this standard, a documented procedure and process for recording, training and reviewing the procedure is required.

3.8 Therapeutic Goods

Therapeutic Goods are any product presented or for any other reason, likely to be taken to be for therapeutic use and includes medical devices and goods declared to be Therapeutic Goods by the Therapeutic Goods Administration.

4 Requirements

4.1 Compliance with Legal and Professional Obligations

There are systems to ensure pharmacists comply with their legal and professional obligations by:

- a) ensuring each pharmacist who is employed or contracted by the pharmacy maintains registration with the Pharmacy Board of Australia
- b) ensuring the pharmacy complies with all legislative requirements for operating the pharmacy
- c) ensuring the pharmacy has access to the current edition of all relevant and/or mandated reference material, standards and codes of conduct
- d) ensuring all pharmacists have reviewed their own professional practice against relevant standards and codes of conduct
- e) maintaining and following a system to ensure the pharmacy meets the requirements for privacy and confidentiality and the Australian Charter of Healthcare Rights including the disposal of records
- f) ensuring the pharmacy maintains professional indemnity, public liability and workers' compensation insurance
- g) ensuring all pharmacists employed, including Contracted or Staff Pharmacists, in the practice maintain individual professional indemnity insurance

4.2 Supply of Medicines, Medical Devices and Poisons

The pharmacy systems shall be designed to ensure the most appropriate medicines and medical devices are supplied and that the consumer is provided with sufficient information to use the Therapeutic Goods safely and effectively.

In the case of prescription medicines, the pharmacy systems should ensure the accurate execution of the prescribers' intent, while being cognisant of the consumers' needs and the legal requirements of supply.

The pharmacy shall have systems to ensure medicines, medical devices and poisons are supplied accurately and appropriately by:

- a) maintaining and following a system for dispensing prescribed medicines
- b) maintaining and following a system for supplying:
 - Non-prescription medicines.
 - Medicines that require special consideration or are subject to misuse.
 - Medical devices.
 - Poisons.
- c) maintaining and adhering to a policy for brand substitution

- d) maintaining and following a system for provision of Consumer Medicines Information and patient care information
- e) maintaining and following a system for distance supply
- f) maintaining and following a system for compounding (extemporaneous dispensing)
- g) maintaining and following a system for storing and re-packaging cytotoxic medicines
- h) ensuring Dispensary Assistants and Pharmacy Assistants are trained, supervised and operate within the limits of their role
- i) maintaining and following a system for the identification, recording and reporting of clinical interventions and adverse drug reactions
- j) maintaining and following a system for medical and other health professional service referrals
- k) maintaining and following a system for the return of unwanted medicines

4.3 Delivery of Health Programs and Services

The pharmacy shall have systems to ensure health programs and services are provided effectively, efficiently and in accordance with professional standards by:

- a) ensuring there are appropriately trained and/or qualified personnel to deliver each program or service offered
- b) ensuring there is access to relevant reference material for each program or service offered
- c) ensuring any facility or equipment required for program or service delivery is provided and any equipment is maintained and remains calibrated where required
- d) maintaining and following a system for delivering and confirming program and service outcomes
- e) maintaining and following a system for recording and providing appropriate data relating to the program or service

4.4 Advertising and Promotions

The pharmacy shall have systems to ensure that advertising and promotion of the pharmacy, pharmacy products or professional services is factual, ethical and legal by:

- a) ensuring any advertising or promotional material used by the pharmacy relating to therapeutic products complies with relevant regulations and legislation
- b) ensuring any clinical or advertising claim is supported by evidence and an evidence-based medicines approach
- c) ensuring all advertising and promotion material is accurate, balanced, does not mislead and is not capable of leading the consumer to unrealistic expectations
- d) ensuring any advertising of a Therapeutic Good does not promote inappropriate or excessive use
- e) ensuring any price list complies with the relevant industry codes of practice and policy

4.5 Pharmacy Premises and Equipment

The pharmacy shall have systems that ensure that the pharmacy premises and equipment are appropriately maintained by:

- a) ensuring the pharmacy is kept clean, tidy and well maintained; consistent with the image of a professional health provider and the requirements of relevant regulations and standards

- b) ensuring the pharmacy has a Professional Services Area distinguishable from the general trading area
- c) ensuring the pharmacy has an appropriate area that allows for private and confidential interactions with consumers
- d) maintaining areas for receiving and storing stock including appropriate storage conditions for:
 - temperature sensitive stock requiring storage between 2°C and 8°C;
 - scheduled medicines;
 - cytotoxic medicines;
 - other stock items;
 - damaged, faulty or expired stock;
 - return of unwanted medicines; and
 - products subject to recall
- e) ensuring all equipment used in the pharmacy is kept clean, serviceable and where required, calibrated and maintained in accordance with manufacturers' specifications
- f) monitoring the compliant dispensary refrigerator daily to ensure it maintains a temperature range of 2°C to 8°C
- g) ensuring the pharmacy has appropriate equipment which has the ability to control the temperature in the professional services, trading and storage areas so it does not exceed 25°C
- h) maintaining lighting levels in excess of 400 Lux
- i) ensuring access into and within the pharmacy caters for people with mobility aids
- j) ensuring a pharmacist has 24 hour access to the pharmacy
- k) ensuring the premises lease is compliant with pharmacy legislation and that the business complies with the lease's requirements, or, if the premises are owned, that the property is maintained at a standard that is appropriate to allow the safe and professional conduct of the pharmacy business

4.6 Operating an Effective and Sustainable Business

The pharmacy will have systems in place to ensure the business operates effectively, maintains profitability and sustainability by:

- a) ensuring the business model/mix is responsive to consumer requirements and market pressures as well as internal business circumstances
- b) maintaining a purchasing policy
- c) maintaining a pricing policy and pricing structure
- d) estimating, monitoring and reporting income, costs and expenses
- e) estimating and preparing for future financial commitments through budget forecasting
- f) ensuring the total business performance is analysed and action taken on key issues to maintain profitability
- g) ensuring the pricing policy, income, costs, budget forecast and profit/loss analysis is reported to all owners at least annually
- h) ensuring use of risk management methodology and relevant business case assessment prior to implementing new professional services or product ranges
- i) preparing a business continuity plan

4.7 Complying with and Improving the Quality Program

The pharmacy will have a system to ensure compliance with, and improvement of the quality management program by:

- a) ensuring there is a staff member who has responsibility for all matters to do with the quality management system
- b) ensuring the responsibilities for the nominated person are documented
- c) maintaining an Operations Manual
- d) maintaining all QCPP and other externally provided material relevant to the maintenance of the quality management system
- e) ensuring all procedures and templates are reviewed at least annually to confirm they comply with the Standards, meet the needs of the business and are consistent with current work practices
- f) maintaining and following a system for recording, reporting, analysing and resolving significant adverse events
- g) maintaining and following a system for improving processes within the pharmacy which incorporates risk management principles and identification of opportunities for improvement

4.8 Requirements for Pharmacy Stock and Services

The pharmacy shall ensure stock and services emphasise and enable the provision of quality healthcare and advice by:

- a) not stocking, selling or promoting tobacco or tobacco/smoking related products or implements
- b) not stocking, selling or promoting alcoholic beverages, home brewing or alcohol distilling kits
- c) not entering into, or being bound by, a contract (including tenancy leases) which restricts the pharmacy's ability to stock products or provide services that meet the therapeutic needs of the consumer
- d) ensuring storage of Therapeutic Goods is in line with relevant regulations and legislation
- e) ensuring no stocked products or consumables used for the delivery of services are out of date
- f) ensuring that no product supplied by the pharmacy is out of date or will become out of date during a normal course of use
- g) ensuring scheduled over the counter medicines are stored and displayed according to legislative requirements, industry standards and protocols

4.9 Ordering, Receiving, Storing, Pricing and Disposal of Stock

The pharmacy shall have systems used for ordering, receiving, storing, pricing and disposal of stock by:

- a) maintaining and following a system for ordering stock
- b) maintaining and following a system for receiving, unpacking, pricing and storing stock that provides for:
 - temperature sensitive stock;
 - scheduled medicines;
 - other stock items

- c) maintaining and following a system for dealing with damaged, faulty or out of date stock and products subject to recall
- d) not storing anything but Therapeutic Goods in the dispensary refrigerator
- e) maintaining and following a system for stock pricing which ensures stock prices are consistent with the planned pricing structure and any advertised price and ensuring any displayed or advertised stock price is consistent with the price charged at the point of sale
- f) maintaining and following a system for the disposal of expired or unwanted products and materials

4.10 Hiring Out of Equipment

The pharmacy shall have a formal process for hiring out of equipment (if a hire service is offered) by:

- a) documenting procedures and recording processes
- b) ensuring all items are serviceable at the time of hire
- c) ensuring all items are measured and fitted (when appropriate) to the consumer at the time of hire
- d) ensuring the consumer understands all aspects of the proper use, safety and care of the item at the time of hire
- e) ensuring all equipment has a hire agreement for each hire event
- f) ensuring all equipment is thoroughly cleaned, inspected and maintained after each hire event

4.11 Customer Service

The pharmacy will ensure there are systems to ensure the provision of good customer service by:

- a) ensuring staff maintain the consumers right to privacy and confidentiality
- b) ensuring pharmacy staff are identifiable, their appearance is professional and their behaviour is appropriate for a professional service provider
- c) maintaining and following a system for dealing with customers, including complaints
- d) maintaining and following a system for processing sales
- e) maintaining and following a system for providing deliveries (if delivery service is offered)
- f) maintaining and following a system for engaging third party service providers, (when third party service providers are engaged)
- g) ensuring pharmacy staff advise consumers if a PBS dispensing service is not available and the consequences
- h) ensuring the pharmacy is able to direct after-hours enquiries to other health professionals in an emergency

4.12 Recruiting Staff

Pharmacy staff are employed using a formal process by:

- a) ensuring position descriptions exist for all staff positions, and are the basis of selecting staff
- b) maintaining and following a system for employing staff
- c) maintaining records of interviews for applicants short-listed in the recruitment process

- d) ensuring a successful applicant is provided with a written Offer of Employment, defining the terms and conditions of engagement prior to commencing employment
- e) ensuring a successful applicant returns a signed copy of the Offer of Employment and storing the signed copy on the applicant's Personnel File
- f) ensuring all interviewees not selected for employment in the recruitment process are advised

4.13 Inducting Staff

The pharmacy will have a system that is used for inducting staff by:

- a) ensuring there is an induction program
- b) ensuring new staff members have completed their induction program within three months of them commencing employment
- c) ensuring new staff members are capable of applying the procedures applicable to them, as identified in their induction program

4.14 Managing Staff

The pharmacy shall have systems to manage staff by:

- a) maintaining a staff roster system which provides for the safe and professional provision of prescriptions and other pharmacy goods and services
- b) maintaining a communication system to inform staff of issues affecting them and/or their work environment
- c) maintaining and following a performance review system to monitor, inform and manage staff performance
- d) ensuring a formal workplace grievance process exists and is used
- e) maintaining a Personnel File for each staff member
- f) maintaining a system that ensures the confidentiality and privacy of staff records and all relevant personnel information

4.15 Ongoing Staff Training

The pharmacy shall ensure ongoing staff training is planned and delivered in a structured manner by:

- a) maintaining a Training Plan for each staff member that records the training needs relevant to the position they hold
- b) ensuring all staff have received both initial and ongoing training on products, services and procedures relevant to the position they hold
- c) providing staff with the opportunity to meet training requirements
- d) maintaining a Training Record for each staff member that details all training undertaken

4.16 Dismissals and Resignations

The pharmacy shall have a system used for staff leaving employment by:

- a) maintaining and following a system when a staff member leaves as a result of dismissal or resignation
- b) ensuring all staff leaving employment are offered an exit interview and recording the fact that the offer was made or keeping records of the interview on the Personnel File
- c) ensuring all departing employees are offered a Statement of Service
- d) ensuring all departing employees are offered a copy of their Training Record

- e) ensuring any relevant feedback provided by staff leaving employment is used for improving the business

4.17 Maintaining Safety and Security

The pharmacy shall have system for identifying and managing potentially dangerous or hazardous situations and emergencies and ensuring the safety and security of staff, customers and assets by:

- a) maintaining and following systems to ensure an effective response to emergencies that may occur
- b) maintaining and following systems to ensure the security of staff, customers and assets
- c) maintaining and following systems to ensure the safety of staff and customers
- d) ensuring that at least one staff member on duty in the pharmacy at all times has a current First Aid qualification
- e) monitoring the effectiveness of the systems for emergencies, security and safety

4.18 Information Technology

The pharmacy shall have systems to ensure the appropriate use and protection of IT resources and electronic data by:

- a) maintaining and following systems to ensure access to computer records is limited to authorised personnel
- b) maintaining and following systems to ensure public do not have unsupervised access to confidential information displayed on computer screens
- c) maintaining and following systems to ensure all data is backed up according to a planned schedule
- d) maintaining and following systems to minimise the potential for external attack on computers (e.g. viruses, worms, spyware)
- e) ensuring computer systems are set up in such a way to support effective workflow and operations of the pharmacy
- f) maintaining a schedule of information relating to the computer system
- g) ensuring the pharmacy has computer equipment and software that provides for internet access, an email system that is regularly monitored and an ability to read current formats of documents used for general distribution
- h) ensuring the pharmacy has an ability to receive and monitor facsimile, email and other electronic messaging systems determined to be relevant to the operation of the pharmacy

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