QUALITY CARE 2020

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REQUIREMENTS

Version 1.1

✓ Contemporary ✓ Relevant ✓ Innovative

DISCLAIMER

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Business owners should seek appropriate independent professional advice, especially for any specific questions relating to the QC2020 Requirements or relevant Commonwealth or State or Territory legislation.

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a. The QCPP Team

b. Guild Member Services and Innovation Committee

c. Communications and Design Team

d. QCPP Impartiality Committee

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Simon Carroll
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Mike Farrell
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Phoebe Mullaly
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FOREWORD

The Quality Care 2020 (QC2020) Requirements mark a major innovation and simplification of the QCPP since it was founded and developed by the Pharmacy Guild of Australia in 1997. The QC2020 reform stemmed from the introduction of the new Australian Standard 85000: 2017 *Quality Care Community Pharmacy Standard.*

The revised and updated QC2020 Requirements are less prescriptive and allow increased flexibility and innovation in the pharmacy, while still maintaining the integrity of the accreditation program. Pharmacies are encouraged to customise policies and procedures and to integrate modern approaches and new technologies into their businesses and quality management systems.

QC2020 is a contemporary program bringing together best-practice business operations with excellence in safe and quality care. The enhanced program has been developed in consultation with pharmacies, business and industry experts, and is aligned with current pharmacy practice. The QC2020 program will endeavour to adapt to industry changes and advancements, to continually improve and remain current, and to ensure the program is practical and represents working towards best practice standards.

While the QC2020 Requirements look different, accredited pharmacies won't need to make significant changes to their policies and procedures. The enhanced accreditation program enables continuous improvement of these policies and procedures and moves beyond compliance to provide a framework that supports the delivery of quality, safe and consistent care to the community.

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INTRODUCING THE QUALITY CARE 2020 REQUIREMENTS

CONTEMPORARY, RELEVANT, INNOVATIVE.

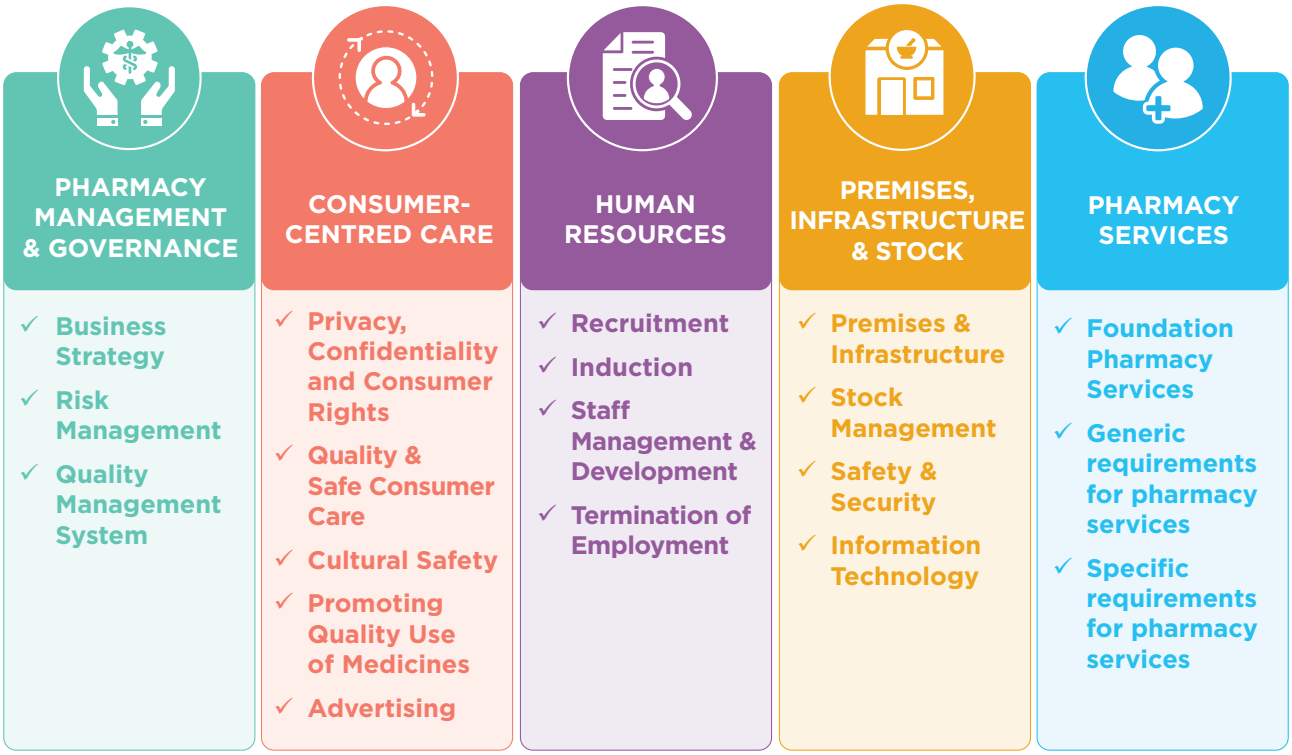
The QC2020 Requirements align to contemporary pharmacy practice and focus on the provision of quality medication advice, robust pharmacy management, and consumer-centred safety and care, which are based on clinical governance principles.

The QC2020 Requirements reflect the current Australian Standard 85000: 2017 *Quality Care Community Pharmacy Standard*, with key enhancements including the:

- Adoption of clinical governance principles
- Inclusion of complex compounding
- Greater emphasis on quality management
- Focus on culture and diverse populations
- Increased focus on patient and consumer engagement
- Increased focus on business governance

The QC2020 Requirements strive to support pharmacies implement quality systems across all aspects of their pharmacy business practice, while still encouraging innovation. It is hoped that these Requirements will be embedded in the day-to-day operations of all Australian community pharmacies, so continuous quality improvements are achieved, and consumers continue to receive high standards of medication advice and care.

The QC2020 Requirements are structured into five domains. The domains each represent a key aspect of business and professional activities centred on safe and quality health care for patients and the community.



CLINICAL GOVERNANCE

Clinical Governance describes the accountability of pharmacy owners in ensuring that all services provided by a community pharmacy are consistent, high quality and safe. Pharmacy owners can demonstrate these clinical governance principles by

a. Engaging with the community to design and deliver services that meet their needs

b. Ensuring systems and processes are in place for all activities and services that addresses patient safety and risk

c. Having systems to record, review and report on safety and quality indicators

d. Encouraging a culture in the pharmacy to continuously improve the quality of services delivered

e. Having systems in place to actively seek feedback from consumers on all activities and services

QC2020 has been developed to align with clinical governance principles for Australian community pharmacy. It highlights new and existing requirements that support clinical governance principles outlined in the Australian Commission for Safety and Quality in Health Care (ACSQHC) National Model Clinical Governance Framework, and in the recent publication of pharmacy–specific clinical governance principles. This ensures community pharmacy integrates into the broader health system to meet patient, community, stakeholder and government expectations in the delivery of health care.

UNDERSTANDING THE QUALITY CARE 2020 REQUIREMENTS

The example below will assist in understanding and interpreting the QC2020 Requirements. It is important to understand the scope and intent of each domain and sub-domain, as well as the relationship to the Australian Standard to ensure the purpose of the QC2020 Requirements are met.

DOMAIN:

The broad subject area that the requirement falls under (e.g., Pharmacy services).

Scope:
The boundaries of each domain describing its subject matter area.

Intent:
The purpose for the domain and what it intends to deliver.

SUB-DOMAIN:

The specific subject area the requirement falls under (e.g., Dose Administration Aids).

Scope:
The boundaries of the sub-domain describing its subject matter area.

Intent:
The purpose of the requirements and what it intends to deliver.

Req. Number	Action required	Assessment evidence	Std. Clause
The QCPP code for the requirement	An explanation of the QC2020 Requirements	What will need to be presented or demonstrated at time of assessment	The relationship of this requirement to the Australian Standard AS85000:2017

- Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.
- Notes are depicted in coloured italic font within the QC2020 Requirements.
- Topic headings in sub-domains are in coloured bold within the QC2020 Requirements.

SUPPORT AND RESOURCES

For support and resources for QC2020 Requirements and preparing for assessments, please visit the QCPP Customer Portal and the QC2020 Knowledge Hub.

Further information can be accessed via the QCPP website **www.qcpp.com** or the QCPP support team:

- **Helpline:** 1300 363 340
- **Email:** **help@qcpp.com**

QCPP has worked with peak bodies and the pharmacy industry to ensure there is diverse and abundant support for QC2020. Please refer to your industry support teams, including banner groups, wholesalers and suppliers, Guild branches and other peak bodies to find out what support and resources are available for your pharmacy.

Some helpful resources and support materials include:

a. Anti-discrimination Acts

b. Australian Charter of Health Care Rights

c. Australian Consumer Law

d. Australian Pharmaceutical Handbook and Formulary

e. Australian Privacy Principles and Privacy Act

f. Business continuity planning standards

g. Fair Work Act and regulations

h. Guides for handling cytotoxic medicines

i. National Competency Standards Framework for Pharmacists in Australia

j. National Vaccine Storage Guidelines – Strive for 5

k. Pharmaceutical Society of Australia Code of Ethics for Pharmacists

l. Pharmaceutical Society of Australia Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people

m. Pharmaceutical Society of Australia Professional Practice Standards

n. Pharmacy Board of Australia codes and guidelines

o. Pharmacy services guidelines e.g., absence from work, vaccination, dose administration aids, etc.

p. QCPP Training Requirements for Pharmacy Medicines and Pharmacist-tOnly Medicines

q. Relevant Commonwealth, State and Territory legislation

r. Relevant immunisation guidelines e.g., Australian Immunisation Handbook

s. Return of Unwanted Medicines project protocols

t. Therapeutic Goods Advertising Code

u. Workplace health and safety legislation and standards

QUALITY CARE 2020

REQUIREMENTS

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DOMAIN 1

PHARMACY MANAGEMENT & GOVERNANCE

Pharmacy owners and managers have a responsibility to provide leadership in developing and maintaining a structured quality management system that supports the provision of safe, consistent and high quality health care, and contributes to positive health outcomes for all Australians.

SCOPE:

The Pharmacy Management and Governance domain relates to activities associated with operating a pharmacy, specifically focusing on leadership, planning, monitoring and organising business activities at a 'whole-of-business' level.

INTENT:

Governance can be described as encompassing the systems that ensure key elements of strategy, risk, compliance, administration, clinical governance and quality management are embedded in the management and operation of the pharmacy.

The Pharmacy Management and Governance domain aims to ensure that the pharmacy has systems in place to effectively operate a sustainable health service and that consumers receive safe and high quality health care.

Robust systems will contribute to a framework for clinical governance, which as an element of overall governance, ensures pharmacy owners, managers and health professionals are accountable for improving the safety and quality of pharmacy services.

NEW REQUIREMENTS:

Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.

SUB-DOMAIN 1: BUSINESS STRATEGY

SCOPE:

The Business Strategy sub-domain relates to activities associated with business planning, performance and measurement, compliance with legislation, and accountability for patient safety.

INTENT:

Developing a strategy and implementing an operational plan for the pharmacy that meets the needs of the community aims to ensure the pharmacy operates effectively, and maintains its viability and sustainability. Defining clear roles and responsibilities ensures owners and employees are aware of the expectations and obligations of their positions in relation to accountability and delivery of safe and quality pharmacy services. Measuring and reporting on indicators, such as financial performance, risks and quality outcomes, assists owners and managers to be aware of and address any issues impeding the pharmacy operating safely and effectively.

Partnering with consumers to plan services means the pharmacy will create a product and service offering which addresses current and future community needs.

Number	Action required	Assessment evidence	Std. Clause
1.1.1	Develop and document a plan that outlines business and operational strategies specific to your pharmacy. The plan will cover total business performance, including **a.** A description of your pharmacy management structure and business model **b.** Goals and objectives, professional services offered, analysis of consumer needs, stakeholder demographics and market pressures **c.** Budget forecasts, such as estimation of income and expenses, which may include future business developments The plan will measure business Key Performance Indicators (KPIs), including **a.** Financial and business trends resulting from analysis of business performance (for example, cash flow, sales revenue, net profit margin, gross profit margin, customer loyalty and retention, staff satisfaction and staff turnover) **b.** Risks to the pharmacy (for example, clinical risk, strategic risk, financial risk, operational risk, environmental risk, reputational risk)	A documented plan that includes business and operational objectives and strategies for the pharmacy, total business performance and measurement of business Key Performance Indicators (KPIs). An explanation of how the KPIs and plan have been reviewed annually and how the plan has been reported to the pharmacy owners and managers (at least annually).	5.7.1 5.7.2 5.7.3 5.7.6 5.6.7 5.6.8

Number	Action required	Assessment evidence	Std. Clause
	c. Quality indicator outcome measures (for example, service activity data, audit of health outcomes or impact of services, adherence to relevant procedures or guidelines) Analyse KPIs and review the plan at least annually. Adjust the plan as required to ensure it continues to meet the needs of the pharmacy and action is taken on key issues to maintain business viability. The plan will be reported to the pharmacy owners and managers at least annually.		
1.1.2	Establish and document a business governance agreement which outlines the roles and responsibilities of the pharmacy owners and managers. A signed attestation statement acknowledging proprietor accountability for overall safety and quality in the pharmacy.	A documented business governance agreement that outlines the roles and responsibilities of the pharmacy owners and managers. A signed attestation statement acknowledging proprietor accountability for overall safety and quality in the pharmacy.	5.7.9
1.1.3	Establish a process for developing a business case prior to implementing new professional services or product ranges. Ensure there is an established process for consumer engagement and co-design of new services to ensure they meet local health care needs. ***Note: Business cases should consider*** **a.** ***Evidence and analysis of consumer need; consider direct consumer involvement in the design of pharmacy services*** **b.** ***How and why the service or product has been selected*** **c.** ***The financial viability of the service and/or product*** **d.** ***Potential risk associated to the implementation of the new service and/or product*** **e.** ***What is the expected demand, how will it be assessed for continuation/suspension of sale?*** **f.** ***Staff training and resource requirements***	An explanation of how a business case was developed, or would be developed, prior to implementing a new pharmacy service or product range. An explanation of how consumer input is sought to inform new pharmacy services.	5.7.12
1.1.4	Consider environmentally friendly, sustainable business practices that support the business model and implement as appropriate. Some examples of sustainable practices include, but are not limited to **a.** Recycling delivery boxes and packaging **b.** Reduction of paper waste **c.** Eliminating the use of plastic bags **d.** LED lighting **e.** Electricity saving initiatives **f.** Energy procurement **g.** On-site water storage	An explanation of how environmentally sustainable business practices have been implemented or considered in the pharmacy.	5.7.13

SUB-DOMAIN 2: RISK MANAGEMENT

SCOPE:

The Risk Management sub-domain relates to activities associated with risk identification, assessment and management, business continuity planning and compliance with legislative requirements for operating the pharmacy. This part of the QC2020 Requirements is focused at a whole-of-business level. More specific aspects of risk management are included in other sections of the QC2020 Requirements.

INTENT:

Risk management is essential for business sustainability, and to give confidence to accountable pharmacy owners and managers that safe and quality pharmacy services are being provided. Identifying and assessing risks via formal and informal processes allow them to be minimised or managed. Risks can include, but are not limited to, legal, professional, safety, reputational or financial.

Risk planning should be appropriate to the pharmacy and level of risk, and not unnecessarily complex. Business continuity planning ensures that the pharmacy can be prepared in the event of an emergency. Creating systems can reduce exposure to and/or ensure ongoing operation and consumer access to medicines in the event of a crisis. Crisis situations can include, and are not limited to, natural disasters, pandemics, staffing issues, inadequate succession planning, or technology failure.

Risk management and business continuity plans cannot be developed for every risk. However, the planning process and systems developed as part of a pharmacy's quality management system will inherently include many aspects and help the business respond better to all threats.

Number	Action required	Assessment evidence	Std. Clause
1.2.1	Develop and maintain a risk management plan which details strategies for dealing with risks specific to pharmacy operations. To develop the plan, the following steps should be undertaken **a.** Identify risks by undertaking a review of the pharmacy business; these may include clinical risk, strategic risk, financial risk, operational risk, environmental risk, reputational risk **b.** Assess each risk to articulate the level of risk. Consider the likelihood of a risk occurring and the impact it might have if it did occur **c.** Manage the risks by avoiding, reducing, transferring or accepting each risk	A documented risk management plan for the pharmacy which outlines potential risks to the pharmacy, an assessment of those risks and strategies to mitigate risk.	5.7.10

Number	Action required	Assessment evidence	Std. Clause
	d. Regularly monitor and review the risk management plan to continuously mitigate risks where possible and identify opportunities for improvement within the pharmacy **e.** The pharmacy's risk management plan may be incorporated into the pharmacy's business plan or be a stand-alone plan		
1.2.2	Develop a plan for business continuity, including systems and processes for maintaining continuity of patient care in the event of a crisis. This plan may be incorporated into the pharmacy's business plan or risk management plan, or be a stand-alone plan. Communicate the plan to staff members and stakeholders. Maintain and implement when needed.	An explanation of your plan for business continuity and how it will be implemented when needed.	5.7.11
1.2.3	Ensure that the operation of the pharmacy complies with all applicable laws by implementing necessary systems.	A signed attestation statement by the pharmacy owner/s that the pharmacy always has in place the necessary systems to ensure that the operation of the pharmacy complies with all applicable laws.	5.1.2
1.2.4	Confirm each health practitioner employed or contracted by the pharmacy has appropriate qualifications and current registration required to perform their expected duties, and that these are maintained or developed according to need and/or changes in roles or responsibilities.	Evidence of current qualifications and registration (i.e., registration certificate or listing on AHPRA Health Practitioner register) for each health practitioner employed or contracted by the pharmacy. An explanation of the process for health practitioners advising of annual registration or changes to their registration status.	5.1.1
1.2.5	Confirm all pharmacists have completed an annual self-assessment against the Professional Practice Standards. Confirm other health practitioners employed or contracted by the pharmacy have completed any relevant self-assessments required. Ensure that training needs identified through self-assessments are planned and documented.	Evidence of self-assessment against the Professional Practice Standards checklist. For other health practitioners employed by the pharmacy, a copy of any relevant self-assessments should be maintained in their employee file. Any training needs identified are documented in training plans.	5.1.4
1.2.6	Confirm all employed or contracted health professionals have current individual professional indemnity insurance.	Certificates of current individual professional indemnity insurance for employed or contracted health professionals or, if within the scope of the pharmacy's professional indemnity insurance, a statement signed by the owners' declaring that the employed or contracted health professionals are covered under the pharmacy's professional indemnity policy	5.1.7
1.2.7	Ensure the pharmacy has current professional indemnity, public liability and workers compensation insurance, and the amount of cover is adequate.	Certificates of Currency or Certificates of Insurance for the following specified insurance policies **a.** Professional indemnity **b.** Public liability **c.** Workers compensation	5.1.6
1.2.8	Maintain access to the current edition of reference materials, standards and codes of conduct required by the pharmacy.	Observation pharmacists have access to the current edition of relevant reference texts, the Professional Practice Standards and Code of Conduct for pharmacists.	5.1.3

SUB-DOMAIN 3: QUALITY MANAGEMENT SYSTEM

SCOPE:

The Quality Management System sub-domain relates to activities associated with maintaining a desired level of quality for operation of the pharmacy and services it provides.

INTENT:

Quality management is a structured system that supports the provision of consistent, safe and high quality pharmacy services to support positive health outcomes for consumers and the community. A quality management system includes the procedures, policies and systems which exist to ensure a desired level of safety and quality is achieved and maintained.

Quality management requires leadership and commitment from pharmacy owners, managers, and all employees as safety and quality is everyone's responsibility when providing health services.

A continuous quality improvement culture is important to respond constructively to incidents, feedback and other quality indicators and to promote opportunities for improvement within all areas of the pharmacy business.

Number	Action required	Assessment evidence	Std. Clause
1.3.1	Determine the individual(s) who will be accountable and responsible for the implementation and maintenance of the pharmacy's quality management system. Document this responsibility and ensure their role is actively supported by all staff, particularly the proprietors and managers.	The position description(s) of the individual(s) accountable for implementing and maintaining the pharmacy's quality management system, which outlines the quality management system roles and responsibilities.	5.8.1
1.3.2	Communicate to all employees their responsibility for participating in and complying with the pharmacy's quality management system. Document this responsibility.	Evidence for each employee that defines roles and responsibilities for participating and complying with the pharmacy's quality management system, signed by the employee.	5.8.2
1.3.3	Establish an Operations Manual for the pharmacy. Develop and implement a procedure for maintaining it. Designate accountable and responsible individual(s) for implementing and maintaining the manual. ***Note: The Operations Manual can be electronic or hard copy.***	The Operations Manual and associated procedure that defines how it is maintained and who is accountable and responsible. Proof that documents contained in the manual are current.	5.8.3

Number	Action required	Assessment evidence	Std. Clause
1.3.4	Establish and maintain a system for reviewing policies, procedures, guidelines and templates at least annually to confirm they continue to meet the needs of the pharmacy and internal work practices align with external guidance documents (for example, Pharmacy Board of Australia Guidelines for dispensing of medicines, Absence from Work Certificates: Guidelines for Pharmacists).	Evidence of a documented review system that records date of review, changes made, reasons for these, and date for next review.	5.8.4
1.3.5	Develop and implement a procedure for the recording, analysis and resolution of complaints, and positive and negative feedback to support continuous improvement.	Documented procedure or log of incidents and feedback. Proof that any negative feedback or complaints have been/are being resolved in a timeframe that reflects the risk presented by the event.	5.8.5
1.3.6	Develop and implement a method of measuring consumer experience and facilitating consumer feedback to improve the level of service provided by the pharmacy.	Demonstration that the pharmacy has a mechanism(s) to measure consumer experience and feedback.	5.8.5
1.3.7	Ensure the pharmacy has a documented continuous quality improvement process that identifies and promotes opportunities for improvement within the business. The continuous improvement process will consider analysis/actions arising from risk, feedback and incidents reports/registers /logs.	Evidence of a documented quality improvement process.	5.8.6

DOMAIN 2

CONSUMER-CENTRED CARE

Pharmacy owners and managers have responsibility to provide leadership in developing and maintaining systems to ensure patient-centred care, including engaging with consumers in the planning and design of services, and providing opportunities for effective communication and receiving feedback.

SCOPE:

The Consumer-Centred Care domain relates to activities associated with ensuring positive consumer outcomes and protecting the rights of consumers in accessing pharmacy services.

INTENT:

As primary health care providers, it is imperative for community pharmacies and their staff to put consumer needs at the centre of their practice. Consumers should be empowered and encouraged to actively participate in decisions about their care, and pharmacy services should be designed in collaboration with consumers to ensure their health needs and preferences are met. Pharmacy staff should work with consumers to improve health outcomes for the community, and communication strategies should be adopted that enhance consumer health literacy and promote informed consumer decisions.

Feedback from consumers should be actively sought as a key indicator of health care quality and safety, and pharmacies should learn from consumer feedback and use this to drive improvement in service delivery. In addition, community pharmacies have an obligation to be responsive to the cultural diversity of the community and provide a culturally-safe environment, to not promote products or services in a manner that misleads or puts consumers at risk, and to provide a level of continuity of care for consumers outside of normal trading hours.

NEW REQUIREMENTS:

Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.

SUB-DOMAIN 1: PRIVACY, CONFIDENTIALITY AND CONSUMER RIGHTS

SCOPE:

The Privacy, Confidentiality and Consumer Rights sub-domain relates to activities associated with maintaining patient confidentiality and upholding consumer rights when accessing health care.

INTENT:

Consumers should expect certain rights when receiving health care from community pharmacies. These include: the right to access safe and high quality health care; to be treated with respect; to be informed/included in decisions about their care, privacy, and confidentiality of personal and health information, and to be able to provide feedback that is dealt with appropriately.

Number	Action required	Assessment evidence	Std. Clause
2.1.1	Establish and implement a policy covering privacy and confidentiality requirements for the pharmacy that includes **a.** The Australian Privacy Principles **b.** The consumers right to privacy and confidentiality **c.** Disposal of records **d.** Conduct on social media **e.** Reference to the Pharmacy Board of Australia Code of Conduct Ensure staff understand and agree to the privacy and confidentiality requirements in the policy, and apply them in all interactions with consumers. Details of the privacy and confidentiality policy can be included in the Contract of Employment or as a separate agreement for each employee to sign. Publicly display the current version of the Australian Charter of Healthcare Rights such that it is easily accessible for consumers and carers. ***Note: The Australian Charter of Healthcare Rights outlines what every individual can expect when receiving health care in Australia. Included is the consumers right to privacy and confidentiality.***	The pharmacy's policy covering privacy and confidentiality. Signed undertakings by all staff members with relation to maintaining consumer privacy and confidentiality. The pharmacy has the current Australian Charter of Healthcare Rights on display.	5.1.5 5.11.1

SUB-DOMAIN 2: QUALITY AND SAFE CONSUMER CARE

SCOPE:

The Quality and Safe Consumer Care sub-domain relates to activities associated with effective communication and engagement with consumers and the delivery of high quality customer service.

INTENT:

Community pharmacies should have clear expectations of their employees with regards to appearance, behaviour and communication with consumers to ensure consistent, safe and high quality service is provided. Employees should consistently engage with consumers in a respectful, responsive, and culturally-appropriate manner and effectively manage consumer feedback. Clear communication about access to available programs and services provided by the pharmacy or after-hour alternatives will assist with continuity of care and consumer choice.

Number	Action required	Assessment evidence	Std. Clause
2.2.1	Develop and implement a policy governing staff and third-party contractor's appearance and behaviour. Issue all staff (and third-party contractors as applicable) with uniform items or name badges as required.	The policy for staff and third-party contractor's appearance and behaviour, and demonstration the policy is adhered to.	5.11.2
2.2.2	Develop and implement a consumer care statement, consumer care policy and procedure for communicating and engaging effectively with consumers, including handling consumer feedback. Ensure staff are trained in the policy and procedure. Publicly display the Consumer Care Statement.	The Consumer Care Policy, and procedure for communicating and engaging with consumers. The Consumer Care Statement is publicly displayed. An explanation of how consumer feedback is handled by the pharmacy.	5.11.3
2.2.3	Establish and implement a process of informing consumers of the programs and services offered and not offered by the pharmacy, and where to access such programs and services when the pharmacy is closed.	Demonstrate how consumers are advised of the programs and services offered and not offered by the pharmacy and how they are referred to other health professionals after hours.	5.11.6
2.2.4	Establish, maintain and follow a process for managing the sale of products and services in the pharmacy.	The pharmacy's procedure for managing sales and demonstration the procedure is followed.	5.11.7

SUB-DOMAIN 3: CULTURAL SAFETY

SCOPE:

The Cultural Safety sub-domain relates to activities associated with provision of care that is responsive to the needs of culturally diverse populations, including Aboriginal and Torres Strait Islander peoples.

INTENT:

Community pharmacies should recognise and respond to the specific needs of the diverse cultures of their local community. Ensuring that the pharmacy provides a culturally-safe environment and prioritises the health needs of Aboriginal and Torres Strait Islander peoples is important in addressing the inequities in health outcomes and life expectancy experienced by our First Nations people.

Number	Action required	Assessment evidence	Std. Clause
2.3.1	Ensure the pharmacy and staff provide a culturally-safe environment and are responsive to the needs of culturally-diverse populations in the local community, including Aboriginal and Torres Strait Islander peoples, to ensure their health care needs are met. Develop and implement a cultural awareness policy. Ensure staff have education and training on how to engage with culturally diverse groups and provide culturally-safe care.	An explanation of the predominant cultural groups in the local community and any specific cultural needs the pharmacy considers when providing care and services to such consumers. The pharmacy's cultural awareness policy and evidence that staff are aware and have been trained on the policy.	5.11.4

SUB-DOMAIN 4: PROMOTING QUALITY USE OF MEDICINES

SCOPE:

The Promoting Quality Use of Medicines sub-domain relates to activities associated with health literacy and health promotion.

INTENT:

Community pharmacies provide information about the quality use of medicines and health conditions and should ensure that this information is able to be understood by consumers. Pharmacies should consider the level of health literacy of each individual, and consider language and cultural needs to tailor the information provided and confirm that it is understood.

Number	Action required	Assessment evidence	Std. Clause
2.4.1	Establish, maintain and follow a policy for providing health information to improve consumers' knowledge and understanding of their health. The policy should address how consumers' cultural needs, language and level of health literacy are accommodated when providing information to ensure key messages are understood. Educate staff on the policy and the important role pharmacy can play in health promotion.	The pharmacy's policy for providing health information and demonstration or explanation of how the policy is followed.	5.11.5

SUB-DOMAIN 5: ADVERTISING

SCOPE:

The Advertising sub-domain relates to activities associated with the advertising of therapeutic goods.

INTENT:

Community pharmacies that advertise or promote their pharmacy, pharmacy products, and professional services must ensure that they are aware of and comply with relevant codes, guidelines, and legislation. Advertising must be accurate, ethical and not mislead consumers, or promote inappropriate or excessive use of medicines.

Number	Action required	Assessment evidence	Std. Clause
2.5.1	Ensure all advertising and promotion of products and services complies with professional and regulatory obligations, and the quality use of medicines, by **a.** Being supported by evidence and an evidence-based approach **b.** Being accurate, balanced and not misleading consumers or giving unrealistic expectations **c.** Not promoting inappropriate or excessive use of a therapeutic good **d.** Prescription price lists comply with the Therapeutic Goods Advertising Code	A random sample of promotional materials will be reviewed to ensure **a.** An explanation can be given as to how the claim is supported by evidence **b.** It is accurate, balanced and does not mislead the consumer **c.** Does not promote inappropriate or excessive use **d.** Price lists comply with the Therapeutic Goods Advertising Code (Schedule 4)	5.5.1 5.5.2 5.5.3 5.5.4

DOMAIN 3

HUMAN RESOURCES

Human Resources refers to the pharmacy's systems and processes used to employ staff with the appropriate qualifications, skills and competency in order to provide safe and quality health care to consumers and achieve the pharmacy's business objectives.

SCOPE:

The Human Resources domain relates to activities associated with the recruitment, employment, professional development and management of employees. Where relevant, this domain also applies to third-party contractors, students, volunteers and official visitors.

INTENT:

Pharmacy employees must have the appropriate skills and abilities to provide safe and quality health care and meet the pharmacy's objectives. Pharmacy owners should have systems to ensure the pharmacy's recruitment, training and development activities support the achievement of this aim.

Strong human resources management and activities assist employees to achieve high performance, provide safe and quality care, and facilitate strong business outcomes. Poor human resources management increases the risk of inefficiency, poor business outputs and safety incidents, including the potential for reputational, legislative and financial harm.

Human Resources is a highly regulated and complex area. Legislation relevant to human resources includes, but is not limited to

a. Fair Work Act and Regulations
b. Anti-discrimination legislation and regulations
c. Superannuation and taxation legislation and regulations
d. Relevant industrial awards and instruments

NEW REQUIREMENTS:

Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.

SUB-DOMAIN 1: RECRUITMENT

SCOPE:

The Recruitment sub-domain relates to the recruitment of employees and other workers.

INTENT:

Strong, robust and effective recruitment systems are essential for developing a team that is effective in its work and achieves the business' objectives. Pharmacy owners and managers are responsible for ensuring the staff they employ are appropriately qualified, skilled and competent to undertake their defined roles and responsibilities.

Number	Action required	Assessment evidence	Std. Clause
3.1.1	Develop position descriptions for all employee positions/roles at the pharmacy. Use the position descriptions as the basis for any selection process.	Position descriptions used for employment positions must be available to the assessor on the day of assessment. Position descriptions should include **a.** Description of role responsibilities **b.** Authorities **c.** Align the position with the classification definitions in the relevant award or enterprise agreement **d.** Skills, knowledge and experience required for the role **e.** Where the role is located **f.** What position the role reports to **g.** Qualifications required **h.** Date reviewed and by who	5.12.1
3.1.2	**a.** Establish, maintain and follow procedures for employing staff and engaging contractors **b.** Ensure the recruitment process is not discriminatory (e.g., positions are advertised) **c.** Develop interview questions based on selection criteria and inherent responsibilities of the role, as well as behavioural questions **d.** Confirm candidates have the right to work in Australia and possess the required qualifications, registrations and insurances for the role	A copy of the procedures for employing staff and engaging contractors.	5.12.2
3.1.3	Ensure records of interviews with short-listed applicants are maintained.	Record of interviews conducted.	5.12.3

Number	Action required	Assessment evidence	Std. Clause
3.1.4	Develop an employee contract which sets out the terms and conditions of engagement. Provide the contract to the successful applicant prior to commencing employment. Obtain and store a signed copy of the contract in personnel files. ***Note: Contracts can be electronic or written, however need to be in English and on an accessible system. These records must be kept for at least seven years.***	All employment contracts must be available to the assessor on the day of assessment. The Contract must be signed by the employee and include **a.** Start date **b.** Hours of work **c.** Classification of role (e.g., award) **d.** Salary/hourly rate **e.** Superannuation **f.** Probation period **g.** Employee name and address **h.** Employer name and address **i.** Work location	5.12.4 5.12.5
3.1.5	Implement a method for advising all unsuccessful short-listed applicants that they have not been successful.	Evidence that unsuccessful applicants have been advised they were not selected. Examples of suitable evidence could include **a.** A copy of any correspondence sent **b.** A diary note that they were phoned and advised of the decision	5.12.6
3.1.6	Develop a policy, or agreement, for supporting experiential placements of pharmacy students (as applicable to your pharmacy).	A copy of the policy or agreement which supports pharmacy student placements (as applicable).	5.12.7

SUB-DOMAIN 2: INDUCTION

SCOPE:

The Induction sub-domain relates to activities associated with induction of employees and other workers to the pharmacy or to new roles and responsibilities within the pharmacy.

INTENT:

Successful induction ensures employees and other relevant individuals understand their role and responsibilities, and the systems and procedures they work with. Induction should mitigate risks posed by non-conformance to the pharmacy's policies and procedures and will ensure consumers receive consistent service. Staff induction relates to new employees and new roles/functions for existing employees.

Number	Action required	Assessment evidence	Std. Clause
3.2.1	Establish and implement an induction process for all new employees, third-party health providers, students, volunteers and official visitors into the pharmacy. The process should include **a.** Role-specific induction checklists with the information, procedures, policies and systems relevant to each employee position **b.** A timeframe for new employees to complete their induction process (must be within three months of commencement) **c.** Documented confirmation that new employees can apply relevant processes, policies and procedures identified during induction	An induction procedure and checklist. Completed induction checklists and evidence that new employees can apply relevant processes, policies and procedures (for example, a signed declaration, training records, assessment quiz, etc.).	5.13.1 5.13.2 5.13.3

SUB-DOMAIN 3: STAFF MANAGEMENT AND DEVELOPMENT

SCOPE:

The Staff Management and Development sub-domain relates to activities associated with employee training, development and management.

INTENT:

Pharmacy owners and managers are responsible for ensuring employees are qualified, trained and adequately supervised to fulfil the requirements of their role. Staff management refers to the activities and systems used to monitor and manage employee performance to ensure delivery of safe and quality pharmacy services.

Proactive and collaborative staff management approaches are most likely to empower employees, minimise grievances and ensure retention of high quality, high performing staff.

Number	Action required	Assessment evidence	Std. Clause
3.3.1	Ascertain and document details of relevant qualifications and/or training undertaken by all staff and contractors to ensure they operate within the scope of their role and expertise. Where necessary, develop a process for supervising staff who need assistance in performing in their role.	Documented details of qualifications and/or training undertaken by all staff and contractors. An explanation of how staff are supervised when required.	5.2.7
3.3.2	Determine how employee performance will be monitored and formally reviewed, including how details will be recorded and how often performance reviews will take place (including during an employee's probationary period). Records of performance review activities must be signed by both the employee and their manager, and be stored in the employee's personnel file.	A performance review procedure which includes planned reviews as well as timely feedback in response to incidents or consumer feedback. Evidence of completed performance reviews signed by both the employee and their manager.	5.13.4 5.13.7
3.3.3	Maintain an employee roster and, if the roster is in written form, display it in a prominent position in the pharmacy. ***Note: Considerations include anticipated resource needs for dispensary, front of shop and provision of pharmacy services.***	Proof that there is a staff roster (electronic or hardcopy). The roster must ensure **a.** At least one pharmacist is always rostered on **b.** Adequate staffing for safe business operations Explanation of how the roster system provides for the safe and professional provision of prescriptions and other pharmacy services.	5.13.5

Number	Action required	Assessment evidence	Std. Clause
3.3.4	Establish and maintain a process for facilitating two-way communication between management and employees on issues affecting them and/or their work environment, including workplace safety.	Explanation or demonstration of the process used for communicating to employees. Examples of communication processes include, but are not limited to **a.** Staff meetings **b.** Hard copy or electronic communication book/diary **c.** Newsletters **d.** Information on notice boards **e.** Email groups **f.** Electronic messaging platforms such as WhatsApp and Facebook Messenger **g.** Diary notes	5.13.6
3.3.5	Establish a formal workplace grievance process. Develop an appropriate procedure and ensure the procedure is followed if a grievance is reported. Inform staff of the process and procedure (i.e., during induction). Maintain records of any workplace grievance, including the outcome of mediation and/or investigation.	A procedure for workplace grievance. Evidence of records, which include outcomes of mediation and/or investigation (where a grievance has been reported).	5.13.8
3.3.6	Develop and maintain a personnel file for each employee.	Personnel files for all staff employed in the pharmacy, including **a.** Recruitment details and employment contract **b.** Induction records **c.** Training and qualifications **d.** Performance records **e.** Leave forms **f.** Exit interviews ***Note: Personnel files can be hard copy or electronic, however need to be in English and in a format that is easily accessible.***	5.13.9
3.3.7	Establish and implement a process that ensures employee records and all relevant personnel information are kept private and confidential.	An explanation of how privacy and confidentiality of staff records and all relevant personnel information is maintained.	5.13.10
3.3.8	Develop a policy which outlines how the pharmacy will have oversight of providers contracted by a third-party to deliver a health service in the pharmacy, and ensure the third-party provider meets the objectives of their engagement, including provision of safe and quality health services.	A policy for managing providers contracted by a third-party to deliver a health service within the pharmacy, and an explanation of how the pharmacy ensures providers are appropriately qualified, skilled, registered and insured to undertake the health service.	5.13.11

Number	Action required	Assessment evidence	Std. Clause
3.3.9	Establish, implement and maintain a documented training and development plan for each employee which records the training needs relevant to their role. The training and development plan should consider how employees **a.** Are appropriately qualified, experienced and/or trained to perform duties and responsibilities of their role **b.** Operate within the limits of their role ***Note: Training and development plans can be individualised plans or one plan containing different training requirements for each employee can be used.***	Training plans for each employee. Proof the training plan has been implemented and any training completed has been recorded on their training record.	5.14.1
3.3.10	Establish a system to identify the training needs of your employees, and provide the required resources and opportunities to meet identified training needs.	Training records for all staff that demonstrate staff have been provided with training opportunities relevant to the positions they hold. For pharmacy assistants, this includes initial training by a Registered Training Organisation (RTO) in the Provision of Pharmacy Medicines and Pharmacist-Only Medicines, as well as three hours per year of approved refresher training related to the provision of Pharmacy and Pharmacist-Only Medicines.	5.14.2
3.3.11	Determine what employee training is required for products, services and procedures relevant to the pharmacy's business plan and the employee's position/role. Identify who will provide the training and how it will be delivered. Document completed training on staff training records. ***Note: Consider the different training needs of pharmacists and pharmacy assistants.***		5.14.3
3.3.12	Develop and maintain a training record for each employee that details all training offered and undertaken. The training records should be stored in each employee's personnel file.		5.14.4

SUB-DOMAIN 4: TERMINATION OF EMPLOYMENT (RESIGNATIONS AND DISMISSALS)

SCOPE:

The Termination of Employment sub-domain relates to activities associated with employee separations, such as resignations and dismissals.

INTENT:

Pharmacy owners and managers should ensure they have effective and appropriate processes to support employees leaving their employment, and that minimises any industrial and financial risk.

Number	Action required	Assessment evidence	Std. Clause
3.4.1	Establish and implement a process to be followed when an employee leaves as a result of resignation or dismissal. Develop and maintain a procedure that includes **a.** Keeping records of each resignation on file, including communication of last day of work (Fair Work Act requirement) **b.** Keeping records of each dismissal on file which describe the nature of the termination; some legislation requires documentation be kept of dismissals due to redundancies, under-performance and misconduct **c.** Keeping records of notice periods and legal obligations **d.** Offering departing employees a statement of service and copy of training record **e.** Tracking reasons and trends for resignations and dismissals	A copy of the procedure to be followed when an employee leaves and proof that the procedure has been followed. Documentation which tracks the reasons and trends for staff resignations and dismissals.	5.15.1 5.15.2
3.4.2	Offer all departing employees an exit interview. Establish and implement a process for documenting the offer of an exit interview and for recording exit interviews conducted. Ensure records are kept in the departing employee's personnel file.	The records associated with the offer of an exit interview, or exit interviews conducted for staff who have left.	5.15.3
3.4.3	Offer all departing employees a Statement of Service and keep a copy of the statement provided.	Records of the Statement of Service provided to departing employees.	5.15.4
3.4.4	Offer all departing employees a copy of their training and development record. Ensure the pharmacy keeps a copy of the training and development records provided.	Documentation of the training and development record provided to departing employees.	5.15.5

Number	Action required	Assessment evidence	Std. Clause
3.4.5	Establish an approach for documenting any feedback provided by departing employees. Review the feedback provided and use any relevant feedback to improve the pharmacy business. Record any improvements implemented on the pharmacy's improvement register/log.	Records of feedback provided by departing employees. An explanation of how feedback is reviewed, and any records of improvements made as a result.	5.15.6
3.4.6	Ensure the pharmacy keeps all employment records relating to an individual for a minimum of seven years after resignation or dismissal.	An explanation of how records are securely maintained for the required period.	5.15.7

DOMAIN 4

PREMISES, INFRASTRUCTURE AND STOCK

Pharmacy owners and managers have responsibility to ensure the pharmacy premises, infrastructure and stock is fit for purpose, meets legislative and regulatory requirements, and does not pose a safety risk for consumers or employees.

SCOPE:

The Premises, Infrastructure and Stock domain relates to activities associates with the physical and virtual location of the pharmacy, and the equipment, technology, tools, resources and stock within it. This domain is focused at a whole-of-business level. Aspects of premises, infrastructure and stock relating to specific pharmacy services are included in other sections of the QC2020 Requirements.

INTENT:

Community pharmacies have a unique position of being a primary health care service in a retail environment. Promoting the pharmacy as a health care destination is important to ensure public trust in the profession, and to meet consumer expectation of the delivery of safe and high quality pharmacy services and medicines.

NEW REQUIREMENTS:

Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.

SUB-DOMAIN 1: PREMISES AND INFRASTRUCTURE

SCOPE:

The Premises and Infrastructure sub-domain relates to activities associated with the physical environment of the pharmacy, the infrastructure and equipment used, and leasing agreements.

INTENT:

Community pharmacies should reflect a professional health care destination and ensure that all equipment and infrastructure is fit-for-purpose and meets legislative and regulatory requirements. The premises and equipment should be well-maintained and monitored, including having systems for ensuring maintenance of the cold chain and action in the event of a temperature breach. There should be dedicated areas for receiving, handling and disposal of stock.

Lease agreements or other contracts should not restrict access to the pharmacy, or the ability to stock products or provide services that meet the health needs of consumers.

Number	Action required	Assessment evidence	Std. Clause
4.1.1	Confirm there are no tenancy lease conditions or contracts with marketing groups or other suppliers that restrict the pharmacy's ability to stock products or provide services that meet the therapeutic needs of consumers. Implement alternative arrangements if such conditions are found, if possible. If the pharmacy premises are owned, ensure it is maintained to a standard that is appropriate to allow the safe and professional conduct of the pharmacy business.	If applicable, a description of any contracts (i.e., tenancy leases) the pharmacy has entered into and whether there are any restrictions impacting the pharmacy's ability to stock products or provide services that meet the needs of consumers. If restrictions apply, an explanation of how the pharmacy implements alternative arrangements.	5.6.1 5.9.4
4.1.2	Implement a system to ensure the pharmacy is kept clean, tidy and well maintained, and consistent with the image of a professional health care destination.	Observation that the pharmacy is kept clean and tidy and consistent with the image of a professional health care destination.	5.6.2
4.1.3	Identify the Professional Services Area within the pharmacy and ensure it **a.** Is distinguishable from the general trading area **b.** Can be supervised by a pharmacist **c.** Includes the dispensary **d.** Includes an area for confidential conversations **e.** Contains only health-related products and services **f.** Contains all scheduled medicines located in appropriate sections	Observation that the Professional Services Area **a.** Is distinguishable from the general trading area **b.** Can be supervised by a pharmacist **c.** Includes the dispensary and an area for confidential conversations **d.** Contains only health-related products/ services **e.** Contains scheduled medicines located in appropriate sections	5.6.3

Number	Action required	Assessment evidence	Std. Clause
4.1.4	Ensure there is an area which allows for private conversations with consumers.	Observation there is a consultation area that allows for private conversations with consumers (e.g., a separate room or area with barriers).	5.6.4
4.1.5	Ensure areas for receiving, storing and disposal of stock are maintained and include appropriate storage conditions for the product and its schedule, especially **a.** Temperature sensitive stock **b.** Scheduled medicines **c.** Controlled medicines **d.** Cytotoxic medicines **e.** Other stock items **f.** Damaged, faulty or expired stock **g.** Return of unwanted medicines **h.** Products subject to recall	Observation that there are areas for receiving, storing and disposal of stock, including **a.** A fit-for-purpose dispensary refrigerator **b.** A drug safe **c.** Having cytotoxic medicines and/or their locations clearly labelled **d.** An area(s) to segregate damaged, faulty or expired stock, as well as products subject to recall **e.** A RUM approved container and lid **f.** An explanation of how stock is stored in appropriate conditions at all times, including maintenance of cold chain	5.6.5
4.1.6	Establish, maintain and follow a procedure to actively monitor each dispensary refrigerator that includes **a.** A method of recording the maximum and minimum temperatures, at least twice daily **b.** A cold chain breach protocol **c.** Safeguards to ensure consumers cannot be supplied a product that has been subject to a cold chain breach **d.** Certification of each refrigerator by a reputable provider every two years at a minimum	The procedure for active monitoring of each dispensary refrigerator. Proof the procedure is followed by providing records of twice daily temperature monitoring for a continuous period, ensuring records are retained for a minimum of two years. Records of action taken if an out-of-range temperature was detected (if applicable). The certification of each dispensary refrigerator from the Cold Chain Testing Centre or other certified provider (i.e., manufacturer/reputable supplier or distributor service, or ARC registered service).	5.6.7
4.1.7	Ensure there is equipment throughout the pharmacy to ensure the temperature does not exceed 25°C, including outside of pharmacy operating hours. Develop a procedure for medicines affected by a maximum temperature breach and implement when required.	Observation there is appropriate equipment that can always control the temperature throughout the pharmacy so it does not exceed 25°C. The procedure for medicines affected by a maximum temperature breach.	5.6.8
4.1.8	Ensure the lighting levels in the professional services area(s) of the pharmacy is sufficient for the safe delivery of pharmacy products and services.	Observation that the lighting levels within the professional services area(s) of the pharmacy are satisfactory for the safe delivery of pharmacy products and services.	5.6.9
4.1.9	Ensure your pharmacy can cater for people with mobility aids. Make any adjustments you consider necessary or appropriate. Provide seating for consumers to use as required. ***Note: Recommendation for seating to have a weight capacity of at least 150kg.***	An explanation and observation of how access into, and within, the pharmacy caters for people with mobility aids. Observation that seating is available for consumers to use. ***Note: The number of seats is at the discretion of the pharmacy manager and should take into consideration the space available and the demand for seating in the pharmacy.***	5.6.10
4.1.10	Confirm a pharmacist has 24-hour access to the pharmacy.	An explanation of how the pharmacy ensures a pharmacist has 24-hour access to the pharmacy.	5.6.11

SUB-DOMAIN 2: STOCK MANAGEMENT

SCOPE:

The Stock Management sub-domain relates to activities associated with the purchasing, pricing and storage of medicines and other products, appropriate product ranges, and management of expired medicines or medicines subject to recalls. It also applies where stock is within the control of the pharmacy, such as delivery services and storage facilities.

INTENT:

Community pharmacies supply a large range of medicines and health related products. Pharmacies may have products available which are not health related and have a responsibility to ensure that the supply of these products are consistent with the practice of pharmacy, and the principles of the Quality Use of Medicines.

Maintaining the quality, safety and integrity of the products is essential for consumer satisfaction, safety and business outcomes.

Stock should be displayed and stored according to jurisdictional requirements, and there should be procedures for the receiving, handling and disposal of stock, including temperature-sensitive or hazardous medicines.

Number	Action required	Assessment evidence	Std. Clause
4.2.1	Establish, implement and maintain a process, and associated procedure, for storing, handling and disposing of hazardous materials, that ensures **a.** Each cytotoxic or hazardous drug product, and/or its shelf location, has a label indicating the drug is cytotoxic or hazardous **b.** Appropriate protective clothing (i.e., gloves and face mask) is worn when repackaging hazardous materials **c.** Separate counting aids (i.e., tray, spatula, tweezers) are used for repackaging hazardous materials **d.** Hazardous materials are stored out of consumer reach and in the dispensary in the case of cytotoxic drug products **e.** Employees are aware of the procedure to follow if there is contact with, or a spillage of, hazardous or cytotoxic materials **f.** Staff involved in repackaging hazardous materials are trained in the procedure	The procedure for storing, handling and disposing of hazardous materials. Observation the procedure is followed by showing **a.** Shelf and/or product labels indicating a drug product is cytotoxic or hazardous **b.** The availability of protective clothing and separate counting aids for repackaging **c.** Hazardous materials are stored out of consumer reach **d.** Cytotoxic drug products are stored in the dispensary Training records for staff involved in handling, repackaging and disposing of hazardous materials.	5.2.4

Number	Action required	Assessment evidence	Std. Clause
4.2.2	Establish, implement and maintain a purchasing policy and a system for ordering, storing and tracking pharmacy stock to ensure consumer needs are met while reducing the risk of loss.	Documentation of the purchasing policy and evidence of a stock management system.	5.7.4
4.2.3	Develop and maintain a pricing policy and pricing structure, ensuring it is reviewed at least annually.	A documented pricing policy and structure, and an explanation of the annual review process.	5.7.5
4.2.4	Ensure no tobacco, or tobacco/smoking-related products or implements, are stocked, being sold or promoted in the pharmacy (including online).	Observation that no tobacco or tobacco/smoking related products or implements are stocked, being sold or promoted by the pharmacy. Note: this does not include/apply to Schedule 4 nicotine vaping products supplied for therapeutic purposes.	5.9.1
4.2.5	Ensure there are no alcoholic beverages, home brewing or alcohol distilling kits stocked, being sold or promoted by the pharmacy (including online). Similarly, ensure the pharmacy does not stock, sell or promote products that promote the use of alcohol.	Observation that no alcoholic beverages, home brewing or alcohol distilling kits, or products that promote the use of alcohol are stocked, being sold or promoted by the pharmacy.	5.9.2
4.2.6	Ensure no non-therapeutic goods which do not enhance the practice of pharmacy are stocked, being sold or promoted (this includes online).	Observation that the pharmacy does not stock, sell or promote (including on a pharmacy's website) any non-therapeutic goods which do not enhance the practice of pharmacy.	5.9.3
4.2.7	Ensure Therapeutic Goods are stored and displayed according to relevant regulations, legislation, industry standards and guidelines. Ensure that **a.** Pharmacy Medicines are in the Professional Services Area, and if required by jurisdictional legislation, consumers do not have direct access **b.** Pharmacist-Only Medicines are in the Professional Services Area and **i.** Are within sight, hearing and supervision of the pharmacist **ii.** Can't be accessed by consumers, and consumers are unable to self-select **c.** Any items identified as being subject to inappropriate use are stored under the direct supervision of the pharmacist **d.** All solid dose 'pseudoephedrine plus antihistamine' and single-entity pseudoephedrine products, including sustained release single ingredient products, are placed out of reach and sight of consumers **e.** All other pseudoephedrine containing products are placed out of reach with no direct consumer access **f.** That no more than one shelf facing per product type of any pseudoephedrine product is displayed	Observation that Pharmacy Medicines and Pharmacist- Only Medicines are in the Professional Services Area, within sight, hearing and supervision of the pharmacist. Observation that Pharmacy Medicines (where applicable) and Pharmacist-Only Medicines are stored so that consumers do not have direct access to products and are unable to self-select. Observation items identified as being subject to inappropriate use are stored under the direct supervision of the pharmacist. Observation that all pseudoephedrine products are placed out of reach of consumers with no direct access, and that solid dose 'pseudoephedrine plus antihistamine' and single-entity pseudoephedrine products, including sustained release single ingredient products, are also placed out of sight of consumers. Observation there is only one shelf facing of each pseudoephedrine product type on display.	5.9.5 5.9.6

Number	Action required	Assessment evidence	Std. Clause
4.2.8	Establish and implement a procedure for checking expiry dates for stock and consumables. Confirm there are no products or consumables that are out of date (or will become out of date during a normal course of use) or subject to recall on display. Remove any out-of-date or recalled stock or consumables and dispose of them appropriately.	The procedure for checking expiry dates. Products on display will be checked to ensure they have not expired and are not subject to recall.	5.9.7 5.9.8
4.2.9	Establish, maintain and follow a process for ordering stock for the dispensary, professional services area and remaining sections of the pharmacy. Develop an associated procedure which includes **a.** Routine reorders **b.** Stock outs **c.** Emergency and special orders **d.** High cost drugs	The procedure for ordering stock for the dispensary, professional services area and remaining sections of the pharmacy, and an explanation of how the procedure is followed.	5.10.1
4.2.10	Establish, maintain and follow a process for receiving, unpacking, pricing and storing stock, including temperature sensitive stock and medicines. Develop an associated procedure.	The procedure for receiving, unpacking, pricing and storing stock. An explanation of how the procedure is followed.	5.10.2
4.2.11	Establish, maintain and follow a process for managing and reporting products subject to recall. Develop an associated procedure.	The procedure for managing products subject to recall. An explanation of how the procedure is followed and any associated records for products subject to recall.	5.10.3
4.2.12	Establish, maintain and follow a process for dealing with damaged, faulty or out-of-date stock, including stock received from suppliers, stock already in store and consumer returns. Develop an associated procedure.	The procedure for dealing with damaged, faulty or out-of-date stock. An explanation of how the procedure is followed.	5.10.4
4.2.13	Communicate to employees that only Therapeutic Goods can be stored in the dispensary refrigerator. Confirm only therapeutic goods are stored in the dispensary refrigerator.	Observation only therapeutic goods are being stored in the dispensary refrigerator.	5.10.5
4.2.14	Establish, implement and maintain a process for stock pricing which ensures consistency between stock prices, the pharmacy's pricing structure and the price charged at the point of sale. Determine how price discrepancies will be dealt with and develop and implement an associated policy.	The policy for dealing with any discrepancy between a displayed or advertised price and the price charged at the point of sale. A random sample of products will be checked to confirm the displayed or advertised price is consistent with the price charged at the point of sale.	5.10.6

Number	Action required	Assessment evidence	Std. Clause
4.2.15	Establish, maintain and follow a procedure for the return and disposal of expired or unwanted medicines, products and materials. The pharmacy must ensure **a.** They have a RUM (Return Unwanted Medicines) approved container and lid **b.** The RUM container (and sharps container if used) are out of reach of the public **c.** The RUM (and sharps container if used) are not overfilled **d.** The RUM bin is sealed with a tamper evident lid once full **e.** Any Controlled Drugs (Schedule 8) returned for disposal are recorded and disposed of by a pharmacist in accordance with state or territory legislation **f.** Consumers can be directed to local cytotoxic and sharps disposal services, if not provided by the pharmacy	The procedure for the return and disposal of unwanted medicines, products and materials. An explanation of how the procedure is followed. Observation a RUM approved container and lid is being used.	5.2.10 5.10.7

SUB-DOMAIN 3: SAFETY AND SECURITY

SCOPE:

The Safety and Security sub-domain relates to activities associated with providing a safe and secure environment for consumers and employees, and maintain the safety of assets in response to internal and external threats.

INTENT:

Pharmacy owners and managers are responsible for ensuring the safety of all persons on the pharmacy premises, including consumers, employees, students, and visitors.

Common safety and security risks for pharmacy include, but are not limited to, armed hold-up, physical hazards (e.g., trip hazards), shoplifting, fire, medical emergencies and manual handling.

Number	Action required	Assessment evidence	Std. Clause
4.3.1	Determine safety risks that may affect the pharmacy, consumers and employees. These safety risks should include **a.** Physical hazards **b.** Manual handling **c.** Smoking in the pharmacy **d.** Undesirable consumer behaviour Implement measures to prevent potential risks identified. Develop and apply safety procedures. Ensure any incidents that occur are recorded.	The procedures for maintaining safety of consumers and employees. Observation the procedures are followed by an absence of physical hazards and a demonstration by an employee of safe manual handling. An explanation of any measures implemented to prevent identified risks. Evidence of a system for recording incidents.	5.16.1
4.3.2	Determine emergencies that may affect the pharmacy, consumers and employees. Where possible, implement measures to prevent emergencies or minimise their potential impact. These should include **a.** Armed robbery **b.** Bomb threat **c.** Extortion or threatening demand **d.** Fire **e.** Accident **f.** Medical emergency Develop emergency procedures to ensure effective responses to the emergencies identified. Apply emergency procedures as required.	Emergency procedures. Documentation or demonstration that employees are aware of these procedures. Evidence may include **a.** Completed induction incorporating familiarisation with emergency procedures **b.** Training record **c.** Explanation from employees	5.16.2

Number	Action required	Assessment evidence	Std. Clause
4.3.3	Determine security issues that may affect the pharmacy, consumers and employees. These should include **a.** Opening and closing the pharmacy **b.** Shoplifting **c.** Cash control **d.** Staff purchases Develop and implement security procedures and policies to ensure security of consumers, staff and the business.	Security procedures and policies. Demonstration the procedures and policies are understood and followed as required.	5.16.3
4.3.4	Determine which employees have a current First Aid (including CPR) qualification. Ensure there is an appropriately-qualified staff member rostered at all times or organise training as required.	Documentation to show that at least one staff member is qualified to provide First Aid (including CPR) at all times.	5.16.4
4.3.5	Determine what emergency, security and safety systems need to be tested to maintain the safety and security of consumers, employees or the business. Develop a schedule for testing these systems. Complete and document testing according to the schedule. ***Note: Examples of systems include*** a. ***Fire extinguishers*** b. ***Smoke, duress or intruder alarms*** c. ***Electrical equipment*** d. ***Evacuation procedures***	The schedule for testing the emergency, security and safety systems. Records to show the systems have been tested in accordance with the schedule.	5.16.5

SUB-DOMAIN 4: INFORMATION TECHNOLOGY

SCOPE:

The Information Technology sub-domain relates to activities associated with information technology and communication infrastructure and systems.

INTENT:

Community pharmacies rely heavily on Information Technology and Communication infrastructure to effectively operate, including ready access to clinical records.
The pharmacy should always have systems in place to protect the consumer confidentiality and allow access only to authorised persons. IT systems should incorporate safeguards to aid effective and efficient business operation, and to protect this information and technology from unauthorised access, malicious attacks, theft or damage.

Number	Action required	Assessment evidence	Std. Clause
4.4.1	Determine how you will protect your IT systems from attacks (e.g., viruses, worms, spyware, cyber hacking) that could compromise the integrity, confidentiality and availability of such systems. Implement your strategy.	An explanation or demonstration of the system for protecting IT systems from external attack (e.g., viruses, worms, spyware, hacking).	5.17.1
4.4.2	Determine what IT equipment, systems and communication infrastructure the pharmacy requires to operate efficiently. Install the required equipment and systems and maintain them accordingly. Periodically review whether the equipment and systems continue to meet the needs of the pharmacy and update them accordingly.	Demonstration 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 (including electronic prescriptions as required).	5.17.2
4.4.3	Determine who needs access to IT systems and electronic information systems and the level of access they require. Provide access appropriate to each user. Develop a policy outlining how computer access is controlled and how security of confidential information held or accessed by the pharmacy is maintained.	Demonstration of how access to confidential information is restricted to authorised personnel and where this access is documented. The policy for computer and electronic information systems access and security.	5.17.3 5.17.4
4.4.4	Establish, maintain and follow a procedure for completing routine data backups to ensure the pharmacy can recover and restore IT systems and information in the event of infrastructure loss. The procedure must include provision for off-site storage of backup information.	A procedure for data backup, including provision for off-site storage of backup information. Evidence data is backed up according to a planned schedule.	5.17.5

Number	Action required	Assessment evidence	Std. Clause
4.4.5	Develop an IT Hardware and Data Recovery Plan to be implemented in response to a crisis event so the pharmacy can recover and resume normal operations as quickly as possible. Ensure key personnel are aware of, and how to implement the Plan should the need arise. ***Note: The IT Hardware and Data Recovery Plan can be a separate plan, or it can be included in the Business Continuity Plan. Consider the loss of IT systems and electronic information and how you can minimise interruptions if these systems are lost. Also consider who may need to be notified (i.e., regulatory bodies etc.) of the loss of IT systems and electronic information.***	Documentation of the IT Hardware and Data Recovery Plan and how it will be implemented when needed.	5.17.6

DOMAIN 5

PHARMACY SERVICES

Pharmacy owners and managers are accountable and responsible for the delivery of safe and quality pharmacy services that meet the needs of the community.

SCOPE:

The Pharmacy Services domain relates to activities associated with the delivery of services within or from the pharmacy. The domain includes generic requirements to address for the delivery of any service the pharmacy provides or is considering providing. Specific requirements have been developed for additional pharmacy services that have special or complex requirements such as Vaccination Services and Complex Compounding.

INTENT:

Community pharmacies offer a range of health and non health-related services to consumers and other businesses. Some health services are inherent to the practice of community pharmacy and will be offered by all community pharmacies, such as dispensing of medicines and non-prescription medicine supply.

Other health services are developed in response to identified community need and the service offering will vary between pharmacies. The offering will also change as pharmacies develop, revise or cease services in response to consumer need, achievement of positive outcomes, or business sustainability.

For any service, consistent, safe and quality services depend on people, training, environment, resources, procedures and records. All services offered should be considered against these requirements. How the requirements apply to each service will differ slightly, guided by consumer needs, relevant guidelines and legislation. For example, there are professional practice standards and guidelines to guide most pharmacy services, such as dose administration aids. Similarly, non-health services may have legislation or codes of practice which guide how those services are to be provided.

These requirements provide a structure to which any service can be quality assured, which will include reference to relevant legislation and guidelines. Pharmacies will only be assessed against the services they provide.

NEW REQUIREMENTS:

Requirements that have been shaded indicate a new requirement, or a new component of the Requirements that was not included in the QCPP Requirements 2011 edition.

SUB-DOMAIN 1: FOUNDATION PHARMACY SERVICES

SCOPE:

The Foundation Pharmacy Services sub-domain relates to activities associated with development, implementation and delivery of services offered by all community pharmacies, including dispensing, supply of non-prescription medicines, simple compounding and supply of medical devices.

INTENT:

Maintaining robust systems and procedures for the delivery of foundation pharmacy services ensures effective and efficient operation of the core activities provided by the pharmacy daily, and consistent, safe and high quality supply of medicines and health-related products.

Number	Action required	Assessment evidence	Std. Clause
5.1.1	Develop and implement a dispensing procedure that ensures the safety and quality of the activity.	The procedure for dispensing that includes or refers to **a.** Accepting prescriptions **b.** Processing the prescription **c.** Labeling prescription items **d.** Checking the prescription **e.** Storage of dispensed medicines prior to collection **f.** Counseling and hand over of prescription item(s) **g.** Provision of Consumer Medicines Information (CMI) **h.** Use of Real Time Prescription Monitoring system for Schedule 8 medicines* Observation that the procedure is followed. Note: both hard copy and electronic prescriptions will need to be considered in the development of the procedure. Pharmacy's will need to decide if they have separate procedure for electronic prescription or if combined. *Check your state for schedule 8 recording requirements	5.2.1
5.1.2	Establish, maintain and follow a process for the provision of consumer health information which includes Consumer Medicines Information and information to support the safe and effective use of medicines more generally.	An explanation of the Consumer Medicines Information (CMI) process and provision of other consumer health care information to support the safe and effective use of medicines.	5.2.5

Number	Action required	Assessment evidence	Std. Clause
5.1.3	Establish, maintain and follow a process for handling and supplying the following **Non-prescription medicines.** The process must include or refer to **a.** Maintaining adequate staffing levels to ensure that consumers have timely access to pharmacists and other pharmacy staff **b.** Ensuring all staff who directly supply Pharmacy Medicines or assist the pharmacist with Pharmacist-Only Medicines have received initial training and ongoing refresher training in supplying Pharmacy Medicines and Pharmacist-Only Medicines	The documented process (e.g., procedure/ checklist/policy/protocol) for the provision of non-prescription medicines. Evidence the process is adhered to by staff is **a.** Explanation of how the staffing levels provide sufficient and timely access to a pharmacist and other pharmacy staff **b.** Records showing all staff who supply Pharmacy Medicines and Pharmacist-Only Medicines have received initial training via a Recognised Course and 3 hours of ongoing Refresher Training is completed annually	5.2.2
	c. Ensuring all Pharmacist-Only Medicines are provided to consumers with the direct involvement of the pharmacist **d.** Ensuring consumers have access to current information on Pharmacy Medicines and Pharmacist-Only Medicines and related conditions **e.** Maintaining a list of recordable Pharmacist-Only Medicines that conforms with relevant legislative requirements. Confirm all staff are aware of and have access to the list **f.** Maintaining a list of Pharmacy Medicines and Pharmacist-Only Medicines that may be subject to inappropriate use **g.** Maintaining signage within the Professional Services Area that encourages consumers to seek advice from pharmacy staff regarding pharmacy Medicines and related conditions **h.** Maintaining a system for documenting inappropriate use of pharmacy Medicines and Pharmacist-Only Medicines	**c.** Demonstrate that pharmacy staff who are trained in the supply of Pharmacy Medicines and Pharmacist-Only Medicines are always visible and approachable for consultation in the Professional Services Area **d.** Demonstrate the Pharmacist-Only Medicines are provided to consumers with the direct involvement of the pharmacist **e.** Demonstrate the pharmacy has access to current sources of clinical information relating to the provision of Pharmacy Medicines and Pharmacist-Only Medicines **f.** Demonstrate how consumers have access to current information on Pharmacy Medicines and Pharmacist- Only Medicines and related conditions **g.** Signage within the Professional Services Area of the pharmacy that encourages consumers to seek advice from pharmacy staff regarding Pharmacy Medicines and related conditions **h.** List of recordable Pharmacist-Only Medicines **i.** List of Pharmacy Medicines and Pharmacist-Only Medicines that may be subject to inappropriate use **j.** Explanation of the process for recording the supply of recordable Pharmacist-Only Medicines and an example of such a record	

Number	Action required	Assessment evidence	Std. Clause
	Medicines that require special consideration or are subject to misuse. This includes, but is not limited to, products containing pseudoephedrine. The process must include **a.** Sighting of identification from consumers (when required to do so by legislation) **b.** Guidance for the refusal of sale **c.** Recording the supply of products, including pseudoephedrine containing medicines (where applicable) **d.** Ensuring that pseudoephedrine containing products are not advertised or promoted	The process (e.g., policy/procedure) for the provision of medicines that require special consideration or are subject to misuse. An explanation of **a.** When or for what products consumer identification must be sighted **b.** Guidance for refusal of sale **c.** The process for recording sales of pseudoephedrine-based products Observation that pseudoephedrine containing products are not advertised or promoted.	
	Medical devices The process must include or refer to how the pharmacy ensures **a.** Any medical device supplied complies with the Australian Standard or is listed on the Australian Register of Therapeutic Goods **b.** Consumers are given adequate instructions for use	The process (e.g., procedure/checklist/ policy/protocol) for the provision of medical devices. Evidence the process is adhered to by staff.	
	Poisons (e.g., hydrogen peroxide) The process must include or refer to **a.** Ensuring the safe storage of poisons and chemicals of concern **b.** Ascertaining the validity of the intended use prior to supplying **c.** Counselling the consumer on the proper use and disposal of the poison **d.** Ensuring the container displays appropriate warning labels and records details of the supply (if required)	The process (e.g., procedure/checklist/ policy/protocol) for the provision of poisons. Evidence the process is adhered to by staff.	

Number	Action required	Assessment evidence	Std. Clause
5.1.4	Establish, maintain and follow a process for simple compounding/extemporaneous dispensing, which includes a compounding procedure. The compounding procedure must include or make reference to ensuring **a.** Any compounding is undertaken by a pharmacist (if possible) or a suitably qualified and supervised staff member **b.** Ingredients are available, have been stored appropriately, are uncontaminated, are of pharmacopoeial standard, are not expired, and the containers are suitable and clean (i.e., light-resistant containers) **c.** There is an area prepared for compounding which is away from other dispensing activities but within the area in which dispensing occurs **d.** All surfaces and equipment are clean prior to compounding **e.** All equipment has been calibrated **f.** The compounded medicine label includes the approved pharmacopoeial name (when available) **g.** Recording each product that is compounded	The pharmacy's simple compounding procedure and associated compounding records.	5.2.3
5.1.5	Establish, maintain and follow a process for the timely and appropriate identification, management, recording and analysis of **a.** Clinical interventions **b.** Adverse drug reactions **c.** Dispensing errors, including near-miss events **d.** Inappropriate care or advice	Demonstrate the process for the identification and recording of clinical interventions, including adverse drug reactions. Demonstrate the process for recording, reporting and resolving dispensing errors, and other significant errors, omissions, incidents or non-compliances. Demonstrate that any dispensing, or other significant errors, omissions, incidents, complaints or non-compliances have been investigated, reported and resolved or are being resolved. Demonstrate that any actions or improvements resulting from the incident are documented in the pharmacy's quality improvement log/register.	5.2.8

SUB-DOMAIN 2: PHARMACY SERVICES – GENERIC REQUIREMENTS

SCOPE:

The Pharmacy Services – Generic Requirements sub-domain relates to activities associated with the development, implementation and delivery of any pharmacy service. It provides a list of key aspects of a pharmacy service that need to be considered. Design of new pharmacy services, in collaboration with consumers and continuous quality improvement aspects, are covered in other areas of the QC2020 Requirements.

INTENT:

The following pharmacy services requirements are designed to apply to any service offered by a pharmacy. They outline service requirements that are common to all formal pharmacy services, such as the need for procedures, trained personnel, access to reference materials, appropriate equipment, and facilities and a robust recording and evaluation process. Regardless of the services offered, a pharmacy can use these requirements to guide development, delivery or evaluation of a service (this includes new pharmacy services).

For some pharmacy services, professional standards and guidelines dictate further requirements, and these are outlined later in this document. Please note the requirements below must be adhered to for all services and any subsequent specific service requirements are to be met in addition to the below.

The initial design of new services or improvements to existing services should include engagement with consumers to ensure that they meet the current and future health needs of the community.

Number	Action required	Assessment evidence	Std. Clause
5.2.1	For each service offered, ensure that staff have the specific qualifications, competency and training to deliver the service, including training in the use of any testing equipment or therapeutic devices. Ensure all employees involved in delivery of each service have been trained in the policies, procedure(s) and guidelines, and their roles and responsibilities are documented. Facilitate completion of any required training prior to offering the service.	Evidence there are appropriately trained and/or qualified personnel to deliver each program or service offered. Staff training records showing completion of any specific qualifications (if applicable), training in policies, procedures and guidelines, as well as training in the use of testing equipment and therapeutic devices required to deliver each program or service.	5.4.1
5.2.2	For each service offered, ensure that access to the current editions of relevant reference materials is available such as service guidelines and other evidence-based information that will help inform the delivery of the service.	Observation there is access to relevant reference material for each program or service offered.	5.4.2

Number	Action required	Assessment evidence	Std. Clause
5.2.3	For each service offered, ensure there is an appropriate area of the pharmacy to deliver the service that is fit for purpose, maintained and meets any legislative or professional practice requirements. Ensure the services are delivered in this area only.	Demonstration that an appropriate area/facility is used for the delivery of pharmacy services and is well maintained. The area/facility must **a.** Allow for a confidential conversation where conversations at normal speaking volume cannot be overheard by other pharmacy visitors or staff **b.** Be neat, clean and hazard-free **c.** Not be in the dispensary or in a location accessed through the dispensary **d.** Not be located where stock is unpacked, sorted or other administrative pharmacy duties or services are carried out that may breach pharmacy and patient confidentiality, unless the area is set up for counselling only	5.4.3
5.2.4	For each service offered, ensure any equipment or therapeutic device required for the delivery of the service is available, clean, calibrated (if required), maintained in good working order and serviced as per the manufacturer's instructions. Ensure any equipment or therapeutic device used is fit-for-purpose for the service being provided and complies with Australian Standards or is listed on the Australian Register of Therapeutic Goods.	Observation that any equipment or therapeutic devices required for the delivery of each service is **a.** Available **b.** Clean and serviceable **c.** Maintained and/or calibrated in accordance with manufacturers specifications **d.** Fit-for-purpose Calibration/maintenance records of equipment requiring calibration/ maintenance.	5.4.4 5.6.6
5.2.5	Establish, maintain and follow a procedure to ensure consistent, safe and quality delivery of each service offered. As a part of the procedure for each service offered, ensure the pharmacy is adequately resourced to support service delivery. If a pharmacist is delivering the service, ensure they are not simultaneously required to **a.** Directly supervise dispensing; or **b.** Undertake other professional duties during consumer consultations Ensure the roles and responsibilities of employees involved in the delivery of each program or service are documented.	The procedures for the delivery of each service, and an explanation of how resources are assigned to cover the delivery of pharmacy services. Documentation of the roles and responsibilities of staff involved in the delivery of each program or service.	5.4.5
5.2.6	Establish, maintain and follow a system for recording all relevant details and indicators of each pharmacy service that is delivered. Ensure the system for recording allows retrieval, analysis and reporting of information in a timely and accurate manner, including the capability to report the number of patients or activities completed for each program or service. Ensure records are maintained securely (including when in transit) according to relevant jurisdictional and program requirements.	Demonstration there is a system for recording, either electronic or hard copy, the details of each time a pharmacy service is delivered. A demonstration of how data is reported to relevant stakeholders. An explanation of how records are securely stored for the required period.	5.4.6

Number	Action required	Assessment evidence	Std. Clause
5.2.7	Establish, maintain and follow a system for evaluating and improving the consumer health outcomes of the services offered. Record any improvements identified in the pharmacy's quality improvement log/register.	Demonstrate the system for evaluating and improving the consumer health outcomes of the services offered. The record of any improvements identified in the pharmacy's quality improvement log/register.	5.4.7
5.2.8	Establish, maintain and follow a system for communicating with prescribers and other relevant health care professionals associated with each pharmacy service. Ensure the pharmacy has a system for documenting each occasion of inter-professional collaboration.	Demonstration the pharmacy has a system for communication with prescribers and other relevant health care professionals associated with pharmacy services. Records of inter-professional collaboration must include **a.** The date the interaction occurred **b.** Name of the pharmacist performing the collaboration **c.** Name and discipline of the other health professional **d.** A short description of the interaction **e.** The actual or anticipated result of the collaboration	5.2.9
5.2.9	Ensure there is a process for obtaining informed consent prior to delivery of each service offered. Document consent appropriately and according to jurisdictional requirements, considering the need for written consent for services which could cause potential harm.	An explanation of the process for obtaining informed consent. Documentation of informed consent, where applicable.	NA

SUB-DOMAIN 3: ADDITIONAL REQUIREMENTS FOR COMPLEX COMPOUNDING

SCOPE:

The Additional Requirements for Complex Compounding sub-domain relates to activities associated with complex compounding. Complex compounding services include the preparation of complex non-sterile formulations and sterile compounds in a dedicated facility. The requirements outlined below which are specific to complex compounding services, are to be met in addition to the generic requirements outlined above.

INTENT:

Community pharmacies providing complex compounding services must ensure that they have adequate systems, qualified and trained personnel, and appropriate facilities and equipment in place to mitigate risks and maximise repeatable high quality output of compounded medicines. They must ensure they meet relevant professional guidelines and legislative and regulatory requirements.

Number	Action required	Assessment evidence	Std. Clause
5.3.1	Ensure personnel involved in preparing compounded medicines have the required training/qualifications and competency required. Ensure ongoing workplace training is provided.	Evidence of participation in a formal training program and/or training plans or training records showing competency to prepare complex compounded medicines has been achieved. An explanation of how ongoing workplace training is provided.	5.3.1
5.3.2	Ensure there are standard operating procedures and relevant reference material for all compounds prepared by the pharmacy.	Observation there is access to standard operating procedures and relevant reference material for all compounds prepared, which includes a register of safety data sheets (SDS) and reputable master extemporaneous formulary database. e.g. The Australian Pharmaceutical Formulary Handbook (APF), United States Pharmacopeia (USP), Martindale, Medisca and Professional Compounding Centres of America (PCCA).	5.3.2

Number	Action required	Assessment evidence	Std. Clause
5.3.3	Ensure there is a designated and fit-for-purpose area for complex compounding and a separate dedicated area for sterile compounding, as required. Ensure there is a procedure for cleaning and, where applicable, disinfecting the area for complex compounding.	Demonstration that there is a dedicated and fit-for-purpose facility for complex compounding, and a separate dedicated area and equipment for sterile compounding, if provided. The area for complex compounding must **a.** Be separated from other areas of the pharmacy by floor to ceiling walls or partitions and have at least one door to allow access **b.** Not allow access by unauthorised personnel (e.g., lockable doors or accessed only through dispensary) **c.** Have an impervious floor covering and surfaces (walls/countertops, etc.) that are washable **d.** Contain a sink with hot and cold water or hand sanitising products (if accessible sink is outside of this area) **e.** Include a powder containment cabinet certified against an Australian Standard for activities likely to release a powder **f.** Have at least one bench that provides enough working space for compounding activities **g.** Have clearly identifiable and dedicated area(s) to isolate raw materials, and compounds not to be used or released to consumers (e.g., unchecked orders, product recalls and expired stock) **h.** Maintain an ambient temperature of 25 degrees Celsius or less, evidenced by a temperature log **i.** A clearly observable area for quarantine of finished products which need to be checked before final release **j.** The procedure for cleaning and, where applicable, disinfecting the area for complex compounding	5.3.3
5.3.4	Ensure a risk assessment for workplace health and safety is undertaken for all staff working in the compounding facility, and implement steps to eliminate or mitigate risks where possible.	The risk assessment and explanation of how workplace health and safety risks are identified and eliminated or mitigated (where elimination is not possible). Observation that personal protective equipment is available (e.g., laboratory coat, surgical face mask, disposable gloves, hair covers and protective eyewear). Staff working with hormones should have had baseline hormone testing at least each accreditation cycle.	5.3.4
5.3.5	Ensure there is a risk management plan with respect to appropriate circumstances for compounding, patient safety, product formulation and product quality. Implement steps to eliminate or mitigate risks where possible.	The risk management plan. Record of risk assessments for patients presenting a new prescription. An explanation of how patient safety, product formulation and product quality are maintained, and how potential risks are identified and eliminated or mitigated (where elimination is not possible).	5.3.5

Number	Action required	Assessment evidence	Std. Clause
5.3.6	Ensure there is a system for identifying, handling, storing and disposing of materials, including raw and compounded.	The procedure for identifying, handling, storing and disposing of materials, including raw and compounded. Training records showing all staff have been trained in the procedure. Observation of five raw ingredients to ensure **a.** Suppliers of raw materials hold a TGA licence, and/or raw materials are manufactured in a facility that holds a TGA (or equivalent, e.g. FDA, European GMP) licence if manufactured overseas. **b.** Raw ingredients are stored in accordance with safety data sheets (SDS) and labelled with expiry dates and batch numbers **c.** Hazardous raw ingredients are labelled and stored separately in a dedicated area to minimise risk and contamination	5.3.6
5.3.7	Ensure there is a system to ensure consistency, safety and quality of compounded products, including a system for final product potency testing.	The procedure for ensuring consistency of compounded products including a system for final product potency testing. Documentation of results from final product potency tests completed. A final product potency test must be completed on two different drugs and two different dosage forms per technician per year.	5.3.7
5.3.8	Ensure there is a system for appropriate packaging, labelling, and storage of finished compounded products. Establish a process for ensuring patient counselling and consumer information is provided as necessary.	The procedure for appropriate packaging, labelling, and storage of finished compounded products. Evidence of appropriate packaging to maintain quality and stability of compounded products. Observation that packaging is stored off the floor to prevent contamination. Observation that compounded products are labelled (including correct naming and expiry dates) and stored appropriately. An explanation of how patient counselling occurs, what written information is provided and how staff handle enquiries.	5.3.8
5.3.9	Ensure there is a system for initiating, managing and reporting a product recall of compounded products.	An explanation of how a product recall of a compounded product is initiated, managed and reported, including how consumers affected are identified and notified of product recalls, as well as any associated documentation if applicable.	5.3.9
5.3.10	Ensure there is a written agreement with any referring pharmacy acting as a third-party supplier.	The written agreement with any referring pharmacy acting as a third-party supplier. The agreement must include the responsibilities of each pharmacy including **a.** Transfer of prescription and privacy implications **b.** Conduct of a risk assessment **c.** Payment **d.** Counselling **e.** Identification checks **f.** Storage of compounded medication	NA

SUB-DOMAIN 4: ADDITIONAL REQUIREMENTS FOR MEDICINE MANAGEMENT SERVICES

SCOPE:

The Additional Requirements for Medicine Management Services sub-domain relates to activities associated with Medicine Management Services, including, but not limited to, adherence services, in-pharmacy medicine reviews (e.g., MedsCheck), Home Medicines Reviews (HMRs) and Residential Medication Management Reviews (RMMRs). The requirements outlined below which are specific to Medicine Management Services, are to be met in addition to the generic requirements outlined above.

INTENT:

Community pharmacies providing Medicine Management Services in or from the pharmacy must have systems in place to ensure that there are adequate resources and trained staff or contractors to respond to requests within a timely period. Systems for documentation of the service in a clinical record and provision of reports to relevant health practitioners should be in place as well as the ability to monitor and report on the occasions of service.

Number	Pharmacy Service	Action required	Assessment evidence
5.4.1	HMR/RMMR	Ensure there are adequate resources to act on any Medication Management Review (MMR) referrals within two weeks.	Evidence that MMR requests are responded to within two weeks of referral, evidenced by the date the consumer was contacted or referral forwarded to third-party contractor/ accredited pharmacist.
5.4.2	HMR/RMMR	Ensure the pharmacists(s) involved in performing the tasks associated with MMR services maintains the required training and accreditation relevant to those tasks.	Evidence that any pharmacist involved in delivering MMR services has current accreditation to do so.
5.4.3	HMR/RMMR	Maintain a list of elements of the MMR services designating which task(s) will be performed by the accredited pharmacist and which tasks will be performed by the community pharmacist (if different).	A documented breakdown of tasks for the accredited pharmacist and the community pharmacist to complete (as applicable).
5.4.4	HMR/RMMR	Ensure a copy of the MMR report provided to the referring GP is kept for all MMRs conducted or facilitated by the pharmacy.	Copies of MMR reports provided to the referring GP for all MMRs conducted or facilitated by the pharmacy.
5.4.5	In-Pharmacy Medicines Review	Ensure there is an appropriate consultation area available within the pharmacy to conduct in-pharmacy medicines reviews.	Observation there is a consultation area that allows for a confidential seated consultation between the pharmacist and consumer.

Number	Pharmacy Service	Action required	Assessment evidence
5.4.6	In-Pharmacy Medicines Review	Ensure there is a system to document and record the In-Pharmacy Medicine Review service. Ensure the recording system can report the number of consumers who have participated in the service.	Records of in-pharmacy medicine reviews conducted by the pharmacy, ensuring each patient record includes **a.** Consumer's name and address **b.** Consumer's date of birth **c.** A medication profile that includes the date the profile was established, and the date of information changes or review recorded **d.** A record of activities undertaken, strategies developed to date, and pharmacist's name **e.** Outcomes of activities undertaken during the in-pharmacy medicine review and all information provided to the consumer **f.** Copy of any report or documentation provided to another health professional if relevant
5.4.7	Medicines adherence	Maintain and follow a system to identify consumers who may benefit from an adherence program service.	An explanation of how the pharmacy identifies consumers who may benefit from an adherence service.

SUB-DOMAIN 5: ADDITIONAL REQUIREMENTS FOR DOSE ADMINISTRATION AID SERVICES

SCOPE:

The Additional Requirements for Dose Administration Aid Services sub-domain relates to activities associated with the development and maintenance of systems for packing and supply of dose administration aids (e.g., blister packs or sachets) for consumers is in residential care facilities or in the community. The requirements outlined below which are specific to Dose Administration Aid Services, are to be met in addition to the generic requirements outlined above.

INTENT:

Robust systems for the delivery of a dose dministration aid service is important to maintain a consistent, safe and high quality service to consumers. Systems should address processes involved in the clinical review of consumer medicines, safety and integrity of medicines packed, training and procedures for packing, accuracy-checking and accountability by the supplying pharmacist. Maintenance of error logs and consumer feedback logs allows for opportunities to improve systems and the service.

Number	Pharmacy Service	Action required	Assessment evidence
5.5.1	Dose administration aids	Ensure the supplying pharmacist signs off on each Dose Administration Aid (DAA) indicating their accountability for the provision of a clinically-accurate, safe and quality DAA.	Records that indicate the supplying pharmacist provides final sign-off on each DAA supplied.
5.5.2	Dose administration aids	Develop and maintain a list of items not to be packed in DAAs.	The list of items not to be packed is easily available to employees who pack DAAs and located in the area where DAAs are packed.
5.5.3	Dose administration aids	Ensure staff members packing DAAs have completed training.	Evidence of completion of training for relevant staff members in **a.** The pharmacy's DAA packing procedure **b.** Any computer software/program required for the provision of DAA services
5.5.4	Dose administration aids	Ensure staff members packing DAAs have access to appropriate protective items (i.e., gloves, masks, tweezers).	Observation protective items (i.e., gloves, masks, tweezers) are available for use while packing DAAs.
5.5.5	Dose administration aids	Ensure there is a dedicated area where DAA packing occurs.	A tour of the area where DAAs are packed which is **a.** Clean and free from food and drink **b.** Free from repeated interruptions

Number	Pharmacy Service	Action required	Assessment evidence
5.5.6	Dose administration aids	Develop and implement a hand hygiene procedure. Ensure staff packing DAAs have access to the hand hygiene procedure and hand hygiene facilities.	A hand hygiene procedure is on display in the DAA packing area and hand hygiene facilities are available.
5.5.7	Dose administration aids	Develop and maintain a system for recording DAA service activities. Records of the following should be kept **a.** Current medicines, doses and items not supplied in the DAA for each patient **b.** Changes to medications packed in the DAA **c.** Any significant communications with the prescriber for each patient **d.** Errors in packing (detected after the DAA has been supplied), their origin and resolution, and any quality improvement made as a result **e.** A log of all DAAs packed, checked and supplied endorsed by the supplying pharmacist or other staff according to procedures **f.** Classification of the patient's residential setting, if pharmacy suppling DAAs for patients in more than one residential setting	Records of DAA service activities.

SUB-DOMAIN 6: ADDITIONAL REQUIREMENTS FOR HEALTH ASSESSMENT SERVICES

SCOPE:

The Additional Requirements for Health Assessment Services sub-domain relates to activities associated with the delivery of professional services, including, but not limited to absence from work certificates, disease state management services and screening and/or risk assessment services. The requirements outlined below, which are specific to Health Assessment Services, are to be met in addition to the generic requirements outlined above.

INTENT:

Robust systems for the delivery of a health assessment services is important to maintain a consistent, safe and high quality service to consumers and to meet professional guidelines. Systems should be in place for infection control, clinical waste and sharps disposal, and to ensure personal protective equipment is available for employees.

Number	Pharmacy Service	Action required	Assessment evidence
5.6.1	Absence from work certificates	Ensure there is an appropriate consultation area available within the pharmacy to conduct consultations.	Observation there is a consultation area that allows for a confidential seated consultation between the pharmacist and consumer.
5.6.2	Absence from work certificates	Ensure there is a system for recording the issuing of absence from work certificates.	Records of absence from work certificates issued by the pharmacy, ensuring each record includes **a.** Name and address of person seeking certificate **b.** Whether the request relates to personal leave or carer's leave **c.** Illness/injury described by the person **d.** Visible symptoms or illness/injury **e.** Duration of symptoms **f.** Whether the person has sought medical care for the illness/injury **g.** What (if any) medicines are supplied by the pharmacy **h.** Duration of expected absence from work **i.** Whether a certificate was issues, and if so, the date(s) the certificate covers **j.** Whether the pharmacy referred the person to another health professional

Number	Pharmacy Service	Action required	Assessment evidence
			k. Name and signature of pharmacist issuing the absence from work certificate (signature not mandatory for electronic records) **l.** Consultation date **m.** A copy of the absence from work certificate, if issued
5.6.3	Disease state management (DSM)	Ensure there is a procedure for infection control (if the activity involves physical contact with consumers or skin penetration). If the service involves skin penetration and/or physical contact **a.** Ensure there are disposal containers for clinical waste and sharps. Ensure sharps containers are in an area that cannot be easily accessed by unsupervised children **b.** Ensure staff have access to appropriate protective items (e.g., gloves, masks, eye protection)	The infection control procedure and demonstration that protective items and containers for the disposal of clinical waste and sharps are available to all staff involved in the delivery of disease state management services.
5.6.4	Disease state management (DSM)	Ensure there is a system to document and record the disease state management service. Ensure the recording system can report the number of consumers who have participated in the service for each service offered (e.g., Diabetes DSM, asthma DSM service) and any other indicators as required.	Records of disease state management services provided by the pharmacy, ensuring each record includes **a.** Patient name and address **b.** Date of birth **c.** Health condition which is subject to the service **d.** Date service delivered **e.** Results of any clinical tests conducted **f.** Summary of key points discussed **g.** Planned follow-up (if appropriate)
5.6.5	Screening and risk assessment	Ensure there is a procedure for infection control. If the service involves skin penetration and/or physical contact, ensure **a.** There are disposal containers for clinical waste and sharps. Ensure any sharps container is in an area that cannot be easily accessed by unsupervised children **b.** Staff have access to appropriate protective items (e.g., gloves, masks, eye protection)	The infection control procedure and demonstration that protective items and containers for the disposal of clinical waste and sharps are available to all staff involved in the delivery of screening and risk assessment services.
5.6.6	Screening and risk assessment	Ensure employees involved in screening and risk assessment services are appropriately trained, and are aware of the limitation of their ability to interpret results and provide advice. Ensure staff are aware of referral processes.	Training records for employees involved in screening and risk assessment services. An explanation of how results are provided to consumers and how the pharmacy determines who should be referred for further investigation.
5.6.7	Screening and risk assessment	Ensure there is a system for recording screening and risk assessment activities.	Records of screening and risk assessment services provided by the pharmacy, ensuring each record includes **a.** The key features of any explanation or recommended follow-up action **b.** Details of the person that performed, interpreted and explained the testing and results **c.** Patient details (name, date of birth, customer ID, etc.)

SUB-DOMAIN 7: ADDITIONAL REQUIREMENTS FOR HARM MINIMISATION SERVICES

SCOPE:

The Additional Requirements for Harm Minimisation Services sub-domain relates to activities associated with the delivery of services, including, but not limited to, staged supply, opioid substitution and needle and syringe programs. The requirements outlined below which are specific to Harm Minimisation Services are to be met in addition to the generic requirements outlined above.

INTENT:

Robust systems for the delivery of a health assessment services is important to maintain a consistent, safe and high quality service to consumers and to meet professional guidelines and legislative or regulatory requirements. Systems should be in place for communication with prescribers, record management, training of staff, including in safe sharps disposal management of needlestick injuries and maintaining measuring equipment to the necessary degree of accuracy.

Number	Pharmacy Service	Action required	Assessment evidence
5.7.1	Needle and Syringe Program	Ensure there is an up-to-date list of other health professionals and support organisations (e.g., drug and alcohol support services, mental health services) that consumers accessing the needle and syringe service may require.	The list of other health professionals and support organisations.
5.7.2	Needle and Syringe Program	Ensure that, in conjunction with needles and syringes, there are small sharps containers for sale in the pharmacy to encourage the safe disposal of clinical waste and sharps. Ensure the sharps containers have appropriate warning labels.	Observation the pharmacy has small sharps containers for sale as required.
5.7.3	Needle and Syringe Program	Ensure pharmacies that choose to provide a sharps container or are required to provide a sharps container as part of a structured NSP scheme, have the container located in an area that cannot be easily accessed by unsupervised children.	Observation of where the sharps container is kept in the pharmacy.
5.7.4	Needle and Syringe Program	Ensure all staff are trained in the pharmacy's procedure, relevant guidelines and safe handling of sharps.	Evidence of completion of training.
5.7.5	Needle and Syringe Program	Ensure there is a system for recording and reporting needle stick injuries as required.	An explanation of how needle stick injuries are recorded and reported. Documentation of any needle stick injuries that have occurred.

Number	Pharmacy Service	Action required	Assessment evidence
5.7.6	Opioid Substitution Program	Ensure there is an up-to-date list of contact details for other referral and advice services related to opioid substitution.	The list of other referral and advice services.
5.7.7	Opioid Substitution Program	Ensure the pharmacy has equipment capable of measuring to the necessary degree of accuracy (e.g., Pumps and syringes)	A demonstration of the equipment used to deliver accurate doses.
5.7.8	Opioid Substitution Program	For consumers who receive a dose of their medicine in the pharmacy, ensure **a.** Only disposable single use cups are used **b.** Administration of doses. Occurs in a discreet area of the Professional Services Area of the pharmacy **c.** The person receiving the dose has access to drinking water	A tour of the area where opioid substitution services are provided in the pharmacy and evidence drinking water is available or provided to consumers who require it. Proof that only disposable single use cups are used.
5.7.9	Opioid Substitution Program	Ensure take away doses are contained in child- resistant packaging.	An explanation of how take away doses are provided to consumers. Evidence of child-resistant packaging.
5.7.10	Opioid Substitution Program	Ensure the pharmacy has an appropriately sized drug safe to accommodate opioid substitution stock.	Observation the drug safe is large enough to accommodate enough opioid substitution stock, with or without a dosing device attached.
5.7.11	Opioid Substitution Program	Ensure there is a system for recording opioid substitution therapy provided by the pharmacy.	Records of opioid substitution services provided by the pharmacy, ensuring each patient record includes **a.** A clear photograph of the consumer **b.** A signed agreement to participate **c.** Details of the prescriber and other relevant health care workers **d.** Any special notes **e.** Records of significant communications with the prescriber **f.** A record of each supply **g.** Expiry date of the current prescription
5.7.12	Staged Supply	For patients administered a dose of their medicine in the pharmacy **a.** Ensure only disposable single use cups are used **b.** Ensure administration of doses occurs in a discreet area of the Professional Services Area of the pharmacy **c.** Ensure the person receiving the dose has access to drinking water	Demonstration of where staged supply is provided in the pharmacy and how drinking water is provided to consumers who require it. Observation disposable single use cups are used.
5.7.13	Staged Supply	Ensure there is a system for recording each instance a patient is supplied a medicine under a staged supply arrangement.	Records of staged supply services provided by the pharmacy, ensuring each patient record includes **a.** A signed agreement between the consumer and the pharmacy **b.** Prescriber details and details of other relevant health care workers **c.** Communication with the prescriber **d.** A record of each supply event, including date, time, quantity, signature of consumer acknowledging receipt, pharmacist signature, and fee paid (if pharmacy charges a fee)

SUB-DOMAIN 8: ADDITIONAL REQUIREMENTS FOR OTHER HEALTH SERVICES

SCOPE:

The Additional Requirements for Other Health Services sub-domain relates to specific activities associated with the delivery of services, including, but not limited to, health promotion activities, vaccination services and services to residential care facilities. The requirements outlined below, which are specific to Other Health Services, are to be met in addition to the generic requirements outlined above.

INTENT:

Robust systems for the delivery of other health services is important to maintain a consistent, safe and high quality service to consumers and to meet professional guidelines and legislative or regulatory requirements. This sub-domain highlights specific considerations or requirements for the listed services in addition to generic requirements.

Number	Pharmacy Service	Action required	Assessment evidence
5.8.2	Health promotion	Ensure there is a system for recording health promotion activities.	Records of health promotion activities provided by the pharmacy, ensuring each record includes details of **a.** Activities undertaken **b.** When the activities were undertaken **c.** The target audience **d.** Impact/outcomes (as appropriate) **e.** Evaluation and feedback received **f.** Quality improvement actions taken as a result of health promotion activity evaluation and feedback
5.8.3	Services to residential care facilities	Maintain a contract with each facility serviced.	The contract with individual facilities serviced. The contract must include **a.** Roles and responsibilities of the pharmacy and facility **b.** Provision of education, stock control, storage and services **c.** Requirements for improving medication related services within the facility **d.** Arrangements for change of contract to another service provider
5.8.4	Services to residential care facilities	Maintain an accurate, complete and comprehensive record of medicines for each resident.	Records of medicines for each resident.
5.8.5	Services to residential care facilities	Develop and follow a system for recording and reporting medication related incidents.	The records of medication related incidents for each facility serviced.

Number	Pharmacy Service	Action required	Assessment evidence
5.8.6	Vaccination services	Ensure personnel administering vaccines hold appropriate qualifications.	Certificates of vaccination qualifications, first aid, CPR and anaphylaxis training.
5.8.7	Vaccination services	Ensure personnel involved in the vaccination service have access to appropriate personal protective equipment (PPE).	Observation that protective equipment is available to all staff involved in the vaccination service.
5.8.8	Vaccination services	Ensure personnel have access to appropriate first aid and medical emergency equipment and are trained in responding to a medical emergency. Ensure there is an anaphylaxis kit available.	Demonstration that first aid and medical emergency equipment are available, and evidence personnel involved in the vaccination service are trained to respond to a medical emergency. Sighting of an anaphylaxis kit.
5.8.9	Vaccination services	Ensure there is a fit for purpose area for providing vaccination services as defined by relevant state/territory legislation and regulations.	An inspection of the area where vaccination services are provided which meets relevant state/territory legislation and regulations.
5.8.10	Vaccination services	Ensure there is a procedure for hand hygiene and ensure staff involved in vaccinations have access to the hand hygiene procedure. Ensure hand hygiene facilities are available.	A hand hygiene procedure is on display in the vaccination area and hand hygiene facilities are available.
5.8.11	Vaccination services	Ensure there is a system for recording the administration of a vaccine.	Records of vaccinations provided by the pharmacy, ensuring each record includes **a.** Consumer's full name and date of birth **b.** Details of the vaccine administered including name, dose, batch number, date, time, site of administration **c.** Details of the person administering the vaccine, and the pharmacy in which it was administered **d.** If appropriate, the date that the next vaccination is due **e.** Confirmation of consumer information provided outlining the vaccine administered, potential side effects, who to contact in the event of an adverse effect and the date the next vaccination is scheduled **f.** If appropriate, notification to the appropriate national vaccination database and My Health Record
5.8.12	Vaccination services	Ensure there is a procedure for infection control ensuring there are disposal containers for clinical waste and sharps. Ensure any sharps container is in an area that cannot be easily accessed by unsupervised children.	The infection control procedure and demonstration that containers for the disposal of clinical waste and sharps are available.

SUB-DOMAIN 9: ADDITIONAL REQUIREMENTS FOR NON-HEALTH SERVICES

SCOPE:

The Additional Requirements for Non-Health Services sub-domain relates to specific activities associated with the delivery of services, including, but not limited to, indirect supply (e.g., internet pharmacy services and deliveries by third-party service providers) and delivery services by pharmacy staff. The requirements outlined below which are specific to non-health services, are to be met in addition to the generic requirements outlined above.

INTENT:

Robust systems for the delivery of other non-health services is important to maintain a consistent, safe and high quality service to consumers and to meet professional guidelines and legislative or regulatory requirements.

Community pharmacies offering delivery or indirect supply of medicines should consider the stability of medicines and those appropriate for transport by employees or third-party contractors. Systems should be in place to maintain consumer privacy and integrity of data, and mechanisms for deliveries to be tracked. Records of each occasion of indirect supply must be kept.

Number	Pharmacy Service	Action required	Assessment evidence	Std. Clause
5.9.1	Indirect supply	Establish, maintain and follow a procedure for the indirect supply of pharmacy products which covers **a.** Ordering products via the internet, post, telehealth and facsimile and/or **b.** Delivery by a third-party on behalf of the pharmacy	The pharmacy's procedure for the indirect supply of pharmacy products.	5.2.6
5.9.2	Indirect supply	Maintain a list of medicines not suitable for delivery by a third-party (i.e., cold chain medicines) and ensure all staff are aware of the list.	The list of medicines not suitable for delivery by a third-party.	NA
5.9.3	Indirect supply	Maintain a list of medicines prohibited for transport by a third-party (i.e., cytotoxic medicines) and ensure all staff are aware of the list.	The list of medicines prohibited for transport by a third-party.	NA
5.9.4	Indirect supply	Ensure the pharmacy has adequate and appropriate packaging for supply items to ensure manufacturer's storage and delivery specifications are met.	An explanation of how items are packaged for supply by a third-party to ensure manufacturer's storage and delivery specifications are met.	NA

Number	Pharmacy Service	Action required	Assessment evidence	Std. Clause
5.9.5	Indirect supply	Ensure any internet pharmacy service has an agreement with service providers that ensures all intellectual property and access to data remains with the pharmacy.	A copy of the agreement with service providers for internet pharmacy services.	NA
5.9.6	Indirect supply	Ensure any internet pharmacy service has data protected by encryption and caters for a user name and password.	An explanation of how data is protected as part of internet pharmacy services.	NA
5.9.7	Indirect supply	Develop a system for recording each occasion of indirect supply. Records must include **a.** An application form for indirect supply, including–as a minimum– personal details, medication history and known allergies **b.** Date patient medication record verified **c.** Date of request and date of supply **d.** Log that links date of original request with date and details of dispatch and dispensing record **e.** Patient contact information including the date of the contact, the pharmacist's name and details of any information provided **f.** An audit trail or delivery tracking record, and a delivery confirmation receipt with a specification to return to sender if not delivered **g.** The consumer's preferred mode and time of delivery	Records of indirect supply provided by the pharmacy.	NA
5.9.8	Delivery services	Ensure the pharmacy has a process for providing delivery services by pharmacy staff, which includes a procedure and register to track deliveries.	The pharmacy's procedure for deliveries by pharmacy staff and proof it is followed. Evidence of a deliveries register.	5.11.8

SUB-DOMAIN 10: ADDITIONAL REQUIREMENTS FOR DIGITAL HEALTH

SCOPE:

The Additional Requirements for Digital Health sub-domain relates to activities associated with the use of digital health advancements, including, but not limited to, My Health Record (MHR). The requirements outlined below which are specific to Digital Health, are to be met in addition to the generic requirement outlined above.

INTENT:

Community pharmacies using digital health systems such as My Health Record must ensure they have robust procedures to maintain consistent, secure, and high-quality service to consumers. Systems and policies should be in place for staff training, protecting consumer confidentiality, restricting access to authorised persons and procedures in the event of a clinical incident or access/data breach.

Number	Pharmacy Service	Action required	Assessment evidence
5.10.1	MHR	Ensure staff members uploading to, or accessing a patients' MHR, have been educated and trained in the relevant guidelines, pharmacy policies and procedures, use of the system, etc.	Documented details of training undertaken by all staff, including pharmacy assistants, who have access to MHR in the pharmacy.
5.10.2	MHR	Establish and implement a policy for the security and access of the MHR system which includes: **a.** Pharmacy name **b.** Version number **c.** Version date **d.** Responsible Officer (RO) name **e.** Organisation Maintenance Officer (OMO) name(s) **f.** Process for providing access to staff. **g.** Strategies to minimise risk to ensure the security of information and access **h.** Training provided **i.** How to act in a clinical incident **j.** Signed and dated by RO and OMO **k.** Ensure the policy is maintained and has been reviewed in the last year	The pharmacy's policy covering the security and access of the MHR system and evidence that the policy is maintained.
5.10.3	MHR	Ensure pharmacy holds a valid National Authentication Service for Health (NASH) Public Key Infrastructure (PKI) Organisation certificate.	Demonstrate pharmacy holds a valid NASH PKI Organisation certificate by showing one of the following: **a.** Access to a patient MHR **b.** Linked services in Healthcare Organisation (HPI-O) PRODA account **c.** Organisation snapshot in Health Professional Online Services (HPOS)

Number	Pharmacy Service	Action required	Assessment evidence
5.10.4	MHR	Ensure there is a process in place in the event of a clinical incident or access/ data breach.	Explanation of what is done in the event of a clinical incident or access/data breach.

Glossary

Term	Definition
Adverse drug reaction	Unwanted and sometimes harmful occurrences from the use of medicine.
Australian Charter of Healthcare Rights	Specifies the key rights of patients and consumers when seeking or receiving healthcare services.
Budget Forecast	A summarised expected financial forecast.
Business Continuity Plan	A plan designed to help your pharmacy respond to a crisis event, minimise interruptions, recover and resume normal operations as quickly as possible. A crisis event may be a fire, flood, loss of key staff etc.
Business model	A plan for the successful operation of a business by identifying sources of revenue, the intended customer base, products and details of financing.
Business Performance	The use of quantifiable metrics to analyse and measure business success.
Business plan	A written description and plan of a business's future.
Calibration	A process of ensuring a device reads or takes measurements accurately, in accordance with its manufacturer's instructions.
Clinical Intervention	A professional activity undertaken by a registered pharmacist directed towards improving quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour.
CMI (Consumer Medicines Information)	Leaflet that contains information on the safe and effective use of a prescription or specified non-prescription medicines.
Community Pharmacy Service Charter	The Community Pharmacy Service Charter adopts the principles of the Australian Charter of Healthcare Rights and describes how it applies to community pharmacy.
Complementary medicines	Include products containing herbs, vitamins, minerals, nutritional supplements, homeopathic medicines, certain aromatherapy products and traditional Chinese medicines.
Complex Compounding	The preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for supply for a specific patient, and that requires or involves special competencies, equipment, processes and facilities. Sterile, cytotoxic, hormone, micro-dose, single-unit dosage forms, sustained-release and modified-release preparations.
Consultation Area	An identifiable area or separate room within the Professional Services Area that allows for confidential interactions and conversations at normal speaking volume without being overheard by others.
Consumer/Stakeholder demographics	Characteristics of your consumer base.
Contract of employment	A contract of the rights, responsibilities and obligations of a working relationship between an employer and an employee.
Controlled medicines	Schedule 8 medicines; medicines with strict legislative requirements for storage and supply.
CPR : Cardiopulmonary Resuscitation	Emergency protocol for providing oxygen to a casualty that consists of alternating chest compressions with mouth-to-mouth breathing.

Term	Definition
Cytotoxic Medicines	Medicines which have a deleterious effect upon cells and may be mutagenic, teratogenic or carcinogenic. These medicines are predominantly used to treat cancer or autoimmune disorders and require special handling.
Declaration	A formal statement by a person specifying facts and circumstance.
Disease State Management	A service that supports consumers who have been diagnosed with a chronic health condition that entails monitoring and ongoing management.
First aid qualification	The first aid qualification is to be the 'Senior First Aid' certificate and should be current as per the accredited training provider's guidelines.
General Trading Area	Location of the pharmacy that excludes the professional services area, usually used for general retail products and sales.
Hazardous Materials	An item or agent, which has the potential to cause harm, whether by itself or with other factors.
Health Promotion	A process/activity where the pharmacy actively engages consumers and the community to promote health and wellbeing at a group or population level.
HMR: Home Medicines Review	A medicines review conducted by an accredited pharmacist in the patients' home, usually initiated by referral from the patient's practitioner.
Key Performance indicators (KPIs)	Measurable indicators to assess performance of the business and employees.
Induction checklist	A process and list to welcome new employees and to ensure they are prepared for their role.
In-Pharmacy Medicines Review	An in-pharmacy review of a consumer's medicines which focuses on education and self-management e.g., MedsCheck.
Market Pressures	External stresses that can affect a business.
Medical Devices	A health-related 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 health care
Medicines	Medicines are therapeutic goods utilised to achieve an intended health outcome, including all prescription medicines, non-prescription medicines and complementary medicines.
Medicines Adherence	A program that encourages consumers to take prescribed medicines consistently and according to the regimen intended.
Mobility aids	Equipment that assists mobility for disabled or injured people, or those with a mobility impairment.
My Health Record (MHR)	My Health Record is a secure online summary of an individual's health information and is available to all Australians. Health care providers authorised by their healthcare organisation can access My Health Record to view and add patient health information.
NASH PKI Certificate	The National Authentication Service for Health (NASH) is used by health care providers and supporting organisations to securely access and share health information. NASH Public Key Infrastructure (PKI) certificates help you to: access My Health Record system.
Needle and Syringe Program	Provides sterile injecting equipment and education to prevent blood-borne disease for injecting drug users.
Non-prescription medicines	Medicines that do not require a prescription to be attained.

Term	Definition
Operational plan	A detailed plan that explains a business's objectives, goals, procedures and timelines, as well as day to day tasks.
Opioid Substitution Program	A harm minimisation treatment program for opioid dependence offered by the pharmacy, usually in conjunction with a state/territory health program.
PCCA	Professional Compounding Chemists of Australia.
Pharmacist-Only Medicine (S3)	Non-prescription medicines with special storage requirements that require direct sale and advice by a pharmacist.
Pharmacy Medicine (S2)	Non-prescription medicines available only in pharmacies (or licensed person), which may require advice from a pharmacist.
Point of sale	The place where retail transactions are carried out.
Price List	A list of prices for products sold by the pharmacy, usually predominately in the context of Prescription Medicines.
Procedure	A sequential set of steps which describes a process for doing something.
PRODA	An online identity verification and authentication system. It allows secure access to government online services.
Professional Service Area	A continuous area established within a pharmacy where only health-related products and services are provided and is supervised by a pharmacist.
Purchasing Policy	A policy that focuses on placing requirements for employees seeking to acquire goods and services by use of the company.
Quality Management System	A structured system that supports the provision of consistent, safe and high quality pharmacy services to support positive health outcomes for consumers and the community.
Recognised Course	A course recognised by QCPP.
Refresher Training	Ongoing training in Pharmacy Medicines and Pharmacist-Only Medicines.
RMMR (Residential Medication Management Review)	A medicines review conducted by an accredited pharmacist for patients living in an aged care facility.
Return of Unwanted Medicines (RUM) program	A service patients can utilise to return unwanted or expired medicines to the pharmacy which are disposed of in a RUM container for safe disposal.
Scheduled medicines	Medicines contained in the Standard for the Uniform Scheduling of Medicines and Poisons that have been classified into varying levels of restrictions to protect public health safety.
Screening and Risk Assessment	The undergoing of tests or questions to identify patients who may be of risk or have a health condition which requires further investigation.
Self-Assessment	The evaluation of performance without external input.
Sharps Container	Impervious sealable container of appropriate dimensions to safely store needles, syringes and other sharp contaminated objects to assist in the prevention of needlestick injuries.

Term	Definition
Simple Compounding	The preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need. It involves extemporaneous dispensing from formulations published in reputable references, such as the *APF*, and formulations for which information confirming quality, stability, safety, efficacy, and rationality is available and excludes preparations of sterile products.
Staged Supply	A clinically-indicated, structured pharmacist service involving the supply of medicine to a patient in periodic instalments as requested by the prescriber or carer.
Supply of Medicines	The provision of medicines from a pharmacy which includes prescriptions from a health professional or requests from a consumer and covers the assessment of the consumers requirements and the provision of professional advice.
System (in context of a requirement)	Procedure consistent with best-practice guidelines which includes a process for recording, training and reviewing the procedure and expected outcomes.
TGA	Therapeutic Goods Administration.
Therapeutic Goods	Goods that are represented in any way to be, or that are likely to be, taken for therapeutic use or used as an ingredient or component in the manufacture of therapeutic goods.
Training and development record	A record of training and/or development activities for each employee, including details such as dates, duration and learning objectives.
Training Plan	A documented training and development plan for employees which helps identify and undertake activities to meet their professional development needs or skills required for their role.
Workplace Grievance Process	A process to address any problem, concern or complaint related to an employee work or work environment.

Helpline: 1300 363 340 | **Email:** help@qcpp.com