Pharmaceutical Society of Australia

Professional Practice Standards

VERSION 5 | 2017

PSA Australia's peak body for pharmacists

Disclaimer

The Professional Practice Standards (PPS) is intended to provide guidance on the expected standards of professional behaviour of pharmacists towards individuals, the community and society. It has been designed for use by individual pharmacists to assess their own practice. It is the sole responsibility of the individual pharmacist to determine, in all circumstances, how to apply the criteria and actions in these standards.

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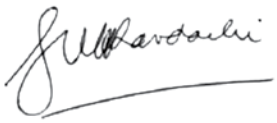
Foreword

The publication of ***Professional Practice Standards (PPS),*** Version 5, represents the culmination of a comprehensive review process involving many pharmacy and consumer organisations and an extensive range of subject matter experts across various areas of pharmacy practice, as well as consultation with the wider pharmacy and medical professions. The resulting document is a testament to the commitment of those involved to enhancing the quality of pharmacy practice in Australia.

This latest version of the PPS reflects the important role of pharmacists in the evolving healthcare sector. There is a renewed focus on patient-centred collaborative care, and importantly, new standards detail emerging professional activities such as vaccination and minor ailment services. The creation of four key streams in the document–Foundations of practice, Providing therapeutic goods, Providing health information and Delivering professional services–clearly highlights the breadth of professional roles and activities that contemporary pharmacists undertake. The standards have been endorsed by the Pharmacy Board of Australia.

We sincerely thank and acknowledge the work of all those involved in the review as part of the Project Advisory Group or Standards Review Groups, as well as the numerous pharmacists and professional bodies who provided feedback and advice in the public consultation period. These contributions have helped shape the PPS into a document that reflects both professional requirements of contemporary pharmacist practice, and expectations of Australian healthcare consumers.

To pharmacists across the profession, familiarise yourself with these standards and use them to assess and guide your practice as a means to optimising the contribution of the profession to improving the health of all Australians.



Grant Kardachi

Chair, Project Advisory Group

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The Pharmaceutical Society of Australia (PSA) thanks all those involved in the review process and, in particular, gratefully acknowledges the contribution of the following individuals and organisations.

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Abbreviations

AEFI	adverse event following immunisation
DAA	dose administration aid
PBS	Pharmaceutical Benefits Scheme
PBA	Pharmacy Board of Australia
PSA	Pharmaceutical Society of Australia
PPS	Professional Practice Standards
QUM	quality use of medicines
SOP	standard operating procedure
TGA	Therapeutic Goods Administration
WHS	work health and safety

About PSA

The Pharmaceutical Society of Australia (PSA) is recognised by the Australian Government as the peak national professional pharmacy organisation. It represents Australia's 29,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high-quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline healthcare professionals.

PSA is also a registered training organisation, and offers qualifications including certificate- and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Introduction

Purpose and scope of the standards

Pharmacists in Australia are facing new and evolving challenges related to an increasingly complex healthcare system. In addressing these challenges, it is paramount that pharmacists practise ethically and professionally at all times, and know how to respond to the specific needs of individuals and the community. Ethical, professional practice is central to PSA's vision of "improving our nation's health through excellence in the practice of pharmacy".

The PSA's Professional Practice Standards (PPS) articulate the expected standards of professional behaviour of pharmacists in Australia. Pharmacists have an ethical and legal commitment to the community to ensure safe and effective delivery of pharmacy services; the PPS enable the profession to qualitatively and quantitatively measure the commitment to the quality and reliability of healthcare services and products.

The PPS underpin the professional practice of all pharmacists in Australia, regardless of the role, scope, level or location of practice:

- For those **entering** or **planning to return** to the profession, the PPS identify the basic professional requirements of pharmacist care, and serve as a source of education and reflection.
- For those **within** the profession, the PPS serve as a basis for pharmacists to monitor their own professional conduct and that of their colleagues, and encourage involvement in professional services.
- For those **outside** the profession, the PPS provide guidance for assessing or learning about the minimum professional conduct expected of pharmacists.

Note that the Pharmacy Board of Australia's (the Board's) definition of 'practice' (adapted below) applies to the context of the PPS.[2]

> *To practise as a pharmacist means undertaking any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. Practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.*

The Board endorses the PPS. It advises pharmacists to consider the relevance of the PPS to their own professional practice and to be guided by appropriate standards of the PPS, in the context of relevant legislation, codes, guidelines and other standards. In its role of public protection, the Board may refer to, or use, the PPS when considering complaints or notifications involving the conduct or behaviour of pharmacists. Breaches of these standards may result in notification to the Board.

Furthermore, compliance with PSA's *Code of Ethics* and PPS is a requirement for pharmacists to be able to dispense and supply medicines on the Pharmaceutical Benefits Scheme,[3,4] and is relevant to the delivery of professional services by pharmacists.

Relationship of the standards to other guidance documents

The PPS sit within a broader hierarchy of guidance underpinning and supporting the practice of pharmacists (see Figure 1).

Figure 1. Broad hierarchy of guidance and regulation of pharmacy practice

Commonwealth, state and territory legislation forms the foundation on which our practice is based. **Pharmacists must fulfil legal obligations at all times, and no part of the PPS must be interpreted as permitting a breach of the law or discouraging compliance with legal requirements**. If conflict arises between the legislation and these standards, legislative requirements must be adhered to.

The Board is the registering authority of pharmacists in Australia. The standards, guidelines and codes developed by the Board outline specific requirements for pharmacists to maintain their registration.

Further to our legal responsibilities, pharmacists are required to apply codes relevant to their practice. These may include the PSA *Code of Ethics for pharmacists*,[5] the Society of Hospital Pharmacists of Australia *Code of Ethics*[6] and the Medicines Australia *Code of Conduct*.[7] These codes state the principles by which pharmacists interact with patients, other healthcare professionals and the community when delivering pharmacy services.

The *National Competency Standards Framework for Pharmacists in Australia*[8] describes the skills, attitudes and other attributes (including values and beliefs) attained by an individual based on knowledge and experience that together enable the individual to practise effectively as a pharmacist.

In addition to competency, pharmacists must also focus on delivering services that are consistent and of a high quality. The PPS relate to the systems, procedures and information used by pharmacists to achieve a level of conformity and uniformity in their practice. They allow pharmacists to reflect on, and measure, their professional practice. They also serve as a self-assessment quality improvement tool for members of the profession to meet appropriate standards for the professional services they provide, and to make efficient and effective use of resources. There is an inherent assumption that pharmacists using the PPS are competent. Personal competence and the adoption of such standards are both required to ensure that professional services deliver optimal health outcomes.

Finally, practice guidelines can support pharmacists and their staff in the implementation of quality professional services. Practice guidelines are generally service- or activity-specific, and provide detailed information about how best to deliver services consistent with professional standards.

Each of these documents provides pharmacists with the guidance and framework required to practise pharmacy in a professional and ethical manner. This ensures that pharmacy services are delivered to expected standards, and benefit the health and wellbeing of patients.

Structure of the standards

The 16 individual standards in the PPS are grouped into streams – Foundations of Practice, Providing Therapeutic Goods, Providing Health Information and Delivering Professional Services – to promote clarity and help practitioners to navigate the document (see Figure 2).

The streams in the document are hierarchical. The two standards in the Foundations of Practice stream – Fundamental Pharmacy Practice, and Leading and Managing Pharmacy Practice – are overarching, and apply to all pharmacists, regardless of setting or scope of practice. The standards in the Providing Therapeutic Goods and Providing Health Information streams detail key functions of pharmacists relevant to the provision of activities and services covered by the standards in the Delivering Professional Services stream. The Collaborative Care standard applies to all other standards.

Individual standards are interrelated, with links made between standards that have similar criteria and actions. Each standard should be applied in conjunction with all related standards; any specific criteria or actions identified should be given particular consideration.

A comparison of the standards in version 4 (2010) and version 5 (2017) of the PPS is presented at Appendix 1.

Figure 2. Structure of the standards

Standard: The standard statement describes the expected professional behaviour of pharmacists in relation to an activity or service.

Background and scope: Background and scope provides background information to the standard, the context including the role of the pharmacist, relevant definitions and highlights where the standards should be used in conjunction with other standards.

Foundations of Practice

Standard 1: Fundamental Pharmacy Practice

The pharmacist displays professional and ethical behaviour, maintains the patient's right to privacy and confidentiality, and aims to achieve the quality use of medicines to promote health and wellbeing.

Background and scope

Pharmacy practice must be underpinned by professionalism and ethical behaviour, and should reflect principles of equity, patient-centred care, cultural safety, evidence-based practice and the quality use of medicines (QUM).This standard is relevant to all aspects of pharmacy practice across all healthcare settings. In the context of this standard, practice means "any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession" and "is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession".[1]

As a foundation standard, this standard should be used in conjunction with all other standards in this document, noting the broader hierarchy of guidance underpinning and supporting the practice of pharmacists (Figure 1, p. 7).

Criteria to achieve the Fundamental Pharmacy Practice Standard

Ethics and professionalism
Privacy and confidentiality
Cultural safety and health equality
Documentation
Continuity of care
Quality use of medicines
Evidence-based practice
Communication and collaboration
Patient-centred care

Standard 1: Fundamental Pharmacy Practice

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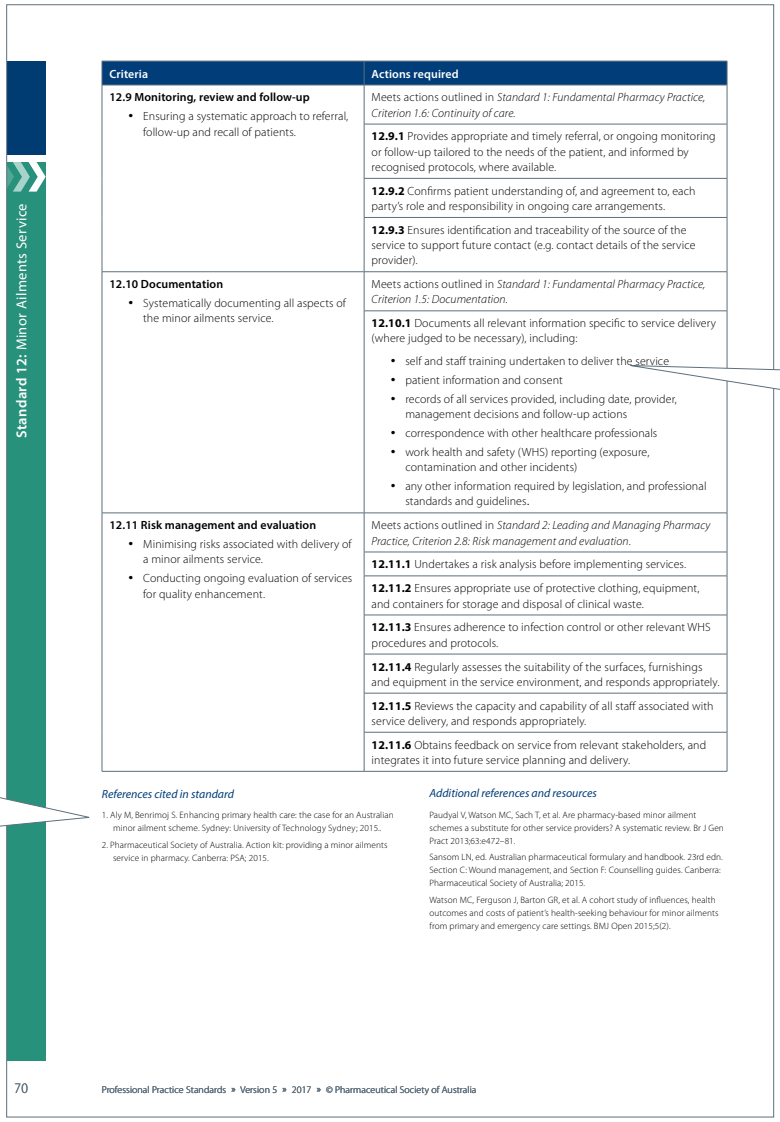
Stream: Four key streams have been developed based on professional roles and activities: **Foundations of Practice, Providing Therapeutic Goods, Providing Health Information** and **Delivering Professional Services**.

Overview of criteria: Criteria within individual standards are grouped into thematic areas.

As displayed by this schema, patient-centred care is central to the delivery of all activities and services.



Standard 12: Minor Ailments Service

Criteria	Actions required
12.9 Monitoring, review and follow-up • Ensuring a systematic approach to referral, follow-up and recall of patients.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	12.9.1 Provides appropriate and timely referral, or ongoing monitoring or follow-up tailored to the needs of the patient, and informed by recognised protocols, where available.
	12.9.2 Confirms patient understanding of, and agreement to, each party's role and responsibility in ongoing care arrangements.
	12.9.3 Ensures identification and traceability of the source of the service to support future contact (e.g. contact details of the service provider).
12.10 Documentation • Systematically documenting all aspects of the minor ailments service.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	12.10.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • self and staff training undertaken to deliver the service • patient information and consent • records of all services provided, including date, provider, management decisions and follow-up actions • correspondence with other healthcare professionals • work health and safety (WHS) reporting (exposure, contamination and other incidents) • any other information required by legislation, and professional standards and guidelines.
12.11 Risk management and evaluation • Minimising risks associated with delivery of a minor ailments service. • Conducting ongoing evaluation of services for quality enhancement.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	12.11.1 Undertakes a risk analysis before implementing services.
	12.11.2 Ensures appropriate use of protective clothing, equipment, and containers for storage and disposal of clinical waste.
	12.11.3 Ensures adherence to infection control or other relevant WHS procedures and protocols.
	12.11.4 Regularly assesses the suitability of the surfaces, furnishings and equipment in the service environment, and responds appropriately.
	12.11.5 Reviews the capacity and capability of all staff associated with service delivery, and responds appropriately.
	12.11.6 Obtains feedback on service from relevant stakeholders, and integrates it into future service planning and delivery.

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Criteria and actions: The standard is broken down into Criteria (left column) and Actions required (right column), which articulate to pharmacists the expected standard of professional practice, and guidance on how to meet that standard, respectively.

References and Resources: References cited in standard, and additional references and resources relevant to the standard are provided to assist application. All references and resources are current at the time of publication.

Terminology

Consistent terminology has been used in the PPS to promote clarity and understanding, and to align with related documents, including the *National Competency Standards Framework for Pharmacists in Australia* (2016) and the *Code of Ethics for Pharmacists* (2017). For a number of terms used in this version (version 5) of the PPS, several related terms with equivalent or similar meaning may be equally appropriate in certain contexts (see Table 1).

Table 1. PPS and equivalent or related terms

PPS term	Equivalent or related terms
Patient	Client, consumer, individual, person
Healthcare professional	Healthcare practitioner, healthcare provider, health professional
Healthcare record	Medication profile, medication record, patient profile, patient record
Setting	Environment, facility, service recipient For example, Aboriginal and Torres Strait Islander health service, Aboriginal Community Controlled Health Organisation, general practice, residential care facility, correctional facility
Medicine	Drug, medication, pharmacotherapy, preparation, product
Carer or authorised representative	Guardian, power of attorney

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Standard 1: Fundamental Pharmacy Practice

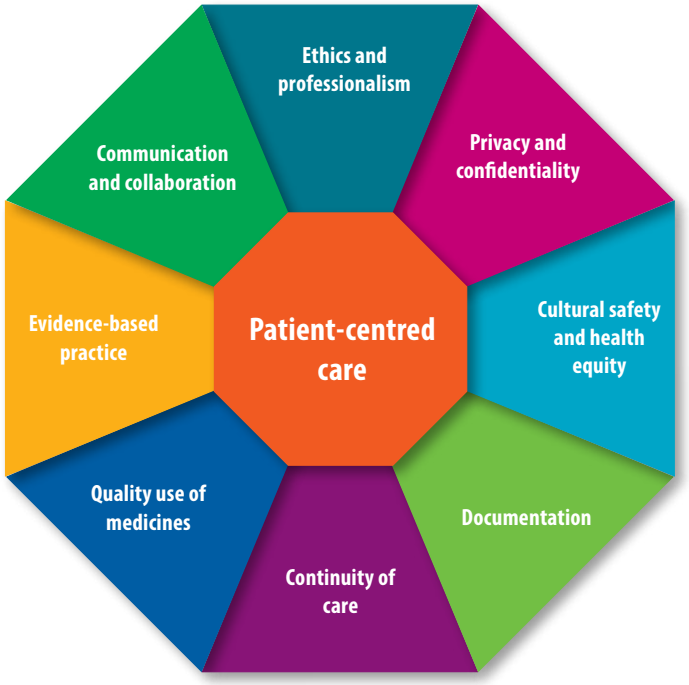
The pharmacist displays professional and ethical behaviour, maintains the patient's right to privacy and confidentiality, and aims to achieve the quality use of medicines to promote health and wellbeing.

Background and scope

Pharmacy practice must be underpinned by professionalism and ethical behaviour, and should reflect principles of equity, patient-centred care, cultural safety, evidence-based practice and the quality use of medicines (QUM).This standard is relevant to all aspects of pharmacy practice across all settings. In the context of this standard, practice means "any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession" and "is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession".[1]

As a foundation standard, this standard should be used in conjunction with all other standards in this document, noting the broader hierarchy of guidance underpinning and supporting the practice of pharmacists (Figure 1, p. 8).

Criteria to achieve the Fundamental Pharmacy Practice Standard



Standard 1: Fundamental Pharmacy Practice

Criteria	Actions required
1.1 Patient-centred care • Recognising the cultural diversity of all Australians, including Aboriginal and Torres Strait Islander people. • Ensuring that patient and community health needs, including cultural needs, are foremost in the delivery of care. • Delivering holistic healthcare solutions.	**1.1.1** Determines specific health needs, including cultural needs, of the patient and/or community, and ensures that services are adaptable and responsive.
	1.1.2 Considers patient health needs and preferences to optimise integration of service delivery.
	1.1.3 Responds to patients, authorised representatives and other healthcare professionals in a timely manner to ensure that the needs of patients and community are met in a consistent manner.
	1.1.4 Documents and responds appropriately when services are provided, when services are refused or when a patient complains.
	1.1.5 Respects patient autonomy and facilitates patient participation in decision making with regard to their healthcare needs.
1.2 Ethics and professionalism • Incorporating relevant codes of professional conduct into everyday practice. • Encouraging co-workers and colleagues to adopt equivalent behaviour. • Managing conflicts of interest ethically.	**1.2.1** Understands and upholds relevant codes of ethics and codes of conduct.
	1.2.2 Ensures that pharmacy services are delivered to patients in accordance with appropriate codes; guidelines; and legal, ethical and professional standards.
1.3 Privacy and confidentiality • Maintaining privacy and confidentiality of the patient. • Practising in accordance with current privacy legislation. • Managing documentation and systems with regard to patient privacy and confidentiality. • Obtaining informed patient consent and exercising duty-of-care requirements.	**1.3.1** Provides a setting for information exchange and service delivery that is appropriate to the patient.
	1.3.2 Obtains informed consent before delivery of services, including consent for how data will be stored and used.
	1.3.3 Confirms continued consent before sharing information with other healthcare professionals.
	1.3.4 Considers role of data and reporting to support and enhance individualised patient care, ensuring that patient interests outweigh potential commercial interests.
	1.3.5 Ensures appropriate access to, and use of, shared patient records.
	1.3.6 Ensures the secure storage, appropriate management and destruction of confidential documentation.
	1.3.7 Transparently documents, and informs affected parties of, instances where patient privacy and confidentiality are breached, and reviews processes to implement preventive measures.
1.4 Cultural safety and health equity • Recognising and responding to the specific health needs of Aboriginal and Torres Strait Islander people, and other populations identified as experiencing healthcare inequity. • Ensuring that all individuals are treated with respect, and consideration of their beliefs, cultures and practices. • Delivering health care equitably. • Conducting regular review of self, co-workers and the workplace for cultural and social responsiveness.	**1.4.1** Consults with the patient to offer tailored healthcare services and information that are consistent with their cultural and social beliefs and needs.
	1.4.2 Recognises and respects the cultural diversity of the patient using healthcare services.
	1.4.3 Supports principles of equity in the delivery of healthcare services by self, co-workers and colleagues.
	1.4.4 Seeks to promote cultural safety, responsiveness and equity in service delivery and the practice environment.

Criteria	Actions required
1.5 Documentation • Completing and maintaining all required documentation for services provided, including relevant documentation required by specific practice settings. • Facilitating secure, timely and accurate information transfer between the patient and all members of the healthcare team. • Supporting the use of patient healthcare plans or patient-managed records. • Fulfilling documentation requirements for internal and external quality and evaluation processes. • Developing and documenting a medication management plan for patients under their care. See Appendix 2: Patient healthcare plan.	**1.5.1** Requests access to relevant patient health information before service delivery.
	1.5.2 Documents patient consent before provision of service, or transfer of related service information to members of the patient's healthcare team.
	1.5.3 Systematically documents the service provided to the patient or setting. Includes relevant patient health history, problems identified, actions taken, date and details of contact with other healthcare professionals, and the outcomes of the actions.
	1.5.4 Stores records safely, securely and in a dedicated location.
	1.5.5 Ensures that all documentation for services provided is current, accurate and accessible to designated members of the healthcare team.
	1.5.6 Optimises the storage and accessibility of relevant documentation required by legislation.
	1.5.7 Where appropriate (e.g. clinical need, duty of care, professional judgement), records conversations involving the patient, authorised representatives, healthcare professionals and the setting on issues such as improving quality use of medicines, the health system, service outcomes, and patient health care.
	1.5.8 Employs the most appropriate mode of delivery to facilitate secure, timely and accurate information transfer between the patient and all members of the healthcare team.
	1.5.9 Supports the use of patient-held or patient-managed records through patient education and access to initiatives.
	1.5.10 Documents feedback and recommendations provided by patients and other stakeholders regarding pharmacists' practice and services, with transparent reporting of actions and outcomes.
	1.5.11 Documents referrals and sharing of information in a way that facilitates ongoing communication, clinical review and reflection. See Appendix 3: Template referral letter.
1.6 Continuity of care • Empowering patients to be active participants in, and responsible guardians of, their own health care, thereby supporting the continuity of their health care. • Ensuring that information transfer is timely, accurate and aimed at optimising patient health outcomes.	**1.6.1** Enables patients to take responsibility for their health care by assisting them to develop medication records and/or healthcare plans.
	1.6.2 Facilitates streamlined transfer of information between relevant healthcare professionals and upholds duty-of-care requirements in the process. See Appendix 4: Process for managing transitions of care.
	1.6.3 Facilitates appropriate alternative access to healthcare services not provided, including in circumstances of conscientious objection, and when products are out of stock or not stocked.
	1.6.4 Maintains knowledge of relevant healthcare and other services available locally, and instigates patient referral, where appropriate. See Appendix 8: The healthcare team.

Criteria	Actions required
1.7 Quality use of medicines • Promoting judicious, safe and effective use of medicines at all times. • Promoting optimal use of all health resources and therapeutic goods through careful selection, appropriate instruction and regular evaluation of intended impact.	**1.7.1** Systematically collects, interprets and analyses relevant patient information using a variety of sources (e.g. medication history, discharge medication), and considers risks, benefits and patient preferences to determine appropriate treatment options.
	1.7.2 Actively engages the patient in informed decision making by providing evidence-based advice on available pharmacological, non-pharmacological and lifestyle management choices.
	1.7.3 Monitors patient adherence and persistence patterns, and uses this information in conjunction with clinical expertise to encourage patients to set achievable health goals. Regularly checks for patient understanding. See Appendix 5: Adherence assessment tool.
	1.7.4 Evaluates patient progress against set health goals, and monitors health outcomes of therapeutic goods and services.
	1.7.5 Facilitates periodic patient follow-up and, where appropriate, recommends alternative management options or referral.
1.8 Evidence-based practice • Providing current, relevant and evidence-based information about therapeutic goods and services. • Translating evidence-based information to be appropriate to the audience.	**1.8.1** Consults a wide range of evidence-based resources and professional guidelines in accordance with principles for the quality use of medicines, to formulate patient-centred solutions.
	1.8.2 Accesses, interprets and clearly translates clinical evidence of patient benefit for current and emerging therapeutic goods, services and health information, using a variety of modes of delivery.
	1.8.3 Communicates the evidence for the use of therapeutic goods clearly and transparently.
1.9 Communication and collaboration • Practising and facilitating teamwork. • Supporting and encouraging adaptability in roles within the immediate team and the wider healthcare team. • Developing collaborative relationships with other healthcare professionals to support team-based delivery of health care. • Communicating effectively within and across sectors for optimal patient and community health outcomes. • Communicating professionally with patients, authorised representatives, healthcare team members and other healthcare professionals.	**1.9.1** Cultivates a team-based approach to patient and community health care within the immediate workplace, local community, healthcare sector and other related sectors.
	1.9.2 Facilitates collaboration among members of the healthcare team and other healthcare professionals, with the primary aim of optimising patient health outcomes (e.g. Health Care Homes).
	1.9.3 Cultivates a work environment that supports and engenders teamwork built on trust. Endeavours to uphold the principles of teamwork with patients at the centre.
	1.9.4 Encourages the healthcare team to identify and address lifelong learning requirements (specific to communication, professionalism and teamwork), and supports required education and training needs of all team members and self.
	1.9.5 Reviews self, the team and the wider healthcare team on a regular basis to ensure that skill mix, competence and qualifications are adequate for current and emerging service requirements.
	1.9.6 Uses available data and technologies (e.g. real-time reporting) to support clinical decision making by self and other healthcare professionals.
	1.9.7 Communicates and collaborates effectively with other healthcare professionals to ensure that the patient has appropriate and ongoing access to healthcare services.

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Standard 2: Leading and Managing Pharmacy Practice

The pharmacist shows leadership in organising and managing the sustainable use of health resources for optimal patient health outcomes.

Background and scope

Leading and managing pharmacy practice highlights the importance of a profession that is agile and can respond to rapid change in the increasingly complex health system to deliver optimal patient care. A shared vision, shared leadership, systems thinking, clear policies, workforce development, and a sustainable and ethical transformational change culture[1] are required to achieve global healthcare reform.[2–4]

As key members of the healthcare team, pharmacists can contribute to a patient-centred, strong, flexible and adaptable healthcare workforce.[3] Pharmacists must invest in a new paradigm for pharmacy practice.[5] This will require coordinated leadership and management. Leadership involves compassion and empathy; shared vision; and the ability to share decisions, communicate and manage effectively.[3,5]

Professional development described in this standard refers to the pharmacist's role in supporting and contributing to the ongoing development of the current and future pharmacy workforce. Standard 7: Health Promotion and Education, on the other hand, relates to the provision of education to patients, authorised representatives, communities and other healthcare professionals.

This standard applies to all aspects of pharmacy practice across all practice settings. As a foundational standard, it is to be applied in conjunction with all other standards in this document, as well as codes of ethics, competency standards and professional practice guidelines.

Criteria to achieve the Leading and Managing Pharmacy Practice Standard

Standard 2: Leading and Managing Pharmacy Practice

Criteria	Actions required
2.1 Shared vision and leadership • Recognising that everyone has leadership capacity and the potential to be a powerful contributor. • Encouraging shared leadership and appropriate task delegation. • Creating a culture of accountability; responsibility; and pride in the profession, professional services, and relationships with patients and the community. • Managing health goals and associated projects (at the patient and community levels).	**2.1.1** Facilitates the contribution of the patient and all members of their healthcare team to achieve agreed health outcomes.
	2.1.2 Enables team members to take ownership, responsibility and accountability for their contributions.
	2.1.3 Delegates responsibly and ethically, with consideration of each individual's capacity (time and resources), competence, willingness, reliability and integrity.
	2.1.4 Initiates or encourages others to plan, manage, implement, review and integrate their work to achieve predefined success criteria.
	2.1.5 Works with team members to ensure that planned objectives align with relevant organisational and professional strategies.
	2.1.6 Ensures that appropriate governance and guidance are available to staff, students, interns and others in the work environment.
2.2 Transformational change • Advocating and facilitating appropriate change. • Leading by example. • Encouraging the healthcare team and other healthcare professionals to be change makers and innovators, and practise to the full breadth of their scope.	**2.2.1** Creates a safe environment for feedback, evaluation, discussion, sharing of ideas and improvement of services.
	2.2.2 Builds trust with patients, within the immediate team, and across healthcare teams and other relevant sectors.
	2.2.3 Engages team members to formulate a clear vision for goals and strategies for healthcare delivery. Meets to identify and review goals regularly.
	2.2.4 Critically appraises and evaluates services, strategies and methods of delivery, and considers principles of best practice for current and future service requirements.
	2.2.5 Considers, and is empathetic to, the needs and perspectives of all parties. Exercises a patient, yet persistent, approach to desired action for desired outcomes.
2.3 Professional development • Taking responsibility and accountability for own service delivery. • Ensuring that knowledge and skills of self and the team are sufficient to deliver current and emerging healthcare services. • Managing staff performance. • Participating in, and contributing to, professional development strategies (education and training) to improve current and future professional practice. • Ensuring that contracts with third-party providers support the safety of all parties in service provision. • Contributing to development of the healthcare team and healthcare delivery.	**2.3.1** Self-assesses own knowledge, skills and attitudes (competence) to construct, complete and review a continuing professional development plan relevant to the scope of practice, to inform additional learning and training needs.
	2.3.2 Works with a mentor for peer review of practice or to assist in meeting professional development goals.
	2.3.3 Allocates or encourages staff to work with suitable mentors for professional development requirements.
	2.3.4 Supports implementation of a formal process for goal setting and recognising the achievement of professional development goals.
	2.3.5 Ensures that goal setting and employer expectations are consistent, and linked to transparent financial promotion and increased responsibilities.
	2.3.6 Supports team members to self-assess against standards and, if necessary, upskill in the context of service delivery.
	2.3.7 Responds to the health literacy and digital literacy needs of self and team, to optimise safe and effective service delivery.

Criteria	Actions required
2.3 Professional development (continued)	**2.3.8** Creates a culture of lifelong learning, and recognises contributions of students, interns and peers in all mentoring opportunities.
	2.3.9 Contributes to, and participates in, professional development, resource development and educational programs for the profession, locally and nationally.
	2.3.10 Implements formal performance management processes to optimise the skills mix of staff or those under the pharmacist's direct supervision.
2.4 Systems thinking and governance • Developing, evaluating and improving systems. • Considering the people, process and tools, and the specific relationships between them, to safely deliver pharmacy services to patients. • Considering all components of a system and interrelated systems from a big-picture perspective to ensure integrated healthcare delivery. • Sharing responsibility and accountability for continuous quality improvement to foster excellence in patient care.	**2.4.1** Creates and uses efficient, effective and user-friendly systems in practice.
	2.4.2 Organises all elements of an appropriate system, including people, processes and tools, and optimises these for safe and consistent health outcomes for the patient and communities.
	2.4.3 Determines whether systems need to be linked within the immediate environment or with external and related services.
	2.4.4 Communicates and collaborates with other healthcare professionals to streamline services and systems.
2.5 Policy and procedures • Developing, evaluating, endorsing, and practising in accordance with, workplace and professional policies and procedures. • Confirming that all legislative, professional indemnity insurance and workplace insurance requirements are met before services are delivered.	**2.5.1** Uses appropriate professional and workplace policies, procedures and guidelines.
	2.5.2 Regularly appraises relevant policies, procedures and guidelines to ensure their currency and applicability to context.
	2.5.3 Provides prompt feedback to organisations or individuals, as appropriate, in response to inadequacies or the potential for improvement in policies, procedures and guidelines.
	2.5.4 Identifies potential or existing risks to service delivery or patient safety, and develops appropriate policies, procedures and guidelines for the workplace in response.
	2.5.5 Provides appropriate education to the team to ensure that policies, procedures and guidelines are embedded into practice.
	2.5.6 Actively monitors own practice and that of others under direct supervision for adherence to policies and procedures, and responds appropriately.
	2.5.7 Maintains insurance appropriate for the delivery of all pharmacy services provided.
	2.5.8 Ensures that a contract with third-party providers exists that: • provides a clear definition of the roles and responsibilities of each provider • specifies the start date and end date of the arrangement • includes a risk assessment of the arrangement or service • nominates an agreed communication method, and other relevant expectations and requirements • is consistent with Pharmacy Board of Australia guidelines.

Criteria	Actions required
2.6 Work environment • Managing the work environment for self, people under direct supervision and patients. • Ensuring that the work environment is safe and appropriately resourced. • Maintaining a work environment that reflects professional practice and patient-centred services, and projects a professional image of quality service delivery. • Meeting Pharmacy Board of Australia requirements for third-party providers.	**2.6.1** Delivers services only with appropriate workforce capacity and resources, and in accordance with local practice and legislative requirements.
	2.6.2 Optimises the service environment for vulnerable patient groups (e.g. dementia patients).
	2.6.3 Ensures access and use of a private area or appropriate service environment to maintain patient privacy and confidentiality.
	2.6.4 Determines and allocates resources required for delivery of healthcare services within, or directly relevant to, scope of practice (of self, team and healthcare team).
	2.6.5 Enhances the breadth of healthcare services available to patients by identifying local needs of the community and responding through provision of services or working with suitable healthcare professionals to facilitate access.
	2.6.6 Ensures that all services delivered within the practice environment are consistent with the role of pharmacists.
	2.6.7 Manages risks associated with third-party services provided within the practice environment, including by confirming that third-party providers are appropriately qualified to deliver that service.
	2.6.8 Manages risk and enacts risk assessment in line with state or territory work health and safety (WHS) requirements.
2.7 Resource management • Managing service and business requirements. • Allocating, and monitoring use of, resources, staffing, human resources and documentation. • Balancing the cost and quality of services to promote the sustainable use of healthcare resources.	**2.7.1** Plans, uses, evaluates and systematically documents the use of healthcare and pharmacy resources.
	2.7.2 Manages and reports against quality and risk associated with service delivery and related business practices (e.g. WHS, financial, legal).
	2.7.3 Conducts regular financial and quality reviews to guide the efficient, effective and sustainable use of healthcare and pharmacy resources.
2.8 Risk management and evaluation • Implementing systems to reduce or manage risk. • Considering credentialing and training requirements of third-party providers. • Evaluating services with independent feedback. See Appendix 6: The plan-do-study-act cycle.	**2.8.1** Undertakes a risk analysis before implementing services.
	2.8.2 Ensures appropriate use of protective clothing, equipment, and containers for storage and disposal of waste.
	2.8.3 Appropriately disposes of confidential documentation, medicines, clinical waste and other consumables.
	2.8.4 Ensures adherence to infection control and other relevant WHS procedures and protocols.
	2.8.5 Regularly assesses the suitability of the surfaces, furnishings and equipment in the service environment, and responds appropriately.
	2.8.6 Reviews the capacity and capability of all staff and third-party providers associated with service delivery, and responds appropriately.
	2.8.7 Obtains feedback on the service from relevant stakeholders, and integrates it into future service planning and delivery.

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Standard 3: Dispensing and Other Supply Arrangements

The pharmacist ensures that all dispensed and supplied therapeutic goods and associated pharmacy services reflect the prescriber's intentions, and are consistent with the quality use of medicines and the patient's health goals and values.

Background and scope

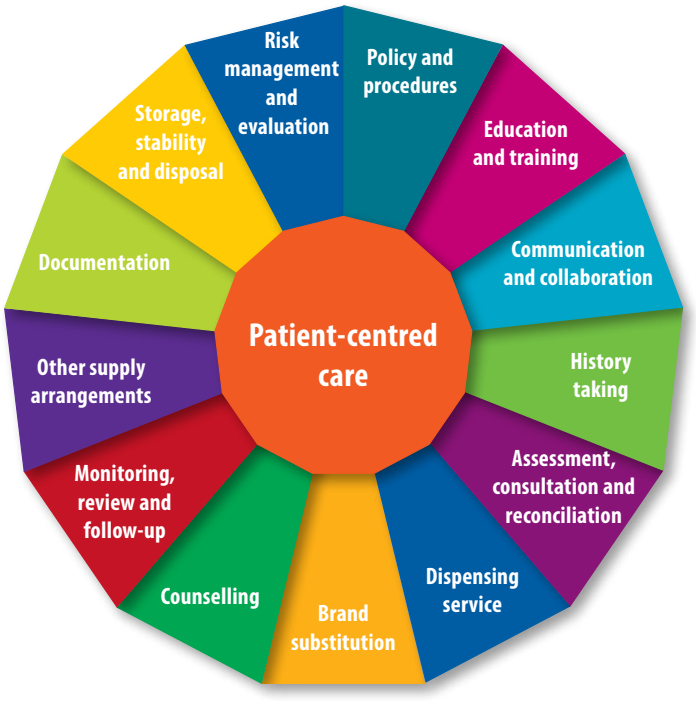
Good dispensing and supply practices are required to ensure the safe provision of prescription medicines and devices,[1] and should reflect and uphold the principles of quality use of medicines.

For the purposes of this standard, dispensing is "the review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient".[2] Other supply arrangements may include provision of dose administration aids for residents in residential care facilities, supply of imprest stock to a hospital ward, supply of pharmacotherapy to correctional facilities or staged supply of medicines.

This standard applies to pharmacists dispensing or otherwise supplying prescription medicines, or supervising other pharmacy staff involved in these processes. In accordance with their training and experience, pharmacy technicians may perform dispensing tasks, including data entry, medicine selection, labelling and assembly. However, a pharmacist must be responsible for assessing the suitability of the medicines (taking into account the full patient history), the final check of dispensed medicines and patient counselling (unless otherwise stated by legislation).

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 8: Counselling, Standard 13: Disease State Management and Standard 16: Harm Minimisation, as well as relevant professional practice guidelines.

Criteria to achieve the Dispensing and Other Supply Arrangements Standard



Standard 3: Dispensing and Other Supply Arrangements

Criteria	Actions required
3.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
3.2 Policy and procedures • Upholding all appropriate standards, guidelines and regulatory requirements (in accordance with legislation) in the dispensing process.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	3.2.1 Follows a systematic and safe approach to dispensing of products, as required by Pharmacy Board of Australia guidelines.
	3.2.2 Ensures that all services align with relevant clinical guidelines and program guidelines.
	3.2.3 Reviews all services to ensure compliance with relevant legislative requirements.
	3.2.4 Maintains a standard operating procedure, which includes: • elements of service delivery (e.g. collection of patient information, safe handling and administration, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment, and risk management and evaluation of the service.
	3.2.5 Adheres to relevant legislation in supervision of others in the dispensing process, as required.
	3.2.6 Ensures that appropriate contracts exist for other supply arrangements to healthcare settings.
	3.2.7 Defines the roles and responsibilities of all parties involved in other supply arrangements.
3.3 Education and training • Ensuring that pharmacy staff involved in dispensing or stages of the dispensing service and other supply arrangements have adequate training relevant to their role.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development*.
	3.3.1 Directs and educates the team involved in dispensing and associated services to refer to a pharmacist when necessary.
	3.3.2 Supports and educates pharmacy team members to follow a systematic procedure for gathering relevant information from the patient, facility or healthcare environment.
	3.3.3 Provides regular education and training to staff on dispensing processes, which is consistent with contemporary evidence and best-practice guidelines.
3.4 Communication and collaboration	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.9: Communication and collaboration*.
3.5 History taking • Ensuring a thorough, accurate and systematic approach to history taking. • Identifying the most appropriate time(s) in the dispensing process to take a history or repeat history taking. • Considering the reliability of the patient (or third party) as an accurate historian. • Documenting essential information. • Collecting or obtaining access to minimum essential information, including current prescription and non-prescription medicines, health conditions, allergies, adverse effects and patient preferences.	**3.5.1** Establishes a patient healthcare record (profile).
	3.5.2 Collects or accurately records sufficient patient details, and a complete medication and health history in the record to optimise service provision and ensure a safe dispensing process.
	3.5.3 Collects or accurately records any special needs of the patient in their profile so that counselling and associated resources are tailored accordingly.
	3.5.4 Assesses factors likely to influence reliability of information source(s), and responds appropriately if uncertainty exists.
	3.5.5 Checks the dispensing history and/or electronic healthcare record to determine appropriateness of new medicines.

Criteria	Actions required
3.5 History taking (continued)	**3.5.6** Gathers and reviews all available information to identify factors likely to influence the action or effect of prescribed medicines, and/or patient health outcomes, including: • current medicines (prescription, non-prescription, complementary, other) • disease states (including pregnancy or lactation status) • lifestyle factors (e.g. alcohol intake, smoking) • adverse drug reactions (allergies or other).
	3.5.7 Confirms that all health and medicines information, and healthcare plans are current and accurate.
	3.5.8 Confirms recent transitions in care, and (with patient consent) contacts the most recent health setting or healthcare professional responsible for the patient's care to confirm current medicines, allergies and medical conditions. See Appendix 4: Process for managing transitions of care.
	3.5.9 Prompts the patient to disclose all current medicines (e.g. medicines from health food store, supermarket, service station).
	3.5.10 Considers potential drug interactions every time a medicine is dispensed.
3.6 Assessment, consultation and reconciliation • Tailoring dispensing and other supply arrangement services to the individual patient. • Reconciling all available information to confirm optimisation of patient treatment.	**3.6.1** Gathers relevant patient information from all available sources.
	3.6.2 Uses current information pertaining to clinically significant interactions, contraindications, precautions and disease states.
	3.6.3 Consults with the patient, carer or authorised representative, and other healthcare professionals involved in the patient's care to ensure that advice is consistent with patient goals and will optimise patient health outcomes.
	3.6.4 Synthesises all the available information and uses informed professional judgement to formulate and present the most appropriate treatment option(s) to the patient.
3.7 Dispensing service • Implementing systems of good dispensing practice. • Using a systematic approach to all activities associated with the dispensing of medicines, from prescription receipt to supply and follow-up. • Ensuring clear delegation of roles and responsibilities of all members of the pharmacy team to enable a timely, safe and sequenced dispensing process and provision of therapeutic goods. • Responding to issues in continuity of care by offering alternatives where stock shortages or supply issues exist.	**3.7.1** Employs a systematic dispensing procedure as required by Pharmacy Board of Australia guidelines.
	3.7.2 Implements, checks and maintains dispensing software, systems or robots used throughout the dispensing process.
	3.7.3 Checks that dispensing software and systems are designed and maintained to capture and collate essential patient information and medicines throughout the dispensing process.
	3.7.4 Complies with legislation specific to particular supply arrangements (e.g. PBS, continued dispensing, emergency supply, clozapine, mifepristone, medicinal cannabis, opioid substitution therapy).
	3.7.5 Ensures that dispensing processes align with professional guidelines and principles of quality use of medicines (QUM).
	3.7.6 Ensures that dispensing processes are safe, timely and optimised for the patient, and for staff involved in the delivery of dispensing and associated services.
	3.7.7 Reconstitutes prescribed medicines, where required, according to manufacturers' instructions.
	3.7.8 Implements processes (e.g. barcode scanning) to ensure optimised and safe dispensing practices and a coordinated team effort.
	3.7.9 Implements and uses systems that prompt follow-up of patients requiring ongoing care or specific follow-up.
	3.7.10 Ensures adequate training and constant review of staff involved in dispensing.

Criteria	Actions required
3.8 Brand substitution • Considering the substitutability of prescribed therapeutic goods. • Obtaining informed consent from the patient before substitution. • Substituting therapeutic goods in a manner consistent with regulations, patient safety and optimal health outcomes. • Establishing the health literacy of individuals, determining appropriateness of substitution, and tailoring information on substitution accordingly. • Contributing to the responsible and sustainable use of medicines.	**3.8.1** Ensures that the patient fully understands the nature of substitution and has adequate opportunity to contribute to the decision before it occurs.
	3.8.2 Confirms that the 'not for substitution' box has not been selected by the prescriber on the original prescription before offering substitution to the patient.
	3.8.3 Follows a process to inform patients when brand substitution is permitted and available, and consistent with the patient's existing healthcare plan.
	3.8.4 Considers appropriate strategies and applies clinical judgement to minimise medication misadventure and patient confusion, to promote optimal health outcomes.
	3.8.5 Substitutes only when the patient has provided informed consent and substitutability has been confirmed by the pharmacist (e.g. permitted by regulation, bioequivalence or biosimilarity has been established, substitution is consistent with patient safety and optimal health outcomes).
	3.8.6 Records in the dispensing history or patient healthcare plan and on the medicine label when initial brand substitution occurs.
	3.8.7 Ensures that any substitution is directly, clearly and appropriately discussed and/or demonstrated with the patient in the counselling process.
	3.8.8 Creates awareness about the availability and appropriateness of brand substitution, and the contribution it makes to the sustainable use of health resources.
3.9 Counselling	Meets actions outlined in *Standard 8: Counselling*.
3.10 Monitoring, review and follow-up • Ensuring meaningful and quality engagement with all patients and members of their healthcare team. • Identifying and acting to address the needs of the patient. • Instigating referral or follow-up arrangements. See Appendix 3: Template referral letter.	**3.10.1** Monitors patient(s) to determine whether medications and healthcare services are being optimised.
	3.10.2 Identifies at-risk patients in need of referral and/or follow-up services.
	3.10.3 Offers or facilitates follow-up with self or other appropriate healthcare professionals.
	3.10.4 Educates patients to facilitate access to other relevant services.
	3.10.5 Responds to identified needs of the patient.
	3.10.6 Recognises when care is outside the pharmacist's scope, and refers the patient to other appropriate healthcare professionals or healthcare services accordingly.
	3.10.7 Documents referral and follow-up actions, including recording them as clinical interventions, where appropriate.

Criteria	Actions required
3.11 Other supply arrangements • Considering the specific needs of the setting, healthcare professionals and patients, as relevant. • Communicating on a regular basis with the setting to ensure that supply arrangements are consistent with service needs. • Ensuring optimal supply and storage arrangements for therapeutic goods. • Maintaining service processes to support timely, safe and consistent supply arrangements. • Monitoring and mitigating risks associated with other supply arrangements.	**3.11.1** Implements systems that enable the sustainable supply, disposal and use of health resources, including systems designed to enhance stock control, storage and access to therapeutic goods.
	3.11.2 Follows a documented process when a patient under their care or contract arrangement is transferred between settings, to allow timely access to medicines.
	3.11.3 Dispenses medications for patients in response to a prescription order in accordance with the contractual arrangements with the health setting.
	3.11.4 Ensures that a process is in place for supplying medicines for stock in response to a requisition from the facility, in accordance with contractual (or other agreed) arrangements.
	3.11.5 Takes appropriate steps to ensure that indirect provision arrangements will not lead to harm, loss or inappropriate use of medicines.
	3.11.6 Liaises with appropriate staff to address issues relating to medicines administration.
	3.11.7 Supports the setting to maintain medicines safety and stock control systems.
	3.11.8 Liaises with the setting to ensure that all medicines are stored in accordance with legislative and manufacturers' requirements.
3.12 Documentation • Supporting the patient to maintain a current medication record and/or healthcare plan. • Documenting all significant exchanges with patients or their authorised representatives. • Recording clear justification when professional judgement and advice to the patient or decision making throughout the dispensing process are not consistent with the prescriber's initial intentions. • Maintaining stock availability records to support ordering for consistent access to medicines.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	3.12.1 Applies a documented procedure to detect and appropriately address excessive supply, fraudulent prescriptions and adherence issues.
	3.12.2 Documents on the prescription and in the dispensing history or healthcare plan all communication with the prescriber about prescriptions, medicines and patient health issues.
	3.12.3 Documents on the prescription and in the patient profile or healthcare plan, where possible, all changes to the treatment regimen authorised by the prescriber.
	3.12.4 Documents all instances when medicines or health advice are offered to a patient, including when they are declined.
	3.12.5 Uses software to record the details of responsible individuals involved in the dispensing process, to facilitate process evaluation and patient recall.
	3.12.6 Documents and highlights all known and suspected adverse drug reactions, contraindications and precautions relevant to the patient's current presentation and prescription order.
	3.12.7 Documents all clinical interventions detected and acted on throughout the dispensing process.
	3.12.8 Submits details of patient adverse drug reactions to the appropriate regulatory reporting body through approved systems.
	3.12.9 Ensures that documentation procedures and systems support QUM, optimised use of resources, and patient referral to other pharmacy and healthcare services.
	3.12.10 Maintain a list of preferred suppliers for immediate reference.

Criteria	Actions required
3.13 Storage, stability and disposal • Maximising the stability of medicines throughout the dispensing and delivery process, and giving advice to patients, authorised representatives or facilities on end-use conditions.	**3.13.1** Adheres to evidence-based information sources to meet storage and stability requirements of medications (e.g. cold chain, protection from light or moisture), and follows documented procedures, if required.
	3.13.2 Adheres to best-practice guidelines to inform decisions surrounding pre-use (source and storage), re-use and disposal of medicines.
	3.13.3 Disposes of medicines responsibly according to relevant legislation, considering environmental impact, sustainability principles and best-practice guidelines (e.g. return unwanted medicines (RUM) bins).
3.14 Risk management and evaluation	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*

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Supplementary information: other supply arrangements

Pharmacists must comply with rules and regulations that apply to the particular medicine supply arrangement being implemented. The most common scenario is the dispensing of items subsidised through the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). However, PBS (or RPBS) dispensing can involve extended or alternative supply arrangements, and there are also other (non-PBS) supply arrangements. Some examples are provided below (the list is not exhaustive).

Section 100 items

Under section 100 of the ***National Health Act 1953***, a number of medicines are available as PBS items but under alternative arrangements:

Highly Specialised Drugs Program (e.g. HIV antiretroviral therapies, medicines used in the treatment of hepatitis B and clozapine) – see www.pbs.gov.au/info/browse/section-100/s100-highly-specialised-drugs

Efficient Funding of Chemotherapy – see www.pbs.gov.au/info/browse/section-100/chemotherapy

Botulinum Toxin Program – see www.pbs.gov.au/info/general/changes-to-certain-s100-programs

Growth Hormone Program – see www.pbs.gov.au/browse/section100-gh and www.pbs.gov.au/general/changes-to-certain-s100-programs/faqs-growth-hormone-1-sept-2015.pdf

In Vitro Fertilisation Medicines Program – see www.pbs.gov.au/browse/section100-if and www.pbs.gov.au/general/changes-to-certain-s100-programs/revised-faqs-ivf-medicines-25-june-2015.pdf

Opiate Dependence Treatment Program – see www.pbs.gov.au/browse/section100-md

Closing the Gap for PBS prescriptions

The Closing the Gap (CTG) PBS Co-payment Measure helps an Aboriginal or Torres Strait Islander Australian with chronic disease or at risk of chronic disease to obtain most prescription medicines at a lower price, or free of charge (with a Health Care Card). The prescriber assesses eligibility for the scheme and arranges registration. Prescriptions written under this measure are referred to as CTG prescriptions, and the normal PBS prescription requirements apply. Pharmacists need to:

- indicate in the dispensing software that a CTG prescription is being dispensed
- check that prescriptions are correctly annotated by the prescriber
- ensure that the CTG annotation code is keyed for each prescription being dispensed.

More information is available at https://www.humanservices.gov.au/health-professionals/enablers/education-guide-closing-gap-pbs-co-payment-measure-supporting-indigenous-health

Dextropropoxyphene

The registration and supply of dextropropoxyphene-containing products, *Di-Gesic* and *Doloxene*, are subject to specific conditions – for more information, see:

- www.tga.gov.au/alert/dextropropoxyphene-pain-killers-containing-dextropropoxyphene-di-gesic-and-doloxene
- www.tga.gov.au/alert/dextropropoxyphene-questions-and-answers
- www.psa.org.au/downloads/ent/uploads/filebase/guidelines/member-only-guidelines/guidance-di-gesic%20and%20doloxene.pdf

To view a copy of the Prescriber confirmation form, see https://aspenpharmacare.box.com/shared/static/iwt13v07nmsadfihz6qb.pdf

Accessing unapproved products

- Special Access Scheme – this arrangement provides patient access to medicines that are not on the Australian Register of Therapeutic Goods; see www.tga.gov.au/form/special-access-scheme
- Clinical trials – see www.tga.gov.au/clinical-trials-glance and www.tga.gov.au/clinical-trials-faqs
- Personal Importation Scheme – see www.tga.gov.au/personal-importation-scheme and www.tga.gov.au/sites/default/files/access-personal-import-guidelines.pdf

Medicinal cannabis

A regulatory framework to allow Australian patients to legally access medicinal cannabis products is being developed. Because information in this area is changing very rapidly (at the time of publication of these standards), pharmacists should seek advice and information from relevant bodies, such as the Therapeutic Goods Administration (www.tga.gov.au), the Office of Drug Control (www.odc.gov.au), and state or territory health departments.

Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices

The pharmacist ensures that the provision of non-prescription medicines and therapeutic devices is consistent with quality use of medicines and appropriate to the needs of the patient.

Background and scope

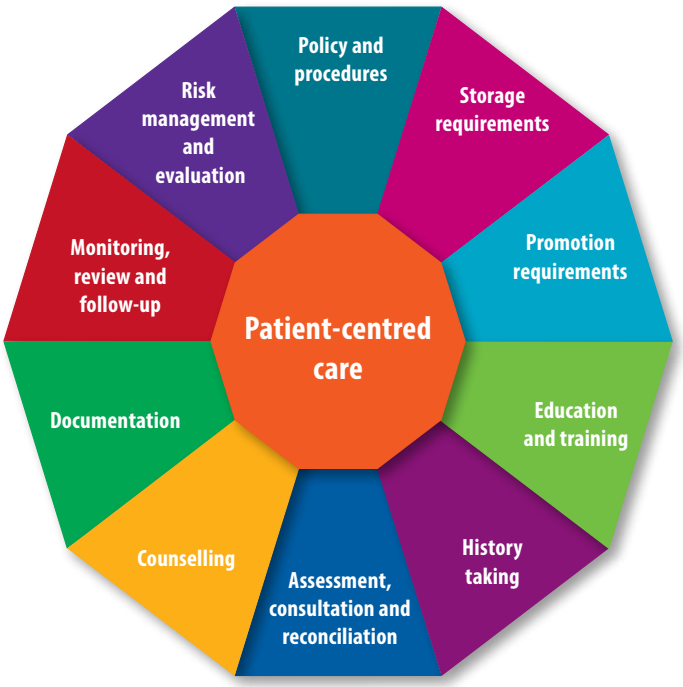
Pharmacists have an important role in supporting responsible self-care, and the provision of non-prescription medicines and therapeutic devices is a key component of this role. The successful use of non-prescription medicines to treat minor conditions increases patient confidence in managing their own health, which can have positive impacts on long-term wellbeing.[1]

All therapeutic goods must be delivered to patients in a manner that is consistent and safe, and meets best-practice expectations. Adequate information must be provided at the time of supply to support improved patient health outcomes and the optimal health of the community.

This standard applies to pharmacists providing non-prescription medicines and therapeutic devices, or supervising other pharmacy staff doing so. The pharmacist must ensure that pharmacy staff are adequately resourced and supported to enable the safe and effective provision of non-prescription medicines and therapeutic devices.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 6: Medicines Information and Standard 8: Counselling, as well as relevant professional practice guidelines.

Criteria to achieve the Provision of Non-prescription Medicines and Therapeutic Devices Standard



Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices

Criteria	Actions required
4.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
4.2 Policy and procedures • Complying with all appropriate standards, guidelines and regulatory requirements (in accordance with legislation) in each instance of provision. • Describing the roles and responsibilities of the team in provision of non-prescription medicines and therapeutic devices. • Following relevant legislation in the promotion and advertising of therapeutic goods and services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	4.2.1 Ensures that provision aligns with relevant clinical guidelines and program guidelines.
	4.2.2 Follows a systematic and safe approach to the provision of non-prescription medicines and therapeutic devices.
	4.2.3 Maintains a standard operating procedure, which includes: • provision and refusal of non-prescription medicines and therapeutic devices • elements of service delivery (e.g. collection of patient information, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • risk management and evaluation of the service.
	4.2.4 Provides those under direct supervision with clear position descriptions, including roles and responsibilities in the provision of non-prescription medicines and therapeutic devices.
	4.2.5 Reviews all policies, procedures and actions to ensure compliance with relevant legislation.
4.3 Storage requirements • Ensuring that non-prescription medicines and therapeutic devices are stored safely and in a manner that reflects their risk profile. • Reviewing storage to ensure compliance with relevant legislation and manufacturer recommendations. • Providing adequate space and appropriate storage conditions for all non-prescription medicines and therapeutic devices.	**4.3.1** Stores non-prescription medicines and therapeutic devices in accordance with scheduling classifications and relevant legislation.
	4.3.2 Identifies non-prescription medicines and therapeutic devices subject to misuse or abuse, and stores them in an area of the pharmacy that is under the direct supervision of a pharmacist.
	4.3.3 Considers the influence of the placement of non-prescription medicines and therapeutic devices on patients' perception of risk (e.g. easily accessible products may be assumed to have a low risk profile), and responds appropriately.
4.4 Promotion requirements • Promoting non-prescription medicines and therapeutic devices in a manner that supports the quality use of medicines (QUM), and reflects their risk profile. • Maintaining the professional and ethical image of the profession through promotion and provision of non-prescription medicines and therapeutic devices.	**4.4.1** Displays and promotes non-prescription medicines and therapeutic devices in a professionally responsible manner, consistent with principles of QUM and legislation.
	4.4.2 Ensures that advertising materials are evidence based, and do not promote excessive or unnecessary use of non-prescription medicines or therapeutic devices.
	4.4.3 Considers the influence of promotion (display or advertising materials) on patients' perception of the efficacy of non-prescription medicines and therapeutic devices, and responds appropriately.

Criteria	Actions required
4.5 Education and training • Ensuring that pharmacy staff involved in the provision of non-prescription medicines and therapeutic devices have adequate training relevant to their roles. • Ensuring that education and training on the provision of non-prescription medicines and therapeutic devices is evidence based and optimises the provision of therapeutic goods.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development*.
	4.5.1 Directs and educates the team involved in provision of non-prescription medicines and therapeutic devices to refer to a pharmacist when necessary.
	4.5.2 Supports and educates pharmacy team members to follow a systematic procedure for gathering relevant information from the patient.
	4.5.3 Provides regular and timely education and training to staff on the provision of non-prescription medicines and therapeutic devices, which is consistent with contemporary evidence and best-practice guidelines.
4.6 History taking	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.5: History taking*.
4.7 Assessment, consultation and reconciliation • Following a systematic process for gathering patient information, determining the severity of patient condition(s), and discussing potential solutions and points for referral. • Providing patients with appropriate care and potential health solutions tailored to their needs. • Accessing information (e.g. real-time reporting databases) to inform clinical decision making and the appropriateness of supply.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.3: Privacy and confidentiality,* and *Criterion 1.5: Documentation;* and *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.6: Assessment, consultation and reconciliation.*
	4.7.1 Ensures that the team follows a systematic process in the provision or refusal of non-prescription medicines and therapeutic devices.
	4.7.2 Engages meaningfully with patients upon request of non-prescription medicines or therapeutic devices.
	4.7.3 Assesses risks and benefits of non-prescription medicines and therapeutic devices before provision.
	4.7.4 Selects and recommends the most appropriate non-prescription medicines and therapeutic devices for patients' described healthcare needs and goals.
	4.7.5 Assists pharmacy team members in the provision of non-prescription medicines and therapeutic devices, when requested.
4.8 Counselling	Meets actions outlined in *Standard 8: Counselling*.
	4.8.1 Demonstrates the correct and effective use of therapeutic devices, and uses appropriate techniques to confirm patient understanding.
	4.8.2 Provides advice to optimise use of non-prescription medicines and therapeutic devices.
	4.8.3 Provides primary health care to patients, and offers information on alternative non-pharmalogical options and lifestyle advice to complement the use of non-prescription medicines or therapeutic devices, or when the pharmacist's judgement is that provision of non-prescription medicines or therapeutic devices is inappropriate or unnecessary.
	4.8.4 Confirms that the patient understands when treatment is no longer appropriate, and/or the condition has worsened and requires follow-up with the pharmacist or another healthcare professional.
4.9 Documentation • Recording provision of non-prescription and therapeutic devices, consistent with legislative requirements. • Using professional judgement to document provision, refusal and associated recommendations made to the patient.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation*.
	4.9.1 Records the supply of non-prescription medicines and therapeutic devices in accordance with relevant legislation and professional responsibilities (e.g. *Pharmacist Only Medicines*).
	4.9.2 Documents instances of refusal of provision when supported by professional judgement.
	4.9.3 Uses professional judgement to document any significant recommendations made to patients in the provision of non-prescription medicines and therapeutic devices.

Criteria	Actions required
4.10 Monitoring, review and follow-up • Supporting continuity of care. • Identifying and maintaining knowledge of appropriate local healthcare professionals and services. • Initiating follow-up with identified at-risk individuals.	**4.10.1** Monitors for potential inappropriate use of non-prescription medicines and therapeutic devices by the patient, and responds appropriately.
	4.10.2 Refers patients to other healthcare professionals when necessary.
	4.10.3 Confirms that the patient is aware of ongoing arrangements for access to the pharmacist and other healthcare professionals.
	4.10.4 Works collaboratively with peers and other healthcare professionals to ensure that patient outcomes are optimised and principles of QUM are upheld in the provision of non-prescription medicines and therapeutic devices.
4.11 Risk management and evaluation	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*

References cited in standard

1. GAP Taskforce on Self Care. Towards responsible self care: the role of health literacy, pharmacy and non-prescription medicines. Final report, June 2015. Sydney: Global Access Partners Pty Ltd; 2015.

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Sansom LN, ed. Australian pharmaceutical formulary and handbook. 23rd edn. Section G: Provision of *Pharmacist Only* medicines. Canberra: Pharmaceutical Society of Australia; 2015.

Standard 5: Compounding

The pharmacist prepares and dispenses compounded preparations to ensure timely access to a safe, efficacious and quality product.

Background and scope

Pharmacists are permitted to compound (extemporaneously prepare) medicines for human and animal patients. A product should only be compounded if an appropriate commercial product is not available or a commercial product is not suitable for the patient. Compounded medicines should only be provided if the medicine is safe and appropriate for the patient.[1]

For the purpose of this standard, compounding refers to "the extemporaneous 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".[1] In Australia, therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG), and must be manufactured in premises licensed by the Therapeutic Goods Administration (TGA) unless exempt. A compounded product prepared in a community or hospital pharmacy for a specific patient is exempt from the requirement for entry in the ARTG. When compounded products are supplied from the pharmacy premises, and not on a wholesale basis, the premises do not need to be licensed by the TGA to comply with the Guide for Good Manufacturing Practice for Medicinal Products (GMP).[2] The product must nevertheless be prepared according to accepted professional standards.[3]

This standard is intended to apply to both simple compounding and complex compounding, as defined by the Pharmacy Board of Australia. **In this standard, actions applying only to complex compounding are indicated by shading.**

This standard is not intended to apply to:

- aseptic transfer or the reconstitution of manufactured medicines, including antibiotic solutions and suspensions, if undertaken in accordance with the manufacturer's instructions
- batch preparation (refer to Pharmacy Board of Australia *Guidelines on Compounding of Medicines*, 2015, pp. 9–10).

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, and Standard 8: Counselling, as well as relevant professional practice guidelines.

Criteria to achieve the Compounding Standard

Standard 5: Compounding

Criteria	Actions required
5.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
5.2 Quality assurance • Employing a systematic approach to quality assurance of compounding activities using good compounding practice.	**5.2.1** Uses appropriately trained, qualified and competent personnel.
	5.2.2 Uses quality, dedicated ingredients from approved sources (i.e. ingredients from suppliers granted a licence under the *Therapeutic Goods Act 1989*). Risk assessment is required for ingredients sourced from suppliers not licensed under the Act or sourced from proprietary products, to determine whether the material is safe and appropriate for its intended use and meets applicable pharmacopoeial standards.
	5.2.3 Labels, stores and handles ingredients in accordance with safety and stability requirements (e.g. safety data sheet, manufacturer's product information, other professional guidance).
	5.2.4 Maintains a library of current editions of relevant reference texts, Pharmacy Board of Australia guidelines, other relevant guidelines, and state and territory documents.
	5.2.5 Maintains dedicated, clean and suitable equipment and facilities to prevent contamination and cross-contamination.
	5.2.6 Follows reproducible, consistent and documented standard operating procedures (SOPs).
	5.2.7 Maintains appropriate documentation and records for investigation, correction and prevention of errors or problems.
5.3 Policy and procedures • Developing, evaluating and practising in accordance with workplace policies and procedures.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	5.3.1 Confirms that all compounding activities are supported by appropriate evidence-based reference sources (e.g. published literature, relevant clinical guidance).
	5.3.2 Implements and maintains SOPs, which include: • service delivery (e.g. collaboration with prescribers, product preparation, safe handling – including response to cytotoxic or hazardous spills, counselling, waste disposal, dealing with complaints, product recall and follow-up) • roles, responsibilities and training requirements for all staff involved in compounding • management of personal health conditions (e.g. pregnancy, illness, injury) that may increase the risk to the product or compounder • requirements for the facility, work environment and equipment, including environmental monitoring • application of expiry dates to compounded products • documentation of the service • risk assessment and mitigation (including corrective actions, if required) • evaluation of the service.
	5.3.3 Reviews and evaluates existing processes and procedures against principles of quality use of medicines to determine whether amendments or additional procedures are required, and responds appropriately.
	5.3.4 Uses appropriate evidence-based references, or advice of individuals with relevant expertise, and best-practice principles to develop or renew process documents, processes and procedures.

Criteria	Actions required
5.4 Training and education • Ensuring that compounding staff are suitably trained. • Ensuring that all compounding staff under direct supervision maintain the essential competencies (knowledge and skills) to safely compound and produce quality products.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	5.4.1 Ensures that self and others under the pharmacist's direct supervision have competency-assessed training and education appropriate to the role, and in line with best practice, including consideration of patient factors (e.g. children or animal species) and formulation requirements.
	5.4.2 Implements, documents and regularly reviews a training and education plan for self and others under the pharmacist's direct supervision, as appropriate to the role and job description.
	5.4.3 Ensures that self and others associated with complex compounding have, and maintain, adequate therapeutic knowledge and practice skills to complete their designated tasks (e.g. principles of sterile compounding, preparation of micro-dose single-use dosage forms, safe handling procedures for cytotoxic and hormone products and ingredients, aseptic technique, veterinary compounding).
	5.4.4 Promotes staff understanding of the purpose, limitations and levels of risk associated with complex compounding, and strategies to mitigate these risks.
	5.4.5 Ensures that staff are aware of the hazard level of ingredients (as per safety data sheet) and are trained to respond rapidly to adverse events associated with exposure to hazardous substances, including cytotoxic spills.
5.5 Risk management and evaluation • Assessing and managing risks. • Evaluating compounding services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	5.5.1 Adheres to relevant codes, standards and guidelines in the delivery of a compounding service.
	5.5.2 Assesses and monitors the risks associated with preparation of the product, including: • product-related risks (e.g. ingredients and formulation, preparation process, intended use of the product) • personnel-related risks (e.g. exposure to hazardous substances, capacity and capability of staff) • premises-related risks (e.g. equipment maintenance and calibration; suitability of surfaces, spaces, furnishings and equipment).
	5.5.3 Uses an appropriate decision support and risk assessment tool to determine whether the compounder is adequately skilled and resourced to compound a product. See Apprendix 7: Compounding decision support and risk assessment tool.
	5.5.4 Manages identified risks appropriately, considering evidence and best-practice guidelines (e.g. use of personal protective equipment, containers for storage and disposal of clinical and hazardous waste, adherence to relevant work health and safety [WHS] procedures, aseptic technique, infection control procedures).
	5.5.5 Conducts, regularly maintains and documents operator validation.
	5.5.6 Regularly conducts and documents environmental monitoring of the cleanroom and ancillary areas, and initiates corrective action, as required.
	5.5.7 Confirms sterility of ingredients used for aseptic compounding via a certificate of analysis.
	5.5.8 Applies validated sterilisation processes to compounded products, where relevant.
	5.5.9 Periodically conducts sterility testing of samples of compounded product (e.g. excess or unused product), in accordance with SOPs.

Criteria	Actions required
5.5 Risk management and evaluation (continued)	**5.5.10** Evaluates compounding services using independent feedback and periodic quality enhancement cycles.
5.6 Documentation • Documenting details of compounding.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	5.6.1 Documents information specific to compounding a product to enable easy access to information required for traceability and recall of the product, and reproducibility of the compounding process. This may include: • preparation details (refer to 'Extemporaneous dispensing' in the current edition of *Australian Pharmaceutical Formulary and Handbook*) • details of hazardous substances used and a safety data sheet (available from wholesalers) for each ingredient • risk assessment and mitigation • date for follow-up or date of next treatment (if required).
	5.6.2 Cites references relating to safety, efficacy, stability (expiry), suitability of dose form and other relevant factors when a non-pharmacopoeial formula is used, or the preparation is for off-label use.
	5.6.3 Documents information relevant to provision of a compounding service, including: • staff training and quality assurance processes, including competency assessment • equipment maintenance and calibration, including details of cleaning and temperature monitoring • WHS reporting • complaints and recalls (e.g. ingredient, equipment, product) • any other information required by legislation, standards and guidelines.
	5.6.4 Stores the compounding documentation in a readily accessible format and location for 3 years from the date of dispensing, or in accordance with legislation.
	5.6.5 Documents, reviews and stores manufacturer's certificate of analysis of ingredients in a readily accessible format and location.
	5.6.6 Documents and reviews master formulation worksheets at regular intervals, in accordance with SOPs.
	5.6.7 Documents the temperatures of air-conditioned rooms, refrigerators and freezers within the sterile compounding facility on a daily basis.
	5.6.8 Documents environmental monitoring of the cleanroom and ancillary areas.
	5.6.9 Documents the applicable environmental monitoring of isolators, laminar flow cabinets, and laminar flow workbenches.
5.7 Facilities and equipment • Ensuring that facilities and equipment comply with standards and guidelines relevant to compounding products. • Ensuring that all required equipment is appropriate for the intended purpose, and maintained and checked regularly.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.6: Work environment.*
	5.7.1 Dedicates a clean and appropriately maintained area (away from routine dispensing, counselling and high-traffic areas) designed and equipped for compounding products and disposing of associated waste. Refer to 'Extemporaneous dispensing' in the current edition of *Australian Pharmaceutical Formulary and Handbook*.

Criteria	Actions required
5.7 Facilities and equipment (continued)	**5.7.2** Monitors and reacts promptly to control deviations in environmental conditions (e.g. temperature, pressure, humidity, light) during production, quality control and storage (including cold storage).
	5.7.3 Ensures that the compounding area allows for orderly placement of equipment and ingredients to prevent mix-ups among ingredients, containers, labels, in-process materials and the finished preparation.
	5.7.4 Prepares all compounded preparations using dedicated equipment. Refer to 'Extemporaneous dispensing' in the current edition of *Australian Pharmaceutical Formulary and Handbook*.
	5.7.5 Ensures that disposal equipment is accessible, appropriate and used appropriately.
	5.7.6 Uses personal protective equipment and additional precautions (e.g. eye protection, dust mask, powder containment systems) appropriate to the level of risk when compounding hazardous substances.
	5.7.7 Stores and labels equipment used for the preparation of hazardous substances (e.g. cytotoxic drug products, hormones) separately from other equipment.
	5.7.8 Uses equipment for complex compounding that meets relevant Australian Standards.
	5.7.9 Ensures that sterile compounding is undertaken: • within cleanrooms and ancillary areas that meet Australian Standards • using isolators, laminar flow cabinets, and laminar flow workbenches that meet Australian Standards and are appropriate to risk • using protective clothing appropriate to risk • using equipment specifically designed for, and dedicated to, the preparation of sterile products • using dedicated ingredients from approved sources (i.e. TGA-registered sources, if available) • using appropriately sterilised measuring equipment.
	5.7.10 Ensures the availability of a spill kit (for spills involving hazardous or cytotoxic ingredients), showers and eyewash facilities, as appropriate.
5.8 Storage, stability and disposal • Identifying stability requirements associated with medicine storage, handling and packing. • Educating patients and others on the appropriate storage of medicines. • Safely disposing of cytotoxic and hazardous waste and sharps.	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.13: Storage, stability and disposal.*
	5.8.1 Adheres to evidence-based information sources to optimise storage and stability requirements of raw ingredients and compounded preparations, including when assigning expiry dates.
	5.8.2 Implements cold chain management protocols for purchasing, transporting, storing, and monitoring temperature consistency of raw ingredients and compounded preparations, in accordance with stability requirements.
	5.8.3 Evaluates and validates cold chain procedures.
	5.8.4 Ensures the availability of cold chain facilities and equipment, which are validated at appropriate intervals and serviced in accordance with the manufacturer's recommendations.
	5.8.5 Activates contingency plans in the event of mechanical or power failure, and reports cold chain breaches, as appropriate.
	5.8.6 Uses appropriate containers for compounded preparations in accordance with stability requirements (e.g. light resistant, airtight, moisture-proof) and safety requirements (e.g. child resistant).

Criteria	Actions required
5.8 Storage, stability and disposal (continued)	**5.8.7** Minimises the duration for which compounded preparations are exposed to the environment (e.g. light, air) by promptly transferring them into the final container.
	5.8.8 Minimises the duration between packing and supply or dosing.
	5.8.9 Heat-seals the immediate container of a cytotoxic product into a suitable impervious outer packaging.
	5.8.10 Uses storage facilities that meet Australian Standards for storing all ingredients required for the preparation of sterile products.
	5.8.11 Disposes of cytotoxic and hazardous waste and sharps in specified containers, to enable clear identification, and arranges regular collection.
5.9 Dispensing and other supply arrangements	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements.*
	5.9.1 Ensures that advertising of compounding services to other health professionals or patients adheres to relevant legislation, codes, standards and guidelines (e.g. Australian Consumer Law, *Therapeutic Goods Act 1989*, Therapeutic Goods Advertising Code, Australian Code of Good Manufacturing Practice for Veterinary Chemical Products, Poisons Standard, Pharmacy Board guidelines).
	5.9.2 Ensures that arrangements, with other health practitioners or third parties, for the exclusive supply of compounded medicines are not entered into.
5.10 Compounding practice • Compounding preparations in accordance with best-practice guidelines and patient needs. • Upholding hygiene procedures to reduce the risk of contamination. • Preparing sterile preparations in a manner that ensures the quality and sterility of the final product.	**5.10.1** Ensures that a medication order or prescription has been obtained before compounding begins, if required by legislation.
	5.10.2 Conducts a risk assessment of the compounding process, and responds appropriately (i.e. compounds the product in accordance with SOPs, contacts the prescriber or facilitates supply via an alternative provider). See Appendix 7: Compounding decision support and risk assessment tool.
	5.10.3 Identifies and responds to the clinical needs of the patient, and liaises with the prescriber, as required, to tailor the compounded preparation.
	5.10.4 Cleans and disinfects all compounding areas and equipment regularly, in accordance with SOPs, and follows good personal hygiene practices (e.g. handwashing).
	5.10.5 Follows SOPs for entering and exiting the controlled environment.
	5.10.6 Ensures that all ingredients are correct, stable, compatible, within expiry date (for the expected duration of use of the compounded preparation), and appropriately stored before compounding.
	5.10.7 Uses Purified Water BP or Water for Irrigation BP when water is required as an ingredient in non-sterile preparations.
	5.10.8 Uses Water for Injection BP when water is required as an ingredient in sterile preparations.
	5.10.9 Compounds, or supervises staff compounding, to ensure that products are prepared in accordance with SOPs, including checking measurements, packaging and labelling.
	5.10.10 Incorporates quality control measures into the compounding process (e.g. double-checking, environmental monitoring).
	5.10.11 Compounds products that are terminally sterilised separately from those that are prepared aseptically.

Criteria	Actions required
5.10 Compounding practice (continued)	**5.10.12** Compounds sterile cytotoxic products in a cabinet separate from that used for non-cytotoxic products, unless a closed system transfer device is used in the compounding process.
	5.10.13 Completes and documents the final check of compounded preparations against the medication order, prescription or formula.
	5.10.14 Labels compounded preparations with the relevant information. Refer to 'Extemporaneous dispensing' in the current edition of *Australian Pharmaceutical Formulary and Handbook*.
5.11 Counselling • Promoting understanding of the unique requirements of compounded preparations.	Meets actions outlined in *Standard 8: Counselling*.
	5.11.1 Explains in language appropriate to the audience what a compounded preparation is, how it has been prepared and why it has been prescribed.
	5.11.2 Highlights the expiry date of the compounded preparation and provides information on appropriate disposal.
	5.11.3 Educates other health professionals about appropriate preparation and administration of complex compounded preparations.
5.12 Monitoring, review and follow-up	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.10: Monitoring, review and follow-up*.

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Standard 6: Medicines Information

The pharmacist provides evidence-based, unbiased and accurate medicines and healthcare information that is appropriate to the audience.

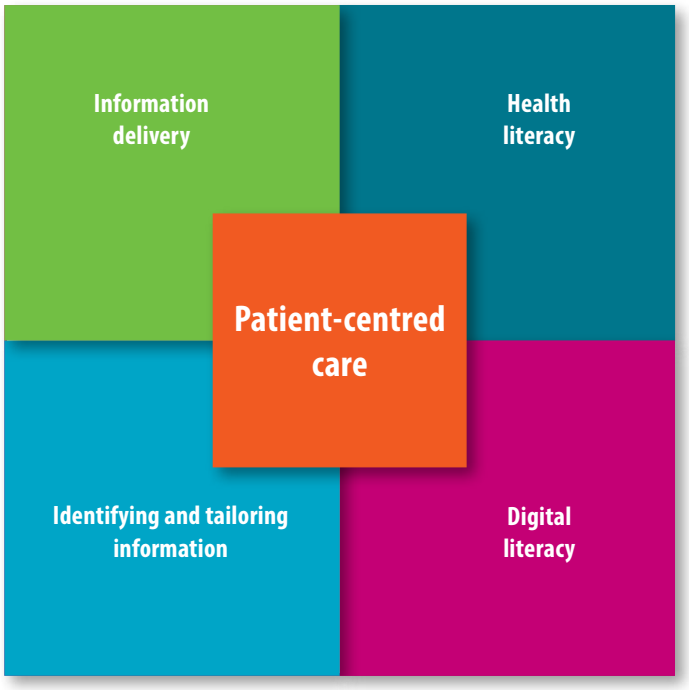
Background and scope

Evidence-based medicine and healthcare information that is tailored to individuals can optimise medication use and reduce medication misadventure.[1] It has been estimated that people with low individual health literacy are between one-and-a-half and three times more likely to experience an adverse health outcome.[2] A tailored approach is needed to ascertain individual patient preference for medicine information and select the most appropriate mode to deliver the information.[3]

Recognised as medicines experts,[4] pharmacists are accessible healthcare professionals who are trained in locating, interpreting and communicating medicines information.[5] In the context of this standard, pharmacists have the capacity to empower other healthcare professionals, patients and their authorised representatives to access evidence-based health information, and support the development of health literacy and digital literacy of patients so that they can be active participants in their health care.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 7: Health Promotion and Education, and Standard 8: Counselling, as well as relevant professional practice guidelines.

Criteria to achieve the Medicines Information Standard



Standard 6: Medicines Information

Criteria	Actions required
6.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
6.2 Health literacy • Providing services to meet the health literacy needs of patients, authorised representatives and the community. • Developing resources and skills to provide services and education consistent with health literacy principles. • Empowering patients by providing appropriate information and resources so that they can actively participate to achieve their own healthcare goals.	**6.2.1** Reviews, tailors and prioritises health information, considering all relevant factors, including the social determinants of health of the patient and the local community.
	6.2.2 Ensures that knowledge and skills of self and the team are sufficient to deliver services in line with health literacy principles.
	6.2.3 Identifies and implements appropriate solutions with the patient, the team and other healthcare professionals to overcome barriers associated with low health literacy.
	6.2.4 Selects appropriate resources, services and educational materials (developed by self or others) that are consistent with health literacy principles.
	6.2.5 Uses appropriate methods to determine whether the information provided has been understood and the patient can apply it meaningfully.
6.3 Digital literacy • Assessing, responding to, and supporting digital literacy, where appropriate. • Contributing to the digital literacy of patients, authorised representatives and the community. • Supporting patients to access appropriate electronic health information. • Empowering patients to improve their digital literacy and participation in their own health outcomes.	**6.3.1** Responds to the needs of the individual by providing digital health information, if appropriate.
	6.3.2 Empowers patients to improve their own digital health literacy by supporting them to appraise health information that is available online (including providing resources; directing patients to resources, website applications and software; and giving tips on where to look and where not to look).
	6.3.3 Contributes to the development of resources and education required to support individuals using technology to optimise health outcomes.
	6.3.4 Establishes the patient's level of digital literacy, and, if appropriate, encourages the patient to use and maintain their electronic health record.
	6.3.5 Supports the team, peers and individuals to use electronic health records effectively.
	6.3.6 Considers how health information and health solutions delivered in technologically enhanced ways can best support patient health outcomes.
6.4 Identifying and tailoring information • Ensuring that information exchange is patient centred. • Ensuring that information is accurate, relevant, timely and understood. • Applying evidence-based practice principles. • Providing adequate and balanced information to enable individuals to make informed medication and healthcare choices. • Ensuring that product promotion and advertising are appropriate.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.8: Evidence-based practice.*
	6.4.1 Collects appropriate information to inform the response to a patient's request.
	6.4.2 Obtains a current history from the patient to enable accurate information exchange.
	6.4.3 Ensures that the patient is offered relevant information to make informed healthcare choices.
	6.4.4 Appraises advertising and promotional materials to deliver unbiased and appropriate health messages for individuals and the community.
	6.4.5 Appraises the healthcare setting and workplace to determine whether they are consistent with health literacy principles, and responds appropriately.
	6.4.6 Applies evidence-based practice principles to provide accurate, timely and tailored medicines and health information to patients, authorised representatives and communities.

Criteria	Actions required
6.5 Information delivery • Using appropriate modes (e.g. in person, phone, email, electronic) for delivering health and medicines information. • Selecting appropriate medium (e.g. written, verbal, digital) for the patient's requirements (e.g. hearing, sight, literacy, language) and the complexity of the information delivered. • Facilitating access to an interpreter or other service to optimise information transfer, as required. • Maintaining the privacy and confidentiality of the patient in information exchange. • Considering the literacy of the individual.	**6.5.1** Ensures that knowledge and skills of self and the team are sufficient to deliver information and education associated with services provided.
	6.5.2 Selects the most appropriate mode for delivery of health and medicines information. Considers literacy, language, urgency, convenience, complexity and privacy.
	6.5.3 Facilitates information transfer and understanding through careful selection of appropriate medium\tailored to the patient's needs.
	6.5.4 Optimises information delivery skills (self and others) to service the needs of people in the local area. If needs are not met, responds appropriately to address the gap, or identify and refer to an alternative service provider.
	6.5.5 Upholds confidentiality and privacy at all times, and reviews processes for potential risks.
	6.5.6 Provides information in a culturally safe and responsive way.

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Supplementary information: Medicines Information Centres	
Poisons Information Centre (Australia wide)	Ph: 131 126
NPS MedicineWise	Ph: 1300 MEDICINE (1300 633 424) from anywhere in Australia Website: www.nps.org.au/contact-us/medicines-line Hours of operation: 9.00 am to 5.00 pm Monday–Friday (excluding NSW public holidays)
NSW Clinical Information Access Portal (CIAP)	Website: www.ciap.health.nsw.gov.au
NSW Medicines Information Centre	Ph: 02 8382 3047, fax: 02 8382 3048 Email: nswmic@svha.org.au Website: www.ciap.health.nsw.gov.au/mic/index.html Hours of operation: 9.00 am to 5.00 pm Monday–Friday
Victorian Poisons Information Centre	Ph: 13 11 26 (24 hours a day, 7 days a week) Website: www.austin.org.au/poisons
Medicines Information Centre, Monash Medical Centre	Ph: 03 9594 2361
Medicines Information Centre, Royal Children's Hospital, Melbourne	Ph: 03 9345 5208 Website: www.rch.org.au/pharmacy/medicines-information
ACT Health, Medicines Information Service	Ph: 02 6244 3333 Hours of operation: 9.00 am to 5.00 pm Monday–Friday
Queensland Poisons Information Centre	Ph: 13 11 26 Website: www.childrens.health.qld.gov.au/chq/our-services/queensland-poisons-information-centre/
Northern Territory Medicines and Poisons Control	Ph: 08 8922 7341, fax: 08 8922 7200 Website: https://health.nt.gov.au/professionals/environmental-health/medicines-and-poisons-control
Medicines in pregnancy	Website: www.tga.gov.au/prescribing-medicines-pregnancy-database
State and territory information on medicines in pregnancy	Website: www.tga.gov.au/obstetric-drug-information-services
Medicines in breastfeeding	Website: www.breastfeeding.asn.au/bf-info/safe-when-breastfeeding/breastfeeding-and-prescription-medications?q=bfinfo/drugs.html

Standard 7: Health Promotion and Education

The pharmacist facilitates and empowers patients, authorised representatives and the community to manage their health and wellbeing.

Background and scope

Pharmacists partner with governments, other healthcare professionals and the community to address gaps in healthcare services and respond to community need. Pharmacists ensure that access to their services is not dictated by social or geographical barriers.

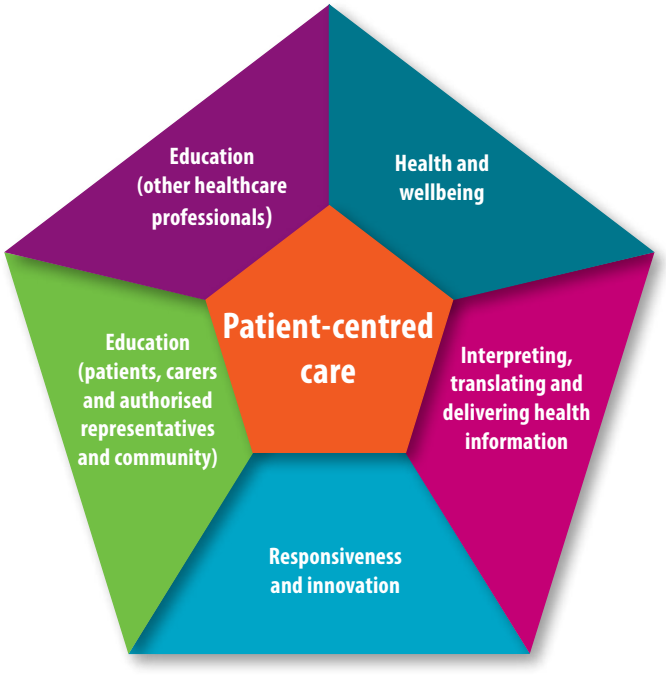
Health promotion is the process of enabling people to increase control over their health and its determinants, and thereby improve their health and wellbeing.[1] This requires pharmacists to consider the needs of the patient, and undertake effective communication and education to empower individuals to take ownership of their health and wellbeing. Health promotion is the responsibility of all Australians.[2] With the support of pharmacists, communities can reduce knowledge gaps associated with socioeconomic differences and access to health care, improve health-related behaviours, and decrease the incidence of preventable health conditions.[3,4]

Pharmacists can encourage their patients to identify social support networks, adopt healthy lifestyles and consider the effect of their health choices on their wellbeing. Pharmacists have the ability to raise awareness of the risks of poor health through evidence-based pharmacy services and advice.[2] Australian Government-funded professional pharmacy programs and services recognise the well-established role of pharmacists in disease prevention.[5]

In the context of this standard, education involves the provision of education to patients, their authorised representatives, communities and other healthcare professionals. Professional development (Criterion 2.3) in Standard 2: Leading and Managing Pharmacy Practice refers to the pharmacist's role in supporting and contributing to the ongoing development of the current and future pharmacy workforce.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 6: Medicines Information, and Standard 8: Counselling, as well as relevant professional practice guidelines.

Criteria to achieve the Health Promotion and Education Standard



Standard 7: Health Promotion and Education

Criteria	Actions required
7.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
7.2 Health and wellbeing • Complementing services and goods provided with appropriate health and medicines information. • Identifying opportunities and providing preventive healthcare measures for patients, authorised representatives and communities. • Promoting health and wellbeing throughout the patient's life.	**7.2.1** Maintains awareness of relevant healthcare services, resources and organisations.
	7.2.2 Determines and provides the most appropriate and relevant information that should accompany any service or therapeutic good provided by self or the team to the patient.
	7.2.3 Engages with health promotion services available locally, nationally and globally to facilitate patient access.
	7.2.4 Empowers patients, authorised representatives and the community with relevant health information to encourage them to actively participate in their own health and wellbeing.
	7.2.5 Uses evidence-based strategies (e.g. motivational interviewing, stages of change) to explore and change health behaviours.
	7.2.6 Works with local stakeholders to identify and provide services needed by the community.
	7.2.7 Evaluates health promotion activities, resources and services, and adapts each to meet local community needs.
7.3 Interpreting, translating and delivering health information • Locating evidence-based health information. • Interpreting, translating and delivering evidence-based health information to support its optimal use by the end user. • Selecting appropriate mode of delivery, environment and time for provision of health information.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.7: Quality use of medicines* and *Criterion 1.8: Evidence-based practice.*
	7.3.1 Interprets health information according to the principles of evidence-based practice.
	7.3.2 Appraises information and resources to ensure their currency and credibility.
	7.3.3 Translates health information into a message or resource appropriate to the end user.
	7.3.4 Determines appropriate mode (e.g. in person, phone, email, electronic, newsletter) to deliver required health information to patients, authorised representatives, other healthcare professionals or the community.
	7.3.5 Delivers health information in an environment appropriate to the setting and the end user (e.g. patient counselling room, school group education session or assembly, newsletter).
7.4 Responsiveness and innovation • Using expertise and available resources to create new models and services for current and emerging health challenges.	**7.4.1** Identifies current and emerging healthcare needs of the local community.
	7.4.2 Uses expertise and available resources to design new models of healthcare services.
	7.4.3 Develops new resources to address identified needs.
7.5 Education (patients, carers or authorised representatives and community) • Identifying and responding to the health education needs of individuals, communities, organisations and others. • Working with others in the healthcare team locally, nationally and globally to ensure that education on health is responsive to the needs of the individual(s) and readily available to all relevant stakeholders.	**7.5.1** Delivers context-specific health education to patients, communities, organisations and others.
	7.5.2 Designs and delivers education on health issues in response to local, national and global community needs.
	7.5.3 Identifies and responds to current and emerging health education needs of individuals, communities, organisations and other stakeholders.

Criteria	Actions required
7.6 Education (other healthcare professionals) • Applying expert knowledge of medicines and other knowledge derived from scope of practice to contribute to the professional development of other healthcare professionals. • Facilitating information exchange and embracing all modes of delivery.	**7.6.1** Identifies educational requirements and selects appropriate opportunities to provide education on medicines to other healthcare professionals.
	7.6.2 Uses expert knowledge and skills in medicines management and other areas of practice to support development of other healthcare professionals.
	7.6.3 Responds to requests from other healthcare professionals, healthcare teams or other sectors to provide education on medicines and health (within scope and area of expertise).

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Standard 8: Counselling

The pharmacist provides counselling to patients to support the safe and optimal use of all therapeutic goods.

Background and scope

Patient counselling is an integral part of the process of dispensing and supplying medicines and therapeutic devices. It ensures that the patient has an adequate understanding of the medicine or device, and how to use it safely and effectively. It also provides a final check to confirm that the correct medicine or device is being supplied to the patient for whom it was intended. Although pharmacists should make every effort to counsel a patient whenever a medicine or therapeutic device is supplied, they must defer to the patient's right to refuse counselling.[1]

In the context of this standard, counselling refers to a two-way communication process between the pharmacist and the patient in which the pharmacist ascertains the needs of the patient and provides them with information required to effectively use medicines and/or therapeutic devices.

The scope of counselling is influenced by a range of factors, including the expressed needs of the patient, the pharmacist's professional judgement (particularly with regard to the patient's level of understanding) and the context in which counselling is required.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 6: Medicines Information, and Standard 7: Health Promotion and Education, as well as relevant professional practice guidelines.

Criteria to achieve the Counselling Standard

Standard 8: Counselling

Criteria	Actions required
8.1 Patient-centred care • Ensuring that patient and community health needs are foremost in the delivery of counselling by the pharmacist.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
	8.1.1 Communicates with the patient to identify their specific information needs throughout the counselling process.
	8.1.2 Tailors counselling to the needs and understanding of the patient.
	8.1.3 Empowers the patient to make informed decisions and be actively involved in setting their healthcare goals.
8.2 Policy and procedures • Aligning all counselling services with best practice. • Ensuring that a current standard operating procedure (SOP) informs all service delivery.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	8.2.1 Ensures that all counselling services align with relevant clinical guidelines and program guidelines.
	8.2.2 Reviews all counselling services to ensure compliance with relevant legislative requirements.
	8.2.3 Maintains a SOP, which includes: • identification of at-risk patients or populations who would benefit from counselling • elements of the counselling process • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • risk management and evaluation of the service.
8.3 Education and training • Ensuring that self and staff have appropriate knowledge and skills to deliver counselling to patients.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	8.3.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of counselling activities delivered.
	8.3.2 Assesses the roles and responsibilities of all staff under direct supervision to ensure the provision of consistent and quality counselling to patients.
	8.3.3 Revisits the counselling framework to ensure that all members of the pharmacy team are appropriately trained to support the delivery of counselling.
	8.3.4 Facilitates training required to deliver counselling in line with best-practice requirements.
	8.3.5 Promotes staff understanding of the purpose and limitations of counselling.
8.4 Privacy and confidentiality	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.3: Privacy and confidentiality.*
8.5 Cultural safety and health equity	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.4: Cultural safety and health equity.*
8.6 Accessibility • Ensuring accessible and timely delivery of counselling. • Managing workflow to ensure the visibility and approachability of the pharmacist.	**8.6.1** Proactively identifies patient circumstances requiring prioritisation and/or intervention.
	8.6.2 Minimises barriers that may influence essential patient access to pharmacist counselling.
	8.6.3 Ensures that adequate resources and staff are available and/or can be organised to deliver consistent counselling.

Criteria	Actions required
8.7 Assessment, consultation and reconciliation • Ensuring a thorough, accurate and systematic approach to history taking. • Identifying the most appropriate time(s) in the counselling process to take a history or repeat history taking. • Documenting essential information. • Collecting or obtaining access to minimum essential information, including current prescription and non-prescription therapies, health conditions, allergies, adverse effects and patient preferences.	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.5: History taking,* and *Criterion 3.6: Assessment, consultation and reconciliation.*
	8.7.1 Checks the dispensing history and/or electronic healthcare record to determine the appropriateness of information being sought and provided.
	8.7.2 Synthesises all the available information with informed professional judgement to formulate and present the most appropriate counselling, lifestyle advice and treatment options to the patient.
	8.7.3 Accesses and assesses current information on clinically significant interactions, contraindications, precautions and disease states.
8.8 Counselling practice • Ensuring the use of a systematic framework to support a simple, stepwise approach to counselling. • Supporting consistent provision of counselling. • Incorporating best-practice guidelines to ensure optimal patient outcomes. • Using a range of communication methods to ensure effective counselling. • Identifying and appropriately responding to communication barriers. • Confirming patient engagement and understanding.	Meets actions outlined in *Standard 6: Medicines Information,* and *Standard 7: Health Promotion and Education.*
	8.8.1 Identifies and applies an agreed process to facilitate counselling.
	8.8.2 Identifies barriers to effective communication.
	8.8.3 Uses appropriate strategies, resources and services to overcome communication barriers (e.g. language, cultural, physical and mental health considerations).
	8.8.4 Demonstrates the appropriate use of medicines, delivery aids, therapeutic devices and dose administration aids.
	8.8.5 Provides information on the appropriate use of medicines, delivery aids, therapeutic devices and dose administration aids.
	8.8.6 Provides information on the correct handling and storage of cytotoxic and other hazardous medicines, including compounded preparations.
	8.8.7 Provides (or informs patient how to access) written information (e.g. dispensing labels, cautionary advisory labels, *Consumer Medicine Information*) to reinforce verbal counselling.
	8.8.8 Uses appropriate techniques* to ensure patient understanding of counselling provided, and confirm that they can use the medicine, delivery aid, therapeutic device or dose administration aid correctly.
8.9 Communication and collaboration	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.9: Communication and collaboration.*
8.10 Documentation • Ensuring the systematic documentation of all counselling events that are considered clinically significant. • Recording recommended actions and timelines for follow-up in the patient's medication profile, healthcare plan or record, where appropriate. • Documenting instances where counselling is offered and refused.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	8.10.1 Documents significant counselling issues or events in the patient's healthcare plan.
	8.10.2 Documents reasons why counselling and/or written information, including *Consumer Medicine Information*, were not provided, where considered important.
	8.10.3 Uses appropriate systems to facilitate the secure electronic transfer of the patient's healthcare plan.
	8.10.4 Ensures that all counselling activities consistent with the definition of a clinical intervention are recorded accurately.

* For example, the Teach-back technique (see 'Additional references and resources').

Criteria	Actions required
8.11 Monitoring, review and follow-up • Ensuring meaningful and quality engagement with all patients and members of their healthcare team. • Identifying and acting to address the needs of the patient. • Initiating referral or follow-up arrangements. See Appendix 3: Template referral letter.	**8.11.1** Monitors the patient to determine whether medications and healthcare services are being optimised.
	8.11.2 Identifies at-risk patients in need of referral and/or follow-up services.
	8.11.3 Offers or facilitates follow-up with self or other appropriate healthcare professionals.
	8.11.4 Educates patients to facilitate access to other relevant services.
	8.11.5 Responds to identified needs of the patient.
	8.11.6 Recognises when care is outside the pharmacist's scope, and refers the patient to other appropriate healthcare professionals or healthcare services accordingly.
	8.11.7 Documents referral and follow-up actions, including recording actions as clinical interventions, where appropriate.

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Supplementary information: examples of clinically significant information to document following counselling*	
Examples	**What to record**
Consideration when communicating with the patient or nominated carer (e.g. vision impairment, hearing impairment, cognitive impairment, language or cultural differences)	• Patient's preferred mode of communication
Potential adherence issue	• Adherence issue identified • Advice provided • Follow up planned
Drug interaction that is clinically significant for the patient	• Drug interaction identified • Advice provided or action taken • Follow up planned
Adverse drug reaction (ADR) or allergy	• ADR or allergy identified • Advice provided or action taken • Follow up planned • ADR notification to Therapeutic Goods Administration
Medicine ceased	• Reason for cessation
Dose change	• Dose change confirmed • Reason for dose change • Advice provided regarding expected outcomes

*Pharmacists are reminded to use their professional judgement when deciding which issues are relevant to document.

Standard 9: Collaborative Care

The pharmacist works within the healthcare team to support optimal use of medicines and patient health outcomes.

Background and scope

Increasingly complex patient care relies on collaboration between professions. Greater collaboration between medical practitioners, pharmacists and other primary healthcare professionals can optimise patient care.[1]

The breadth of locations in which pharmacists work and their important contribution in each of these settings are well aligned with the shift towards more collaborative and patient-centred models of health care. These models are designed to improve the efficiency and effectiveness of the health system, particularly for patients with chronic disease.[2,3] There are opportunities to establish collaborative care arrangements even where healthcare professionals are not co-located – community pharmacists are a good example.

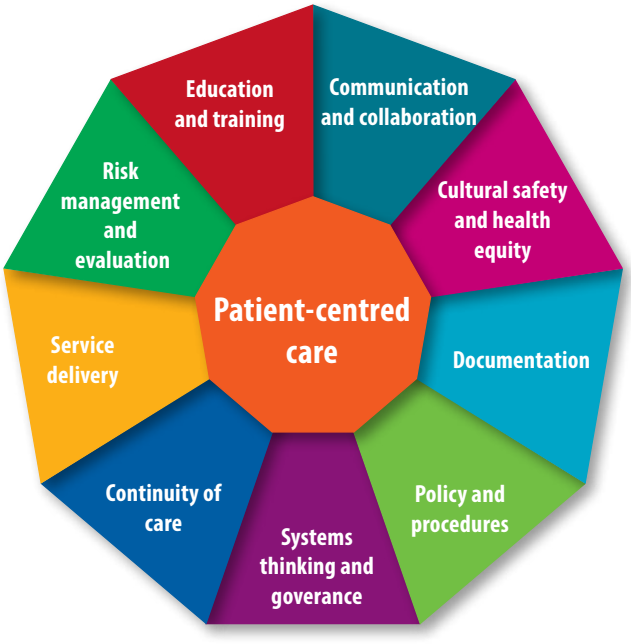
The World Health Organization states that collaborative care is when "multiple health workers from different professional backgrounds work together with patients, families, authorised representatives and communities to deliver the highest quality care. Elements of effective collaborative practice include respect, trust, shared decision-making and partnerships".[4]

In the context of this standard, collaboration in health care is defined as healthcare professionals assuming complementary roles and cooperatively working together, sharing responsibility for problem solving, and together making decisions to formulate and implement plans for patient care. The healthcare team includes medical practitioners, nurses, pharmacists, other healthcare professionals and the patient. Collaboration between team members increases awareness of each other's knowledge, skills and experience, leading to continued improvement in decision making.[5] See Appendix 8: The healthcare team.

This standard applies to all pharmacists working in collaborative care settings and/or delivering medication management services. Settings may include hospitals, general practice, Aboriginal and Torres Strait Islander healthcare services, residential care facilities, community pharmacy, chronic disease clinics and Health Care Homes.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 6: Medicines Information, Standard 7: Health Promotion and Education, and Standard 8: Counselling, as well as relevant professional practice guidelines.

Criteria to achieve the Collaborative Care Standard



Standard 9: Collaborative Care

Criteria	Actions required
9.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
9.2 Communication and collaboration • Facilitating professional relationships among all members of the healthcare team. • Recognising different skills and expertise of members of the healthcare team, and working in partnership to deliver quality health care in a synergistic, cohesive and holistic manner. • Modelling excellent interpersonal and communication skills, including the ability to influence and facilitate change. • Developing trust with the healthcare team, both professionally and clinically. • Consistently maintaining the visibility of services to patients, other members of the healthcare team, and relevant or at-risk individuals and communities in the setting.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.9: Communication and collaboration.*
	9.2.1 Assists in the development of a position description for pharmacists working in collaborative care arrangements, and educates others about the roles and responsibilities of the pharmacist.
	9.2.2 Ensures that all staff working under direct supervision or in close working arrangements with the pharmacist have their roles and responsibilities clearly defined.
	9.2.3 Takes all due diligence to ensure that those working within third-party contractual arrangements are appropriately certified and trained for their roles.
	9.2.4 Identifies common barriers to interprofessional communication and collaboration, and works to resolve them.
	9.2.5 Develops a shared vision among healthcare team members around intended service outcomes and patient healthcare goals.
	9.2.6 Recognises and understands the different skills and expertise of each member of the healthcare team, and works in partnership with others to resolve patient health challenges.
	9.2.7 Displays courtesy, tact, discretion and respect, to facilitate professional working relationships among all members of the healthcare team, support workers, patients and communities.
	9.2.8 Takes accountability and responsibility by exercising powers and discretions appropriate to individual role in service- or team-based care arrangements.
	9.2.9 Communicates with other healthcare professionals and authorised representatives to help identify patients in need of services.
	9.2.10 Develops and practises interpersonal and communication skills, including the ability to influence and facilitate change.
	9.2.11 Establishes a consistent and visible pharmacist presence and provides services appropriate to the setting.
	9.2.12 Recognises the health literacy of the patient, service providers and service settings, and tailors responses and services accordingly.
9.3 Cultural safety and health equity	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.4: Cultural safety and health equity*.
9.4 Documentation	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*

Criteria	Actions required
9.5 Policy and procedures • Delivering services in accordance with relevant legislation. • Adhering to relevant practice protocols, procedures and guidelines. • Developing, maintaining, using and reviewing protocols in the context of the healthcare team to optimise services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	9.5.1 Delivers all services in accordance with relevant legislation.
	9.5.2 Ensures that the healthcare team is aware of, and complies with, all relevant legislation.
	9.5.3 Establishes and adheres to service contracts (except when changes to contract arrangements are outside the pharmacist's control).
	9.5.4 Adheres to any relevant practice protocols, procedures and guidelines.
	9.5.5 Contributes to the development and review of relevant policies, procedures and resources associated with services (e.g. review of medicines policy and procedures in residential care facilities).
9.6 Systems thinking and governance • Implementing and managing systems within and across services and facilities to ensure optimised patient health outcomes.	**9.6.1** Implements systems to proactively identify, track and follow up at-risk patients or communities.
	9.6.2 Implements systems that support coordinated care models and enables all members of the patient's healthcare team to contribute to their care.
	9.6.3 Implements systems that enable the sustainable supply, disposal and use of health resources, including systems designed to enhance stock control, storage and access to therapeutic goods.
	9.6.4 Considers systems for their flexibility to respond to unknown or emerging healthcare needs of the local community or patients.
	9.6.5 Maintains a system (in conjunction with the patient, community group, facility or setting) that identifies at-risk patients who are in need of additional services or referral (e.g. dose administration aid, medication review, disease state management, clinical audit, referral to other members of the healthcare team).
	9.6.6 Shares responsibility and accountability for the quality of care, continuously improving, minimising risks and fostering an environment of excellence in patient care.
9.7 Continuity of care • Enhancing the continuity in care of all patients by establishing systems, protocols and resources to support patients and all members of their healthcare team. • Supporting continuity of care in response to duty-of-care requirements. • Liaising with all relevant members of the patient's healthcare team when they are transferring between settings or when significant changes occur that may affect their healthcare plan. • Transferring information to relevant healthcare professionals in a timely manner.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	9.7.1 Understands and acts on the principles of continuity of care and quality use of medicines (QUM) in the delivery of all services.
	9.7.2 Cultivates networks to promote effective communication of accurate, complete and comprehensive information across the healthcare system.
	9.7.3 Identifies, and takes steps to reduce, potential risks to the patient when transferring between healthcare settings and healthcare professionals.[4]
	9.7.4 Implements systems designed to identify at-risk individuals transitioning between facilities and reduce medication-related misadventure.
	9.7.5 Makes all reasonable attempts to facilitate the continuation of essential services by a reliable alternative provider if current service arrangements need to be paused or discontinued.[5]
	9.7.6 Actively facilitates referral and confirms that the patient knows how to access these services.
	9.7.7 Assists the patient and other members of the healthcare team to develop an agreed healthcare plan and supports transition of care across settings.

Criteria	Actions required
9.8 Service delivery • Ensuring that services are coordinated and delivered in the best interests of the patient, in collaboration with other healthcare professionals, and considering the sustainable use of health resources. • Delivering high-quality healthcare services to patients and communities. • Adhering to relevant practice guidelines and considering principles of QUM in the delivery of all services. • Managing service delivery and the service environment, resourcing staff, maintaining equipment, and managing work health and safety. • Tailoring services to the patient's needs (including cultural needs), beliefs, goals and preferences. • Conducting needs analyses. • Maintaining awareness of local or global issues affecting provision of healthcare services and therapeutic goods.	**9.8.1** Conducts needs analyses to determine the needs and priorities of the team and patient, to inform services offered in the setting.
	9.8.2 Adheres, where appropriate, to relevant practice guidelines and considers principles of QUM in the delivery of service.
	9.8.3 Ensures that the service environment, staffing, equipment and associated resources are consistent with specific service guidelines.
	9.8.4 Implements a referral system to streamline service provision.
	9.8.5 Monitors patterns of use of therapeutic goods, services and other relevant health resources that affect safety and budget considerations. Reports back to facilities and, where necessary, the state/territory or Australian government, to enable monitoring or timely reallocation of funds.
	9.8.6 Responds both reactively and proactively to the needs, including cultural needs, of the patient and healthcare team members.
	9.8.7 Follows a systematic approach to identifying, discussing and resolving the patient's individual health goals, adverse drug events, medicines interactions and other health-related challenges.
	9.8.8 Prioritises workloads according to patient risk and availability of team members.
	9.8.9 Responds to the findings of the needs analysis to consider and implement appropriate change.
	9.8.10 Raises patient or community awareness of relevant programs or services that support QUM and patient healthcare goals.
9.9 Risk management and evaluation • Implementing transparent, ethical and reliable mechanisms to evaluate services. • Obtaining feedback from all relevant stakeholders, including patients, authorised representatives and other members of the healthcare team. • Acting on evaluation findings to improve services, and associated systems and processes. • Evaluating the capacity of self and the team to safely deliver services and maintain continuity of patient care.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	9.9.1 Conducts periodic self and/or peer review of services, using a peer-endorsed evaluation process.
	9.9.2 Evaluates service delivery and associated systems to ensure that services lead to equitable and sustainable use of health resources, and appropriate distribution of workload across healthcare professionals and the sector.
	9.9.3 Contributes to a system that prompts and supports evaluation of the service at regular intervals. Uses a recommended review framework (e.g. plan, act, evaluate, reflect, implement).
	9.9.4 Participates in workplace quality improvement activities, which may include independent evaluation or anonymous feedback systems, to obtain feedback from all relevant service stakeholders (patients, authorised representatives, healthcare team members and others).
	9.9.5 Analyses the validity, reliability and clinical relevance of services on a regular basis. Reports against identified goals or parameters to determine whether service goals have been achieved. Provides relevant stakeholders and external auditors with access to outcomes.
	9.9.6 Integrates the findings into ongoing service delivery. Considers the findings in the context of the evidence base to determine whether the service is worthwhile and should be continued in the current setting.

Criteria	Actions required
9.10 Education and training • Providing education and training tailored to the practice context, the service, and the needs of the healthcare team and patients, authorised representatives or communities.	**9.10.1** Delivers evidence-based and timely education sessions to patients and other members of the healthcare team.
	9.10.2 Facilitates the education and training of all team members (under direct supervision) associated with the delivery of services. Ensures that continuity of service delivery is supported by diversity in staff knowledge and skills.
	9.10.3 Ensures that staff (under direct supervision) are educated so that services delivered are consistent with principles of health literacy, cultural safety and responsiveness, diversity and inclusiveness.
	9.10.4 Provides health and medicines information to individual patients, authorised representatives, community groups, healthcare professionals, healthcare workers and facilities. Supports at-risk groups to adhere to QUM, and optimise health choices in their context and in accordance with the priorities (including beliefs) of the patient.
	9.10.5 Delivers information and education both reactively and proactively, according to the needs analyses of the setting.
	9.10.6 Advises the setting, facilities and healthcare team members about recommended information sources that should be maintained and used in delivery of their healthcare services.

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Standard 10: Screening and Risk Assessment

The pharmacist uses evidence-based screening and risk assessment to detect possible risk of medical conditions in at-risk individuals, and provides referral as appropriate.

Background and scope

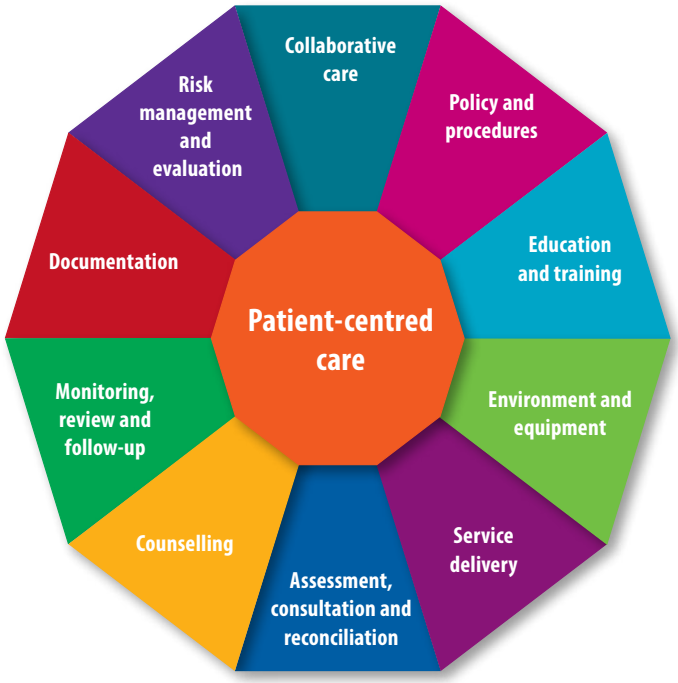
Screening and risk assessment is a key component of Australia's strategy to reduce the burden of preventable disease.[1,2] There is strong evidence that appropriate screening and risk assessment targeted at preventable conditions such as diabetes, cardiovascular disease, chronic kidney disease and osteoporosis is cost-effective and significantly improves population health.[1]

Pharmacists, in partnership with other healthcare professionals, have an important role in promoting access to health promotion, prevention, screening and early intervention.[3]

In the context of this standard, screening and risk assessment is a systematic process used to identify members of a defined population who may be at risk of a disease, evaluate that risk and provide referral as appropriate.[4] Screening and risk assessment services should not be used to make a diagnosis, or as the basis for initiating or altering medical treatment. Screening should not be conducted unless there is a reasonable likelihood that patients who screen positive can access an effective treatment or management.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 7: Health Promotion and Education, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Screening and Risk Assessment Standard



Standard 10: Screening and Risk Assessment

Criteria	Actions required
10.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
10.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative Care.*
10.3 Policy and procedures • Aligning all screening and risk assessment services with best practice. • Ensuring that a current standard operating procedure informs all service delivery.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	10.3.1 Ensures that all screening and risk assessment services align with clinical guidelines and program guidelines.
	10.3.2 Reviews all screening and risk assessment services to ensure compliance with relevant legislative requirements.
	10.3.3 Maintains a work health and safety (WHS) protocol to minimise the risk of needlestick injury, exposure to blood and body fluids, and transmission of infectious diseases; and to inform hand hygiene protocol and practices.
	10.3.4 Maintains a standard operating procedure, which includes: • identification of at-risk patients or populations who would benefit from the service • consent requirements • elements of service delivery (e.g. collection of information and samples, assessment and interpretation of results, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • arrangements for third-party providers (e.g. pathology service, on-site nurse) • risk management and evaluation of the service.
	10.3.5 Ensures that a contract with third-party providers exists, including: • clear definition of the roles and responsibilities of each provider • start date and end date of the arrangement • risk assessment of the arrangement and service • agreed communication methods • other relevant expectations and requirements • consistency with Pharmacy Board of Australia guidelines.
10.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver screening and risk assessment services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	10.4.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of services delivered.
	10.4.2 Facilitates training required to deliver services in line with best-practice requirements.
	10.4.3 Promotes staff understanding of the purpose and limitations of screening and risk assessment services.

Criteria	Actions required
10.5 Environment and equipment • Providing an appropriate service environment for screening and risk assessment. • Maintaining equipment required to deliver services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.6: Work environment,* and *Criterion 2.7: Resource management.*
	10.5.1 Delivers the service in a location that protects patient privacy and confidentiality.
	10.5.2 Ensures that the service environment has appropriate surfaces and furnishings consistent with the professional requirements of the service.
	10.5.3 Uses equipment that meets relevant Australian standards, and is appropriate for the intended purpose.
	10.5.4 Calibrates equipment according to manufacturers' instructions.
	10.5.5 Ensures that equipment is serviced regularly according to manufacturers' instructions.
	10.5.6 Provides all necessary protective clothing, equipment, and containers for storage and disposal of clinical waste.
10.6 Service delivery • Performing all services in a manner consistent with current best practice. • Adopting universal precautions to prevent contamination for any assessment requiring collection of blood or other biological samples.	**10.6.1** Refers to relevant professional clinical guidelines, and program guidelines and standards when delivering screening and risk assessment services.
	10.6.2 Ensures that staff contribute to screening and risk assessment services only when they are equipped and capable to do so.
	10.6.3 Obtains informed consent from the patient before service delivery.
	10.6.4 Uses screening and risk assessment tests and tools that have been validated (evidence based, accurate and effective).
	10.6.5 Where relevant, targets services to at-risk patients and others who would benefit from screening.
	10.6.6 Uses a consistent and systematic approach to the collection of relevant patient information and measurements, including appropriate disposal of waste and consumables.
	10.6.7 Interprets test results in the context of the patient's medical and medication history.
	10.6.8 Communicates results to the patient in a timely and appropriate manner.
	10.6.9 Facilitates proactive referral and follow-up, as required, and takes responsibility for ensuring ongoing care and an appropriate response to results. See Appendix 9: Screening and risk assessment record and referral form.
10.7 Assessment, consultation and reconciliation • Tailoring screening and risk assessment services to the individual patient. • Synthesising all available information to interpret test results.	**10.7.1** Selects tests and tools consistent with patient preferences, and confirms that the choice reflects the intent of screening.
	10.7.2 Explains potential implications of screening (e.g. possible diagnosis and treatment, prevention of complications).
	10.7.3 Considers all patient factors likely to influence the accuracy of the results (e.g. patient medical history, medications, lifestyle factors).
	10.7.4 Considers all relevant information that can be obtained to complete the test (including other relevant tests and tools).

Criteria	Actions required
10.8 Counselling • Promoting understanding of the process, results and ongoing care associated with screening and risk assessment services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	10.8.1 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	10.8.2 Provides results to the patient, or carer or authorised representative, in a sensitive and timely manner.
	10.8.3 Explains test results, including their significance and limitations, in the context of the patient's health, lifestyle and risk factors.
	10.8.4 Empowers the patient to act on their results, as appropriate, in the context of their healthcare plan and goals.
	10.8.5 Offers tailored verbal and written health information consistent with the patient's needs.
	10.8.6 Counsels on the intervals between screening and ensures that the patient is aware of whether and when it should be repeated.
10.9 Monitoring, review and follow-up • Ensuring a systematic approach to follow-up and recall of patients who have used the service.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	10.9.1 Provides appropriate and timely referral, immediate management or ongoing monitoring tailored to the test results.
	10.9.2 Ensures patient understanding and agreement of each party's role and responsibility in ongoing care arrangements.
	10.9.3 Ensures identification and traceability of the source of the service to support future contact (e.g. contact details of the service provider or third-party provider).
10.10 Documentation	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	10.10.1 Documents all relevant information specific to service delivery, where necessary, including: • self and staff training undertaken to deliver the service • patient information and consent • records of all service provided, including date, provider, results and follow-up actions • correspondence with other healthcare professionals • equipment, maintenance and calibration • WHS reporting for spillages, contamination, needlestick injuries and other incidents • any other information required by legislation, and professional standards and guidelines. See Appendix 9: Screening and risk assessment record and referral form.
10.11 Risk management and evaluation	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*

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Supplementary information: examples of validated screening and risk assessment tools

Condition	Tool	Link
Cardiovascular disease	Absolute Cardiovascular Disease Risk Calculator	www.cvdcheck.org.au
Diabetes	AUSDRISK	www.health.gov.au/preventionoftype2diabetes
Obstructive sleep apnoea	STOP–Bang	www.stopbang.ca/osa/screening.php
Skin cancer	Fitzpatrick Skin Type quiz	www.skincancer.org/prevention/are-you-at-risk/fitzpatrick-skin-quiz

Standard 11: Vaccination Service

The pharmacist ensures that vaccination services are delivered safely and professionally according to patient needs.

Background and scope

Immunisation is a vital public health initiative that improves the health of individuals and populations by reducing the incidence and spread of disease.[1–3] Vaccination services provided through pharmacies – and by pharmacists in other settings – may increase accessibility to vaccinations and relevant information, and improve immunisation coverage in Australia.[4]

Pharmacists have always had a role in dispensing and distributing vaccines, with a focus on critical cold chain management procedures for vaccine products. Although these services remain essential, pharmacists now have a broader role in immunisation, including administering vaccines in accordance with relevant legislation.[4]

This standard applies to pharmacists administering vaccines as an authorised immuniser, or overseeing another authorised immuniser in a pharmacy setting.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 7: Health Promotion and Education, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Vaccination Service Standard

Standard 11: Vaccination Service

Criteria	Actions required
11.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
11.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative Care.*
11.3 Policy and procedures • Aligning all vaccination services with best practice. • Ensuring that a current standard operating procedure informs all service delivery.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	11.3.1 Ensures that vaccination services align with relevant clinical guidelines and program guidelines.
	11.3.2 Reviews vaccination services to ensure compliance with relevant legislative requirements.
	11.3.3 Maintains a standard operating procedure, which includes: • identification of at-risk patients or populations who would benefit from the service • patient consent requirements • elements of service delivery (e.g. collection of information, vaccination, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • risk management and evaluation of the service.
	11.3.4 Uses a vaccination service checklist and staff training schedule.
	11.3.5 Confirms that the authorised immuniser has professional indemnity insurance and that the delivery site has insurance policies appropriate for the delivery of a vaccination service.
	11.3.6 Maintains a work health and safety (WHS) protocol to minimise the risk of needlestick injury, exposure to blood and body fluids, and transmission of infectious diseases; and to inform hand hygiene protocol and practices.
	11.3.7 Ensures that a contract with third-party providers exists, including: • clear definition of the roles and responsibilities of each provider • start date and end date of the arrangement • risk assessment of the arrangement and service • agreed communication methods • other relevant expectations and requirements • consistency with Pharmacy Board of Australia guidelines.
11.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver a vaccination service.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	11.4.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of services delivered.
	11.4.2 Facilitates training required to deliver services in line with best-practice requirements.
	11.4.3 Ensures that staff associated with the delivery of the service maintain required credentials.
	11.4.4 Ensures that staff associated with the service have adequate therapeutic knowledge and practice skills to complete their designated tasks within the service.

Criteria	Actions required
11.4 Education and training (continued)	**11.4.5** Maintains knowledge of current immunisation policy advice and scientific evidence, and relevant resources to support patients and communities with appropriate information about vaccination and immunity by addressing their questions and concerns.
	11.4.6 Promotes staff understanding of the purpose and risks of a vaccination service.
	11.4.7 Confirms that immunisers and others involved in service delivery have sufficient understanding of reporting requirements to inform patients about the purpose and function of the various vaccination registers.
	11.4.8 Educates people responsible for the provision of a vaccination service about protocols for the disposal of sharps and medical waste, and procedures for post-exposure prophylaxis, or confirms that they have this knowledge.
	11.4.9 Ensures that staff are trained to respond to adverse events following immunisation (AEFI).
11.5 Environment and equipment • Providing an appropriate service environment for vaccination. • Maintaining equipment required to deliver services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.6: Work environment* and *Criterion 2.7: Resource management*.
	11.5.1 Delivers the service in a location that is acceptable to the patient, and protects their privacy and confidentiality.
	11.5.2 Ensures that the service environment has appropriate surfaces, spaces and furnishings consistent with the professional requirements of the service.
	11.5.3 Ensures that equipment, hand hygiene and sanitation facilities, and documentation required for the service are easily accessible.
	11.5.4 Provides access to appropriate information resources to support the service.
	11.5.5 Uses equipment that meets relevant Australian standards.
	11.5.6 Provides all necessary protective clothing, equipment, and containers for storage and disposal of clinical waste.
	11.5.7 Provides appropriate seating and space for vaccination recipients to remain in the general vicinity for at least 15 minutes following vaccination to monitor for AEFI.
	11.5.8 Provides ready access to a copy of the *National Vaccine Storage Guidelines*, the current edition of the *Australian Immunisation Handbook*, and state or territory regulations and guidelines.
11.6 Cold chain management • Managing the cold chain cycle, including transport, storage and delivery of vaccination products. • Responding to breaches in cold chain management.	**11.6.1** Implements cold chain management protocols for purchasing, transporting, storing, managing and monitoring temperature consistency of vaccines.
	11.6.2 Develops a written vaccine management protocol to ensure that the cold chain is maintained and auditable (included in the policy and procedure manual).
	11.6.3 Evaluates and validates cold chain procedures and the quality of vaccination products.
	11.6.4 Ensures that all relevant cold chain equipment is accessible to the authorised immuniser, including appropriate and designated refrigeration space.
	11.6.5 Ensures that staff follow protocols for purchasing, transporting, storing, managing and monitoring temperature consistency of vaccines.

Criteria	Actions required
11.6 Cold chain management (continued)	**11.6.6** Activates contingency plans in the event of mechanical or power failure, and reporting of cold chain breaches.
	11.6.7 Ensures safe and appropriate storage and handling of vaccines.
	11.6.8 Maintains a reliable and stable refrigerator with adequate capacity for storing vaccines at between +2 °C and +8 °C (or as specified in the approved product information) to ensure potency.
11.7 Service delivery • Performing all services in a manner consistent with current best practice.	**11.7.1** Ensures that resources (human, environment, etc.) are appropriately allocated when promoting and explaining vaccination services to patients, communities and local healthcare professionals.
	11.7.2 Refers to relevant professional clinical guidelines, and program guidelines and standards when delivering a vaccination service.
	11.7.3 Ensures that staff contribute to a vaccination service only when they are equipped and capable to do so.
	11.7.4 Ensures that any person administering vaccines is an authorised immuniser in accordance with legislation.
	11.7.5 Ensures availability of: • documentation, stored patient consent and associated service forms for the duration described in guidelines • adrenaline (epinephrine) for anaphylaxis treatment, and anaphylaxis information (posters) • a suitably private area to administer vaccines • a cold chain management system for vaccines and vaccine products • a disposal system for sharps and medical waste • personal protective equipment for the authorised immuniser • serviced and quality equipment, calibrated when necessary • the policy and procedures manual for the service.
	11.7.6 Obtains informed consent from the patient before service delivery (including the collection, storage and sharing of patient details).
	11.7.7 Provides the patient with adequate details of the service, and each party's roles and responsibilities in the service.
	11.7.8 Ensures that the authorised immuniser complies with relevant guidelines.
	11.7.9 Employs a consistent and systematic approach to the collection of relevant patient information and delivery of the service.
	11.7.10 Considers the suitability of vaccination in the context of the patient's medical and medication history.
	11.7.11 Reconstitutes vaccines according to manufacturers' instructions, if required.
	11.7.12 Encourages the patient to notify relevant healthcare professionals and registers of receipt of the service.
	11.7.13 Discards medical waste and sharps carefully and immediately using approved containers.

Criteria	Actions required
11.8 Assessment, consultation and reconciliation • Tailoring a vaccination service to the individual patient. • Synthesising all available information to inform delivery of a vaccination service and associated advice.	**11.8.1** Targets services to at-risk patients and others who would benefit from the service.
	11.8.2 Educates patients about immunisation recommendations, assists patients to identify their vaccination status, and motivates at-risk patients to be immunised.
	11.8.3 Conducts a pre-vaccination screening, including a clinical needs assessment, with consideration of medical and medication history, vaccination records, contraindication, precautions, allergies, patient preferences, and fears or concerns.
	11.8.4 Identifies and responds to the patient's information needs, tailoring the delivery as required.
	11.8.5 Refers patients to other services, as appropriate, if vaccination requested is outside approved scope for the pharmacist or to promote continuity of care.
11.9 Counselling • Promoting understanding of the process, results and ongoing care associated with a vaccination service. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	11.9.1 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service delivery, and when changes to arrangements are necessary.
	11.9.2 Highlights to the patient if the service provided is part of a trial or research.
	11.9.3 Ensures that patients are offered appropriate immunisation information, including the risks of vaccination and of not being vaccinated.
	11.9.4 Provides advice to patients about their immunisation needs and 'catch-up' services, and/or refers them to their primary healthcare professional, where appropriate.
	11.9.5 Maintains an emergency response protocol and offers information on AEFI to patients.
	11.9.6 Offers patients information on the vaccine administered, potential side effects, who to contact in the event of an AEFI and (if relevant) the date of the next vaccination.
11.10 Monitoring, review and follow-up • Systematically monitoring, reviewing and providing follow-up associated with service. • Facilitating referral to other healthcare professionals, where necessary. See Appendix 3: Template referral letter. • Ensuring that information transfer is timely, accurate and aimed at optimising patient health outcomes.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	11.10.1 Provides appropriate and timely referral or ongoing monitoring in response to the service.
	11.10.2 Ensures that the patient healthcare plan includes updated vaccination records.
	11.10.3 Liaises with other members of the patient's healthcare team to ensure continuity of care and optimised patient health outcomes.
	11.10.4 Ensures identification and traceability of the source of the service (authorised immuniser details) and vaccination batch numbers to support future contact, when necessary.

Criteria	Actions required
11.11 Documentation • Systematically documenting all aspects of the vaccination service. • Ensuring accurate reporting to immunisation registers and reporting any AEFI that occur.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	11.11.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • self and staff training undertaken to deliver the service • patient information and informed consent • details of the vaccine administered, including name, batch number, dose, date, and time and site of administration • authorised immuniser details and address of administration site • date for follow-up or next vaccination • correspondence with other healthcare professionals • equipment maintenance and calibration • WHS reporting • any other information required by legislation, or professional standards and guidelines.
	11.11.2 Documents a service agreement with any contracted external authorised immunisers or service providers, to outline the roles and responsibilities of each party.
	11.11.3 Uses a secure and user-friendly booking and reminder system, where appropriate.
	11.11.4 Confirms that the authorised immuniser will report the vaccination of each patient to relevant external immunisation registers (e.g. Australian Immunisation Register).
11.12 Risk management and evaluation	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation*.
	11.12.1 Seeks specific patient-reported outcomes (e.g. AEFI during and within scope of service), and responds and reports appropriately (e.g.Therapeutic Goods Administration AEFI report).

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2. Andre FE, Booy R, Bock HL, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bull World Health Organ 2008;86(2):140–6. At: www.who.int/bulletin/volumes/86/2/07-040089/en
3. Australian Government Department of Health. Immunise Australia Program. About the program. 2015. At: www.health.gov.au/internet/immunise/publishing.nsf/Content/about-the-program
4. Pharmaceutical Society of Australia. Practice guidelines for the provision of immunisation services within pharmacy. Canberra: PSA; 2014. At: www.psa.org.au/policies/guidelines-for-the-provision-of-immunisation-services-within-pharmacy

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Australian Government Department of Health and Ageing. National vaccine storage guidelines: strive for 5. 2nd edn. Canberra: Department of Health and Ageing; 2013. At: www.health.gov.au/internet/immunise/publishing.nsf/content/D7EDA378F0B97134CA257D4D0081E4BB/$File/strive-for-5-guidelines.pdf

National Health and Medical Research Council. Australian immunisation handbook. 10th edn. Canberra: NHMRC; 2016. At: www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home

Supplementary information: state and territory standards, codes, guidelines and protocols		
State	Name of document	Link
ACT	Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2016 (No. 3)	www.legislation.act.gov.au/di/2016-248/default.asp
NSW	NSW Pharmacist Vaccination Standards	www.health.nsw.gov.au/pharmaceutical/Documents/pharmacist-vacc-standards.pdf
NT	Scheduled substance treatment protocol – pharmacist-led administration of vaccines to adults at pharmacy premises in the Northern Territory (NT)	www.nt.gov.au/ntg/gazette/2016/docs/S4-2016.pdf#page=1
QLD	Queensland Pharmacist Vaccination Standard	www.health.qld.gov.au/__data/assets/pdf_file/0016/444130/standard-pharmacy-vaccination.pdf
SA	Vaccine Administration Code	www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/legislation/controlled+substances+legislation/vaccine+administration+code
TAS	Tasmanian Vaccination Program guidelines	www.dhhs.tas.gov.au/__data/assets/pdf_file/0020/211808/Tasmanian_Vaccination_Program_Guidelines_Feb_2016.pdf
VIC	Victorian Pharmacist-Administered Vaccination Program guidelines	https://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers/guidelines
WA	Structured administration and supply arrangements – administration of influenza vaccines by pharmacists.	http://ww2.health.wa.gov.au/Articles/S_T/Structured-Administration-and-Supply-Arrangements

Standard 12: Minor Ailments Service

The pharmacist provides a timely, structured and consistent minor ailments service to patients, informed by evidence-based practice and quality use of medicines.

Background and scope

A minor ailments service is a structured primary care service that effectively supports the population to manage their minor ailment symptoms in an effective and timely manner.[1]

Pharmacists, as highly skilled and accessible healthcare professionals, are well placed to assist patients to manage minor ailments by providing non-prescription medicines and self-care advice. Providing information on minor ailment management and facilitating self-care are considered key professional activities for pharmacists.[1]

In the context of this standard, a minor ailment is considered to be "a condition that is often self-limiting with symptoms easily recognised and described by the patient and falling within the scope of pharmacist knowledge and training to treat".[2] This standard does not apply to the management of conditions outside this definition.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices, Standard 7: Health Promotion and Education, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Minor Ailments Service Standard

Standard 12: Minor Ailments Service

Criteria	Actions required
12.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
12.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative Care.*
12.3 Policy and procedures • Aligning all minor ailment services with best practice. • Ensuring that a current standard operating procedure informs all service delivery.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	12.3.1 Ensures that all minor ailment services align with relevant program guidelines and evidence (where available).
	12.3.2 Reviews service policies and procedures to ensure compliance with relevant legislative requirements.
	12.3.3 Maintains a standard operating procedure, which includes: • identification of patients (i.e. symptom-based or product-based requests) • consent requirements • elements of service delivery (e.g. clinical assessment, treatment, referral, counselling, documentation, follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • risk management and evaluation of the service.
	12.3.4 Ensures that a contract with third-party providers exists, including: • clear definition of the roles and responsibilities of each provider • start date and end date of the arrangement • risk assessment of the arrangement and service • agreed communication methods • other relevant expectations and requirements • consistency with Pharmacy Board of Australia guidelines.
12.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver minor ailments services.	**12.4.1** Creates awareness and understanding of the roles, responsibilities and general procedures for the range of services delivered.
	12.4.2 Facilitates training required to deliver services in line with best-practice requirements.
	12.4.3 Promotes staff understanding of the intention, risks and limitations of the service.
12.5 Environment and equipment • Providing an appropriate service environment to deliver a minor ailments service. • Ensuring access to products and consumables required to deliver services.	**12.5.1** Delivers the service in a location that is acceptable to the patient, and protects their privacy and confidentiality.
	12.5.2 Ensures that the service environment has appropriate surfaces and furnishings consistent with the professional requirements of the service.
	12.5.3 Provides products and consumables required to deliver the service.
	12.5.4 Provides all necessary protective clothing, equipment, and containers for storage and disposal of clinical waste.

Criteria	Actions required
12.6 Service delivery • Performing all minor ailments services in a manner consistent with current best practice. • Ensuring that services are responsive to patient needs and provided in a timely manner.	**12.6.1** Refers to relevant program guidelines and standards when delivering minor ailments services.
	12.6.2 Ensures that staff contribute to minor ailments services only when they are equipped and capable to do so.
	12.6.3 Obtains informed consent from the patient before service delivery.
	12.6.4 Employs a consistent and systematic approach to the clinical assessment of minor ailments, including eliciting relevant patient information.
	12.6.5 Uses recognised, evidence-based protocols, where available, to inform clinical assessment and patient management decisions (i.e. treat or refer).
	12.6.6 Provides information to support the safe and effective use of medicines, healthcare products, and non-medicinal management strategies.
	12.6.7 Facilitates proactive referral and follow-up, as required. See Appendix 3: Template referral letter.
	12.6.8 Ensures that workflow processes are flexible and adaptive enough to respond to minor ailment presentations.
12.7 Assessment, consultation and reconciliation • Synthesising all available information to assess patient presentations and guide appropriate patient management. • Providing non-prescription medicines in a manner consistent with Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices.	**12.7.1** Uses clinical assessment, supported by recognised protocols, where available, to: • conduct an accurate differential diagnosis of the presenting complaint • differentiate between a minor ailment and major disease • identify and respond to urgent and emergency presentations.
	12.7.2 Considers all patient factors likely to influence the management of minor ailments (e.g. patient medical history, allergies, medications and lifestyle factors).
	12.7.3 Identifies contraindications or precautions, and responds appropriately in the context of the patient's health, allergies, lifestyle and risk factors.
	12.7.4 Promotes the use of non-medicinal management options, where appropriate.
	12.7.5 Advises on prevention in future, if relevant, and management of symptoms if different from management of the condition.
	12.7.6 Refers to, and upholds, the relevant criteria in *Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices* when providing products or devices for the management of a minor ailment.
12.8 Counselling • Promoting understanding of management options and ongoing care associated with minor ailments services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	12.8.1 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	12.8.2 Explains management options to the patient, or carer or authorised representative, in a sensitive and timely manner.
	12.8.3 Empowers the patient to consider and take action on their results in the context of their healthcare plan and goals.
	12.8.4 Offers tailored verbal and written health information consistent with the patient's needs.
	12.8.5 Facilitates understanding of ongoing care arrangements, including monitoring, follow-up and referral.

Criteria	Actions required
12.9 Monitoring, review and follow-up • Ensuring a systematic approach to referral, follow-up and recall of patients.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	12.9.1 Provides appropriate and timely referral, or ongoing monitoring or follow-up tailored to the needs of the patient, and informed by recognised protocols, where available.
	12.9.2 Confirms patient understanding of, and agreement to, each party's role and responsibility in ongoing care arrangements.
	12.9.3 Ensures identification and traceability of the source of the service to support future contact (e.g. contact details of the service provider).
12.10 Documentation • Systematically documenting all aspects of the minor ailments service.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	12.10.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • self and staff training undertaken to deliver the service • patient information and consent • records of all services provided, including date, provider, management decisions and follow-up actions • correspondence with other healthcare professionals • work health and safety (WHS) reporting (exposure, contamination and other incidents) • any other information required by legislation, and professional standards and guidelines.
12.11 Risk management and evaluation • Minimising risks associated with delivery of a minor ailments service. • Conducting ongoing evaluation of services for quality enhancement.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	12.11.1 Undertakes a risk analysis before implementing services.
	12.11.2 Ensures appropriate use of protective clothing, equipment, and containers for storage and disposal of clinical waste.
	12.11.3 Ensures adherence to infection control or other relevant WHS procedures and protocols.
	12.11.4 Regularly assesses the suitability of the surfaces, furnishings and equipment in the service environment, and responds appropriately.
	12.11.5 Reviews the capacity and capability of all staff associated with service delivery, and responds appropriately.
	12.11.6 Obtains feedback on service from relevant stakeholders, and integrates it into future service planning and delivery.

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Standard 13: Disease State Management

The pharmacist supports the patient to develop and, where possible, take responsibility for their healthcare plan. The pharmacist raises awareness of the risk factors associated with chronic disease states, and works with members of the healthcare team to facilitate patient health and wellbeing.

Background and scope

Disease state management is a system of continuous and coordinated healthcare interventions and communication focused on enabling patients with chronic conditions, in partnership with healthcare professionals, to manage their disease and prevent complications.[1,2]

Pharmacists can have a significant role in assisting patients to manage chronic disease through structured disease state management services. In the context of this standard, disease state management services may include monitoring, counselling, education, improvement of self-management, and quality use of medicines (QUM) activities.

This standard reflects the overarching principles underpinning disease state management. It applies to pharmacists delivering any service aimed at managing a chronic condition, including asthma, cardiovascular disease, diabetes, smoking and weight management.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 4: Provision of Non-prescription Medicines and Therapeutic Devices, Standard 7: Health Promotion and Education, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Disease State Management Standard

Standard 13: Disease State Management

Criteria	Actions required
13.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
13.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative Care.*
13.3 Policy and procedures • Aligning all disease state management services with best practice. • Ensuring that a current standard operating procedure informs all service delivery.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	13.3.1 Ensures that all disease state management services align with relevant clinical guidelines and program guidelines.
	13.3.2 Reviews all disease state management services to ensure compliance with relevant legislative requirements.
	13.3.3 Maintains a standard operating procedure, which includes: • identification of at-risk patients or populations who would benefit from the service • consent requirements • elements of service delivery (e.g. collection of information, assessment and interpretation of results, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • risk management and evaluation of the service.
	13.3.4 Ensures that a contract with third-party providers exists, including: • clear definition of the roles and responsibilities of each provider • start date and end date of the arrangement • risk assessment of the arrangement and service • agreed communication methods • other relevant expectations and requirements • consistency with Pharmacy Board of Australia guidelines.
13.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver disease state management services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	13.4.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of disease state management services delivered.
	13.4.2 Facilitates training required to deliver services in line with best-practice requirements.
	13.4.3 Ensures that self and all staff associated with the delivery of the service maintain required credentials.
	13.4.4 Ensures that self and staff associated with the service have adequate therapeutic knowledge and practice skills to complete their designated tasks within the service.
	13.4.5 Promotes staff understanding of the purpose and limitations of disease state management services.
13.5 Quality use of medicines	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.7: Quality use of medicines.*

Criteria	Actions required
13.6 Environment and equipment • Providing an appropriate service environment for disease state management. • Maintaining equipment required to deliver services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.6: Work environment* and *Criterion 2.7: Resource management*.
	13.6.1 Delivers the service in a location that is acceptable to the patient, and protects their privacy and confidentiality.
	13.6.2 Ensures that the service environment has appropriate surfaces and furnishings consistent with the professional requirements of the service.
	13.6.3 Provides access to appropriate information resources to support the service.
	13.6.4 Uses equipment that meets relevant Australian standards.
	13.6.5 Calibrates equipment according to manufacturers' instructions.
	13.6.6 Ensures that equipment is serviced regularly according to manufacturers' instructions.
	13.6.7 Provides all necessary protective clothing, equipment, and containers for storage and disposal of clinical waste.
13.7 Service delivery • Performing all services in a manner consistent with current best practice.	**13.7.1** Refers to relevant professional clinical guidelines, program guidelines and standards when delivering disease state management services.
	13.7.2 Ensures that staff contribute to disease state management services only when they are equipped and capable to do so.
	13.7.3 Obtains informed consent from the patient before service delivery (including the collection, storage and sharing of patient details).
	13.7.4 Provides the patient with adequate details of the service, and each party's roles and responsibilities in the service.
	13.7.5 Targets services to patients at risk of disease state-associated complications and others who would benefit from the service.
	13.7.6 Employs a consistent and systematic approach to the collection of relevant patient information and measurements.
	13.7.7 Conducts relevant physical assessments (e.g. weight, height measurements), and obtains and uses available laboratory information.
	13.7.8 Considers presentation in the context of the patient's medical and medication history.
	13.7.9 Communicates results to the patient in a timely and appropriate manner.
	13.7.10 Facilitates proactive referral and follow-up, as required. See Appendix 3: Template referral letter.

Criteria	Actions required
13.8 Assessment, consultation and reconciliation • Tailoring disease state management services to the individual patient, in collaboration with other healthcare professionals. • Synthesising all available information to inform disease state management advice.	**13.8.1** Conducts a patient interview to obtain information relevant to optimal management of the patient's medical condition(s), including assessment of patient knowledge of disease state(s), symptoms, preferences, lifestyle, and social and family history.
	13.8.2 Considers all patient factors likely to influence the outcomes of the disease state management advice provided (e.g. patient medical history, adherence patterns, preferences, medications, allergies, adverse reactions, interactions, contraindications, lifestyle factors).
	13.8.3 Identifies and responds to the patient's information needs, tailoring the delivery as required.
	13.8.4 Considers all factors likely to influence the accuracy of the assessments.
	13.8.5 Supports the patient and other relevant members of their healthcare team to develop, review and maintain an achievable healthcare plan or make necessary changes to therapy.
13.9 Counselling • Promoting understanding of the process, results and ongoing care associated with disease state management services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	13.9.1 Raises awareness of the implications of chronic disease and the value of preventive strategies, achievable healthcare plans and medication management.
	13.9.2 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	13.9.3 Provides assessment results to the patient, or carer or authorised representative, in a sensitive and timely manner.
	13.9.4 Explains assessment results, including their significance and limitations, in the context of the patient's health, lifestyle and risk factors.
	13.9.5 Tailors motivational techniques in response to the patient's preferences.
	13.9.6 Checks for patient understanding of conditions, treatments, assessment results and information provided.
	13.9.7 Empowers the patient to consider and respond positively to their assessment in the context of their own healthcare plan and goals.
	13.9.8 Offers evidence-based and tailored verbal and written health information consistent with the patient's needs.
	13.9.9 Facilitates understanding of ongoing care arrangements, including monitoring, follow-up and referral.
13.10 Monitoring, review and follow-up • Ensuring a systematic approach to follow-up and recall of patients who have used the service.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	13.10.1 Provides appropriate and timely referral or ongoing monitoring in response to the assessment.
	13.10.2 Ensures that the patient's healthcare plan is updated with the results and recommendations from the disease state management service. See Appendix 2: Patient healthcare plan.
	13.10.3 Confirms patient understanding of, and agreement to, each party's role and responsibility in ongoing care arrangements.
	13.10.4 Liaises with other members of the patient's healthcare team to ensure continuity of care and optimised patient health outcomes.

Criteria	Actions required
13.10 Monitoring, review and follow-up (continued)	**13.10.5** Employs a systematic approach to patient follow-up to support regular review of motivation, adherence, results and progress, to inform renewal of the patient care plan.
	13.10.6 Ensures identification and traceability of the source of the service to support future contact (e.g. contact details of the service provider).
13.11 Documentation	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	13.11.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • self and staff training undertaken to deliver the service • patient information and consent • records of all service provided, including date, provider, results and follow-up actions • correspondence with other healthcare professionals • equipment, maintenance and calibration • work health and safety reporting • any other information required by legislation, and professional standards and guidelines.
13.12 Risk management and evaluation	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*

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Standard 14: Medication Review

The pharmacist works with the patient to reconcile their medication regimen and undertakes a systematic assessment to identify potential areas for improvement, informed by quality use of medicines. The pharmacist provides information and advice to the patient and their healthcare providers.

Background and scope

A medication review is a structured and collaborative service aimed at identifying and resolving medication-related problems, to optimise the impact of medicines on patient health outcomes.[1,2] The term encompasses a continuum of processes in various formats and complexities, from opportunistic discussion with patients to a more systematic and proactive approach to reviewing the patient's medication regimen and healthcare plan.[2]

This standard reflects the key principles underpinning all types of systematic medication review. It applies to pharmacists delivering services including hospital inpatient medication reviews, MedsChecks, Home Medicines Reviews (HMR) and Residential Medication Management Reviews (RMMR). Opportunistic medication history reviews that occur at the time of dispensing are covered in Standard 3: Dispensing and Other Supply Arrangements.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 6: Medicines Information, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Medication Review Standard

Standard 14: Medication Review

Criteria	Actions required
14.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
14.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative Care.*
14.3 Policy and procedures • Ensuring that a current standard operating procedure informs all service delivery. • Confirming that all legislative requirements, professional indemnity insurance and workplace insurance are met before medication review services are delivered.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	14.3.1 Ensures that all medication review services are consistent with relevant clinical guidelines and comply with program guidelines.
	14.3.2 Reviews all medication review services to ensure compliance with relevant legislative requirements.
	14.3.3 Maintains a standard operating procedure, which includes: • consent requirements • elements of service delivery • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment • third-party provider arrangements • work health and safety (WHS) requirements • risk management and evaluation of the service.
	14.3.4 Ensures that any pharmacist under direct supervision or under contract in third-party arrangements is appropriately qualified to deliver the services.
	14.3.5 Develops and maintains a service agreement with each party involved in the review. Ensures that the contract includes an outline of the roles and responsibilities of each party.
14.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver medication review services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	14.4.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of medication review services delivered.
	14.4.2 Accesses evidence-based resources about disease states, medicines, therapeutic devices and lifestyle solutions to support service delivery.
	14.4.3 Facilitates training required to deliver services in line with best-practice requirements.
	14.4.4 Ensures that self and staff associated with the service have adequate therapeutic knowledge and practice skills to complete their designated tasks within the service.
	14.4.5 Supports professional development of students, interns and other pharmacists through mentoring and role modelling best practice.
	14.4.6 Promotes understanding of the purpose of medication review services.

*Third-party provider arrangements refer to the situation where a community pharmacy subcontracts an accredited pharmacist to provide the HMR or RMMR service.

Criteria	Actions required
14.5 Assessment, consultation and reconciliation • Tailoring medication review services to the individual patient. • Synthesising all available information to inform the review, medication management and recommendations.	**14.5.1** Determines and uses the preferred method of communication for the patient or authorised representative, and other healthcare professionals associated with the patient's care.
	14.5.2 Conducts a patient interview to compile a best possible medication history (including over-the-counter medicines, complementary medicines, nutritional supplements, borrowed medicines and illegal drugs). Where direct communication with the patient is not possible, uses professional judgement to obtain a history from other appropriate sources (e.g. authorised representative; electronic healthcare plan; other healthcare professionals, including other pharmacists involved in care).
	14.5.3 Requests a healthcare plan and/or dispensing history from the community pharmacy or the patient's most recent healthcare setting.
	14.5.4 Performs medication reconciliation. Reconciles the patient's current medication regimen with their healthcare plan, pharmacy records, medical and laboratory assessments and tests, and information from other healthcare professionals associated with the patient's care.
	14.5.5 Supports the patient, or carer or authorised representative, to develop a healthcare plan, in collaboration with other healthcare professionals actively involved in the patient's care.
	14.5.6 Assesses adherence, and discusses concerns with the patient, or carer or authorised representative, to develop solutions. See Appendix 5: Adherence assessment tool.
	14.5.7 Discusses with the patient their medication experience, including burdens; medication beliefs, concerns and knowledge; health conditions; medical assessments; laboratory tests; and relevant lifestyle factors. Reconciles these against the patient's healthcare plan to determine actual medication-related issues.
14.6 Service delivery • Ensuring that the service includes patient clinical assessment, risk assessment and associated after-care.	**14.6.1** Confirms that the patient (or their authorised representative) has provided informed consent for the service, access to their medical records and communication with healthcare professionals nominated in their healthcare team.
	14.6.2 Conducts the medication review in an environment that is consistent with program specific guidelines, patient preferences and health needs, and is safe for the patient and pharmacist.
	14.6.3 Completes the medication review in a timely manner as determined by urgency and in accordance with guidelines. Notifies the referring healthcare professionals if there is to be a delay.
	14.6.4 Prioritises any identified issues and addresses them in a timely manner.
	14.6.5 Completes a medication profile that is current at the time of the review for each patient.
	14.6.6 Provides a report of recommendations, follow-up actions and outcomes (as appropriate) to the medical practitioner, the patient's nominated community pharmacy and, if requested, the patient.
	14.6.7 Provides appropriate follow-up and associated after-care if required.

Criteria	Actions required
14.7 Documentation and data management • Maintaining a comprehensive medication profile, in collaboration with the patient and other relevant healthcare professionals. • Ensuring accurate and timely reporting of adverse events discovered during the interview or review to relevant authorities.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	14.7.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • patient information and consent • details of the service provided, any recommendations made and action plans provided, including name of patient and pharmacist, contact details, service type, date and time • pharmacist details, including phone number and email for follow-up contact • date for follow-up or suggested date of next review • correspondence with other healthcare professionals • WHS reporting • any other information required by legislation, or professional standards and guidelines • self and staff training undertaken to deliver the service.
	14.7.2 Uses suitable secure electronic solutions (portal, system, computer system) to record relevant patient details in the medication profile and healthcare plan (e.g. electronic healthcare plan).
	14.7.3 Records all activities undertaken in the course of the medication review.
	14.7.4 Records any follow-up actions and patient outcomes resulting from the medication review.
	14.7.5 Records medical practitioner's comments on each recommendation, if provided.
	14.7.6 Stores all medication review documentation in a safe, systematic and secure manner that allows timely and accurate retrieval.
	14.7.7 Uses suitable systems (e.g. computer software and eHealth record to maintain relevant patient details in the medication profile) to ensure reliable and timely transfer of patient information and review findings.
	14.7.8 Uses a secure booking and reminder system, where appropriate.
14.8 Counselling • Providing patient and other relevant healthcare professionals with relevant information to optimise the patient's healthcare plan. • Promoting understanding of the role of medication reviews and ongoing care associated with these services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	14.8.1 Ensures that the costs (if any) associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	14.8.2 Confirms that the patient, or carer or authorised representative, understands the process, requirements, benefits and limitations of the service.
	14.8.3 Tailors counselling to the individual patient's needs.
	14.8.4 Ensures that information provided to the patient is appropriate and will not result in unintended outcomes, confusion or harm, and aims to minimise provision of information that may conflict with other healthcare professionals' advice or counselling.
	14.8.5 Demonstrates and confirms patient competence with therapeutic devices and aids designed to support medication use and adherence.

Criteria	Actions required
14.8 Counselling (continued)	**14.8.6** Discusses the details of the medication review and reconciled profile with the patient or authorised representative, and empowers them to discuss their healthcare plan with other healthcare providers (highlighting its importance in the continuity of care).
	14.8.7 Recommends appropriate resources to support adherence, and patient access to appropriately delivered evidence-based medicines information and health education.
14.9 Continuity of care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care*.
	14.9.1 Requests or suggests a home medication review for at-risk patients following recent hospital discharge, or recent transition in their living or care arrangements (e.g. respite to home).
	14.9.2 Reconciles the management plan created by the medical practitioner with the medication review recommendations made by the pharmacist.
	14.9.3 Provides other key healthcare professionals active in the patient's care (including a nominated community pharmacist) with a copy of the medication review report, with relevant information to ensure continuity of care.^
14.10 Monitoring, review and follow-up • Monitoring patients following medication review services. • Following up any issues arising from the medication review. • Ensuring that all medication issues identified in the review are highlighted to the patient, authorised representative, patient's medical practitioner and other relevant healthcare professionals.	**14.10.1** Constructs a clear plan that includes roles and responsibilities for each member of the healthcare team (e.g. community pharmacist, hospital pharmacist, patient, medical practitioner, other healthcare professionals) in the review and follow-up process.
	14.10.2 Addresses any potential or actual medication-related problems identified in the medication review, in collaboration with other healthcare professionals active in the patient's care.
	14.10.3 Provides accurate and relevant written and verbal information to each nominated healthcare professional active in the patient's care.#
	14.10.4 Liaises with other pharmacists and healthcare professionals involved in the review to support information continuity and optimised patient outcomes.
14.11 Storage, stability and disposal • Maximising the appropriate storage, use and disposal of medicines.	**14.11.1** Provides information to the patient, authorised representative, facilities and healthcare professionals active in the patient's care on considerations for the safe and appropriate storage and stability of medicines.
	14.11.2 Provides information to the patient, authorised representative, facilities and healthcare professionals active in the patient's care on the sustainable, safe and environmentally conscious disposal of medicines that are unwanted, expired or no longer used.
	14.11.3 Obtains and documents consent from the patient before removing the patient's medicines for safe disposal.
	14.11.4 Disposes of medicines in an appropriate manner (e.g. return unwanted medicines (RUM) bin, destruction) consistent with relevant state or territory requirements.
14.12 Risk management and evaluation • Minimising risks associated with the medication review service. • Conducting ongoing evaluation of services for quality enhancement.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	14.12.1 Seeks specific patient-reported outcomes (e.g. adverse reactions during and within scope of service), and responds and reports appropriately (e.g. TGA Adverse Event Notification).

^Patient must consent to a copy of the medication review report being made available to community pharmacy.

#Patient must consent to a copy of the medication review report being made available to other nominated healthcare professionals.

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Therapeutic Goods Administration. Reporting adverse drug reactions: information for health professionals. 2014. At: www.tga.gov.au/publication/reporting-adverse-drug-reactions

Standard 15: Dose Administration Aid Service

The pharmacist provides a dose administration aid service to improve adherence and quality use of medicines, and optimise patient health outcomes.

Background and scope

Dose administration aid (DAA) services are holistic services that encompass medication assessment and reconciliation, packing of DAAs, and the professional support provided to ensure the optimal use of DAAs, to support the safe and effective administration of the patient's medication and improve adherence.[1,2]

In the context of this standard, a DAA is "a tamper-evident, well-sealed device or packaging system that allows for organising doses of medicine according to the time of administration".[3] However, if the pharmacist provides a non-tamper evident DAA at the patient's request, the service should still meet the criteria in this standard. Pharmacists must ensure that all criteria and actions are adhered to for both robotic offsite and manual packing methods.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Dose Administration Aid Service Standard

Standard 15: Dose Administration Aid Service

Criteria	Actions required
15.1 Patient-centred care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
15.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative care.*
15.3 Policy and procedures • Aligning all DAA services with best practice. • Ensuring that a current standard operating procedure informs all service delivery. • Confirming that all legislative requirements, professional indemnity insurance and workplace insurance are met before DAA services are delivered.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	15.3.1 Ensures that all DAA services align with relevant clinical guidelines and program guidelines.
	15.3.2 Reviews all DAA services to ensure compliance with relevant legislative requirements.
	15.3.3 Maintains a standard operating procedure, which includes: • identification of at-risk patients or populations who would benefit from the service • consent requirements • elements of service delivery (e.g. collection of information, prescriptions, medicines, packing, disposal, counselling, payment, delivery, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • dedicated packing days for optimal workflow • requirements of the service environment (e.g. adequate bench space, ventilation and lighting; storing Controlled Drugs packed in DAAs in a locked safe) • third-party provider arrangements • work health and safety requirements • risk management and evaluation of the service.
	15.3.4 Ensures that a contract with third-party providers exists, including: • clear definition of the roles and responsibilities of each provider • start date and end date of the arrangement • risk assessment of the arrangement and service • agreed communication methods • other relevant expectations and requirements • response to changes to DAA/'pm' medicines, and expectations around timeframes for change and resupply • consistency with Pharmacy Board of Australia guidelines.
	15.3.5 Follows a consistent process for managing brand substitutions.
	15.3.6 Implements a system that facilitates the separation and clear identification of non-modifiable preparations for patients or authorised representatives.
	15.3.7 Implements supply, storage, monitoring and disposal processes to prevent medicines being re-used or repacked.
	15.3.8 Implements a reporting system to ensure that prescriptions required for medicines packed in DAAs are regularly provided.
	15.3.9 Develops transparent and fair arrangements with service settings around repacking and supply expectations on weekends and public holidays.
	15.3.10 Encourages the patient, carer or authorised representative, and healthcare professionals to systematically record and report adverse drug reactions to the pharmacist and/or Therapeutic Goods Administration.

Criteria	Actions required
15.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver DAA services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development*.
	15.4.1 Creates awareness and understanding of the roles, responsibilities and general procedures for the range of services delivered.
	15.4.2 Facilitates training required to deliver services in line with best-practice requirements.
	15.4.3 Ensures that self and all staff associated with the delivery of the service maintain required skills and credentials.
	15.4.4 Ensures that self and staff associated with the service have adequate therapeutic knowledge and practice skills to complete their designated tasks within the service.
	15.4.5 Promotes staff understanding of the purpose and limitations of a DAA service.
15.5 Assessment, consultation and reconciliation • Tailoring DAA services to the individual patient. • Synthesising all available information to inform delivery of the DAA service and associated advice. • Monitoring all patients who use DAAs that were supplied through their service.	**15.5.1** Establishes the patient's level of autonomy (ability to care for themselves) and considers this to assess the appropriateness of the DAA service.*
	15.5.2 Considers alternative methods of administration, and tailors the service accordingly.
	15.5.3 Collaborates with the patient and other healthcare professionals to address any medication management issues that arise throughout service delivery.
	15.5.4 Consults with the patient, or carer or authorised representative, to regularly review the current medicine regimen and medication history, with the aim of medicines optimisation.
	15.5.5 Reconciles the patient's medication history, medication order, reports and other available information to ensure that medication records are current and accurate.
	15.5.6 Accesses current information on medicines that should not be removed from their original packaging and therefore should not be repacked into a DAA.
	15.5.7 Uses professional judgement to decide whether to pack particular medicines into a DAA. Where appropriate, involves the patient in the decision or communicates the decision to the patient.
	15.5.8 Monitors patient adherence and persistence with medications, and addresses any concerns with the patient or their nominated healthcare professionals.

* For example *Shared Decision Making* (ACSQHC) and *Medicines Optimisation: the Safe and Effective Use of Medicines to Enable the Best Possible Outcomes* (NICE) (see Additional references and resources).

Criteria	Actions required
15.6 Service delivery • Ensuring that the service includes patient clinical assessment, risk assessment and associated patient after-care.	**15.6.1** Reconciles the patient's medication before commencement of the DAA service and at relevant frequent intervals, to ensure medicines optimisation.
	15.6.2 Obtains a medicine order from an appropriate prescriber before packing a DAA.
	15.6.3 Confirms that medicines packed in a DAA match the patient's current medication order.
	15.6.4 Ensures adherence to hand hygiene, storage and stability requirements throughout the packing processes (e.g. separates equipment used to pack hazardous medicines).
	15.6.5 Ensures a dedicated area for packing and checking DAAs.
	15.6.6 Systematically checks the contents and packing records for all DAAs packed under the pharmacist's supervision before supply.
	15.6.7 Ensures that the person packing the DAA is not responsible for other services at the time of packing, to minimise interruptions (and consequent errors) during the packing process.
	15.6.8 Minimises interruptions to the workflow of the checking pharmacist (e.g. diverts phones, schedules checking times, reviews resources and staffing, and checks the environment and spaces).
	15.6.9 Ensures that all DAAs are provided to the patient, carer or authorised representative, or facility in a timely manner.
	15.6.10 Labels each DAA with the patient's name; and the pharmacy name, address and telephone number.
15.7 Documentation • Systematically documenting all aspects of service delivery. • Ensuring accurate reporting to adverse events registers when notified that such events have occurred.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	15.7.1 Documents and updates the patient's healthcare plan with medication order, medication review outcomes, medical conditions, formulation requirements, allergies, lifestyle considerations and preferences.
	15.7.2 Supports the patient, or their carer or authorised representative, to update their healthcare plan and notify healthcare professionals involved in their care when experiencing transitions in care or living arrangements (e.g. hospital admissions, family holiday, respite care). See Appendix 4: Process for managing transitions of care.
	15.7.3 Maintains and documents a current and complete medication profile that includes medicines packed and not packed in the DAA, and decisions not to pack. Where possible, links this to the patient's healthcare plan.
	15.7.4 Maintains documentation that tracks which DAAs have been packed and supplied, by whom, and when, and enables immediate contact for queries (phone number or email of the service provider or responsible pharmacist).
	15.7.5 Maintains accurate and clear records of all medications packed into DAAs (e.g. date, quantity, instances where brand substitution occurred, packed by [signature], checked by [signature]).
	15.7.6 Includes the patient's name; and the address, telephone number and email of the service provider or responsible pharmacist on the DAA label.
	15.7.7 Follows a consistent process for recording which patients cannot swallow tablets, capsules or medicines; and which medicines can be crushed or modified.
	15.7.8 Ensures that the font size of labelling is appropriate to the recipient (where possible).

Criteria	Actions required
15.7 Documentation (continued)	**15.7.9** Ensures that DAA labelling identifies the active ingredient, the brand name (where possible), the strength of the medicine and directions for use.
	15.7.10 Ensures that labelling enables identification of individual medicines (e.g. colour, shape, size, manufacturers' marks) and any specific instructions relevant to the medicines.
	15.7.11 Uses appropriate and legally required cautionary and advisory labels, and ensures that the words 'Keep out of reach of children' are placed on the DAA label.
	15.7.12 Ensures that the packing date, intended date of commencement and expiry date are consistent with the stability of the medicines included in the pack, and dates are clearly documented on the DAA label.
	15.7.13 Documents relevant conversations regarding the medication, the healthcare plan and packing arrangements with the patient, carer or authorised representative, and healthcare professionals.
	15.7.14 Documents any changes to the medicine regimen, healthcare plan or packing arrangements, including details of the change, the date, who authorised the change, and the pharmacist's name and signature.
	15.7.15 Maintains and displays a list of medicines not suitable for packing for ready reference during the packing process.
15.8 Counselling • Promoting understanding of the role of DAA and ongoing care associated with DAA services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	15.8.1 Confirms that the patient, or carer or authorised representative, understands the process, requirements, benefits and limitations of the service.
	15.8.2 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	15.8.3 Commences the service with comprehensive instructions to the patient, or carer or authorised representative, about the optimal handling and storage of the DAA.
	15.8.4 Provides ongoing support, tailored to the individual patient (selecting the most appropriate methods – written, phone, other) for counselling for the duration of the service.
	15.8.5 Supports the patient to manage any medications not packed in the DAA.
	15.8.6 Empowers the patient, or carer or authorised representative, to ensure accurate and appropriate update of the healthcare plan, medication records and DAA.
15.9 Continuity of care	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	15.9.1 Ensures that interim measures or alternative arrangements are in place if DAAs are delayed or cannot be provided.

Criteria	Actions required
15.10 Monitoring, review and follow-up • Systematically monitoring, reviewing and providing follow-up associated with the service. • Facilitating referral to other healthcare professionals, where necessary. • Ensuring that information transfer is timely, accurate and aimed at optimising patient health outcomes.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	15.10.1 Provides appropriate and timely referral or ongoing monitoring in response to the service. See Appendix 3: Template referral letter.
	15.10.2 Ensures that the patient's current medication order and DAA-related records are updated and linked to the healthcare plan.
	15.10.3 Liaises with other members of the patient's healthcare team to ensure continuity of care and optimised patient health outcomes.
	15.10.4 Uses the medication review service to regularly review the appropriateness of the patient's medication administration solution(s) or DAA device and adjusts arrangements in response.
	15.10.5 Ensures identification and traceability of the source of the service (e.g. contact details of offsite packing organisation), to support future contact.
	15.10.6 Facilitates communication to enable streamlined notification of regimen changes, and modification of current and future DAAs.
15.11 Storage, stability and disposal • Maximising the stability of medicines throughout the DAA packing process and distribution, and giving advice to patients, authorised representatives or facilities on end-use conditions.	**15.11.1** Adheres to evidence-based information sources to optimise storage and stability requirements of medications and DAAs, once packed.
	15.11.2 Adheres to best-practice guidelines to inform decisions about pre-use (source and storage), re-use and disposal of medicines.
	15.11.3 Uses professional judgement (with relevant evidence base) to determine whether medicines supplied by the patient, the hospital or others should be packed in a DAA. Considers storage and stability history, patient preferences, urgency of DAA supply, safety, financial implications to the patient and individual requirements of the medicine.^
	15.11.4 Minimises the duration for which medicines are exposed to the environment (e.g. light, air) by promptly transferring them from the original packaging into the DAA.
	15.11.5 Seals the DAA and medicines being packed immediately after medication is set out and packed.
	15.11.6 Stores packed DAAs in an area that is cool, dry and protected from light, to maintain stability of the medicines.
	15.11.7 Minimises the duration between packing and supply/dosage.
	15.11.8 Disposes of medicines responsibly according to relevant legislation, considering environmental impact, sustainability principles and best-practice guidelines (e.g. return unwanted medicines (RUM) bins).
15.12 Risk management and evaluation • Minimising risks associated with DAA service delivery. • Conducting ongoing evaluation of services for quality enhancement.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation*.
	15.12.1 Considers and immediately mitigates risks associated with medication recalls, medication shortages and medication substitution.
	15.12.2 Follows a process to manage shortages of medicines, devices and consumables (e.g. packing equipment).
	15.12.3 Implements a documented procedure for packing DAAs that enables tracking, recall, identification of source of error and system review.
	15.12.4 Employs an overarching quality enhancement system to monitor, record and detect systematic errors in DAA service delivery.

^In situations where a pharmacist is requested to pack or repack a patient's medicines, the patient takes responsibility for the consequences related to poorly stored medications where stability may be an issue. Any medications not in original containers or that have their expiry dates obliterated should not be repacked.

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Standard 16: Harm Minimisation

The pharmacist delivers harm minimisation services to reduce drug-related harm to the patient and the community.

Background and scope

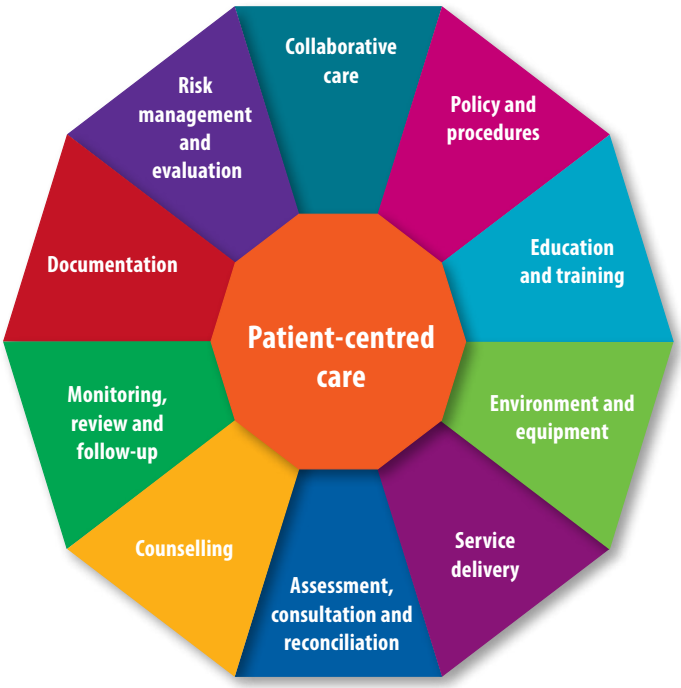
Harm minimisation encompasses policies and programs that focus on reducing drug-related harm, and improving health, social and economic outcomes for both the individual and the community. Australia's harm minimisation strategy focuses on both licit and illicit drugs, and includes a range of approaches aimed at preventing anticipated harm and reducing actual harm.[1]

Pharmacists can have a broad role in delivering harm minimisation services, including providing opioid substitution treatment, and needle and syringe programs. They also have an important role in precursor control, preventing pharmaceutical misuse and providing nicotine replacement therapies.[1]

This standard applies to the delivery of opioid substitution, and needle and syringe programs; and provision of other supervised or restricted supplies, such as benzodiazepine withdrawal regimens and staged supply.

Pharmacists should use this standard in conjunction with Standard 1: Fundamental Pharmacy Practice, Standard 2: Leading and Managing Pharmacy Practice, Standard 3: Dispensing and Other Supply Arrangements, Standard 7: Health Promotion and Education, Standard 8: Counselling, and Standard 9: Collaborative Care, as well as relevant professional practice guidelines.

Criteria to achieve the Harm Minimisation Standard



Standard 16: Harm Minimisation

Criteria	Actions required
16.1 Patient-centred care • Tailoring harm minimisation services to individual patients.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.1: Patient-centred care.*
	16.1.1 Ensures that services are delivered discreetly and in a manner that maintains patient dignity.
16.2 Collaborative care	Meets actions outlined in *Standard 9: Collaborative care.*
16.3 Policy and procedures • Aligning all harm minimisation services with best practice.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.5: Policy and procedures.*
	16.3.1 Ensures that all harm minimisation services align with relevant clinical guidelines and program guidelines.
	16.3.2 Reviews all harm minimisation services to ensure compliance with relevant legislative requirements.
	16.3.3 Maintains a standard operating procedure, which includes: • enrolment processes • consent and patient agreement requirements • elements of service delivery (e.g. dispensing and dosing of opioid substitution therapy, counselling, referral and follow-up) • clear roles, responsibilities and training requirements for all staff associated with the service • requirements of the service environment, including storage of opioid substitution therapies • risk management and evaluation of the service.
16.4 Education and training • Ensuring that self and associated staff have appropriate knowledge and skills to deliver harm minimisation services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.3: Professional development.*
	16.4.1 Promotes staff understanding of the objectives and principles of harm minimisation.
	16.4.2 Creates awareness and understanding of the roles, responsibilities and general procedures for the services delivered.
	16.4.3 Facilitates training required to deliver services in line with best-practice requirements.
16.5 Environment and equipment • Providing an appropriate service environment for harm minimisation services. • Maintaining equipment and resources required to deliver harm minimisation services.	**16.5.1** Delivers the service in a location that is acceptable to the patient, and protects their privacy and confidentiality.
	16.5.2 Ensures that the service environment has appropriate surfaces and furnishings consistent with the professional requirements of the service.
	16.5.3 Stores Controlled Drugs (including prepared doses) used in harm minimisation services according to relevant legislation.
	16.5.4 Provides patients with drinking water and facilities to appropriately dispose of, or adequately clean, drinking cups.
	16.5.5 Maintains access to an approved sharps container.
	16.5.6 Uses appropriate equipment for dosing opioid substitution therapies, including accurate dose dispensing and measuring devices (pumps or syringes), and containers (cups or containers with child-resistant closures if dispensing takeaway doses).
	16.5.7 Calibrates equipment according to manufacturers' instructions.
	16.5.8 Ensures that equipment is serviced regularly according to manufacturers' instructions.
	16.5.9 Provides all necessary protective clothing, equipment, and containers for storage and disposal of clinical waste.

Criteria	Actions required
16.5 Environment and equipment (continued)	**16.5.10** Ensures that current information resources on substance abuse and treatment are available to staff and patients to support service delivery.
	16.5.11 Ensures that the dispensing and dosing procedure document is accessible to the pharmacist.
16.6 Service delivery • Performing all services in a manner consistent with current best practice. • Integrating the delivery of harm minimisation services into pharmacy practice.	**16.6.1** Refers to relevant professional clinical guidelines, program guidelines and standards when delivering harm minimisation services.
	16.6.2 Ensures that staff contribute to harm minimisation services only when trained, equipped and capable to do so.
	16.6.3 Confirms that a pharmacist–patient agreement is in place before providing harm minimisation services.
	16.6.4 Confirms patient identity and treatment authorisation before dosing and dispensing.
	16.6.5 Ensures that supervised dosing occurs for only a single patient at a time.
	16.6.6 Communicates relevant issues, including prescription expiry and other reasons for non-supply, to patients in a timely and appropriate manner.
	16.6.7 Facilitates proactive referral and follow-up, as required. See Appendix 3: Template referral letter.
	16.6.8 Prioritises harm minimisation services within the framework of other service demands.
	16.6.9 Adapts workflow to facilitate the delivery of harm minimisation services.
16.7 Assessment, consultation and reconciliation • Ensuring a thorough, accurate and systematic approach to history taking. • Identifying the most appropriate time(s) in the counselling process to take a history or repeat history taking. • Documenting essential information. • Collecting or obtaining access to minimum essential information, including current prescription and non-prescription therapies, health conditions, allergies, adverse effects and patient preferences.	Meets actions outlined in *Standard 3: Dispensing and Other Supply Arrangements, Criterion 3.5: History taking,* and *Criterion 3.6: Assessment, consultation and reconciliation*.
	16.7.1 Establishes a patient healthcare record (profile).
	16.7.2 Collects or accurately records sufficient patient details, and a complete medication and health history in the healthcare record to optimise harm minimisation services.
	16.7.3 Documents any special needs of the patient in their profile so that counselling and associated resources can be tailored accordingly.
	16.7.4 Assesses factors likely to influence the reliability of sources (e.g. the patient as a historian).
	16.7.5 Checks the dispensing history and/or electronic healthcare record to determine the appropriateness of information being sought and provided.
	16.7.6 Synthesises all available information with informed professional judgement to formulate and present the most appropriate counselling, lifestyle advice and treatment options to the patient.
	16.7.7 Confirms that all health and medicines information, and healthcare plans are current and accurate.
	16.7.8 Gathers information and records details of any adverse drug reactions, including allergies, precautions and contraindications known to the patient.
	16.7.9 Accesses current information on clinically significant interactions, contraindications, precautions and disease states.

Criteria	Actions required
16.8 Counselling • Providing information and counselling specific to harm minimisation services. • Empowering patients to be active participants in their healthcare plans and goals.	Meets actions outlined in *Standard 8: Counselling.*
	16.8.1 Ensures that the costs associated with the service are clearly explained to the patient, or carer or authorised representative, before service provision and when changes to arrangements are necessary.
	16.8.2 Provides information on opioid replacement therapy medicines, including modes of action, significant drug interactions, major side effects, symptoms of overdose, and the effects of poly-drug use and excessive alcohol.
	16.8.3 Facilitates patient access to current sources of information about harm minimisation, including safe injecting techniques.
	16.8.4 Empowers the patient to consider and respond to their own health needs, in the context of their healthcare plan and goals.
	16.8.5 Offers tailored verbal and written health information consistent with the patient's needs.
16.9 Monitoring, review and follow-up • Communicating with the patient's prescriber and other healthcare professionals, as appropriate. • Referring patients to other healthcare professionals and support services, as required.	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.6: Continuity of care.*
	16.9.1 Reports issues relating to the patient's treatment, especially changes in attitude and behaviour – including consecutive missed doses, erratic attendance or unusual behaviour – to the prescriber or other relevant healthcare professional.
	16.9.2 Confirms patient understanding of, and agreement to, each party's role and responsibility in treatment arrangements.
	16.9.3 Refers patients to other healthcare professionals, as required.
	16.9.4 Maintains a current list of support services, and refers patients as needed.
	16.9.5 Maintains a list of referral points for collection of used needles and syringes, when this service is not provided by the pharmacy.
16.10 Documentation	Meets actions outlined in *Standard 1: Fundamental Pharmacy Practice, Criterion 1.5: Documentation.*
	16.10.1 Documents all relevant information specific to service delivery (where judged to be necessary), including: • self and staff training undertaken to deliver the service • patient information, including current photo identification • records of all doses (including takeaways) provided, including date, time, dose, person administering the dose and patient signature • events of non-supply • any events of significance, including disputes, behavioural issues, intoxicated attendance and suspected dose diversion • correspondence with the prescriber or other healthcare professionals • equipment maintenance and calibration • work health and safety (WHS) reporting (spillages, contamination, needlestick injuries and other incidents) • any other information required by legislation, and professional standards and guidelines.

Criteria	Actions required
16.11 Risk management and evaluation • Minimising risks associated with delivery of harm minimisation services.	Meets actions outlined in *Standard 2: Leading and Managing Pharmacy Practice, Criterion 2.8: Risk management and evaluation.*
	16.11.1 Instructs staff on the potential risks associated with the delivery of harm minimisation services.
	16.11.2 Counsels staff on safe disposal of used needles and syringes, and ensures adherence to relevant WHS procedures and protocols, including needlestick events.
	16.11.3 Maintains an appropriate system for the disposal of clinical waste, including full sharps containers.

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Appendix 1: Comparison of standards in versions 4 and 5 of the *Professional Practice Standards*

	Version 5 (2017)	Version 4 (2010)
Foundations of Practice	1: Fundamental Pharmacy Practice	1: Fundamental Pharmacy Practice
	2: Leading and Managing Pharmacy Practice	2: Managing Pharmacy Practice
Providing Therapeutic Goods	3: Dispensing and Other Supply Arrangements	5: Dispensing 6: Indirect Pharmacy Services
	4: Provision of Non-prescription Medicines and Therapeutic Devices	12: Provision of Non-prescription Medicines and Therapeutic Devices
	5: Compounding	10: Compounding 11: Compounding Sterile Preparations
Providing Health Information	6: Medicines Information	14: Medicines Information Centres
	7: Health Promotion and Education	13: Health Promotion
	8: Counselling	3: Counselling 6: Indirect Pharmacy Services
Delivering Professional Services	9: Collaborative Care	8: Services to RCF 9: Medication Liaison Services 15: Services to Aboriginal and Torres Strait Islander Health services
	10: Screening and Risk Assessment	16: Screening and Risk Assessment
	11: Vaccination Service	**New standard**
	12: Minor Ailments Service	**New standard**
	13: Disease State Management	17: Disease State Management
	14: Medication Review	4: Medication Review
	15: Dose Administration Aid Service	7: Dose Administration Aid Service
	16: Harm Minimisation	18: Harm Minimisation

Appendix 2: Patient healthcare plan

Patient details			
Medicare or DVA number			
Name		Date of birth	
Address			
Contact no.		Email address	
Pharmacy details		**Usual GP details**	
Name		Name	
Address		Address	
Contact no.		Contact no.	
Email address		Email address	
Pharmacist details		**Carer details**	
Name		Name	
		Contact no.	
Medicines list (see next page)		**Allergies and adverse reactions**	
Action plan • **List the issues identified during the interview** • **List the outcomes agreed to with the patient including actions/recommendations to the patient's GP and/or other healthcare provider(s)**			

Issue	Outcome/Recommendation *(e.g. referred to GP/Educator/Specialist/HMR)*	For consideration *(tick to indicate responsibility)*		Review date
		Patient	☐	
		Pharmacist	☐	
		Patient's GP	☐	
		Other healthcare provider	☐	
		Patient	☐	
		Pharmacist	☐	
		Patient's GP	☐	
		Other healthcare provider	☐	
		Patient	☐	
		Pharmacist	☐	
		Patient's GP	☐	
		Other healthcare provider	☐	

Medicines list						
Include details of all current, regular (taken on an ongoing basis) and 'prn' (taken when necessary) medicines, including prescription, non-prescription and complementary medicines						
Patient name				Contact no.		
Address						
Pharmacy name				Contact no.		
Address						
Active ingredient	Brand, strength, form	Prescribed by whom	Duration of therapy	Frequency of administration	What is the indication/use?	Special instructions

Appendix 3: Template referral letter

Healthcare provider: .....

Address: .....

.....

Pharmacist: .....

Address: .....

.....

Phone: .....

Date: .....

Re: Patient's name: .....

Patient's address .....

Date of intervention: ..... Discussed via phone: ☐

I have referred ..... to you for review, following the identification of a potential issue concerning their care.

Potential issue (DRP, medications and/or medical conditions involved): .....

.....

.....

Recommendations (e.g. drug change recommended): .....

.....

.....

.....

Advice given (e.g. dose administration aid recommended): .....

.....

.....

Additional notes: .....

.....

.....

References: .....

.....

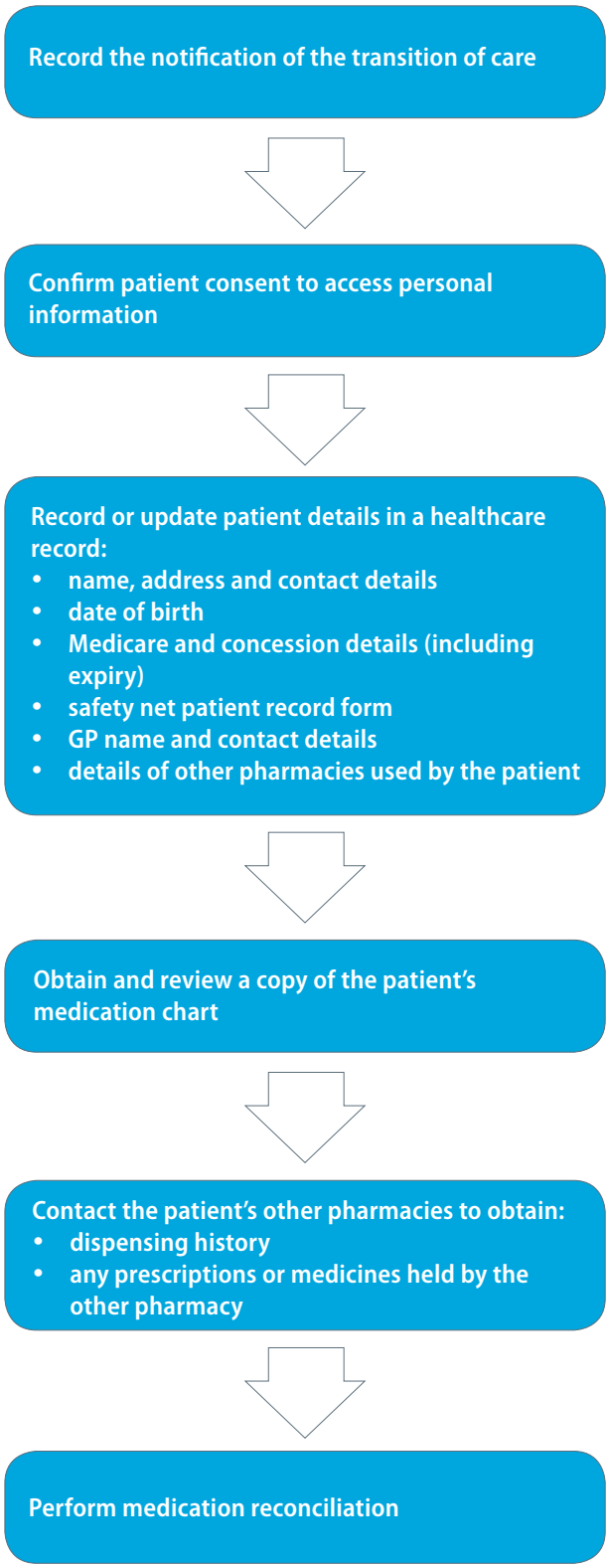
Yours sincerely,

.....

Pharmacist's name: ..... Post nominals: .....

Appendix 4: Process for managing transitions of care

This is a template process for pharmacists to follow upon receiving notification of transitions of care. This template is a guide and can be adjusted to best suit the needs of the individual pharmacy.



Appendix 5: Adherence assessment tool

To help us manage your medicines better, we would like you to answer the following questions. Answer each question based on your personal experience with your medicines. Remember there are no right or wrong answers.

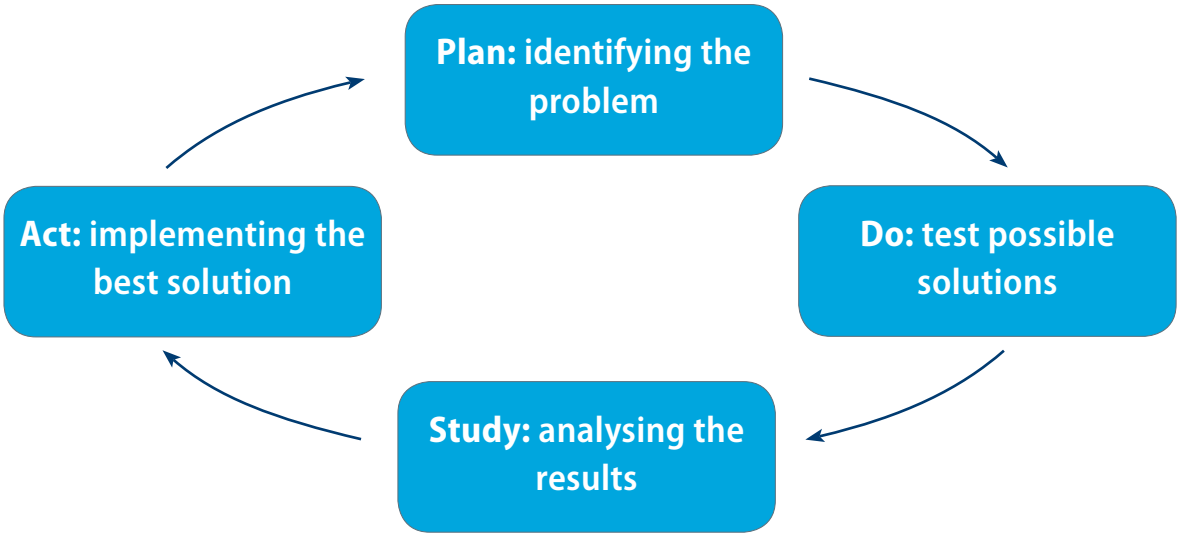
Question	No	Yes
Would you like to know more about your medicines and medical conditions?	☐	☐
Do you sometimes forget to take your medicines?	☐	☐
Thinking over the past 2 weeks, were there any days when you did not take your medicines?	☐	☐
Have you ever reduced or stopped taking your medicines without telling your doctor, because you felt worse when you took it?	☐	☐
When you travel or leave home, do you sometimes forget to take your medicines with you?	☐	☐
Did you take your medicines yesterday?	☐	☐
When you feel like your health is under control, do you sometimes stop taking your medicines?	☐	☐
Do you have difficulty remembering to take all your medicines?	☐	☐
Do you feel that your medicines are causing unwanted effects?	☐	☐

Adapted from Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. Journal of Clinical Hypertension 2008; 10(5):348-354.

Appendix 6: The plan-do-study-act cycle

One model for practice improvement is the plan-do-study-act (PDSA) cycle. This cycle consists of four steps (see Figure A1).

Figure A1. PDSA cycle



Source: Mindtools https://www.mindtools.com/pages/article/newPPM_89.htm

The PDSA cycle can be illustrated using the examples below:

	Dispensing errors	Smoking cessation service
Plan	Record and analyse the source of dispensing errors to identify patterns Review Professional Practice Standards and guidelines for best practice	Identify gaps in service provision based on population demographics (e.g. prevalence of smoking-related illnesses in your community) Review Professional Practice Standards and guidelines for best practice
Do	Adjust staff levels Adjust workflow processes Train staff	Design and deliver a trial smoking cessation service
Study	Review and analyse data resulting from new processes	Analyse trial results and refine processes
Act	Adjust staff levels Adjust workflow processes and implement barcode scanning Train staff	Implement a smoking cessation service to a wider audience

Appendix 7: Compounding decision support and risk assessment tool

Preparation: .....

Date: .....

Compounder: .....

Decision to compound: YES / NO (to be recorded in patient history)

1. Is there a suitable commercially available product?

   Yes No **Comment:** (e.g. dosage form of commercially available product is unsuitable for the patient, patient is allergic to an ingredient in the commercially available product)

2. Is there a suitable commercially available therapeutic alternative?

   Yes No **Comment:**

3. Is it possible to use an existing pharmacopoeial formula?

   Yes No **Comment:** (e.g. using modified formula [insert reference], modification checked with compounding pharmacy and discussed with the prescriber)

4. What risks are associated with compounding this preparation?

Risk	Source of risk	Mitigations	Likelihood	Consequence	RR
Product-related risk					
e.g. raw ingredient is not available	• Wholesaler is unable to supply • Raw ingredient has been discontinued	• Seek an alternative wholesaler • Use an alternative (equivalent) ingredient • Use a different formula	C	3	MR
e.g. complex calculations involved in preparing the product	• Scaling up/down of quantities is required • Multiple ingredients require separate calculation • Prescription has been written in percentages rather than amounts • Dilutions	• Double checking your own calculations • Ask another pharmacist to confirm your calculations are correct • Use a formula worksheet and show all calculation workings	B	2	HR
Personnel-related risk					
e.g. raw ingredient is considered a hazardous substance	• Cytotoxic • Antibiotic • Teratogenic • Reproductive hazard	• Personal protective equipment • Additional precautions for pregnant (or of child-bearing potential) personnel • Appropriate laminar-flow cabinets, isolators	A	2	HR
e.g. staff member is not competent to perform the compounding undertaken by the pharmacy	• Inadequate/inappropriate training • Training has lapsed	• Initiate training/retraining for staff member appropriate for their role in compounding • Ensure availability of appropriately-trained staff members whenever compounding is occurring	C	2	HR

Risk	Source of risk	Mitigations	Likelihood	Consequence	RR
Patient-related risk					
e.g. formulation containing ethanol for a paediatric patient	• Formulation • Stability of the product	• Seek an alternative (stable) formulation that doesn't contain ethanol • Consult the prescriber to discuss whether the benefits of the product outweigh the risk to the patient (informed consent of the parent/carer) • Seek an alternative therapeutic option	C	2	HR
e.g. patient factors	• Pregnancy or breastfeeding • Allergies • Medical history • Other medication	• Ensure access to complete patient history	B	1/2 (depending on source of risk)	ER/ HR

Legend

Risk rating (RR) matrix				
Likelihood of risk	**Consequence of risk**			
	4. Not significant (a safe and quality product can be compounded)	**3.** Minor (a safe and quality product can be compounded with minor intervention)	**2.** Major (a safe and quality product can be compounded with significant intervention)	**1.** Severe (a safe and quality product cannot be compounded)
A. Almost certain (expected to occur)	**LR**	**MR**	**HR**	**ER**
B. Likely (will probably occur)	**LR**	**MR**	**HR**	**ER**
C. Possible (could occur)	**LR**	**MR**	**HR**	**ER**
D. Unlikely (not expected to occur)	**LR**	**LR**	**MR**	**HR**

Risk rating (RR) explanations

Extreme risk (ER): Do not compound; contact prescriber

High risk (HR): Seek expert guidance before compounding, or refer to alternative provider with expertise

Medium risk (MR): Exercise caution when compounding (ensure risk mitigation strategies are in place)

Low risk (LR): Compound in accordance with best practice

Minor intervention examples:

- face mask/gloves are required if there is an unacceptable risk to compounder safety
- substitution of a different (equivalent) ingredient.

Significant intervention examples:

- additional training is required
- expert guidance is required
- specialist equipment is required
- change of formulation.

Appendix 8: The healthcare team

Appendix 9: Screening and risk assessment record and referral form

Record form			Date
Name		Date of birth	
Address			
Email		Phone	
Screening or risk assessment test/s			
Date	Test results	Need for referral	
		Yes	No
		Yes	No
		Yes	No
		Yes	No
		Yes	No
		Yes	No
		Yes	No
Advice and recommendations provided			
Referred to			Date
Address			
Email		Phone	
Pharmacist name		Pharmacist signature	
Pharmacy details			

Note: please attach dispensing history if applicable

Appendix 10: Summary of the history of the *Professional Practice Standards*

1997	The Australian Association of Consultant Pharmacy (AACP) released their final report on the *Framework for Standards for Quality Pharmacy Services* project.[1] Consistent with a recommendation arising from this project, the preferred framework for quality standards identified in the project was endorsed by the Pharmaceutical Society of Australia (PSA) National Council in November 1997.
1998	The PSA National Policy Committee believed in standards that were objective, authoritative statements based on guidelines that represented the requirement for a service to meet a desired level of performance. This led to the publication of the *Pharmacy Practice Handbook*.[2] The Pharmacy Guild of Australia launched the *Quality Care Pharmacy Program* (QCPP), which contained a set of retailing standards for community pharmacies.[3] The PSA supported the Guild's efforts by contributing a set of professional standards to the document[3] that were considered directly relevant to the consumer's 'shopping experience' in community pharmacy.
1999	Separate to the standards contributed to the QCPP, PSA developed the first edition of the *Professional Practice Standards* consistent with the AACP framework and the International Pharmaceutical Federation's *Standards for Quality of Pharmacy Services: Good Pharmacy Practice* guidelines.[4] These standards were designed to define and improve service delivery, and to encourage uniformity of practice performance across different health care settings. The first edition of the *Professional Practice Standards*[5] was published consisting of 11 standards.
2001	As the role of pharmacists in health care delivery expanded, the PSA added continuous quality improvement elements and updated the standards as required. In July, PSA published an interim update to the standards.
2002	The 2001 interim update was followed by an additional eight standards in version 2 of the *Professional Practice Standards* released in October.[6]
2005	A second detailed review of the *Professional Practice Standards* expanded the scope of the standards and included a universal *Fundamental Pharmacy Practice* standard integral to all pharmacy services and all areas of practice. The review conducted by PSA included extensive consultation with key industry stakeholders and experts from across the profession.
2006	The revised *Professional Practice Standards* (version 3) was published in January.[7] PSA committed to regular reviews to ensure with each review and subsequent edition, the *Professional Practice Standards* continues to reflect current practice as pharmacists in Australia face a professional climate of dynamic change.
2010	The *Professional Practice Standards* were reviewed with the aim of broadening the standards to encompass functional areas of pharmacy practice rather than specific services. The development of new standards was supported by a pilot field testing process to refine and enhance the quality of the standards from an assessment perspective. Version 4 of the *Professional Practice Standards* was released in June.[8]

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Glossary

Term	Definition	Source
adherence	A qualitative measure of the extent to which a patient's behaviour corresponds with the recommendations agreed with a healthcare professional, ideally through a concordant approach. Lack of adherence can include accidental non-compliance (e.g. forgetting, misunderstanding directions).	1
adverse drug event	An event where a medicine is implicated as a causal factor. An adverse drug event encompasses both the harm from the intrinsic nature of the medicine (e.g. an adverse drug reaction) and the harm that results from medicine errors or system failures associated with the manufacture, distribution or use of medicines. Drug interactions are also examples of adverse drug events.	2
adverse drug reaction	A drug response that is noxious and unintended, and occurs at doses normally used or tested in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.	2
ancillary area	Sterile area adjacent to the cleanroom, comprising the anteroom (for garbing and gowning) and the buffer room (for wetting and weighing).	3
authorised representative	A person who can participate in and make healthcare decisions for another individual. For the purposes of these standards, an authorised representative is someone who: • has parental responsibility for a person under 18; or • has legal authority to act on behalf of a person who is at least 18 and is not capable of making their own decisions. If no-one has parental responsibility or legal authority, a person who is otherwise appropriate to act on behalf of the individual can be an authorised representative. An individual can have more than one authorised representative.	4, 5, 6
batch preparation	The creation of a batch of multiple units of issue of a product.	7, 8
bioequivalence	Bioequivalence is established when two products produce similar plasma concentrations of the same active ingredient. The peak plasma concentration (Cmax) and the extent of absorption (area under the concentration–time curve, AUC) of the generic medicine and the original brand are compared. To be bioequivalent, the 90% confidence intervals (CI) for the ratio of each pharmacokinetic variable must lie between 0.80 and 1.25.	9
biosimilarity	Demonstrable similarity between a biological reference medicine and biosimilar medicines, in physicochemical, biological and immunological characteristics, efficacy and safety.	10
certificate of analysis	A document provided by the manufacturer (supplier) that certifies the quality of the excipient and demonstrates that the batch conforms to the defined specifications, has been manufactured under excipient good manufacturing practice and is suitable for use in pharmaceuticals.	11
closed system transfer device	A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system.	12
collaboration	In the context of medication management, collaboration is a process whereby patients and healthcare professionals share their expertise and take responsibility for decision making. Accomplishing collaboration requires that individuals understand and appreciate what it is that they, and others, contribute to the 'whole'.	13

Term	Definition	Source
complementary medicines	Medicines that are also known as 'traditional' or 'alternative' medicines. Examples include vitamins, minerals, nutritional and herbal supplements, aromatherapy, and homoeopathic products.	14
compounding (simple)	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 routinely involves the compounding of products from formulations published in reputable references such as the Australian Pharmaceutical Formulary and Handbook (excluding the preparation of sterile products from these formulations, which is considered complex compounding), or using other formulations for which information confirming quality, stability, safety, efficacy and rationality is available.	8
compounding (complex)	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 involves special competencies, equipment, processes or facilities. Examples are sterile preparations, preparations containing ingredients that pose an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single-unit dosage forms containing less than 25 mg (or up to 25% by weight or volume) of active ingredient, and sustained-release or other modified-release preparations.	8
continuing professional development	The means by which members of the profession maintain, improve and broaden their knowledge, expertise and competence, and develop the personal and professional qualities required throughout their professional lives. Continuing professional development is more than just participation in continuing education. It is an ongoing, cyclical process of continuous quality improvement by which pharmacists maintain and enhance their competence in current and possible future roles. It also gives them the responsibility to manage self-appraisal, develop a personalised learning plan, participate in relevant educational activities, implement new knowledge and skills in practice, and evaluate the outcome.	15, 16
counselling	A two-way communication process between the pharmacist and the patient in which the pharmacist ascertains the needs of the patient, and provides them with the information required to safely and effectively use medicines and therapeutic devices.	17
cytotoxic	Medicines used primarily in the treatment of cancer. They have deleterious effects on cells, and many have been found to be mutagenic, teratogenic and carcinogenic.	17
disease state management	A patient-centred process that focuses on managing the health of patients with chronic conditions, with the objective of reducing risk factors through monitoring, counselling, education, enhancing patient self-management, and quality use of medicines.	17
dispensing	The review of a prescription, and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine. It includes counselling to a patient, their agent or another person who is responsible for the administration of the medicine to the patient.	18
dose administration aid	A tamper-evident, well-sealed device or packaging system that allows organisation of doses of medicine according to the time of administration.	19
environmental monitoring	Monitoring of temperature, microbial levels, particulate levels, humidity and pressure, where applicable to the specific compounding activity, based on a risk assessment.	3
evidence-based information	Information that has been critically evaluated for its validity, importance and relevance.	17
evidence-based practice	The integration of best research evidence with clinical expertise and patient values.	20
facility	A residential care facility, which includes aged care homes (low-care, high-care and respite facilities), retirement facilities, supported residential services (previously known as special accommodation homes) and correctional facilities.	17
governance	A framework under which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.	21
harm minimisation	The primary principle underlying the National Drug Strategy. It refers to policies and programs that focus on reducing drug-related harm, and aims to improve health, social and economic outcomes for both the individual and the community. Australia's harm minimisation strategy focuses on both licit and illicit drugs.	22

Term	Definition	Source
hazardous substance	Substances, mixtures and articles that can pose a health or physical hazard to humans. Health hazards are the properties of a chemical that cause adverse health effects. Examples of chemicals with health hazards are poisonous (toxic) chemicals, chemicals that cause skin corrosion (such as acids) and carcinogens (chemicals that cause cancer). Exposure to these chemicals usually occurs through inhalation, ingestion or skin contact. Physicochemical hazards are physical or chemical properties that can result in immediate injury to people or damage to property. Examples of chemicals with physicochemical hazards are flammable liquids, compressed gases and explosives.	23
healthcare goals	Consistent with principles of patient-centred care and self-efficacy, healthcare goals are set by the patient in consultation with their healthcare team. The goal setting is facilitated by appropriate health education. Healthcare goals set by patients have been shown to lead to improved health behaviours, health status and use of healthcare services.	24
healthcare plan	A plan of systematic care outlined for the patient that is provided by the pharmacist in collaboration with the patient and other healthcare professionals. It includes an accurate and comprehensive assessment of the patient's health status, recommendations for pharmacological and non-pharmacological interventions, therapeutic goals that have been developed with the patient, the provision of education and counselling, and regular follow-ups to monitor the patient's progress. See Appendix 2: Patient healthcare plan.	17
healthcare professional	Practitioners who provide services to individuals or communities to promote, maintain, monitor or restore health (such as a general practitioner, dentist, physiotherapist or case worker).	17
healthcare team	A team that delivers multidisciplinary care – when professionals from a range of disciplines work together to deliver comprehensive care that addresses as many of the patient's needs as possible. The care can be delivered by a range of professionals functioning as a team under one organisational umbrella or by professionals from a range of organisations, including private practice, brought together as a unique team. As a patient's condition changes over time, the composition of the team may change to reflect the changing clinical and psychosocial needs of the patient. See Appendix 8: The healthcare team.	25
health literacy	The cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health.	26
health promotion	The process of enabling people to increase control over their health and its determinants, and thereby improve their health and wellbeing. It represents a comprehensive social and political process that embraces actions directed at strengthening the skills and capabilities of individuals, as well as actions directed towards changing social, environmental and economic conditions so as to alleviate their impact on public and individual health.	27
informed consent	Permission granted voluntarily by a consumer or individual who has been adequately informed (e.g. of options, risks, benefits) and has the capacity to understand, provide and communicate their permission. Consent can be verbal, written or implied by actions (e.g. patient providing a prescription to the pharmacist).	28
leadership	The process of influencing the behaviour of others towards a predetermined goal.	29
lifelong learning	A continuously supportive process that stimulates and empowers individuals to acquire all the knowledge, values, skills and understanding they will require throughout their lives.	30
medication	A medicine used by a specific patient according to a particular dosing regimen.	17
medication management plan	A continuing plan for the use of medicines that arises from a medication management assessment. It is developed by the healthcare professional in collaboration with the patient.	17
medication misadventure	All adverse drug events, adverse drug reactions and medication errors fall under the umbrella of medication misadventures. Medication misadventure is a very broad term, referring to any iatrogenic hazard or incident associated with medications.	31
medication record	A list of medications that have been prescribed and dispensed to an individual.	4

Term	Definition	Source
medication review	A retrospective critical review of all prescribed, over-the-counter and complementary (herbal) medications. The aim is to optimise therapy and minimise medication-related problems by assessing any need for changes in medications and ensuring the patient's understanding of the medication regimen.	32
medicine	A chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental welfare of people. It includes prescription and non-prescription medicines (e.g. complementary healthcare products), irrespective of the administered route.	1
medicines information	Written and/or oral information or advice about medicines and pharmacotherapy, in response to a request from other healthcare professionals, patients, media, policy makers and lawyers. This information may be patient specific or general information promoting the safe and effective use of medicines.	1
micro-dose single-use dosage form	A dosage form containing less than 25 mg (or up to 25% by weight or volume) of active ingredient.	8
minor ailment	A condition that is often self-limiting with symptoms easily recognised and described by the patient, and falling within the scope of pharmacist knowledge and training to treat.	33
monitoring	Regular measurement and assessment of specific clinical and social parameters to assist patients undergoing treatment for, or at risk of, specific health conditions.	17
non-prescription medicines	All medicines available for purchase by the public that do not require a prescription. Non-prescription medicines include Pharmacist Only Medicines (S3), Pharmacy Medicines (S2), unscheduled medicines, complementary medicines and nutritional supplements.	17
operator validation	Assessment of the ability to maintain sterility of materials and equipment during the preparation of aseptically prepared products.	34
patient	A person who uses, or is a potential user of, health services, including their family and authorised representative(s).	28
patient-centred care	Health care that is respectful of, and responsive to, the preferences, needs and values of patients and consumers. The widely accepted dimensions are respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of family and carers, and access to care.	35
patient healthcare record	Records that contain sufficient information to identify the patient and document the reason(s) for the patient's visit to a healthcare professional; and information about relevant examination, assessment, management, progress and outcomes. Health records need to include the patient's contact and other demographic information, medical history, consultation notes (including care outside normal opening hours and home visits), letters received from hospitals or consultants, other clinical correspondence, investigations or referrals, and results. The patient healthcare record may also contain other relevant information pertaining to the patient, such as any WorkCover or insurance information or relevant legal reports.	36
persistence	The overall duration of treatment – how long patients continue to take their prescribed medicines.	37
personal protective equipment	Anything that is used or worn by a person to minimise the risk of contamination of the compounded preparation or area, or the risk to the person's health or safety, including shoe covers, hair cover, mask, sterile gown and sterile gloves.	3
Pharmacy Medicines (S2)	Substances whose safe use may require advice from a pharmacist and that should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.	38
Pharmacist Only Medicines (S3)	Substances whose safe use requires professional advice but that should be available to the public from a pharmacist without a prescription.	38

Term	Definition	Source
pharmacy practice	Any role, whether remunerated or not, in which an individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these standards, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and working in any other roles that affect the safe, effective delivery of services in the profession and/or use the pharmacist's professional skills.	15
pharmacy services	Any service provided or activity undertaken within the pharmacist's scope of practice.	39
preventive health care	Encompasses approaches and activities aimed at reducing the likelihood that a disease or disorder will affect an individual, interrupting or slowing the progress of the disorder, or reducing disability. Primary prevention reduces the likelihood of development of a disease or disorder. Secondary prevention interrupts, prevents or minimises the progress of a disease or disorder at an early stage. Tertiary prevention focuses on halting the progression of damage already done.	40
primary health care	Comprehensive primary health care includes health promotion, illness prevention, treatment and care of the sick, community development, advocacy and rehabilitation. Primary healthcare providers include pharmacists, general practitioners, nurses (e.g. general practice nurses, community nurses, nurse practitioners), midwives, dentists and Aboriginal health workers. Multidisciplinary teams are supported by integrated referral systems in a way that gives priority to those most in need and addresses health inequalities; maximises community and individual self-reliance, participation and control; and involves collaboration and partnership with other sectors to promote public health.	41
public health	The science and art of promoting health, preventing disease, and prolonging life through the organised efforts of society.	26
quality enhancement	A systematic, future-directed, continuous cycle of goal setting, planning, managing and reviewing, within an appropriate governance framework, aimed at transformation.	42
quality use of medicines (QUM)	The selection of wise management options, the choice of suitable medicines if a medicine is considered necessary, and the safe and effective use of medicines. The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population.	43
reconciliation	Medication reconciliation is a formal process of obtaining and verifying a complete and accurate list of each patient's current medicines. Medication reconciliation is matching the medicines the patient should be prescribed with those they are actually prescribed.	44
residential care facility	An institution that provides accommodation and health care to its residents. Types of residential care facility include aged care homes, retirement facilities, hostels and supported residential services (previously known as special accommodation homes).	17
risk assessment	See screening and risk assessment.	
risk management	The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution.	45
safety data sheet (previously called a material safety data sheet)	A document that provides information about the safe handling and storage of hazaradous substances. It includes information about the identity of the chemical, health and physicochemical hazards, safe handling and storage procedures, emergency procedures, and disposal considerations.	46, 47
scope of practice	A time-sensitive, dynamic aspect of practice that indicates those professional activities that a pharmacist is educated, competent and authorised to perform, and for which they are accountable.	48
screening and risk assessment	A systematic process used to identify members of a defined population who may be at risk of a disease, evaluate that risk and provide referral, as appropriate.	49
standard operating procedure	A written document with a set or sequence of instructions for a routine or repetitive activity. It is designed to assist the user or compounder in the delivery of a service or activity to a consistent standard and outcome.	3
systems thinking	An approach to problem solving that views 'problems' as part of a wider, dynamic system. Systems thinking involves much more than a reaction to present outcomes or events. It demands a deeper understanding of the linkages, relationships and interactions among the elements that characterise the entire system.	50

Term	Definition	Source
therapeutic device	A therapeutic good (other than a biological) consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning. A therapeutic device does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, although it may be assisted in its function by such means.	17
therapeutic good	In relation to the evaluation, assessment and monitoring by the Therapeutic Goods Administration, therapeutic goods are broadly defined as products for use in humans in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing, inhibiting or modifying a physiological process; testing the susceptibility of people to a disease or ailment; influencing, controlling or preventing conception; or testing for pregnancy. This includes things that are used as an ingredient or component in the manufacture of therapeutic goods, or used to replace or modify parts of the anatomy.	51
transformational change	Change involving radical changes in strategy, structure and capability of an organisation.	52
work health and safety (previously known as occupational health and safety)	Involves the assessment and mitigation of risks that may affect the health, safety or welfare of those in a workplace. This may include the health and safety of customers, employees, visitors, contractors, volunteers and suppliers. Pharmacists must meet relevant state or territory work health and safety requirements (see further information at https://www.business.gov.au/Info/Run/Workplace-health-and-safety/WHS-OH-and-S-Acts-Regulations-and-Codes-of-Practice).	53

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