Pharmaceutical Society of Australia

Professional Practice Standards

VERSION 4
2010

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Disclaimer

These standards have been designed for use by individual pharmacists to assess their own professional practice. They are intended to serve as guidance for desired standards of practice. However, it is the sole responsibility of the individual pharmacist to determine, in all circumstances, whether a higher standard is required. It is equally their responsibility to meet that standard.

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Foreword

The *Professional Practice Standards*, version 4 is the result of many months of consultation with more than 10 organisations and more than 70 experts across various areas of practice in Australia. Involved in the process were consumers, hospital pharmacists, accredited pharmacists, pharmacists from the pharmaceutical industry, community pharmacists, and pharmacists from large metropolitan areas right through to those in small isolated practices. The result is a testament to the commitment of those involved in enhancing the quality of pharmacy practice for our communities.

Although the Professional Practice Standards are used by pharmacy practice accreditation and registration bodies, the principal aim of these standards remains as a tool for us to assess and continuously evaluate the services we deliver through any role in which we use our skills as pharmacists.

We sincerely thank and acknowledge the contributions, submissions, feedback and advice of so many of our colleagues along the way. Their remit was to help ensure the standards are realistic and as easy as possible to use and adopt in daily practice.

What supported this endeavour was a pilot field testing process. This step was introduced in the development of this edition to further test, refine and enhance the quality of the assessment system. More than 20 pharmacists took part in the field testing process that provided an additional layer of consultation and assurance that the PSA Professional Practice Standards in this edition are a progression from those in previous editions.

To all involved in the standards, the PSA owes a debt of gratitude to you. We thank you for your time, advice and counsel, and we trust that you will be available to support us again in the future.

To all pharmacists, I recommend these standards to you. I encourage pharmacists from across the country and from all areas of practice to use these standards to their full intent—to assess your practice against that expected by your peers.

Warwick Plunkett
National President
Pharmaceutical Society of Australia

Introduction

The Professional Practice Standards and the practice of pharmacy

As health professionals with a wide-ranging body of knowledge and skills with regard to medicines and related health products, pharmacists are in a unique position to optimise health outcomes for the community they serve. The primary responsibility of a pharmacist is to ensure safe and effective use of medicines and best possible health outcomes for consumers through the provision of pharmaceutical care. According to the Pharmacy Board of Australia, pharmacy practice can involve direct clinical care or non-clinical relationships with consumers; working in management, administration, education, and research; or being in advisory, regulatory, or policy development roles.[1]

Pharmacists have an ethical and legal commitment to the community to ensure safe and effective delivery of pharmacy services, irrespective of the setting in which they practice. Professional standards allow the pharmacy profession to qualitatively and quantitatively measure this commitment to providing high quality, reliable health care services and products.

The *Professional Practice Standards* is intended to be an educative resource for the self-regulation of pharmacists and the pharmacy profession. The standards in this document encourage pharmacists to be involved in a range of pharmacy services and promote recognition of professional service delivery. They also help consumers recognise and build confidence in the pharmacy profession by ensuring professional activities are performed to a desired level.

The *Professional Practice Standards*, version 4 has been produced with guidance from a Standards Steering Committee composed of representatives from key pharmacy organisations as well as experts from across the profession. The content and relevance of each standard has been reviewed and updated by Expert Review Groups consisting of expert pharmacists and consumer representatives. Please refer to Appendix 13 for a list of project participants. The project team considered and incorporated all feedback before the resulting document was reviewed and endorsed by the Boards of the organisations represented on the Standards Steering Committee.

Background to the Professional Practice Standards

These standards originate from international guidelines for 'Good Pharmacy Practice'[2] that were endorsed by the International Pharmaceutical Federation (FIP) in the Tokyo Declaration of 1993[3] and by the World Health Organisation (WHO) in 1997.[4] They advocate good pharmacy practice in the promotion of good health through the achievement of health objectives, the supply of medicines and medication delivery devices, the provision of medicines for self care, and activities to influence the quality of prescribing or the use of medicines.

The *Professional Practice Standards* was first published in 1999; the standards in the document covered core pharmacy services and selected specialty services. They were developed through extensive consultation with pharmacy organisations and practitioners in Australia, as well as collaboration with consumers and the Australian Government. This is the third revision of the Professional Practice Standards; the standards were previously revised in 2002 and 2006. The regular updates ensure that the standards reflect current pharmacy practice as pharmacists in Australia face a professional climate of rapid and cumulative change.

The *Professional Practice Standards*, version 4 is available on the PSA website at www.psa.org.au.

The broader context of guidance supporting pharmacy practice

The PSA standards in the *Professional Practice Standards* apply to all practising pharmacists irrespective of the setting in which they practice. There are a number of documents that govern how pharmacists in Australia practice (see Figure 1).

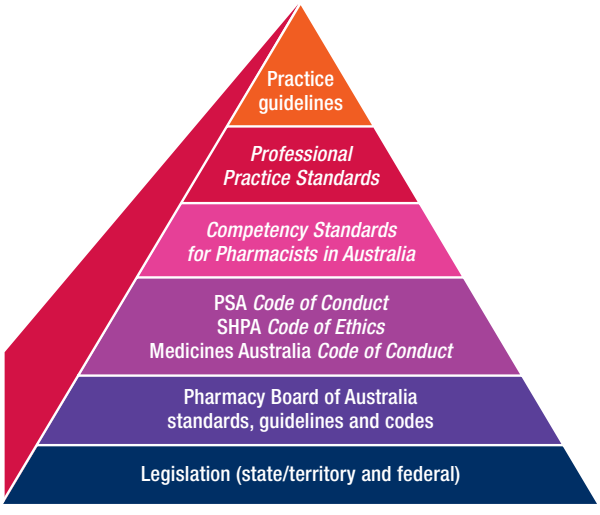


Figure 1. Pyramid of guidance supporting pharmacy practice.

Federal, state and territory legislation then forms a foundation on which our practice is based. It is mandatory that pharmacists comply with all federal, state and territory legislation. If conflict arises between the legislation and these standards, legislative requirements should be adhered to. The Pharmacy Board of Australia

is the registering authority of pharmacists in Australia. The standards, guidelines and codes developed by the Pharmacy Board of Australia outline specific requirements for pharmacists to maintain their registration.[1,5]

Further to our legal responsibilities, pharmacists are required to practice under the PSA *Code of Professional Conduct*,[6] the Society of Hospital Pharmacists of Australia (SHPA) *Code of Ethics*,[7] and the Medicines Australia *Code of Conduct*.[8] These codes publicly state the principles by which pharmacists interact with consumers, other health care providers, and the community when delivering pharmacy services.

Moreover the *Competency Standards for Pharmacists in Australia*[9] outlines the skills, attitudes, and other attributes considered sufficient to enable an individual to practice as a pharmacist. These skills, attitudes and attributes are attained through professional qualifications as well as subsequent experience. The PSA's continuing professional development and practice improvement (CPD&PI) program allows pharmacists to identify areas where improvement in their competency is needed. Workshops are then offered as a means of professional development.

In addition to competency, pharmacists must also focus on delivering services that are both consistent and of a high quality. The standards in the *Professional Practice Standards* are aimed specifically at pharmacists and outline a level of service that is acceptable to both consumers and professional peers. Pharmacists are encouraged to reflect on these standards to ensure consumers are receiving safe and effective pharmacy services.

Finally, practice guidelines outline systems and processes that pharmacists and their staff can use to implement quality services that meet the standards. These practice guidelines are service specific and provide detailed information about how best to deliver these services.

Each of these documents provides pharmacists with the guidance and framework required to practice pharmacy in a professional and ethical manner. This ensures pharmacy services are delivered to benefit the health and wellbeing of all consumers.

General resources for pharmacists

- Australian Government Department of Health and Ageing. National Medicines Policy. www.health.gov.au
- Pharmaceutical Society of Australia. Code of professional conduct. www.psa.org.au
- Medicines Australia. Code of conduct. www.medicinesaustralia.com.au
- Society of Hospital Pharmacists of Australia. Code of ethics. www.shpa.org.au
- Pharmacy Board of Australia. Codes and Guidelines. www.pharmacyboard.gov.au
- Association of Professional Engineers, Scientists and Managers, Australia. www.apesma.asn.au
- Australian Association of Consultant Pharmacy. www.aacp.com.au
- Australian College of Pharmacy. www.acp.edu.au
- Australian Pharmacy Council. www.pharmacycouncil.org.au
- Pharmaceutical Defence Limited. www.pdl.org.au
- Pharmaceutical Society of Australia. www.psa.org.au
- Pharmacy Guild of Australia. www.guild.org.au
- Society of Hospital Pharmacists of Australia. www.shpa.org.au

How to use the *Professional Practice Standards*

The standards in the *Professional Practice Standards*, version 4 provide a framework that defines and describes the qualities required by pharmacists to deliver a range of pharmacy services effectively and to an acceptable level.

The standards are designed for individual pharmacists to self-assess their professional practice, identify areas where improvement is needed, and re-assess their performance after the appropriate changes have been implemented.

Table 1 is designed to aid pharmacists' use of the Professional Practice Standards. It shows which standards are either directly related to each other or those that are only applicable depending on the scope of their practice. The first standard, Fundamental Pharmacy Practice, is the overarching 'universal' standard and is directly related to all other standards regardless of the scope of practice and is to be applied in conjunction with all others.

The second standard, Managing Pharmacy Practice, addresses the responsibilities of pharmacist managers. This standard is directly related to standard 1 but is only applicable to other standards depending on the scope of your practice.

For all other standards, each pharmacist should reflect on their own practice and identify which standards are applicable. The pharmacist can then assess themselves against the relevant standards in addition to the Fundamental Pharmacy Practice standard.

In order to facilitate self-assessment, a box is provided next to each indicator for the pharmacist to mark 'yes' I meet this indicator, 'no' I don't meet this indicator, or this indicator is 'not applicable (NA)' to my practice. If an indicator is considered not applicable to the pharmacist's practice, the reason behind this decision should be documented. Pharmacists should regularly self-assess; for example, once yearly, or when a change occurs in their professional practice.

Significant updates in the *Professional Practice Standards*, version 4

One of the aims of the review of the *Professional Practice Standards*, version 3 (PPSv3) was to broaden the standards to encompass functional areas of pharmacy practice rather than specific services. With this in mind, Table 2 outlines the major changes you will notice in the new *Professional Practice Standards*, version 4.

Table 1. How the individual Professional Practice Standards inter-relate

Professional Practice Standards	Directly Related Standard	Other applicable standards based on scope of practice
1: Fundamental Pharmacy Practice	2–18	
2: Managing Pharmacy Practice	1	3–18
3: Counselling	1	2, 5, 6, 12, 13, 17, 18
4: Medication Review	1, 3	2
5: Dispensing	1, 3	2, 6, 7, 10, 11, 17, 18
6: Indirect Pharmacy Services	1, 3, 5	2, 10, 12
7: Dose Administration Aids	1, 3, 5	2, 4, 6, 8, 9, 15
8: Services to Residential Care Facilities	1	2-5, 7, 9-13
9: Continuity of Care through Medication Liaison Services	1	2-5, 13, 17
10: Compounding (also known as Extemporaneous Dispensing)	1, 3, 5	2, 6, 8, 11
11: Compounding Sterile Preparations	1, 3, 5, 10	2, 8
12: Provision of Non-prescription Medicines and Therapeutic Devices	1, 3	2,13
13: Health Promotion	1	2, 3, 16-18
14: Medicines Information Centres	1	2
15: Provision of Pharmacy Services to Aboriginal and Torres Strait Islander Health Services	1	2-7, 9, 10, 12, 13, 16, 17
16: Screening and Risk Assessment	1	2, 3, 13, 17
17: Disease State Management	1	2-4, 13, 16
18: Harm Minimisation	1, 3, 5	2, 13

Table 2. Overview of significant updates and changes in *Professional Practice Standards*, version 4

New Professional Practice Standard	Old standard(s)	Notes
1: Fundamental Pharmacy Practice	• Fundamental Pharmacy Practice (PPSv3) • Comprehensive Pharmacy Care (PPSv3)	These two standards have been combined into the new Fundamental Pharmacy Practice standard. Historically, Comprehensive Pharmacy Care described a service provided by pharmacists. As pharmacy practice has evolved, the principles of this service have become fundamental to our roles as pharmacists. For this reason, its principles have been incorporated into Fundamental Pharmacy Practice and/or other relevant standards.
4: Medication Review	• Comprehensive Medication Review (PPSv3) • Home Medicines Review (also known as Domiciliary Medication Management Review) (PPS v3) • Medication Profiling Service (developed under the Fourth Community Pharmacy Agreement; not included in PPSv3)	The new Medication Review standard outlines the common principles of all proactive forms of medication review including medication profiling services, Home Medicines Reviews, and Residential Medication Management Reviews. Medication reviews that are part of the dispensing process are covered in Professional Practice Standard 5: Dispensing.
6: Indirect Pharmacy Services	• Distance Supply (PPSv3)	The old title of this standard, Distance Supply, implied a service delivered only in rural and remote areas. In fact, the updated Indirect Pharmacy Services standard is relevant to any supply of medicines, both urban and rural, where face-to-face contact is not possible.

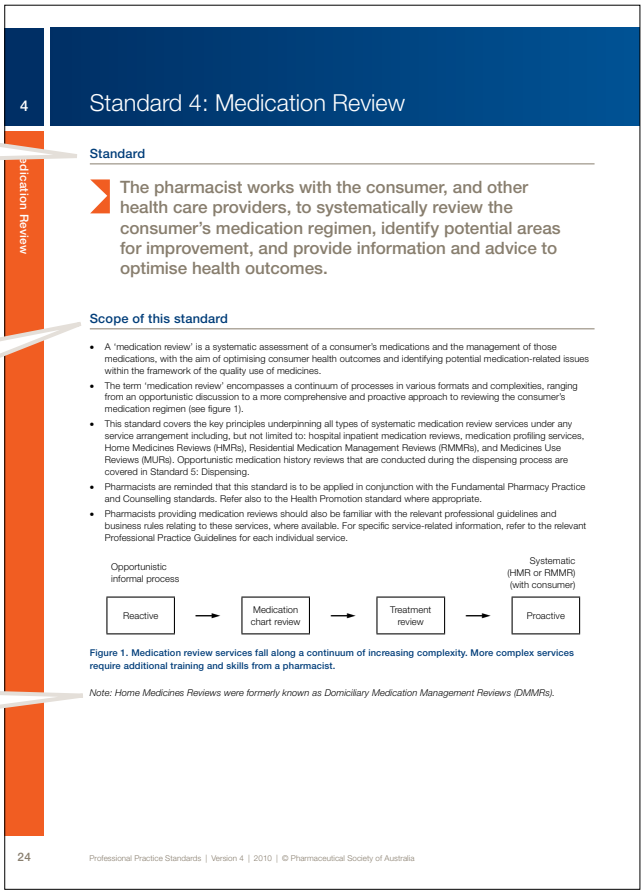
New Professional Practice Standard	Old standard(s)	Notes
9: Continuity of Care through Medication Liaison Services	• Liaison Pharmacy (*Professional Practice Standards*, version 2 but not included in PPSv3)	The pharmacist's role in providing continuity of care is significant, and this standard has been reinstated with a new title in version 4.
10: Compounding (also known as Extemporaneous Dispensing)	• Compounding (also known as Extemporaneous Dispensing) (PPSv3) • Preparation of Cytotoxic Drug Products (PPSv3)	The scope of this standard has been broadened to encompass all principles of non-sterile compounding. The previous criteria from the Preparation of Cytotoxic Drug Products (PPSv3) standard have been incorporated into the new Compounding (also known as Extemporaneous Dispensing) and Compounding Sterile Preparations standards.
11: Compounding Sterile Preparations	• Compounding (also known as Extemporaneous Dispensing) (PPSv3) • Preparation of Cytotoxic Drug Products (PPSv3)	This new standard illustrates the additional requirements for those pharmacists preparing sterile products. The previous criteria from the Preparation of Cytotoxic Drug Products (PPSv3) standard have been incorporated into the new Compounding (also known as Extemporaneous Dispensing) and Compounding Sterile Preparations standards.
12: Provision of Non-prescription Medicines and Therapeutic Devices		This new standard outlines the pharmacist's role in the provision of non-prescription medicines and therapeutic devices. While the *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*[10] highlights the responsibilities of the pharmacy as a whole, this new standard focuses solely on the pharmacist's obligations in relation to the provision of all non-prescription products (scheduled and unscheduled).
14: Medicines Information Centres	• Drug Information Service (PPSv3)	This standard has been renamed in line with current terminology and the content of the updated standard.
15: Provision of Pharmacy Services to Aboriginal and Torres Strait Islander Health Services	• *The Provision of Pharmacy Services to Aboriginal and Islander Health Services* [guidelines and standards] (developed by the PSA in 2005, but not published in PPSv3)	This standard has been included in the new version of the *Professional Practice Standards* so that it could be published together with the other standards.
16: Screening and Risk Assessment	• Monitoring and Case Detection (PPSv3)	This new standard illustrates the services aimed at identifying consumers at risk of chronic disease through screening and assessment processes.
17: Disease State Management	• Monitoring and Case Detection (PPSv3)	This new standard outlines the principles underpinning all disease state management (DSM) services, regardless of the consumer's particular disease state. DSM services involve the monitoring of consumers with a chronic disease to maximise their treatment and quality of life.
18: Harm Minimisation	• Opioid Substitution Program (PPSv3) • Needle and Syringe Program (PPSv3)	The new Harm Minimisation standard combines the principles of both of the previous standards.

A guide to reading the standards

Standard: A statement that describes the qualities required for a service to be provided at the desired level of performance or results.

Scope: The scope provides definitions of, and the context for, the professional service provided, as well as supplying appropriate cross-references if and when other standards apply.

Notes: The notes provide additional background information relevant to the standard.



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Standard 4: Medication Review

Medication Review

Standard

The pharmacist works with the consumer, and other health care providers, to systematically review the consumer's medication regimen, identify potential areas for improvement, and provide information and advice to optimise health outcomes.

Scope of this standard

- A 'medication review' is a systematic assessment of a consumer's medications and the management of those medications, with the aim of optimising consumer health outcomes and identifying potential medication-related issues within the framework of the quality use of medicines.
- The term 'medication review' encompasses a continuum of processes in various formats and complexities, ranging from an opportunistic discussion to a more comprehensive and proactive approach to reviewing the consumer's medication regimen (see figure 1).
- This standard covers the key principles underpinning all types of systematic medication review services under any service arrangement including, but not limited to: hospital inpatient medication reviews, medication profiling services, Home Medicines Reviews (HMRs), Residential Medication Management Reviews (RMMRs), and Medicines Use Reviews (MURs). Opportunistic medication history reviews that are conducted during the dispensing process are covered in Standard 5: Dispensing.
- Pharmacists are reminded that this standard is to be applied in conjunction with the Fundamental Pharmacy Practice and Counselling standards. Refer also to the Health Promotion standard where appropriate.
- Pharmacists providing medication reviews should also be familiar with the relevant professional guidelines and business rules relating to these services, where available. For specific service-related information, refer to the relevant Professional Practice Guidelines for each individual service.

Figure 1. Medication review services fall along a continuum of increasing complexity. More complex services require additional training and skills from a pharmacist.

Note: Home Medicines Reviews were formerly known as Domiciliary Medication Management Reviews (DMMRs).

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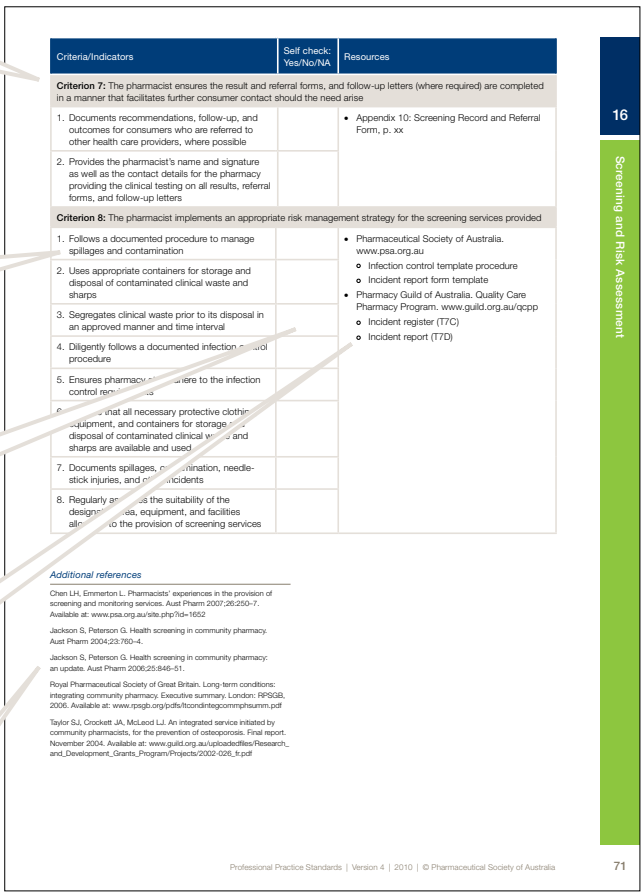
Criteria: The standard is broken down into indicative criteria that broadly express what a competent professional would achieve in terms of observable results or behaviours.

Indicators: Each criterion is broken down into elements that describe a range of activities or tasks that practicably demonstrate or provide measurable evidence that the pharmacist is adherent with the relevant criterion.

Self check: A box is provided for the pharmacist to mark 'yes', 'no' or 'not applicable' to self-assess their adherence with each indicator. Pharmacists should regularly self-assess; for example, once yearly, or when a change occurs in their professional practice.

Resources: References and links to relevant publications and other resources have been provided to help pharmacists adhere with each criterion.

Additional references: Additional resources and references relevant to the standard are provided.



Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 7: The pharmacist ensures the result and referral forms, and follow-up letters (where required) are completed in a manner that facilitates further consumer contact should the need arise		
1. Documents recommendations, follow-up, and outcomes for consumers who are referred to other health care providers, where possible		• Appendix 10: Screening Record and Referral Form, p. xx
2. Provides the pharmacist's name and signature as well as the contact details for the pharmacy providing the clinical testing on all results, referral forms, and follow-up letters		
Criterion 8: The pharmacist implements an appropriate risk management strategy for the screening services provided		
1. Follows a documented procedure to manage spillages and contamination		• Pharmaceutical Society of Australia. www.psa.org.au o Infection control template procedure o Incident report form template • Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp o Incident register (T7C) o Incident report (T7D)
2. Uses appropriate containers for storage and disposal of contaminated clinical waste and sharps		
3. Segregates clinical waste prior to its disposal in an approved manner and time interval		
4. Diligently follows a documented infection [illegible] procedure		
5. Ensures pharmacy [illegible] adhere to the infection control [illegible]		
6. [illegible] that all necessary protective clothing, equipment, and containers for storage and disposal of contaminated clinical waste and sharps are available and used		
7. Documents spillages, [illegible] contamination, needle-stick injuries, and [illegible] incidents		
8. Regularly [illegible] the suitability of the design [illegible] area, equipment, and facilities [illegible] to the provision of screening services		

Additional references

Chen LH, Emmerton L. Pharmacists' experiences in the provision of screening and monitoring services. Aust Pharm 2007;26:250–7. Available at: www.psa.org.au/site.php?id=1652

Jackson S, Peterson G. Health screening in community pharmacy. Aust Pharm 2004;23:760–4.

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Screening and Risk Assessment

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8. Medicines Australia. Code of conduct. 16th edn. Canberra: Medicines Australia, December 2009. Available at: www.medicinesaustralia.com.au/pages/page251.asp
9. Pharmaceutical Society of Australia. Competency standards for pharmacists in Australia 2003. Canberra: PSA, 2003 [under review at June 2010]. Available at: www.psa.org.au
10. Pharmaceutical Society of Australia. Standards for the provision of pharmacy medicines and pharmacist only medicines in community pharmacy. Revised edn. Canberra: PSA, November 2005.

Standard 1: Fundamental Pharmacy Practice

Standard

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

Scope of this standard

- Pharmacists practise in hospitals, clinics, community pharmacies, academia, the pharmaceutical industry, government, and the military, and this standard applies to all pharmacists regardless of the setting in which they practise.
- Pharmacists must comply with all legislation relevant to the provision of pharmacy services.
- This standard is to be applied in conjunction with each of the remaining standards in this publication.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist promotes and delivers all services in an ethical and professional manner		

1. Applies the relevant code(s) of professional conduct to everyday practice		• Pharmaceutical Society of Australia. Code of professional conduct. www.psa.org.au
		• Society of Hospital Pharmacists of Australia. Code of ethics. www.shpa.org.au
		• Therapeutic Goods Administration.www.tga.gov.au
		  ○ Therapeutics goods advertising code
		  ○ Price information code of practice
		• Medicines Australia. Code of conduct. www.medicinesaustralia.com.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Customer service charter (P11B). www.guild.org.au/qcpp
		• Pharmacy Board of Australia. www.pharmacyboard.gov.au
		  ○ Code of conduct for registered health professionals
		  ○ Guidelines on advertising

2. Provides access to accurate information about the pharmacy services available and how to access these services		
3. Applies a documented procedure to ensure all advertising and promotional material: • is accurate • is ethical • contains a statement encouraging consumers to seek advice from a pharmacist or another health care provider on the safe use of therapeutic products • complies with the relevant advertising codes		
Criterion 2: The pharmacist communicates with the consumer and other health care providers in a professional manner		
1. Establishes and maintains professional partnerships with the consumer and their other health care providers		• Professional Practice Standard 3: Counselling, p. 20
2. Actively listens to the needs of the consumer		
3. Recognises and addresses any barriers to communication		
4. Adopts a communication style appropriate for the individual consumer, accounting for language, culture, hearing, visual or speech requirements, or other special needs		
5. Verifies that the information provided to the consumer has been received and understood		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 3: The pharmacist observes the consumer's right to privacy and confidentiality at all times		

1. Provides all pharmacy services in a setting that ensures the privacy of the consumer and the confidentiality of the information exchanged		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Professional practice and the Privacy Act
		  ◦ Summary of obligations for pharmacists
		  ◦ Privacy policy example statement
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Confidentiality policy (P1A). www.guild.org.au/qcpp

2. Provides information and advice in a manner that ensures the consumer's need for privacy and confidentiality		
3. Communicates the workplace privacy policy to consumers		
4. Stores and handles all consumer records securely and restricts access to authorised personnel		
5. Applies a documented procedure to destroy and/or dispose of consumer records in a manner that ensures no breach of privacy occurs		
6. Obtains consent from the consumer for the delivery of specific pharmacy services and to share related information with their other health care providers		
7. Documents any situations where, for the consumer's wellbeing, a breach of their right to privacy and confidentiality occurs		
Criterion 4: The pharmacist promotes the judicious, appropriate, safe, and effective use of medicines at all times		

1. Uses a systematic process for gathering necessary medication history and other relevant consumer information		• Australian Government Department of Health and Ageing. www.health.gov.au
		  ◦ *The National Strategy for Quality Use of Medicines*
		  ◦ National Medicines Policy
		• Pharmaceutical Society of Australia. *Medication Profiling Service* [guidelines and standards]. www.psa.org.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy. (P2I) www.guild.org.au/qcpp
		• Appendix 1: The Medicines Management Pathway, p. 81
		• Appendix 4: Adherence Assessment Tool, p. 87

2. Reviews all relevant medicine and consumer information to identify existing or potential issues and to ensure safe outcomes and minimise harm		
3. Provides the consumer with treatment options, including non-pharmacological and lifestyle interventions, and respects their right to choose their preferred option		
4. Assesses the consumer's adherence to their treatment regimen where necessary		
5. Develops a plan to improve adherence where necessary		
6. Sets goals in agreement with the consumer for any recommended changes to their medication regimen and lifestyle		
Criterion 5: The pharmacist's primary concern in all services provided is the health and wellbeing of the consumer and/or the community		

1. Identifies and addresses the specific needs of the consumer and/or the community		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Ethical issues in declining to supply
		  ◦ Incident report form template
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Incident register (T7C)
		  ◦ Incident report (T7D)

2. Applies a documented procedure for the refusal of service where the consumer's request is unreasonable or unsafe		
3. Responds to the consumer in a timely manner with a referral to an appropriate service provider when unable or unwilling to provide a service		

Criteria/Indicators	Self check: Yes/No/NA	Resources
4. Ensures that the consumer adequately understands the recommendations and the choices they have made		
5. Applies a documented procedure for identifying and resolving issues arising from procedural errors and consumer complaints		
6. Documents issues, resolution, and follow-up as required		
Criterion 6: The pharmacist provides the consumer with current, relevant evidence-based information		

1. Maintains access to current evidence-based resources about medicines, therapeutic devices, general health topics, self-medication, and self-care issues		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Guidelines for Pharmacists on Providing Medicines Information to Patients*
		  ◦ *Consumer Medicine Information and the Pharmacist*
		  ◦ Self care fact cards
		  ◦ Evidence-based medicine: the basics. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 424–8
		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the provision of consumer medicines information by pharmacists in hospitals. J Pharm Pract Res 2007;37:56–8
		• National Prescribing Service. Patient leaflets and action plans. www.nps.org.au
		• Consumer Medicine Information. www.medicines.org.au
		• Australian Government National Health and Medical Research Council. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. www.nhmrc.gov.au
		• Professional Practice Standard 3: Counselling, p. 20

2. Evaluates information based on quality use of medicines principles and current evidence-based clinical guidelines		
3. Reviews the consumer's information needs and provides written and/or verbal evidence-based information and reinforcement as needed		
Criterion 7: The pharmacist refers the consumer to other health care providers or support services when appropriate, and/or when requested by the consumer		
1. Maintains a current list of details of other health care providers and support organisations in the local community		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy (P2I). www.guild.org.au/qcpp • Appendix 5: Details of Local Health Care Providers, p. 88
2. Provides the consumer with the relevant details of support services and/or other health care providers as required		
3. Refers the consumer to other health care providers and/or support services when their needs cannot be met by pharmacy services		
Criterion 8: The pharmacist documents consumer information in a manner appropriate to the pharmacy service provided		
1. Maintains consumer-specific information that is current and accurate		
2. Uses a standard form of documentation for recording consumer information		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 9: The pharmacist adopts a systematic approach to monitoring and follow-up		
1. Uses a documented procedure when follow-up is required or requested by the consumer or another health care provider		
2. Records the date and details of any significant intervention and communication with the consumer or other health care providers		
3. Regularly reviews and monitors the consumer's use of medicines, including adherence, where necessary		
Criterion 10: The pharmacist systematically evaluates their ability to provide pharmacy services		

1. Regularly self-assesses the knowledge and skills required to provide pharmacy services		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Education and professional development
		  ◦ *Guidelines for Managing Pharmacy Systems for Quality and Safety*
		  ◦ *Competency Standards for Pharmacists in Australia 2003* [Under review at June 2010]
		• Pharmacy Board of Australia. *Guidelines: Continuing Professional Development*. www.pharmacyboard.gov.au
		• National Prescribing Service. NPS Pharmacy practice reviews. www.nps.org.au
		• Society of Hospital Pharmacists of Australia. Continuing professional development program. www.shpa.org.au
		• Australian College of Pharmacy. CPD activities. www.acp.edu.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Training plan (T15A)
		  ◦ Training record (T15B)

2. Addresses those areas identified as in need of continuing professional development		
3. Documents participation in a continuing professional development program		
4. Regularly seeks feedback to assess that services meet consumer expectations		
5. Systematically enhances the delivery of services based on consumer feedback		

Additional references

Australian Government Department of Health and Ageing. National Medicines Policy. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-index.htm

Australian Government Department of Health and Ageing. The national strategy for quality use of medicines. Executive summary. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/4CCAC8550BA36A52CA256F1800468A6E/$File/execsumbro.pdf

Pharmacy Board of Australia. Code of conduct for registered health practitioners. Available at: www.pharmacyboard.gov.au

Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: Pharmaceutical Society of Australia, 2009.

Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35:122–46.

Standard 2: Managing Pharmacy Practice

Standard

The pharmacist with management responsibilities adequately addresses all management and organisational needs in order to facilitate the safe, effective, and efficient delivery of pharmacy services.

Scope of this standard

- The 'pharmacist' in this standard refers to a pharmacist with management responsibilities such as, but not limited to, directors of pharmacy, pharmacists in charge, proprietors, pharmacy managers, and accredited pharmacists.
- Pharmacists with management responsibilities should self-assess themselves against the appropriate sections in this standard.
- It is assumed that pharmacists in a management role will also apply the necessary interpersonal and management skills, and experience to their practice.
- Operating procedures developed to meet the Quality Care Pharmacy Program (QCPP) specifications may be used to meet this standard where appropriate.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist ensures the pharmacy environment, the number of individuals, and the skills of the individuals working in the pharmacy are appropriate and adequate for the range of services provided		

1. Provides and maintains areas within the pharmacy that are suited to the privacy and security needs of each service provided		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Competency Standards for Pharmacists in Australia 2003*
		  ◦ The role of non-pharmacist dispensary assistants/technicians
		• Therapeutic Goods Administration. Australian code of good wholesaling practice for therapeutic goods for human use. www.tga.gov.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Staff roster (T14A)
		  ◦ Training plan (T15A)
		  ◦ Training record (T15B)
		  ◦ Confidentiality policy (P1A)
		  ◦ Conducting a performance review (P14C)

2. Provides storage areas for therapeutic goods that comply with the relevant legislation, quality assurance programs, and manufacturers' recommended storage conditions		
3. Employs adequate numbers of staff with suitable qualifications, competence, and training to deliver the pharmacy services offered by the pharmacy		
4. Ensures only suitably trained individuals work in particular areas of the pharmacy where specific skills are required (such as the dispensary)		
5. Obtains a signed confidentiality form from staff involved in providing services to consumers		
6. Facilitates regular training for all individuals working in the pharmacy with regard to their roles and responsibilities, and general pharmacy procedures		
7. Regularly validates and reviews the skills of all individuals working in the pharmacy to ensure competence is maintained		

Criteria/Indicators	Self check: Yes/No/NA	Resources
8. Regularly monitors the resourcing requirements of the pharmacy, and makes adjustments accordingly to ensure quality of the services is maintained		
Criterion 2: The pharmacist provides the necessary resources and equipment for the range of services provided		
1. Provides access to all current, relevant, and essential evidence-based guidelines, business rules, and therapeutic information resources		• Australian Government. Business. Getting started with OH&S in your state or territory. www.business.gov.au
2. Maintains and ensures access to an up-to-date list of local health care providers, community groups, and support organisations		
3. Supplies and maintains protective equipment to ensure staff safety		
4. Ensures the disposal of all clinical waste and sharps complies with Australian safety standards		
Criterion 3: The pharmacist develops, documents and maintains standard operating procedures for all services provided		
1. Establishes, maintains, and routinely updates standard operating procedures for all services provided by the pharmacy		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Procedures. www.guild.org.au/qcpp • Royal Pharmaceutical Society of Great Britain. Developing and implementing standard operating procedures for dispensing. www.rpsgb.org.uk
2. Ensures all individuals working in the pharmacy have access to the procedures and follow them		
3. Develops, documents, and maintains occupational health and safety procedures		
Criterion 4: The pharmacist documents all the necessary information required for the services provided		
1. Stores all documentation in a systematic and secure manner to allow timely retrieval when required		
2. Stores documentation in a manner that protects consumer privacy		
3. Prepares forms and tools to be used by all pharmacy staff when delivering services to consumers		
4. Ensures all individuals working in the pharmacy maintain relevant documentation		
Criterion 5: The pharmacist ensures the range of pharmacy services are systematically evaluated and improved		

1. Maintains a documented quality assurance process appropriate to the services provided		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Guidelines for Managing Pharmacy Systems for Quality and Safety*
		  ◦ Policy/procedure review form
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Maintaining the operations manual (P7A)
		  ◦ Reviewing procedures and templates (P7C)
		• Appendix 2: Quality Use of Medicines and Practice Improvement, p. 84

2. Documents the features of each pharmacy service, and how its effectiveness is to be measured		
3. Evaluates the quality of the pharmacy service at regular intervals		
4. Uses a quality improvement tool to aid in the review process		
5. Seeks feedback from the users of services to assess that services have been provided in a timely and satisfactory manner		

Criteria/Indicators	Self check: Yes/No/NA	Resources
6. Analyses and records the results of service reviews		
7. Uses the findings of the service review to take appropriate action when designing system improvements		

Additional requirements for managing pharmacists providing online pharmacy services

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist ensures that consumers can readily identify the online pharmacy and the services it provides		
1. Clearly displays all details of the pharmacy, including: • name of the practice • street address • approval number • contact details • name(s) of the proprietor(s) and pharmacist managers(s) • service details, terms and conditions, and costs • delivery timelines • privacy and security declaration • date of most recent update of the website		
2. Maintains a document outlining the online services the pharmacy provides, in both electronic and hardcopy format		
3. Provides the details of the online services available each time a product is dispatched or information about the services is requested.		
Criterion 2: The pharmacist adheres to all the ethical and professional requirements of the profession when establishing an internet pharmacy service		
1. Ensures that there are no hyperlinks to promotional material on web pages containing clinical information on Pharmacist Only Medicines (with the exception of those listed in Appendix H of the *Standard for the Uniform Scheduling of Drugs and Poisons*), Prescription Only Medicines, and Controlled Drugs		• Therapeutic Goods Administration. www.tga.gov.au ◦ Appendix H. In: *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) ◦ Advertising therapeutic products in Australia • Medicines Australia. Code of Conduct Edition 16. www.medicinesaustralia.com.au • Pharmacy Board of Australia. www.pharmacyboard.gov.au ◦ Guidelines on Dispensing Medicines ◦ Guidelines on Advertising
2. Ensures that no claims and testimonials are posted on the website that are promotional or comparative in nature		
Criterion 3: The pharmacist ensures that a reliable and secure online pharmacy service is provided		
1. Provides adequate electronic security to prevent access to consumers' electronic records by unauthorised personnel		
2. Provides a privacy and security declaration on the website		
3. Ensures that information transferred to and from consumers via the internet is protected by: • encryption technology • user name and password access • Written, legally binding agreement with third parties, such as webmasters, internet providers, and contracted computer specialists		

Additional requirements for managing pharmacists providing non-sterile compounding services

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist provides a safe working environment for all staff involved in the preparation of high-risk products		
1. Establishes and maintains a documented procedure for monitoring the necessary biological parameters (such as liver function) of staff involved in the preparation of cytotoxic and hazardous products		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35: 44–52
2. Applies a documented procedure to exclude certain staff members from the preparation of cytotoxic and hazardous products (such as pregnant women)		
3. Provides appropriate protective clothing to all staff preparing cytotoxic and hazardous products		
4. Informs all personnel involved in handling cytotoxic products of the potential hazards and precautions required in their handling of such products		
Criterion 2: The pharmacist implements a documented procedure in the event of a needlestick injury or contamination from a cytotoxic spill		

1. Develops a documented procedure to be used in the event of a needlestick injury or an unexpected exposure to a cytotoxic spill		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35: 44–52
		• Pharmaceutical Society of Australia. Clinical resource centre. www.psa.org.au
		  ○ Infection control template procedure
		  ○ Incident report form template
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ○ Incident register (T7C)
		  ○ Incident report (T7D)

2. Trains staff on the actions to be taken in the event of contamination and/or a needlestick injury in accordance with documented procedures		
3. Provides the materials required for cleaning up cytotoxic spills		
4. Ensures adherence to the developed procedures in the event of a needlestick injury or contamination in the area where cytotoxic products are prepared		
5. Establishes a register of any accidents or cytotoxic spills that includes the date, time and place of spill, drug name, approximate drug volume, form of the drug (i.e. liquid or powder), the names of the staff involved and the actions taken to remedy the incident		

Additional requirements for managing pharmacists providing sterile compounding services

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist ensures that pharmacy staff preparing sterile products are specifically trained and assessed in compounding techniques		

1. Develops and applies a documented procedure for training and assessing staff in techniques for the preparation of sterile products		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ○ Staff training (P15A)
		  ○ Training plan (T15A)
		  ○ Training record (T15B)

2. Maintains a current list of trained staff and the date of training/assessment, in accordance with the documented training procedure		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Regularly assesses the aseptic technique and skill of staff members		• Society of Hospital Pharmacists of Australia. SHPA Practice guidelines for aseptic dispensing services. Aust J Hosp Pharm 1994;24:509–12
Criterion 2: The pharmacist develops and maintains policies and procedures that are relevant to sterile compounding		

1. Develops policies and procedures customised to the sterile compounding working environment and facilities		• Pharmaceutical Society of Australia. Extemporaneous dispensing. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 31–4
		• Society of Hospital Pharmacists of Australia. www.shpa.org.au
		  ◦ SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35:44–52
		  ◦ SHPA Practice guidelines for aseptic dispensing services. Aust J Hosp Pharm 1994;24:509–12

2. Develops and maintains a procedure for cleaning and sanitising the controlled areas		
3. Provides all staff with access to the policies and procedures at all times		
4. Regularly reviews the policies and procedures for sterile compounding to reflect current best practice		
5. Regularly monitors adherence to Australian standards, policies, and procedures, and takes appropriate action to ensure these are upheld		
6. Maintains certification of isolators and laminar flow units		
7. Reviews and implements corrective quality assurance checks for all stages of compounding		
8. Establishes a daily operator log of staff involved in preparing cytotoxic products and cleaning the anteroom and clean room		

Additional references

Australian Government Department of Health and Ageing. National medicines policy 2000. Canberra: Commonwealth of Australia, 1999. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm

Australian Government Department of Health and Ageing. The national strategy for quality use of medicines. Plain English edition. Canberra: Commonwealth of Australia, 2002. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pdf-natstrateng-cnt.htm

Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: Pharmaceutical Society of Australia, 2009.

Wilson RM, Runciman WB, Gibberd RW et al. The Quality in Australian Health Care Study. Med J Aust 1995;163:458–71.

Standard 3: Counselling

Standard

The pharmacist works with the consumer to provide tailored verbal and written information to ensure the consumer has sufficient knowledge and understanding of their medicines and therapeutic devices to facilitate safe and effective use.

Scope of this standard

- This standard applies to consumer counselling associated with the supply of prescription and non-prescription medicines and therapeutic devices.
- The term 'counselling' refers to a two-way communication process between the pharmacist and the consumer in which the pharmacist ascertains the needs of the consumer and provides them with the information required to safely and effectively use medicines and/or therapeutic devices.
- It is envisaged that counselling will be offered to all consumers each time a medicine or therapeutic device is requested or supplied, and that where the need for counselling is identified, the pharmacist will be available in a timely manner.
- The expressed needs of the consumer, as well as the pharmacist's professional judgement, particularly with regard to the consumer's level of understanding and the context in which the counselling is required, will influence the scope of the counselling, and how and where it is conducted.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Medication Review, Dispensing, Indirect Pharmacy Services, Dose Administration Aids Service, Provision of Non-prescription Medicines and Therapeutic Devices, Health Promotion, Disease State Management, and Harm Minimisation standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist is available to provide counselling to all consumers		
1. Responds to all requests for consumer counselling		
2. Ensures that the most appropriately trained person undertakes the counselling		
3. Directs and educates pharmacy staff involved in the provision of medicines and therapeutic devices to identify and refer consumers who may benefit from additional counselling by a pharmacist		
Criterion 2: The pharmacist provides counselling that is supported by current, evidence-based information from relevant resources		

1. Regularly accesses current therapeutic information resources		• National Library of Medicine. PubMed. www.ncbi.nlm.nih.gov/pubmed
		• Medical Matrix. www.medmatrix.org
		• National Prescribing Service. www.nps.org.au
		  ◦ Drugs and therapeutic topics
		  ◦ NPS RADAR

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Ensures the information provided is evidence-based and current		• Evidence-based medicine: the basics. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 424–8 • Information from the world wide web. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 429–42 • The Cochrane Collaboration. The Cochrane Library. www.cochrane.org • Veterans' MATES [Medicines Advice and Therapeutics Education Services]. www.veteransmates.net.au • Centre for Evidence-Based Medicine. EBM tools. www.cebm.net • Auspharmacist. AusPharm Research Roundup. www.auspharmacist.net.au
Criterion 3: The pharmacist utilises a range of communication methods to ensure that counselling is effective		
1. Identifies barriers to effective communication and uses strategies to overcome them		• Translating and Interpreting Service (TIS) National. www.immi.gov.au/living-in-australia/help-with-english/help_with_translating Tel: 131 450 • Vision Australia. Resources. Communicating effectively with people who are blind or vision impaired. www.visionaustralia.org • Deaf Society NSW. Information. How to communicate with a deaf person. www.deafsocietynsw.org.au • International Pharmaceutical Federation (FIP). MEPS Pictogram Project. www.fip.org • United States Pharmacopeia. USP Pictograms. www.usp.org • National Prescribing Service. Translated health information about medicines. www.nps.org.au • Health Translations Directory. Translated health information. www.healthtranslations.vic.gov.au • NSW Multicultural Health Communication Service. Publications and resources. www.mhcs.health.nsw.gov.au • Pharmaceutical Society of Australia. *Guidelines for Pharmacists in Providing Services to People with Impaired Vision*. www.psa.org.au • Pharmacy Guild of Australia. Medication Management Review Program. Communication and concordance module. www.guild.org.au • National Health and Medical Research Council. *Communicating with Patients: Advice for Medical Practitioners*. www.nhmrc.gov.au • Mind Tools. Communication skills. www.mindtools.com
2. Uses other appropriate information materials, such as pictures and models, to effectively convey information when comprehension issues arise		
3. Uses a translation service or appropriate alternative where language barriers exist		
4. Confirms consumer understanding during counselling		
Criterion 4: The pharmacist provides counselling according to the needs of the consumer		
1. Communicates with the consumer to identify their information needs		• Harvard School of Public Health. Health Literacy Studies. Innovative materials. Plain language glossaries. www.hsph.harvard.edu/healthliteracy

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Tailors communication to the needs and understanding of the individual consumer		• National Prescribing Service. Medicines Line. Tel: 1300 888 763 • Poisons Information Centre. Tel: 13 11 26
3. Offers consumers the opportunity to return and seek further clarification and information as required		
4. Provides consumers with details of other medicine information services that can be accessed when the pharmacy is closed		
Criterion 5: The pharmacist uses written information or other suitable materials to supplement oral counselling		

1. Has access to written materials that can reinforce oral counselling		• Consumer Medicine Information. www.medicines.org.au
		• National Prescribing Service. www.nps.org.au
		  ◦ Consumer Medicine Information (CMI) search
		  ◦ Patient leaflets and action plans
		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Consumer Medicine Information and the Pharmacist*
		  ◦ *Guidelines for Pharmacists on Providing Medicines Information to Patients*
		  ◦ Self care fact cards
		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the provision of consumer medicines information by pharmacists in hospitals. J Pharm Pract Res 2007;37:56–8
		• Veterans' MATES [Medicines Advice and Therapeutics Education Services]. www.veteransmates.net.au
		• HealthInsite. www.healthinsite.gov.au
		• Better Health Channel. www.betterhealth.vic.gov.au

2. Offers Consumer Medicine Information (CMI) leaflets to consumers and explains the information contained in the CMI and its relevance to the medicine supplied		
3. Provides the consumer with CMI, or other written information, when requested or where necessary		
Criterion 6: The pharmacist adequately explains and/or demonstrates the use of therapeutic devices to the consumer		
1. Has access to common therapeutic devices and demonstrates their use to the consumer during counselling		• Professional Practice Standard 7: Dose Administration Aids Service, p. 36 • National Prescribing Service. Common inhaler devices chart. www.nps.org.au • National Asthma Council. Inhaler technique in adults with asthma or COPD. www.nationalasthma.org.au
2. Confirms by observing that the consumer can demonstrate correct use of the therapeutic device		
Criterion 7: The pharmacist systematically records counselling events that are considered clinically important		
1. Documents significant counselling issues or events in the consumer's profile		• Appendix 6: Documenting Counselling Events and Interventions, p. 89
2. Records recommended actions and timelines for follow-up in the consumer's medication profile, where appropriate		
3. Documents reasons why counselling and/or written information, including CMI, were not provided, where considered important		

Additional references

Adams RJ, Stocks NP, Wilson DH et al. Health literacy – a new concept for general practice? Aust Fam Physician 2009;38:144–7.

HRH Global Resource Center. Counselling, Concordance and Communication: Innovative Education for Pharmacists. Available at: www.hrhresourcecenter.org/node/1938.

Pharmaceutical Society of Australia. Section E: OTC counselling guides. In: Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: PSA, 2009: 373–414.

Pharmacy Board of Australia. Guidelines on dispensing medicines. Available at: www.pharmacyboard.gov.au

Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35:122–46.

Standard 4: Medication Review

Standard

The pharmacist works with the consumer, and other health care providers, to systematically review the consumer's medication regimen, identify potential areas for improvement, and provide information and advice to optimise health outcomes.

Scope of this standard

- A 'medication review' is a systematic assessment of a consumer's medications and the management of those medications, with the aim of optimising consumer health outcomes and identifying potential medication-related issues within the framework of the quality use of medicines.
- The term 'medication review' encompasses a continuum of processes in various formats and complexities, ranging from an opportunistic discussion to a more comprehensive and proactive approach to reviewing the consumer's medication regimen (see Figure 1).
- This standard covers the key principles underpinning all types of systematic medication review services under any service arrangement including, but not limited to: hospital inpatient medication reviews, medication profiling services, Home Medicines Reviews (HMRs), Residential Medication Management Reviews (RMMRs), and Medicines Use Reviews (MURs). Opportunistic medication history reviews that are conducted during the dispensing process are covered in Standard 5: Dispensing.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice and Counselling standards. Refer also to the Health Promotion standard, where appropriate.
- Pharmacists providing medication reviews should also be familiar with the relevant professional guidelines and business rules relating to these services, where available. For specific service-related information, refer to the relevant Professional Practice Guidelines for each individual service.

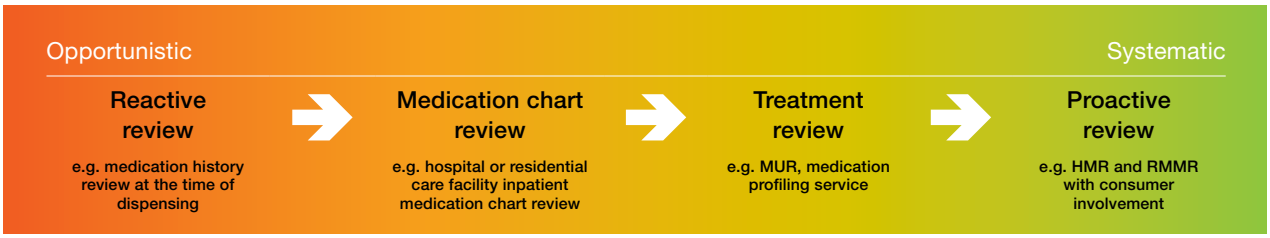

Figure 1. Medication review services fall along a continuum of increasing complexity. More complex services require additional training and skills from a pharmacist.

Note: Home Medicines Reviews were formerly known as Domiciliary Medication Management Reviews (DMMRs).

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist maintains the relevant level of competency necessary to undertake the specific medication review service		

1. Has completed the appropriate level of training and credentialing for the medication review service being delivered		• Australian Association of Consultant Pharmacy. www.aacp.com.au
		  ◦ *AACP Competency Map: Medication Management Reviews*
		  ◦ Accreditation diagram
		  ◦ HMR Mentoring Service
		  ◦ Fact sheet 5. Reaccreditation for MMRs
		• Society of Hospital Pharmacists of Australia. MMR [Medication Management Review] accreditation. www.shpa.org.au

2. Maintains currency of the knowledge and skills required to deliver the medication review service		
3. Accesses appropriate resources to support service delivery		
Criterion 2: The pharmacist works collaboratively with the consumer and other health care providers		
1. Determines and uses the preferred method of communication for the consumer and other health care providers		• Pharmacy Guild of Australia. Medication Management Review Program. Communication and concordance module. www.guild.org.au
2. Ensures the consumer has provided informed consent for both the service and for communication with their other health care provider(s)		
3. Conducts the medication review in an environment that meets the needs of the consumer		
4. Liaises with any other pharmacists involved in the medication review service to ensure all tasks are completed and follow-up occurs if required		
Criterion 3: The pharmacist follows a systematic procedure for conducting the medication review		

1. Forms an agreement with any other pharmacists involved in different aspects of the review to ensure all tasks are performed		• Australian Association of Consultant Pharmacy. www.aacp.com.au
		  ◦ *AACP Procedures and Resources Manual: Medication Management Review*
		  ◦ *Framework Document for Domiciliary Medication Management Reviews*
		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. Appendix A: Accurate medication history. J Pharm Pract Res 2005;35:122–46
		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Guidelines for pharmacists: Domiciliary Medication Management Review*
		  ◦ *Guidelines and Standards for the Collaborative and Pharmacist Residential Medication Management Review (RMMR) Program and Associated Quality Use of Medicines (QUM) Services*
		  ◦ *Medication Profiling Service* [guidelines and standards]
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Home Medicines Review checklist (T3F). www.guild.org.au/qcpp

2. Conducts a consumer interview to compile a medication history, unless direct communication with the consumer is not possible		
3. Reviews consumer's current medication, utilises consumer files, pharmacy records, and information from other health care providers to further inform the medication review		
4. Assesses adherence and provides advice on how to improve adherence if necessary		
5. Assesses the consumer's medication regimen and identifies potential medication-related issues		
Criterion 4: The pharmacist conducts the medication review and reports findings, where relevant, in a timely manner		
1. Completes the medication review within 2–4 weeks of receiving the referral or notifies the referring health care provider if there is to be a delay		

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Completes medication reviews initiated upon hospital discharge, or those indicated as urgent, within 7–10 days of receiving the referral		
Criterion 5: The pharmacist maintains accurate documentation for the medication review service provided		
1. Records all activities undertaken and strategies developed in the course of a medication review		• Australian Association of Consultant Pharmacy. AACP sample agreement between HMR Service Provider and the Accredited Pharmacist. www.aacp.com.au
2. Stores all medication review documentation in a safe, systematic and secure manner that allows timely and accurate retrieval		
3. Prepares a comprehensive report documenting recommendations, if relevant		
Criterion 6: The pharmacist addresses and follows up any issues arising from the medication review		
1. Addresses any current, or potential, medication-related issues identified in the medication review, in conjunction with other health care providers, where appropriate		
2. Prioritises any identified issues and addresses them in a timely manner		
3. Promptly communicates to the appropriate health care provider any findings that may seriously affect the consumer's health		
4. Records any follow-up actions resulting from the medication review, if known		
Criterion 7: The pharmacist creates and maintains a comprehensive medication profile with involvement from the consumer and their other health care providers		
1. Uses suitable computer software to record relevant consumer details in the medication profile		• Pharmaceutical Society of Australia. *Medication Profiling Service* [guidelines and standards]. www.psa.org.au • National Prescribing Service. Medicines list. www.nps.org.au • Australian Government Department of Health and Ageing. Medi-list. www.health.gov.au
2. Maintains a medication profile for each consumer that is current and complete at the time of review		
3. Shares and discusses details of the medication profile with the consumer, including how it can be used as a resource to improve continuity of care		
4. Obtains relevant information from the consumer's other health care providers as required		
Criterion 8: The pharmacist provides the consumer and other health care providers with relevant information to optimise health outcomes		

1. Provides accurate and relevant written and verbal information to the consumer's other health care providers as needed		• Pharmacy Guild of Australia. www.guild.org.au
		  ◦ Medicines Information to Consumers Program
		  ◦ *When to Provide Consumer Medication Information*
		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Consumer Medicine Information and the Pharmacist*
		  ◦ *Guidelines for Pharmacists on Providing Medicines Information to Patients*
		  ◦ Self care fact cards

2. Maintains access to current sources of evidence-based information about medicines, therapeutic devices, and lifestyle issues		

Criteria/Indicators	Self check: Yes/No/NA	Resources

3. Provides the consumer with written and oral information and advice appropriate to their needs		• Consumer Medication Information. www.medicines.org.au
		• National Prescribing Service. www.nps.org.au
		  ◦ Consumer Medicine Information (CMI) search
		  ◦ NPS patient resources for health professionals
		• HealthInsite. www.healthinsite.gov.au
		• Professional Practice Standard 3: Counselling, p. 20

4. Demonstrates and observes the use of any therapeutic devices, aids, and systems designed to assist in medication use and adherence		
5. Provides any other pharmacists involved with the medication review with relevant information to ensure continuity of care		

Additional references

Australian Government Department of Health and Ageing. National Medicines Policy: Quality Use of Medicines (QUM). Available at: www.health.gov.au/internet/main/Publishing.nsf/Content/nmp-quality.htm

Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Canberra: Commonwealth of Australia, 2005.

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Cipolle R, Strand L, Morley P. Pharmaceutical care practice: the clinician's guide. 2nd edn. New York: McGraw-Hill, 2004.

Clyne W, Blenkinsopp A, Seal R; National Prescribing Centre. A guide to medication review, 2008. Liverpool: National Prescribing Centre, 2008. Available at: www.npci.org.uk/medicines_management/review/medireview/library/library_good_practice_guide1.php

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Hughes J, Tenni P, Peterson G. The Australian pharmacist aged care primer. Canberra: Pharmaceutical Society of Australia, 2007.

Medicare Australia. Home Medicines Review (HMR). Available at: www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/hmr.jsp

Medicare Australia. Residential Medication Management Review (RMMR). Available at: www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/rmmr.jsp

Pharmaceutical Society of Australia. Medication review. In: Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: PSA, 2009: 276–9.

Pharmacy Guild of Australia. About Home Medicines Review. Available at: www.guild.org.au/mmr/content.asp?id=53

Pharmacy Guild of Australia. RMMR. Available at: www.guild.org.au/mmr/content.asp?id=62

Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35:122–46.

Standard 5: Dispensing

Standard

The pharmacist ensures that dispensing occurs accurately, reflects the prescriber's intentions, and is consistent with the needs and safety of the consumer.

Scope of this standard

- This standard applies to the dispensing of prescription medicines and to products prepared extemporaneously from the point of receiving the prescription (by hand or electronic means), assessing it against the consumer's needs and any safety concerns, and accurately supplying the medicine.
- It is assumed that the pharmacist has adequate knowledge of the dispensing software and systems he or she uses to meet the requirements of this standard.
- A pharmacy technician may carry out the functions of assembling medicines and data entry (where legally allowed). However, the pharmacist is responsible for assessing the appropriateness of the medicines in relation to the full medication history (or medication profile if available), the final check of dispensed medicines, and the counselling of the consumer.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice and Counselling standards. Refer also to the Managing Pharmacy Practice, Indirect Pharmacy Services, Dose Administration Aids Service, Compounding, Compounding Sterile Preparations, Disease State Management, and Harm Minimisation standards for additional information, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist implements systems of good dispensing practice		
1. Applies and supervises a documented dispensing procedure that covers receipt of prescriptions, preparation, and supply of medicines		• Pharmaceutical Society of Australia. *Dispensing Practice Guidelines*. www.psa.org.au • Pharmaceutical Defence Limited. Guide to good dispensing chart. www.pdl.org.au
2. Checks details of repeat prescriptions against the original prescription		
3. Uses barcode scanners to verify the selection of correct medicines just prior to attaching the label		
4. Applies a documented procedure to detect and appropriately address excessive supply, fraudulent prescriptions, and insufficient or apparent non-adherence		
5. Processes non-prescription items written on prescriptions in the same manner as prescription only items		
Criterion 2: The pharmacist obtains personal details and a complete medication history from the consumer		
1. Collects and accurately records sufficient personal details and a complete medication history to establish a consumer profile when dispensing		
2. Collects and documents any special needs of the consumer in the consumer profile so that verbal counselling or written information can be tailored accordingly		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Considers all the information collected in order to make an informed professional judgement about the supply of the requested medicine		
Criterion 3: The pharmacist reviews and updates the consumer's medication history during the dispensing process		
1. Reviews and considers the multiple sources of medicines (prescription, non-prescription, and complementary) and the influence of relevant disease states on the action and/or effect of prescribed medicines		
2. Confirms that the consumer's information downloaded from e-prescriptions or e-health records is current and accurate		
3. Records all dispensed medicines in the consumer's medication history		
Criterion 4: The pharmacist identifies, records, and considers the consumer's suspected and known adverse drug reactions (ADRs), precautions, and contraindications when dispensing		

1. Gathers information and records details of any ADRs, including allergies, precautions, and contraindications known to the consumer		• Therapeutic Goods Administration.
		  ◦ Report of suspected adverse reactions to medicines/vaccines. www.tga.gov.au/adr/bluecard.htm
		  ◦ Safety alerts and advisory statements. www.tga.gov.au/alerts/
		  ◦ Advisory Committee on the Safety of Medicines. www.tga.gov.au/committee/acsom.htm

2. Uses alerts to remind pharmacy staff of the consumer's known or suspected ADRs, including allergies		
3. Considers potential drug interactions each time a medicine is dispensed		
4. Accesses current information on clinically significant interactions, contraindications, precautions, and disease states		
5. Provides advice to consumers about potential ADRs that is consistent with, and complementary to, the advice given by the prescriber or other relevant health care providers		
6. Discusses potential or existing ADRs with the consumer's other health care providers when required		
7. Reports clinically significant ADRs to the Advisory Committee on the Safety of Medicines where appropriate		
Criterion 5: The pharmacist contacts the prescriber about a prescription or a consumer's therapy when necessary		
1. Documents on the prescription and in the dispensing history, all communication with the prescriber about prescriptions, medicines, and/or consumer issues		
2. Documents on the prescription, and in the consumer profile, where possible, all changes to treatment regimen authorised by the prescriber		
3. Confirms and documents the outcome of any conversation with the prescriber about off-label use		
Criterion 6: The pharmacist uses appropriate care when dispensing cytotoxic medicines		
1. Ensures all cytotoxic medicines stored in the dispensary are clearly identified as such using supplementary labelling		• Society of Hospital Pharmacists of Australia. www.shpa.org.au

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Counts and handles cytotoxic medicines where necessary using equipment that is specifically for cytotoxic use only		◦ SHPA standards of practice for the transportation of cytotoxic drugs from pharmacy departments. J Pharm Pract Res 2007;37:234–5 ◦ SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35:44–52 ◦ SHPA standards of practice for the provision of oral chemotherapy for the treatment of cancer. J Pharm Pract Res 2007;37:149–52
Criterion 7: The pharmacist dispenses medicines with legible and unambiguous labels, and with adequate dosing instructions		
1. Uses labels with clearly marked dark print, ensuring manufacturer's batch number and expiry date are clearly visible, and includes both brand and generic names for prescription medicines		• Counselling and cautionary advisory labels for medicines. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 2–20
2. Considers the need for child-resistant packaging when a medicine that warrants such packaging is repackaged from its original container		
3. Includes manufacturer's batch number and expiry date on the label of the dispensed medicine when repackaging from an original container		
4. Labels medicines with dark print and large font size to allow easier reading for visually impaired consumers		
5. Provides labels with specific and complete instructions for use		
6. Uses cautionary advisory labels to indicate specific usage instructions (e.g. 'Shake well before each use')		
Criterion 8: The pharmacist ensures the consumer has adequate dosing instructions and fully understands how to safely use, store, and dispose of dispensed medicines		
1. Provides additional written medicine dosing instructions, such as Consumer Medicine Information (CMI) or a Medication Profile, where required		• Consumer Medicine Information. www.medicines.org.au • Pharmaceutical Society of Australia. *Consumer Medicine Information and the Pharmacist*. www.psa.org.au • Counselling and cautionary advisory labels for medicines. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 2–20 • Society of Hospital Pharmacists of Australia. SHPA standards of practice for the provision of consumer medicines information by pharmacists in hospitals. J Pharm Pract Res 2007;37:56–8 • Professional Practice Standard 3: Counselling, p. 20
2. Provides written and verbal information in a manner that addresses communication barriers, such as literacy level, cultural background, and language mastery		
3. Uses appropriate cautionary advisory labels on dispensed medicines as recommended in the current edition of the *Australian Pharmaceutical Formulary and Handbook*		
4. Offers counselling to ensure that the consumer has sufficient knowledge of their medications to facilitate their safe and effective use		
5. Offers advice on how to safely store and dispose of dispensed medicines		
6. Provides counselling to a consumer so they understand the benefits and risks associated with any off-label use of medicines		

Criteria/Indicators	Self check: Yes/No/NA	Resources
7. Advises the consumer about the correct handling, storage, and disposal of cytotoxic medicines, particularly for those in tablet form that are not film-coated		
8. Advises the consumer to contact the prescriber when the last repeat of a prescription is dispensed		
9. Provides appropriate advice on the safe storage and handling of dispensed medicines, particularly when child-resistant packaging is used		
Criterion 9: The pharmacist checks the dispensed medicine for accuracy		
1. Checks the dispensed medicine against the original prescription before the medicine is supplied to the consumer		• Pharmaceutical Society of Australia. *Dispensing Practice Guidelines*. www.psa.org.au
2. Checks the expiry date of the dispensed medicine is valid for the expected duration of treatment		
3. Ensures the dispensing record shows which pharmacist dispensed the medicine(s)		
4. Initials the dispensing label when the pharmacist who physically issues the medicine is not the dispensing pharmacist		
5. Uses barcode scanners to verify the correct medicine has been dispensed		
Criterion 10: The pharmacist accurately identifies the consumer or agent when dispensing and supplying the medicine		
1. Seeks confirmation of the consumer's identity prior to dispensing		
2. Seeks confirmation of the consumer's identity to ensure the correct medicine is handed to the correct consumer		
3. Confirms an agent's identity and their authorisation to collect a prescribed item on behalf of the consumer		
Criterion 11: The pharmacist completes all dispensing in a timely manner		
1. Routinely assesses current workload and the number of prescriptions received to determine the likely amount of time the consumer will need to wait		
2. Informs pharmacy staff and the consumer of the anticipated waiting time for the prescription and discourages the expectation of fast service.		
Criterion 12: The pharmacist ensures the consumer fully understands the nature of brand substitution when it occurs		
1. Checks whether the 'not for substitution' box has been ticked on the prescription before offering brand substitution to the consumer		• Pharmaceutical Society of Australia. *Guidelines for Pharmacists on PBS Brand Substitution*. www.psa.org.au
2. Checks whether the 'not for substitution' box has been ticked on the original prescription before dispensing a repeat prescription		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Follows a process to inform consumers of generic brand substitutes where they are available and consistent with the prescriber's intent and desired health outcomes		
4. Records in the dispensing history and on the medicine label when initial brand substitution occurs		
5. Issues the same generic brand as previously given wherever possible to minimise medication misadventure and consumer confusion		
6. Substitutes brands only where bioequivalence has been established and the consumer has consented		
7. Informs the consumer of the risks and/or benefits associated with brand substitution		
8. Counsels the consumer when brand substitution is inappropriate or cannot occur		

Additional references

Pharmaceutical Defence Limited. Guide to good dispensing chart. Available at: www.pdl.org.au/publications/gtgd

Pharmacy Board of Australia. Guidelines on dispensing medicines. Available at: www.pharmacyboard.gov.au

Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: Pharmaceutical Society of Australia, 2009.

Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35:122–46.

Standard 6: Indirect Pharmacy Services

Standard

In circumstances where face-to-face contact is not possible, the pharmacist provides an ethical indirect supply service that maintains the principles of quality use of medicines and consumer privacy.

Scope of this standard

- This standard applies to the provision of medicines and therapeutic devices by a pharmacist to a consumer living at an Australian address where supply occurs without face-to-face contact. Where possible, face-to-face contact with consumers should be encouraged.
- This standard covers the supply of medicines and therapeutic devices via mail, courier, taxi, remote dispensing units, telepharmacy, and depots, as well as the ordering of these via email, internet, teleconference, or facsimile.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice, Counselling, and Dispensing standards. Refer also to the Managing Pharmacy Practice, Compounding, and Provision of Non-prescription Medicines and Therapeutic Devices standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist provides the consumer with information about the indirect pharmacy service		
1. Gives the consumer the full contact details of the pharmacy		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Distance supply checklist (T2A). www.guild.org.au/qcpp • Appendix 7: Indirect Pharmacy Services: New Consumer Details/Change of Consumer Details Form, p. 90
2. Explains the service to the consumer		
3. Advises the consumer when a pharmacist will be available to provide information and counselling		
4. Advises the consumer of the usual delivery timeframe		
5. Advises the consumer of the costs associated with the service provided		
Criterion 2: The pharmacist follows a documented procedure when setting up consumer profiles		
1. Records the contact details of consumers accessing the service, including telephone number and residential street address		
2. Establishes and records a medication history, including all prescription, non-prescription, and complementary medicines		
3. Collects and documents any special needs of the consumer so that oral counselling and the provision of written information can be tailored accordingly		
4. Uses mandatory fields in online application forms to gather all relevant information before dispensing can proceed		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 3: The pharmacist follows a documented procedure for the indirect supply of medicines and therapeutic devices		

1. Documents the date and details of both the request and dispatch in a manner that links this information to the consumer's profile		• Pharmaceutical Society of Australia. *Dispensing Practice Guidelines*. www.psa.org.au
		• Pharmaceutical Defence Limited. Guide to good dispensing chart. www.pdl.org.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ○ Deliveries by pharmacy staff (excluding contractors) (P11F)
		  ○ Distance supply checklist (T2A)
		• Appendix 7: Indirect Pharmacy Services: New Consumer Details/Change of Consumer Details Form, p. 90

2. Exercises due care to ensure all details gathered and supplied are accurate in relation to the consumer, prescriber, prescription, and therapeutic need		
3. Documents in the consumer's profile the medicines supplied, including complementary, prescription, and non-prescription medicines		
4. Applies, and supervises, the pharmacy's documented procedure for the indirect supply of non-prescription medicines and devices, with particular attention paid to relevant state/territory legislation for Pharmacist Only Medicines		
5. Applies the pharmacy's documented procedure to detect and appropriately deal with excessive or fraudulent orders for medicines		
6. Documents the time, date, name of the pharmacist supplying the order, and details of any information provided to the consumer		
Criterion 4: The pharmacist ensures the consumer's profile is current at the time of dispensing and prior to dispatch		
1. Verifies contact details of all consumers at the time of dispensing		
2. Records the date of verification and/or amendments to the consumer profile		
3. Ensures the most recently amended information and its date of entry are easily accessible		
Criterion 5: The pharmacist supplies medicines and therapeutic devices to the consumer in a secure and timely manner		

1. Ensures the privacy and confidentiality of the consumer are maintained throughout all stages of the indirect supply process		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ○ Distance supply checklist (T2A)
		  ○ Deliveries register (T11A)
		• Appendix 8: Medicines that may be Considered Unsuitable for Indirect Supply, p. 91

2. Records the consumer's preferred mode and time of delivery		
3. Maintains a list of medicines that are not suitable for delivery by indirect supply		
4. Ensures the package contains the pharmacy's contact details and instructions to indicate that professional advice is available		
5. Ensures all items are packaged adequately for delivery to meet the manufacturer's specified storage requirements		
6. Ensures all items are packaged securely to protect from damage during transit		
7. Ensures packages containing medicines are labelled in a way that minimises potential loss, diversion, or intentional tampering		

Criteria/Indicators	Self check: Yes/No/NA	Resources
8. Ensures cytotoxic medicines are packaged and labelled adequately, and that specific instructions for disposal and management of spills are included		
9. Uses a reliable and efficient courier with an audit trail or delivery tracking system, a delivery confirmation receipt, and a mechanism to return the package to the sender if undelivered		
10. Instructs all individuals to carry identification when they are involved in the delivery of medicines and therapeutic devices from the pharmacy		
11. Notifies the consumer promptly if the medicines cannot be delivered		
Criterion 6: The pharmacist provides appropriate information to the consumer to enable safe and effective use of the medicines and therapeutic devices supplied		

1. Accesses a range of information resources that can be provided to consumers		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Self care fact cards
		  ◦ *Consumer Medicine Information and the Pharmacist*
		  ◦ *Guidelines for Pharmacists on Providing Medicines Information to Patients*
		• Consumer Medicine Information. www.medicines.org.au
		• Professional Practice Standard 3: Counselling, p. 20

2. Provides a Consumer Medicine Information (CMI) leaflet and/or other written information with all therapeutic goods		
3. Establishes contact with all consumers when a medicine or therapeutic device is supplied for the first time to check they understand how to take or use the medicine or therapeutic device, and to inform them of potential adverse effects and how these might best be managed		

Additional references

Australian Pharmacy Council. Remote Rural Pharmacists Project. Canberra: APC, June 2009. Available at: www.pharmacycouncil.org.au/APC_publications.htm

Pharmaceutical Society of Australia. Position statement. Distance dispensing. November 1997. Available at: www.psa.org.au/site.php?id=3672

Pharmacy Board of Australia. Guidelines on dispensing medicines. Available at: www.pharmacyboard.gov.au

Standard 7: Dose Administration Aids Service

Standard

The pharmacist identifies consumers who would benefit from a Dose Administration Aids Service, and works with them to provide an accurate and tailored service with regular monitoring and advice.

Scope of this standard

- This standard applies to the provision of a Dose Administration Aids Service to assist in the safe and effective administration of a consumer's medication and improve adherence. It is a holistic service that covers the packing of dose administration aids (DAAs) and the professional support services provided to ensure the optimal use of DAAs.
- DAAs are well-sealed, tamper-evident devices that allow individual medicine doses to be organised according to the prescribed dose schedule. Note if the pharmacist provides a non-tamper-evident DAA at a consumer's request, the service provided must still meet the criteria in this standard.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice, Counselling, and Dispensing standards. Refer also to the Managing Pharmacy Practice, Medication Review, Indirect Pharmacy Services, Services to Residential Care Facilities, Continuity of Care through Medication Liaison Services, and Provision of Pharmacy Services to Aboriginal and Torres Strait Islander Services standards, where appropriate.
- Pharmacists providing a Dose Administration Aids Service should also be familiar with the relevant professional guidelines and business rules relating to these services. For specific service-related information, refer to the PSA's *Dose Administration Aids Service* guidelines.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist provides a Dose Administration Aids Service that meets the consumer's needs		

1. Systematically and routinely assesses and documents the consumer's needs		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Dose Administration Aids Service* [guidelines and standards]
		  ◦ Dose Administration Aids Service. Guidance and checklists for service delivery
		  ◦ Appendix 3: Discussion guide and sample agreement for a DAA service. In: *Dose Administration Aids Service*, pp. 17–18
		• Australian Government Department of Veterans' Affairs. www.dva.gov.au
		  ◦ *Dose Administration Aid Service: The Right Dose* [information brief for pharmacists]
		  ◦ *Dose Administration Aid Service: The Right Dose* [brochure for veterans]
		• Professional Practice Standard 3: Counselling, p. 20
		• Professional Practice Standard 9: Continuity of Care through Medication Liaison Services, p. 44

2. Ensures the consumer understands the nature and benefits of the service provided		
3. Provides comprehensive instructions to the consumer relating to the use of the DAA		
4. Follows a process to ensure the provided instructions are clearly understood		
5. Provides ongoing support, such as counselling or Consumer Medical Information (CMI) leaflets, to consumers using DAAs for the duration of the service		
6. Ensures continuity of care when a consumer transfers between different care settings		
7. Ensures that all DAAs are provided to the consumer in a timely manner		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 2: The pharmacist implements systems to ensure accuracy of packing		
1. Generates and maintains a current medication profile		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the provision of medication reconciliation. J Pharm Pract Res 2007;33:231–3 • Pharmaceutical Society of Australia. www.psa.org.au ◦ *Dose Administration Aids Service* [guidelines and standards] ◦ Dose Administration Aids Service. Checklist C: Packing the consumer's DAA. Guidance and checklists for service delivery ◦ Appendix 4: Record of packing dispensed medicines into DAA. In: *Dose Administration Aids Service*, p. 19 ◦ Clinical resource centre. Incident report form template • Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp ◦ Dose Administration Aids source checklist (T3B) ◦ Storing and re-packaging cytotoxic drug products (P2D) ◦ Incident reporting (P7D) ◦ Incident register (T7C) ◦ Incident report (T7D)
2. Implements a documented procedure for the packing of DAAs		
3. Ensures staff involved in packing DAAs have the appropriate skills to perform the task		
4. Checks the contents and packing records of all DAAs packed under the pharmacist's supervision prior to issue		
5. Follows a process to manage medicine recalls		
6. Uses a quality assurance system to record, actively review, and regularly monitor discrepancies to minimise any systematic errors		
7. Maintains documentation that tracks all DAAs packed to ensure the accuracy of DAA packing and distribution processes		
Criterion 3: The pharmacist packs the DAA with reference to the consumer's current medication regimen		
1. Maintains and documents a current and complete medication profile that includes medicines packed and not packed in the DAA, and documents decisions to not pack a medicine		• Pharmaceutical Society of Australia. www.psa.org.au ◦ *Dose Administration Aids Service* [guidelines and standards] ◦ Dose Administration Aids Service. Guidance and checklists for service delivery • National Prescribing Service. Generic medicines training kit: safe and appropriate use of generic medicines. www.nps.org.au
2. Provides medicines packed in a DAA that match the consumer's current medication regimen		
3. Supports the consumer in managing any medications not packed in the DAA		
4. Follows a process to incorporate any regimen changes into an existing DAA		
5. Promotes effective communication with the prescriber, consumer, carer, and family members to ensure accurate and well-timed updates of the DAA and the consumer's medication profile		
Criterion 4: The pharmacist maximises the stability of medicines throughout the process of DAA packing and distribution, and considers end-use conditions		
1. Accesses current information on medicines that should not be removed from their original packaging and therefore not repackaged into a DAA		• Pharmaceutical Society of Australia. Appendix 5: Examples of medicines which should not be packed into DAA. In: *Dose Administration Aids Service*, p. 20. www.psa.org.au • Church C, Smith J. How stable are medicines moved from original packs into compliance aids? Pharm J 2006;276:75–81 • Glass BD, Haywood A, Llewelyn V, Mangan M. Compliance aids and medicine stability: new evidence of quality assurance. Current Drug Safety 2009;4:74–8
2. Assesses the risks and benefits of including medicines in a DAA, and considers alternative methods of administration where appropriate		
3. Adheres to specific manufacturers' instructions that relate to medicine stability		

Criteria/Indicators	Self check: Yes/No/NA	Resources
4. Makes individualised decisions about whether to pack, or not pack, particular medicines into a DAA and documents these decisions		
5. Minimises the duration of time that medicines are exposed to the atmosphere by promptly transferring them from their original packaging into the DAA		
6. Seals the DAA immediately after it is packed		
7. Stores packed DAAs in an area that is cool, dry, and protected from light to protect the stability of the medicines		
8. Minimises the time taken for the packing process		
Criterion 5: The pharmacist ensures that the DAA label contains complete consumer, medicine, and pharmacy details		

1. Clearly displays the consumer's name, and the pharmacy's name, address, and telephone number on the DAA label		• Pharmaceutical Society of Australia. www.psa.org.au
		  ○ *Dose Administration Aids Service* [guidelines and standards]
		  ○ Counselling and cautionary advisory labels for medicines. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 2–20

2. Ensures the DAA labelling identifies the active ingredient, brand name, and strength of the medicines it contains, and the directions for use (in simple English)		
3. Displays the shape, colour, size, and manufacturer's markings for each medicine on the DAA label if possible		
4. Uses appropriate cautionary and advisory labels, and ensures the words 'Keep out of reach of children' are placed on the DAA label		
5. Ensures packing date, date of commencement, and expiry date are included on the DAA label		
Criterion 6: The pharmacist follows a procedure for deciding how to dispose of or re-use returned medicines and the consumer's own medications when packing DAAs		
1. Ensures that no medicines returned to the pharmacy are re-used by other consumers		• Pharmaceutical Society of Australia. *Dose Administration Aids Service* [guidelines and standards] www.psa.org.au • Pharmacy Guild of Australia. Quality Care Pharmacy Program. Return of unwanted medicines (P2J). www.guild.org.au/qcpp
2. Establishes the source and storage conditions of the medicines before deciding whether to re-use or dispose of medicines		
3. Disposes of medicines in a responsible manner, such as via the Return Unwanted Medicines (RUM) bins		
4. Disposes of DAA materials in a manner that protects the privacy of the consumer		
Criterion 7: The pharmacist monitors all consumers who use DAAs		
1. Collaborates with the consumer and other health care providers to address any medication management issues that arise		• Pharmaceutical Society of Australia. Appendix 2: Assessment of consumer non-adherence when considering a DAA. In: *Dose Administration Aids Service*, p. 16. www.psa.org.au • National Prescribing Service. Medicines list. www.nps.org.au
3. Follows a procedure to ensure that the prescriptions required for medicines packed in DAAs are regularly provided		
5. Ensures that the consumer has a current list of all their medications, and encourages them to share this list with their other health care providers		

Criteria/Indicators	Self check: Yes/No/NA	Resources
7. Monitors the consumer's adherence with the DAA, and addresses any concerns with the consumer's other health care providers		
9. Regularly reviews the consumer's medication regimen in line with their needs		

Additional references

Pharmaceutical Society of Australia. Dose administration aids service. Guidelines and standards for pharmacists. Canberra: PSA, July 2007. Available at: www.psa.org.au/site.php?id=2065

Pharmacy Board of Australia. Guidelines on specialised supply arrangements. Available at: www.pharmacyboard.gov.au

Roberts M, Lentile C, Lewis G et al. Effectiveness and cost effectiveness of dose administration aids (DAAs): final report. Brisbane: University of Queensland, 2004.

Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: Pharmaceutical Society of Australia, 2009.

Standard 8: Services to Residential Care Facilities

Standard

The pharmacist provides timely advice, access to medicines, and other required services to support the residential care facility and its residents in achieving safe and effective medicines management.

Scope of this standard

- This standard describes the systems used to support access to, and the management and use of, medicines and therapeutic devices in residential care facilities.
- It is expected that the individual elements of the services provided, and the roles and responsibilities of both parties are clearly defined in a contractual agreement between the relevant pharmacists and the facility.
- For the purpose of this standard, the following definitions apply:
  - the 'facility' refers to the 'residential care facility', which includes, but is not limited to, aged care homes (low care, high care and respite facilities), retirement facilities, supported residential services (previously known as special accommodation homes), and correctional facilities
  - 'resident notes' refers to the facility's progress notes for a particular resident, where available
  - a 'medication chart' refers to the official document used to order, supply, and administer medicines
  - 'pharmacist' may refer to more than one pharmacist providing more than one service; that is, a supply pharmacist or the Residential Medication Management Review (RMMR) pharmacist. In some instances, the same individual pharmacist may provide more than one service.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice. Refer also to the Managing Pharmacy Practice, Counselling, Medication Review, Dispensing, Dose Administration Aids Service, Continuity of Care through Medication Liaison Services, Compounding, Compounding Sterile Preparations, Provision of Non-prescription Medicines and Therapeutic Devices and Health Promotion standards, where appropriate. See Figure 1 for further clarification on the relationship between this standard and the Medication Review and Dose Administration Aids Service standards.

Figure 1. Continuum of services provided to residential care facilities.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist follows a documented process when a resident is admitted into the facility to allow timely access to medicines		
1. Requests routine notification when a resident is admitted, or re-admitted		• Appendix 9: Template Procedure for Consumer Admissions and Readmissions to Residential Care Facilities, p. 92 • Society of Hospital Pharmacists of Australia. SHPA standards of practice for the provision of medication reconciliation. J Pharm Pract Res 2007;37: 231–3
2. Reviews the charted medication chart when a resident has been admitted, or re-admitted after extended leave or hospitalisation		
3. Maintains a copy of the current medication regimen for all residents		
Criterion 2: The pharmacist ensures that medicines are provided to the facility in a timely manner that makes certain the treatment of residents is not compromised		
1. Maintains a regular schedule for delivering medicines, as agreed with the facility, and in consultation with the relevant health care providers		• Pharmaceutical Society of Australia. Appendix A: Sample pharmaceutical services contract. In: *The Provision of Pharmacy Services to Residential Aged Care Facilities*, pp. 7–10. www.psa.org.au
2. Prioritises orders for medicines based on their urgency		
3. Has a contingency plan for the provision of emergency/after-hours services to the facility		
4. Ensures that medicines are delivered to an authorised person and a documented procedure for receipt of medicines is used		
Criterion 3: The pharmacist maintains appropriate systems for the supply of medicines to the facility		
1. Dispenses medications for the resident in response to a prescription order in accordance with the contractual arrangements with the facility		• Pharmaceutical Society of Australia. Appendix A: Sample pharmaceutical services contract. In: *The Provision of Pharmacy Services to Residential Aged Care Facilities*, pp. 7–10. www.psa.org.au
2. Has a process in place for supplying medicines for stock in response to a requisition from the facility in accordance with contractual arrangements		
3. Has a process in place to be notified of changes to medication regimens		
Criterion 4: The pharmacist liaises with appropriate nursing staff/carers to address issues relating to medicine administration		
1. Has systems in place for monitoring patterns of medicine use in the facility		• National Prescribing Service. DUE (Drug Use Evaluation) for aged care facilities. www.nps.org.au • Society of Hospital Pharmacists of Australia. SHPA standards of practice for drug usage evaluation in Australian hospitals. J Pharm Pract Res 2004;34:220–3 • Victorian Government Health Information. Resource kit to enable implementation of the APAC Guidelines for Medication Management in Residential Aged Care Facilities. www.health.vic.gov.au
2. Documents interactions with health care providers with whom medicine-related issues are discussed		
3. Has a process in place to follow up on any medicine administration issues identified		
Criterion 5: The pharmacist supports the facility in maintaining medicines safety systems		
1. Facilitates a system for reporting adverse drug events (ADEs)		• Therapeutic Goods Administration. Report of suspected adverse reaction to medicines/ vaccines. [Blue card] www.tga.gov.au
2. Facilitates a system to prevent ADEs reoccurring		
3. Facilitates a system to identify potential medicines safety issues		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 6: The pharmacist provides information and education on medicines and the quality use of medicines that meets the needs of residents and the facility		

1. Liaises with the director of nursing and/or relevant committees to identify the needs of the facility		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ *Guidelines and Standards for the Collaborative and Pharmacist Residential Medication Management Review (RMMR) Program and Associated Quality Use of Medicines (QUM) Services*
		  ◦ *Guidelines for Pharmacists on Providing Medicines Information to Patients*
		  ◦ Quality Use of Medicines kits
		• Professional Practice Standard 3: Counselling, p. 20

2. Has access to current relevant resources to support the provision of information on medicines		
3. Responds to medicine information queries promptly and efficiently		
4. Delivers information on medicines according to the needs and arrangements of the resident, facility, and other health care providers		
5. Recommends appropriate sources of drug information for use by facility staff		
6. Delivers an education program according to agreed arrangements		
Criterion 7: The pharmacist liaises with the facility to ensure that all medicines are stored according to legislative and manufacturers' requirements		
1. Advises the facility of the need to have a documented procedure for the safe and secure storage of medicines		
2. Provides and documents any advice given to the facility on how to comply with relevant legislation		
3. Liaises with the facility to ensure that medicines held at the facility are regularly checked to ensure they are stored and discarded appropriately		
Criterion 8: The pharmacist supports and advises the facility on stock control systems where appropriate		
1. Facilitates a system to determine the range of commonly used medicines that would be required as stock, where appropriate		
2. Facilitates the regular review of medicine usage to ascertain the appropriateness of medicines held at the facility		
3. Conducts regular checks that sufficient medicines are available and excess stock is not accumulating		
4. Provides education for facility staff on the correct procedure for medicine storage and rotation		
5. Liaises with the facility to assist in the development of systems to monitor expired medicines and other medicines considered unsuitable for use, and, where necessary, to remove those medicines		
Criterion 9: The pharmacist advises the facility on a systematic approach to improving medicine-related systems within the facility		
1. Assists in the evaluation of the medicine-related systems within the facility		• Aged Care Standards and Accreditation Agency Ltd. Assessment modules. Medication administration and management. www.accreditation.org.au

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Provides regular advice to the facility, or appropriate committees, on the relevant quality and safety aspects of medicines within the facility		• Victorian Government Health Information. Resource kit to enable implementation of the APAC Guidelines for Medication Management in Residential Aged Care Facilities. www.health.vic.gov.au • Australian Pharmaceutical Advisory Council. *Guidelines for Medication Management in Residential Aged Care Facilities*. www.health.gov.au • Australian Commission on Safety and Quality in Health Care. Medication Safety. www.safetyandquality.gov.au
3. Contributes to the development and review of relevant medicine policy and procedures		
4. Documents any recommendations provided to the facility and subsequent outcomes		
Criterion 10: The pharmacist supports the continuity of care for residents transferring between health care settings or providers		

1. Liaises with local hospitals and other temporary care facilities to ensure a smooth transition for residents transferring between settings		• Society of Hospital Pharmacists of Australia
		  ◦ SHPA standards of practice for the provision of medication reconciliation. J Pharm Pract Res 2007;37: 231–3
		  ◦ SHPA standards of practice for the community liaison pharmacist. Aust J Hosp Pharm 1996;26:570–2
		• Professional Practice Standard 9: Continuity of Care through Medication Liaison Services, p. 44

2. Communicates with a transferring resident's other health care providers to gather and provide information that will assist in maintaining continuity of care		
3. On termination of a contract with the facility, the departing pharmacist provides relevant information about consenting residents to the incoming pharmacist who will next provide contract pharmacy services to the facility		

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Standard 9: Continuity of Care through Medication Liaison Services

Standard

The pharmacist provides timely and tailored medication liaison services to consumers transferring between health care settings and providers to facilitate quality use of medicines and continuity of care.

Scope of this standard

- The medication liaison pharmacist provides medication management services, including medication review and medicines information, to targeted consumers who are transferring between health care settings and providers. Examples of such transfers may include transfer between the home and hospital or residential care facility settings, and transfer from a GP to a specialist.
- The pharmacist targets medication liaison services to consumers who are most at risk of medication misadventure. These may include consumers who:
  - are on multiple medications
  - have chronic conditions
  - have had their medication regimen changed recently
  - have a history of hospitalisation from medication misadventure or misuse
  - are living alone and/or are housebound
  - are elderly
  - are preparing to enter hospital
  - recently commenced use of a dose administration aid
  - do not have the capacity or support needed to manage their medications
  - have a physical or intellectual disability.
- Medication liaison services are provided by all pharmacists, including community pharmacists, hospital pharmacists, and consultant pharmacists. In some circumstances, there may be a dedicated medication liaison pharmacist as part of a pharmacy team.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Counselling, Medicines Review, Dose Administration Aids Service, Health Promotion, and Disease State Management standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist understands the importance of medication liaison services in ensuring continuity of care		

1. Understands the principles of continuity of care and quality use of medicines		• Australian Government Department of Health and Ageing. www.health.gov.au
		  ◦ *National Medicines Policy: Quality Use of Medicines (QUM)*
		  ◦ *The National Strategy for Quality Use of Medicines*
		  ◦ *Guiding Principles to Achieve Continuity in Medication Management*

2. Understands pharmacy practice in a range of different health care settings such as the community, hospitals, and residential care facilities		
3. Ensures effective communication of accurate, complete and comprehensive information across the health care system		

Criteria/Indicators	Self check: Yes/No/NA	Resources
4. Identifies the potential risk to the consumer of medication misadventure when transferring between health care settings and providers		
Criterion 2: The pharmacist adopts a collaborative approach to providing medication liaison services to the consumer		
1. Informs appropriate health care providers in the community of the medication liaison service		• Australian Government Department of Health and Ageing. *Guiding Principles to Achieve Continuity in Medication Management*. www.health.gov.au
2. Establishes professional relationships with other health care providers and communicates with them to ensure continuity of care		
3. Consults the consumer's other health care providers for the information needed to establish the consumer's medication liaison service, where appropriate		
4. Informs the consumer's other health care provider(s) of the extent of the medication liaison service provided to the consumer		
5. Actively participates in health care educational activities in the community to promote quality use of medicines		
6. Provides health and medicines information to individuals, other health care providers, and support groups to promote quality use of medicines in the community		
7. Refers to a dedicated medication liaison pharmacist, where appropriate		
Criterion 3: The pharmacist systematically identifies consumers at risk of medication misadventure who could benefit from medication liaison services		
1. Uses a system to prioritise consumers in most need of medication liaison services		
2. Communicates with other health care providers to assist in the identification of consumers in need of medication liaison services		
3. Has a system for receiving referrals for at-risk consumers from local hospitals and other health care providers in the community		
Criterion 4: The pharmacist tailors medication liaison services to the needs of the consumer		
1. Follows a systematic procedure for identifying the consumer's individual pharmaceutical needs		• Professional Practice Standard 3: Counselling, p. 20 • Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35: 122–46
2. Where necessary, formulates a medication action plan (MAP) in collaboration with the consumer		
3. Counsels the consumer on safe and effective use of their medications		
4. Facilitates access to other services from which the consumer may benefit		
5. Makes prior arrangements with the consumer when making home visits		
6. Assists the consumer with dose administration aids		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 5: The pharmacist keeps accurate records of the medication liaison services undertaken for each consumer		
1. Systematically documents the medication liaison service provided to the consumer		
2. Documents problems identified, actions taken, date and details of contact with other health care providers, and the outcomes of the actions for each consumer		
3. Stores consumer records safely and securely		
Criterion 6: The pharmacist regularly evaluates the medication liaison service provided		
1. Implements a system to evaluate the medication liaison service at regular intervals		
2. Seeks feedback from consumers and other health care providers to evaluate the medication liaison service		
3. Implements appropriate changes to medication liaison services according to feedback		

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Standard 10: Compounding (also known as Extemporaneous Dispensing)

Standard

The pharmacist prepares and dispenses compounded products in a manner that ensures product quality, safety, and efficacy.

Scope of this standard

- This standard applies to the preparation and supply of a single unit of a non-sterile product intended for immediate use by a specific consumer. It includes the preparation of products whose formulations may be drawn from recognised pharmaceutical formularies, such as the *Australian Pharmaceutical Formulary and Handbook* and other sources.
- Batch manufacturing (also known as extemporaneous manufacturing) and additional requirements for the preparation of sterile products by aseptic technique or sterilisation are not covered in this standard; please refer to the *Guide for Good Manufacturing Practice for Medicinal Products* produced by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme for guidance on these requirements. Refer to the Compounding Sterile Preparations standard for additional requirements for sterile compounding.
- The preparation of cytotoxic products requires specialised equipment and should be undertaken only by trained staff at premises that are adequately designed and equipped, and approved by relevant authorities. The storage, removal and transportation of cytotoxic drug products and contaminated waste beyond the pharmacy are outside the scope of this standard; please refer to the standards for the handling and transportation of cytotoxic drugs produced by the Society of Hospital Pharmacists of Australia for this information.
- Consistent with usual professional practice and competence, quality standards should be applied to starting ingredients and finished products. Medicines supplied under the Pharmaceutical Benefits Scheme are required to conform to standards of composition or purity prescribed in the *Therapeutic Goods Act 1989*. In practice, this means that ingredients (including water) and dosage forms must comply with the standards of the British Pharmacopoeia. Requirements applicable under other Commonwealth, state or territory legislation, such as those concerning weights and measures, may also apply.
- Pharmacists are advised to familiarise themselves with the relevant state or territory occupational health and safety legislation for guidance on handling toxic products.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice, Counselling, and Dispensing standards. Refer also to the Managing Pharmacy Practice, Indirect Pharmacy Services, Services to Residential Care Facilities and Compounding Sterile Preparations standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist reviews the ingredients, preparation process, and the intended use of the product, and conducts a risk assessment		
1. Assesses the use, safety, efficacy, and risks associated with the preparation of compounded products according to professional judgement		• Material Safety Data Sheet database. www.msds.com.au
2. Assesses the risks to staff and the consumer from the preparation, and follows procedures to manage such risks		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Uses protective clothing (such as a laboratory coat, disposable gloves, and a hair cover) and takes additional precautions (such as eye protection, a dust mask, and powder-contamination systems) when compounding high-risk substances		
4. Maintains a register listing each hazardous substance used and a material safety data sheet (available from wholesalers) for each ingredient		
Criterion 2: The pharmacist carries out all compounding, or directly supervises appropriately trained staff in doing so		

1. Ensures all staff authorised to carry out compounding under the pharmacist's supervision are trained and experienced in compounding		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Training plan (T15A)
		  ◦ Training record (T15B)
		• Pharmaceutical Society of Australia. Extemporaneous dispensing form. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, p. 34

2. Checks all measurements, packaging, and labelling of compounded products made by supervised staff		
3. Ensures that staff handling cytotoxic drug products are trained and assessed in the preparation and safe handling of cytotoxic drug products and waste		
4. Maintains the knowledge and skills necessary to deliver the level of compounding required		
Criterion 3: The pharmacist ensures compounding occurs in a dedicated area that is clean and appropriate to the preparation processes to be undertaken		
1. Prepares all compounded products in an area dedicated for the purpose away from routine dispensing activities, counselling, and high-traffic areas		
2. Prepares all compounded products using equipment specifically dedicated for the purpose		
3. Ensures all working surfaces are in good condition, hygienic, and covered with impervious washable materials		
Criterion 4: The pharmacist ensures the equipment used in compounding is in good working order, in accordance with the manufacturers' instructions and other requirements		
1. Uses equipment that is suitable for the task to be performed		• Pharmaceutical Society of Australia. Extemporaneous dispensing. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 31–3 • Pharmacy Guild of Australia. Quality Care Pharmacy Program. Equipment calibration schedule and record (T5B). www.guild.org.au/qcpp
2. Cleans all equipment and work surfaces before and after product preparation		
3. Ensures the equipment is maintained and calibrated regularly, according to a documented procedure		
4. Maintains a record of equipment calibration or maintenance		
5. Ensures all equipment is stored in a manner that protects it from damage and contamination		
6. Clearly labels equipment that is to be used only for the preparation of cytotoxic drug products		
7. Stores equipment used for the preparation of cytotoxic drug products separately from other equipment		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 5: The pharmacist uses pharmaceutical grade ingredients that are stored in accordance with the manufacturers' recommendations		
1. Uses pharmaceutical grade ingredients, when available, that are suitable for administration to humans and comply with pharmacopoeial standards		• Pharmaceutical Society of Australia. Extemporaneous dispensing. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 31–3 • Pharmacy Guild of Australia. Quality Care Pharmacy Program. Temperature record (T5C). www.guild.org.au/qcpp
2. Uses pharmacopoeial grade ingredients that have been stored under recommended conditions		
3. Ensures any cytotoxic drug products and other hazardous ingredients are clearly identified as such and are stored according to the manufacturers' recommendations		
4. Stores ingredients that require storage at room temperature in a cool place away from direct sunlight		
5. Stores ingredients that require refrigeration or freezing in a refrigerator or freezer dedicated to pharmaceuticals		
6. Regularly maintains and records details of temperature-monitoring systems, such as cool rooms, air conditioners, refrigerators, and freezers, to ensure appropriate storage temperatures		
Criterion 6: The pharmacist prepares compounded products in accordance with pharmacopoeial formulations when available, and in a manner that ensures product quality and efficacy		
1. Follows pharmacopoeial or other reputable formulations when compounding		• See Additional Information box, p. 52
2. Accurately measures all ingredients using appropriate measuring equipment		
3. Uses appropriate techniques when compounding to ensure the quality of the final product		
4. Establishes an expiry date for the product based on recommendations in reliable literature		
Criterion 7: The pharmacist documents the details of the compounding procedure		

1. Uses an extemporaneous dispensing form to record the approved pharmacopoeial name (where applicable), the formula and its source (including edition), the procedure, and the strength/amount of any preservatives used		• Pharmaceutical Society of Australia. Extemporaneous dispensing form. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, p. 34
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Simple compounding (P2C)
		  ◦ Compounding worksheet (T2B)

2. Uses the dispensing form to record the source, batch number, and expiry date of ingredients used		
3. Uses the extemporaneous dispensing form to record any considerations about the stability of the product, methodologies, notes, and calculations, with references where appropriate		

Criteria/Indicators	Self check: Yes/No/NA	Resources
4. Uses the duplicate label attached to the extemporaneous dispensing form to record the: • approved pharmacopoeial name (if not a pharmacopoeial formulation, the name and amount of all ingredients must be listed) • strength/amount of any preservative used • instructions for use • date of preparation • expiry date of the product		
5. Records on the extemporaneous dispensing form any ancillary labels or additional instructions used		
6. Signs and dates the extemporaneous dispensing form, noting any supervisory involvement prior to dispensing the product		
7. Stores the extemporaneous dispensing form on the premises for 2 years from the date of dispensing or according to state legislation		
Criterion 8: The pharmacist uses Purified Water BP or Water for Irrigation when water is required as an ingredient in non-sterile preparations		
1. Indicates on the extemporaneous dispensing form the type of water used, its date of preparation or opening, and the manufacturer's batch number (where applicable)		
Criterion 9: The pharmacist uses suitable containers and packaging to maintain the quality and stability of prepared products		
1. Uses light-resistant (amber glass or high-density plastic) containers for the storage of light-sensitive products		• Pharmaceutical Society of Australia. General formulary. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 35–56
2. Uses air-tight packaging for protection from exposure to air if necessary		
3. Uses moisture-proof packaging for moisture-sensitive products		
4. Uses secure packaging such as child-resistant packaging where appropriate		
5. Dispenses liquid cytotoxic drug products (such as ophthalmic preparations and products for instillation into body cavities) in a suitable, ready-to-use unit-dosage form (e.g. a Luer Lock syringe) in a sealed container		
6. Heat-seals the immediate container of a cytotoxic drug product into suitable impervious outer packaging		
Criterion 10: The pharmacist follows a procedure for the disposal of waste (including contaminated waste and sharps) that ensures the safety of staff and the environment		
1. Separates and clearly labels cytotoxic and other hazardous waste from general waste		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35: 44–52
2. Ensures waste products are collected for disposal regularly		
3. Ensures any sharps used in the compounding process are disposed of safely in specified containers		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 11: The pharmacist labels all compounded products to provide adequate identification of all ingredients and clear directions for administration and use		
1. Labels the compounded products with the following information: • the approved pharmacopoeial name (where applicable) • the name and edition of the pharmaceutical formulary • all active ingredients and their amounts/ proportions if the preparation is not a pharmacopoeial formulation • the names and strength/amount of any preservatives used • expiry date • complete and unambiguous directions for use		• Pharmaceutical Society of Australia. www.psa.org.au ◦ General formulary. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 35–56 ◦ Counselling and cautionary advisory labels for medicines. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 2–20 • Society of Hospital Pharmacists of Australia. SHPA standards of practice for the transportation of cytotoxic drugs from pharmacy departments. J Pharm Pract Res 2007;37:234–5
2. Labels products intended for external use with clear instructions indicating they are for external use only		
3. Uses ancillary labels to indicate specific usage instructions (e.g. 'Shake well before each use')		
4. Applies the necessary cytotoxic warning labels on the outer packaging of cytotoxic drug products that are to be delivered		
5. Places cytotoxic drug products into well-marked, rigid containers for transportation		
Criterion 12: The pharmacist provides the consumer with information about the compounded product, including stability, storage, and expiry date		
1. Provides the consumer with instructions on how to use the compounded product and the duration of treatment		• Pharmaceutical Society of Australia. www.psa.org.au ◦ Counselling and cautionary advisory labels for medicines. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 2–20 ◦ General formulary. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 35–56 • Professional Practice Standard 3: Counselling, p. 20
2. Communicates any specific storage requirements that may be indicated on ancillary labels (such as 'Refrigerate – Do Not Freeze' and 'Protect from light')		
3. Highlights the expiry date of the compounded product to the consumer and provides information on appropriate disposal		
4. Provides the consumer with information on the correct handling and storage of cytotoxic or other hazardous preparations		
Criterion 13: The pharmacist uses a documented procedure for complaints and recalls of dispensed compounded products		
1. Documents all complaints and recalls		• Pharmaceutical Society of Australia. Extemporaneous dispensing. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 31–3
2. Investigates all errors, defects, and complaints about compounded products		
3. Takes the necessary steps to remedy the problems associated with the compounded products		
4. Uses a documented procedure for tracking and retrieving any dispensed compounded products		

Additional information

- When a non-pharmacopoeial formulation is prescribed, the pharmacist should first consider using a pharmacopoeial formulation that most closely resembles the prescribed item, and liaise with the prescriber where appropriate.
- If any minor change is made to the pharmacopoeial formulation, the pharmacist must ensure that it does not affect the product's therapeutic efficacy or stability. The exact formula used should be documented on the prescription and on the extemporaneous dispensing form.
- In the absence of a pharmacopoeial formula that closely resembles the prescribed non-pharmacopoeial formulation, the pharmacist should contact the prescriber to find out the indication the prescription is for and the length of treatment required to establish whether there is a reasonable alternative treatment available. If the product must be prepared, the pharmacist should confirm the source of the formula, the stability of the product, the procedure to be used, and the appropriateness of the ingredients and their concentrations. In these situations, formulations may also be sourced from some health care institutions and pharmaceutical manufacturers that have products that are not registered but that have undergone stability tests. The source of such formulations should always be noted on the worksheet. During this process, the pharmacist should liaise with the prescriber as necessary. The pharmacist is responsible for ensuring that the prepared product is physically and chemically stable.

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Standard 11: Compounding sterile preparations

Standard

The pharmacist prepares and dispenses sterile products in such a way that ensures the sterility of the end product, and maximises product quality, safety, and efficacy.

Scope of this standard

- This standard applies to the preparation and supply of a single unit of a sterile product (by aseptic technique or end sterilisation) that is intended for immediate use by a specific consumer. It covers the preparation of products whose formulations may be drawn from recognised pharmaceutical formularies, such as the *Australian Pharmaceutical Formulary and Handbook* and other sources.
- This standard outlines the additional requirements for pharmacists in preparing or supervising the preparation of sterile products. Pharmacists preparing sterile products must also comply with the Compounding standard.
- The quality of compounded sterile products, including cytotoxic and biological agents, cannot be tested once prepared, and therefore, quality assurance processes must be built into the sterile compounding procedure. Compounding sterile products requires specialised equipment and facilities, and should only be undertaken by trained and experienced pharmacists and staff under their supervision.
- Batch manufacturing (also known as extemporaneous manufacturing) is not covered in this standard; please refer to the *Guide for Good Manufacturing Practice for Medicinal Products* produced by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme for guidance on these requirements.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice, Counselling, Dispensing, and Compounding standards. Refer also to the Managing Pharmacy Practice and Services to Residential Care Facilities standards, where appropriate.
- Pharmacists are also advised to familiarise themselves with the relevant state or territory occupational health and safety legislation for guidance on handling toxic products.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist ensures that the sterile compounding environment complies with the relevant Australian standards		

1. Uses clean rooms and anterooms that meet Australian standards for the preparation of all sterile products		• Standards Association of Australia. www.standards.org.au
		  ○ Australian Standard AS 2567–2002. Laminar flow cytotoxic drug safety cabinets
		  ○ Australian/New Zealand Standard AS/NZS ISO 14644.4:2002. Cleanrooms and associated controlled environments Part 4: Design, construction and start-up

2. Uses cabinets and storage facilities that meet Australian Standards for storing all ingredients required for the preparation of sterile products		
3. Uses isolators, laminar flow cabinets, and laminar flow work benches appropriate to the risk levels associated with the preparation of sterile products		
4. Uses Water for Injection BP when water is required as an ingredient in a sterile preparation		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 2: The pharmacist uses equipment that is appropriate for the preparation of sterile products		
1. Uses equipment specifically designed for and dedicated to the preparation of sterile products		
2. Clearly labels equipment used for the preparation of sterile cytotoxic drug products		
3. Stores equipment used for the preparation of sterile cytotoxic drug products separately from other equipment		
4. Uses appropriately sterilised measuring equipment to assist in sterile compounding		
Criterion 3: The pharmacist and all staff working under the pharmacist's supervision receive and maintain the knowledge and skills required for sterile compounding		
1. Maintains training and awareness of sterile compounding techniques		• Standards Association of Australia. Australian Standard AS 2639–1994. Laminar flow cytotoxic drug safety cabinets – Installation and use. www.standards.org.au
2. Maintains knowledge of the different levels of risk associated with sterile compounding		
3. Maintains training and knowledge of the principles and manipulation techniques used when operating isolators, laminar flow cabinets, and laminar flow work benches		
4. Provides relevant ongoing training and education to staff		
5. Regularly validates the aseptic technique of staff under the pharmacist's supervision		
Criterion 4: The pharmacist prepares sterile products in a manner that ensures the quality and sterility of the final product		
1. Cleans and disinfects all controlled areas and equipment regularly, in accordance with workplace procedures		
2. Incorporates quality control measures into the compounding process		
3. Compounds products that are terminally sterilised separate from those that are prepared aseptically		
4. Follows guidelines and instructions on the correct use of laminar flow cabinets and laminar flow work benches		
5. Conducts a risk assessment to classify the compounded preparation as low, medium, or high risk, and prepares the preparation appropriately		
6. Ensures all ingredients are correct, stable, compatible, within expiry date, and appropriately stored prior to compounding		
7. Inspects the containers of ingredients for defects and product integrity, and reports any defect to the manufacturer		
8. Compounds sterile cytotoxic products in a separate cabinet to non-cytotoxic products		

Criteria/Indicators	Self check: Yes/No/NA	Resources
9. Checks all preparations prepared by staff under the pharmacist's supervision		
Criterion 5: The pharmacist takes particular care when labelling and packaging high-risk sterile cytotoxic drug products to ensure safe administration		
1. Applies a documented procedure for labelling and packaging cytotoxic drug products for intrathecal use		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35: 44–52
2. Labels all cytotoxic drug products prepared for intrathecal use with the words 'For Intrathecal Use' in large, bold print		
3. Labels all vincristine products, including outer wraps, with a prominent warning label stating 'FOR INTRAVENOUS USE ONLY – Fatal if given by other routes'		
Criterion 6: The pharmacist follows documented procedures for monitoring the sterility of compounded products and controlled areas		
1. Regularly monitors and documents the microbiological and particulate cleanliness of the air and surfaces within the controlled area using settle plates, and volumetric air or surface sampling		
2. Applies validated sterilisation processes that have been verified and documented		
3. Conducts sterility tests in accordance with workplace procedures		
Criterion 7: The pharmacist and all staff working under the pharmacist's supervision follow hygiene procedures to reduce the risk of product contamination		
1. Adheres to the workplace standard code of hygiene and cleanliness		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for the safe handling of cytotoxic drugs in pharmacy departments. J Pharm Pract Res 2005;35: 44–52
2. Wears protective clothing, including gowns, a face mask, safety glasses, gloves, a hair cover and shoe covers in accordance with workplace procedures		
3. Follows procedures for the changing of clothes, removal of jewellery and make-up, and scrubbing of hands before entering the controlled area		
4. Reports and records any personal health conditions, or those of supervised staff, that may increase the risk of product contamination to the pharmacist in charge		
Criterion 8: The pharmacist records details of sanitisation and temperature controls relating to sterile compounding		
1. Records the temperatures of air conditioned rooms, refrigerators, and freezers within the sterile compounding facility on a daily basis		
2. Records sanitisation levels of the anteroom and clean room		
3. Records the ongoing sanitisation levels of isolators, laminar flow cabinets, and laminar flow workbenches		

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World Health Organization. The International Pharmacopoeia. 4th edn. Geneva: WHO, 2008.

Standard 12: Provision of Non-prescription Medicines and Therapeutic Devices

Standard

The pharmacist is responsible for the safe and judicious provision of non-prescription medicines and therapeutic devices appropriate to the needs of the consumer.

Scope of this standard

- This standard applies to the provision of non-prescription medicines and therapeutic devices by the pharmacist, or by other pharmacy staff under the pharmacist's supervision.
- To achieve this standard, the pharmacist must ensure that pharmacy staff are adequately resourced and supported to enable them to provide consumers with non-prescription medicines and therapeutic devices.
- The pharmacist and their pharmacy staff should also refer to the *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*. These standards contain protocols and procedures to ensure the pharmacy as a whole supports the safe and effective provision of Pharmacy and Pharmacist Only Medicines.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice and Counselling standards. Refer also to the Managing Pharmacy Practice and Health Promotion standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist is directly involved in the provision of Pharmacist Only Medicines (S3)		

1. Follows a systematic procedure when a Pharmacist Only Medicine is requested and supports other pharmacy staff in following the procedure		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Standard 4 and 5. In: *Standard for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*
		  ◦ CARER protocol for providing Pharmacy Medicines and Pharmacist Only Medicines. In: *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*, p. 56
		  ◦ WHAT-STOP-GO protocol for providing Pharmacy Medicines and Pharmacist Only Medicines. In: *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*, p. 57
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Clinical interventions and adverse drug reactions policy (P2H). www.guild.org.au/qcpp

2. Assesses the consumer's therapeutic need for, and the risks involved with, the use of a requested Pharmacist Only Medicine, before deciding whether or not to supply the medicine		
3. Monitors for potential inappropriate use of Pharmacist Only Medicines by the consumer and responds appropriately		
4. Records the supply of Pharmacist Only Medicines in accordance with relevant state or territory legislation and professional responsibilities		
5. Provides advice and information on the use of Pharmacist Only Medicines that is relevant to the consumer's needs and in accordance with principles in the quality use of medicines		
6. Stores Pharmacist Only Medicines in an area of the pharmacy, under supervision of the pharmacist, and out of reach of consumers in accordance with state or territory legislation		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 2: The pharmacist provides assistance in the provision of non-prescription medicines and therapeutic devices, when required		

1. Provides primary health care to consumers		• Pharmaceutical Society of Australia. Standard 2. In: *Standard for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*. www.psa.org.au
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Medical and other health professionals advice referral policy (P2I)
		  ◦ Training and QCPP
		  ◦ *Refresher Training Guidelines*

2. Actively engages with consumers upon request for a non-prescription medicine or therapeutic device		
3. Assists pharmacy staff in the provision of non-prescription medicines and therapeutic devices when requested		
4. Directs and educates pharmacy staff involved in the provision of non-prescription medicines and therapeutic devices to refer to a pharmacist when necessary		
Criterion 3: The pharmacist ensures that appropriate information is gathered when responding to consumer requests for non-prescription medicines and therapeutic devices		

1. Is aware of, and follows, a systematic procedure for obtaining all relevant information from the consumer		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Standard 4. In: *Standard for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*
		  ◦ CARER protocol for providing Pharmacy Medicines and Pharmacist Only Medicines. In: *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*, p. 56
		  ◦ WHAT-STOP-GO protocol for providing Pharmacy Medicines and Pharmacist Only Medicines. In: *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*, p. 57

2. Supports and educates pharmacy staff in following the procedure for gathering the relevant information from the consumer		
Criterion 4: The pharmacist provides consumers with appropriate care and advice tailored to their needs, when required		

1. Makes an assessment of the risks and benefits to the consumer before supplying a non-prescription medicine or therapeutic device		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Standard 4. In: *Standard for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*
		  ◦ Self care fact cards
		  ◦ OTC counselling guides. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 373–414
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy (P2I). www.guild.org.au/qcpp
		• Professional Practice Standard 3: Counselling, p. 20

2. Provides advice on the treatment of symptoms and the appropriate selection and use of non-prescription medicines and therapeutic devices		
3. Demonstrates the correct and effective use of therapeutic devices to consumers as needed		
4. Provides information and advice on alternative options for consumers if the provision of medicines or therapeutic devices is inappropriate or unnecessary		
5. Refers consumers to other health care providers when necessary		
Criterion 5: The pharmacist displays and stores non-prescription medicines and therapeutic devices safely and appropriately		
1. Displays non-prescription medicines and therapeutic devices in a professionally responsible manner		• Pharmaceutical Society of Australia. *Standard 3. In: Standard for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy*. www.psa.org.au

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Stores non-prescription medicines and therapeutic devices in accordance with scheduling classifications and the relevant state or territory legislation		
3. Identifies non-prescription medicines and therapeutic devices subject to misuse or abuse, and stores them in an area of the pharmacy under the direct supervision of a pharmacist		
Criterion 6: The pharmacist has timely access to sources of evidence-based information relating to non-prescription medicines and therapeutic devices		

1. Provides evidence-based information to consumers as appropriate		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Evidence-based medicine: the basics. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 424–8
		  ◦ Information from the world wide web. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 429–42
		• National Prescribing Service. www.nps.org.au
		  ◦ Drugs and therapeutic topics
		  ◦ NPS RADAR
		  ◦ Patient leaflets and action plans
		  ◦ Common inhaler devices chart
		• Veterans' MATES [Medicines Advice and Therapeutics Education Services]. www.veteransmates.net.au
		• HealthInsite. Medicines. www.healthinsite.gov.au
		• National Asthma Council. Inhaler technique in adults with asthma or COPD. www.nationalasthma.org.au
		• Monash Institute of Health Services Research. *Evidence-Based Answers to Clinical Questions for Busy Clinicians*. www.mihsr.monash.org

2. Assists pharmacy staff in accessing relevant information as required		

Additional references

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Pharmacy Board of Australia. Guidelines on practice specific issues. Available at: www.pharmacyboard.gov.au

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Standard 13: Health Promotion

Standard

The pharmacist actively engages the individual consumer and the community to promote health and wellbeing.

Scope of this standard

- This standard encompasses any action of the pharmacist in the practice of health promotion to individual consumers and the community. This includes opportunistic engagement with consumers while providing everyday pharmacy services. It may also include the systematic identification of consumer and community needs; for example, through interaction with other health care providers or community groups, or through utilisation of established health promotion programs.
- The pharmacist plays an important role in supporting pharmacy staff to deliver health promotion activities by providing them with information and appropriate resources.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Counselling, Screening and Risk Assessment, Disease State Management, and Harm Minimisation standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist provides information and resources to enable consumers to take the necessary steps to achieve better health outcomes		

1. Provides health information that is relevant to the consumer		• Pharmaceutical Society of Australia. www.psa.org.au
		  ◦ Self care fact cards.
		  ◦ Health promotion articles in *Australian Pharmacist*
		• HealthInsite. www.healthinsite.gov.au

2. Maintains access to and knowledge of evidence-based health promotion resources		
3. Highlights to consumers that health promotion information is available		
4. Is available to act as an information resource for individuals and community groups		
5. Is aware of health organisations and resources (local, national and international) that can provide additional support to consumers or community groups		
6. Reviews information resources to ensure currency and credibility		
Criterion 2: The pharmacist adopts a collaborative approach to health promotion		
1. Establishes partnerships with other health care providers, consumers, or community groups to promote health		• Pharmacy Guild of Australia. Medication Management Review Program. Communication and concordance module. www.guild.org.au
2. Facilitates the provision of health promotion information to and from community groups and other organisations		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Educates and supports pharmacy staff in the provision of health promotion activities		
Criterion 3: The pharmacist systematically evaluates and refines the health promotion activities undertaken		
1. Selects appropriate measures for evaluation that reflect the structure, process, and outcomes of the health promotion activity undertaken		• ACT Health Promotion. Evaluation basics. www.healthpromotion.act.gov.au • Victorian Government Health Information. Health Promotion. www.health.vic.gov.au/healthpromotion • Appendix 2: Quality Use of Medicines and Practice Improvement, p. 84 • Appendix 3: The Health Promotion Planning Cycle, p. 86
2. Follows a process for obtaining feedback about the health promotion activities provided		
3. Implements appropriate changes to health promotion activities according to evaluation feedback		

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World Health Organization. Ottawa charter for health promotion. WHO/HPR/HEP/95.1. Geneva: WHO, 1986.

Standard 14: Medicines Information Centres

Standard

The pharmacist working in a medicines information centre provides accurate, relevant, and timely information on medicines and pharmacotherapy most commonly to assist centre users in optimising health outcomes.

Scope of this standard

- This standard applies to the provision of medicines information by a medicines information pharmacist in a medicines information centre. It excludes the provision of counselling associated with the supply of a medicine or therapeutic device, and excludes the financial and administrative issues of operating a medicines information centre.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice standard where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist maintains the current knowledge and skills needed to provide a reliable medicines information service		
1. Maintains a current knowledge of applied therapeutics and how to critically analyse information		• Evidence-based medicine: the basics. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 424–8 • Centre for Evidence-Based Medicine. EBM tools. www.cebm.net
2. Maintains a current knowledge of relevant databases, publications, reference materials, guidelines, regulations, and information retrieval systems		
3. Develops and maintains literature research and evaluation skills		
4. Develops and maintains good communication skills to establish the needs of centre users and deliver appropriate information		
Criterion 2: The pharmacist has access to relevant and current medicines information resources to support service delivery		

1. Maintains access to databases and information retrieval systems, including web-based resources		• National Library of Medicine. PubMed. www.ncbi.nlm.nih.gov/pubmed
		• Medical Matrix. www.medmatrix.org
		• National Prescribing Service. www.nps.org.au
		  ◦ Drugs and therapeutic topics
		  ◦ NPS RADAR
		  ◦ Medicines Line. Tel: 1300 888 763
		• Information from the world wide web. In: *Australian Pharmaceutical Formulary and Handbook*, 21st edn, pp. 429–42

2. Maintains access to current publications and reference materials, including journals, reference books, and other materials relevant to medicines information		
3. Maintains access to and knowledge of current Australian guidelines and regulations, and is able to distinguish these from international guidelines and regulations		

Criteria/Indicators	Self check: Yes/No/NA	Resources
4. Maintains access to specialists with expertise in various medical specialties who can provide authoritative advice, when necessary		• Cochrane Collaboration. The Cochrane Library. www.cochrane.org • Veterans' MATES [Medicines Advice and Therapeutics Education Services]. www.veteransmates.net.au • Auspharmacist. AusPharm Research Roundup. www.auspharmacist.net.au • National Health and Medical Research Council. National Institute of Clinical Studies. Clinical Practice Guidelines Portal. www.clinicalguidelines.gov.au • National Electronic Library for Medicines. www.nelm.nhs.uk/en/ • National Prescribing Centre. www.npc.co.uk
5. Maintains a list of other relevant information providers to whom enquiries may be referred, when necessary		
Criterion 3: The pharmacist defines the scope, nature, and availability of the medicines information service		
1. Maintains a policy document that specifies who may use the service		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for drug information services. Aust J Hosp Pharm 1999;29:171–6.
2. Communicates details about the service, including who operates the service, the days and hours of operation, how to access the service, response times, and costs involved in accessing the service as required		
3. Provides a means for centre users to either leave a message or be referred for immediate service elsewhere if the medicines information service is unavailable		
Criterion 4: The pharmacist establishes the nature of the centre user's enquiry		
1. Uses good communication and interview skills to gather all necessary information pertinent to the enquiry, including what the centre user already knows and understands, and the context of the enquiry		
2. Establishes the urgency of the enquiry		
3. Works with the centre user to establish the most practical format for providing the information		
Criterion 5: The pharmacist prioritises medicines information enquiries		
1. Prioritises enquiries based on the urgency of the request and their impact on consumer safety		
2. Refers the centre user to other appropriate sources of information should the enquiry be outside the pharmacist's scope of practice		
Criterion 6: The pharmacist provides appropriate medicines information and advice		
1. Provides medicines information tailored to the needs of the centre user		• Pharmaceutical Society of Australia. *Guidelines for Pharmacists on Providing Medicines Information to Patients*. www.psa.org.au • UK Medicines Information. Guidelines for ensuring quality in enquiry answering. www.ukmi.nhs.uk
2. Communicates the information in a clear and concise manner		
3. Provides the information in a format established in consultation with the centre user, and in a timely manner		
Criterion 7: The pharmacist documents the details of enquiries and consultations		
1. Maintains a system for recording enquiries		

Criteria/Indicators	Self check: Yes/No/NA	Resources
2. Documents the date, time, details of the enquiry, details of the centre user, the pharmacist's name, the response given, and, where possible, the outcome of the enquiry		
3. Documents the resources and references used in formulating the response and includes the date of access when databases and web-based resources are accessed		
4. Stores medicines information service records in a manner that allows timely retrieval of individual enquiries		
Criterion 8: The pharmacist systematically reviews the quality of the medicines information service		

1. Evaluates the service at regular intervals		• UK Medicines Information. www.ukmi.nhs.uk
		  ◦ User satisfaction questionnaire
		  ◦ User survey guidance

2. Uses records of the services provided to assess workloads and quality assurance activities		
3. Seeks feedback from centre users to confirm that the service has been provided in a timely and satisfactory manner		
4. Takes appropriate action after each evaluation		

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Standard 15: Pharmacy Services to Aboriginal and Torres Strait Islander Health Services

Standard

The pharmacist provides pharmacy services to Aboriginal and Torres Strait Islander health services in a timely and culturally sensitive manner, with the primary aim of promoting the quality use of medicines.

Scope of this standard

- In this standard, Aboriginal and Torres Strait Islander health services are referred to as Aboriginal Health Services (AHS).
- This standard outlines the general principles applicable to the range of pharmacy services that may be provided to remote and urban AHS, and is to be read in conjunction with the PSA's *The Provision of Pharmacy Services to Aboriginal and Islander Health Services* guidelines.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Counselling, Medicines Review, Dispensing, Indirect Pharmacy Services, Dose Administration Aids Service, Continuity of Care through Medication Liaison Services, Compounding, Compounding Sterile Preparations, Health Promotion, Screening and Risk Assessment, and Disease State Management standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist is aware of the relevant health and cultural issues facing Aboriginal and Torres Strait Islander communities		
1. Maintains an awareness of local and regional issues that may affect the delivery of a pharmacy service to the AHS		• Pharmaceutical Society of Australia. *QUMAX: An Introduction to Cultural Orientation for Participating Pharmacists*. www.psa.org.au • Pharmacy Guild of Australia. *Pharmacy Information Kit: Section 100 Pharmacy Support Allowance Program*. www.guild.org.au
2. Undertakes appropriate professional development and cultural awareness training		
3. Utilises available programs to assist in providing a high quality, cost-effective service to the AHS		
Criterion 2: The pharmacist has systems in place to receive requests and to enable the timely delivery of medicines and therapeutic devices to the AHS		
1. Establishes and maintains a system for the timely ordering of a standard medicines list		• Pharmacy Guild of Australia. www.guild.org.au ◦ *Pharmacy Information Kit: Section 100 Pharmacy Support Allowance Program* ◦ Section 100 work plan [template form]
2. Maintains a system for the professional supervision of orders for medicines outside the standard medicines list		
3. Maintains a regular schedule for delivering therapeutic goods, as agreed with the AHS		
4. Uses a system for the transportation of medicines to the AHS that meets manufacturers' storage requirements, including cold chain requirements		

Criteria/Indicators	Self check: Yes/No/NA	Resources
5. Establishes and uses a system for the provision of medicines when immediate or urgent supply is required		
Criterion 3: The pharmacist maintains a documented system for the delivery of all pharmacy services to the AHS		

1. Establishes policies and procedures appropriate for the provision of pharmacy services to the AHS		• Pharmaceutical Society of Australia. *The Provision of Pharmacy Services to Aboriginal and Islander Health Services* [guidelines and standards]. www.psa.org.au
		• Pharmacy Guild of Australia. www.guild.org.au
		  ◦ Sample work plan. In: *Pharmacy Information Kit: Section 100 Pharmacy Support Allowance Program*
		  ◦ Section 100 work plan [template form]
		• Professional Practice Standard 4: Medication Review, p. 24
		• Professional Practice Standard 7: Dose Administration Aids Service, p. 36
		• Professional Practice Standard 17: Disease State Management, p. 72

2. Informs the AHS of the types of pharmacy services that the pharmacist can provide and how the AHS can access these services		
3. Documents the details of the services provided to AHS		
4. Maintains a system for providing Dose Administration Aids Services to the AHS		
5. Maintains a system, in collaboration with the AHS, for providing medication review services		
6. Maintains systems for monitoring and notification related to patterns of medicine use in the AHS		
7. Facilitates a system to identify potential medicines safety issues		
8. Maintains a system for delivering disease state management services		
9. Negotiates with the AHS a feasible and cost-effective structure for delivering pharmacy services		
Criterion 4: The pharmacist provides advice and information to the AHS on the safe and effective storage and supply of all medicines		
1. Provides information to AHS staff on the appropriate and safe storage and disposal of medicines		
2. Provides AHS staff with information on stock control procedures, stock rotation, and the management of expired or recalled stock		
3. Assists AHS staff in complying with the legislative requirements of storing and supplying medicines		
4. Monitors AHS staff to ensure that storage, stock control, and supply procedures are being followed in the AHS		
Criterion 5: The pharmacist provides education, training, and supervision to AHS staff on quality use of medicines (QUM)		
1. Maintains a system, in collaboration with the AHS, for identifying the training needs of AHS staff and delivering appropriate training		• Pharmaceutical Society of Australia. *Guidelines for Pharmacists on Providing Medicines Information to Patients*. www.psa.org.au • Australian Indigenous HealthInfoNet. www.healthinfonet.ecu.edu.au
2. Provides current information on medicines and therapeutic devices to AHS staff in a manner that enables them to select, monitor, and adjust drug therapies, taking into account their clients' characteristics and co-morbidities		
3. Collaborates with indigenous AHS staff and/or community members to deliver current medicines information in a manner that enables staff to easily forward the information on to their clients		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 6: The pharmacist maintains the communication channels needed to support continuity of care		
1. Establishes networks, or utilises existing networks, of health care providers and community members in the local and regional area, where possible		
2. Communicates in a manner that is culturally sensitive		
Criterion 7: The pharmacist maintains a system to monitor and evaluate the pharmacy services provided to ensure continuous quality improvement		
1. Identifies the most immediate needs of the AHS and its clients, and prioritises services accordingly		• Pharmacy Guild of Australia. www.guild.org.au ◦ Section 100 needs assessment [template form] ◦ Sample work plan. In: *Pharmacy Information Kit: Section 100 Pharmacy Support Allowance Program* ◦ Section 100 work plan [template form] ◦ Section 100 evaluation feedback [template form]
2. Provides proactive reporting and feedback to the AHS on its management of medicines and pharmacy services		
3. Maintains a system by which the AHS can provide feedback about the pharmacy services being provided		
4. Regularly evaluates the supply of medicines and pharmacy services provided through internal review and feedback from the AHS		
5. Implements the actions required to improve the current service provision systems, based on the feedback provided		
6. Adjusts the existing contract, in collaboration with the AHS, in accordance with any additional service needs that have been identified		

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Standard 16: Screening and Risk Assessment

Standard

The pharmacist uses evidence-based screening tests to systematically identify members of a defined population who may be at risk of disease and complications, and provides referral as appropriate.

Scope of this standard

- This standard applies to those pharmacists who wish to exercise their role in disease prevention by providing screening and risk assessment services. These services can be integrated with those of other health care providers, particularly with medical practitioners, and practice or community nurses.
- Screening and risk assessment services should be used to identify consumers who may be at risk of disease and to refer them for further investigations. This timely intervention can increase consumer awareness on health issues, aid in identifying undiagnosed symptoms, and potentially reduce secondary complications of already diagnosed diseases.
- Common examples of screening services conducted within pharmacies include:
  - blood pressure testing
  - diabetes risk assessment (blood glucose, cholesterol, etc)
  - respiratory disease risk assessment
  - cardiovascular disease risk assessment (body mass index [BMI], waist circumference, weight, blood pressure, cholesterol, etc)
  - chlamydia screening clinics
  - cancer risk assessment (bowel cancer screening)
- It is important to note that screening and risk assessment services should NOT be used for any of the following:
  - to make a diagnosis
  - as the basis for pharmacists initiating medical or drug treatment
  - for altering therapy prescribed by the other health care providers.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Counselling, Health Promotion, and Disease State Management standards, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist undertakes all necessary training needed to deliver a screening and risk assessment service		

1. Regularly undertakes training on the roles, responsibilities, and general procedures for the range of services delivered in the pharmacy		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Training plan (T15A)
		  ◦ Training record (T15B)

2. Documents all training undertaken and date of completion		
3. Is trained to perform any clinical tests required as part of the screening service		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 2: The pharmacist ensures all pharmacy staff authorised to conduct screening services are trained and competent		
1. Ensures pharmacy staff recognise the role screening services provide in illness prevention, managing long-term conditions, and health promotion, and are able to distinguish this service from diagnosis		
2. Ensures only suitably trained staff conduct screening tests and discuss test results with the consumer		
Criterion 3: The pharmacist provides the screening and risk assessment service in an environment that is appropriate		
1. Delivers the service in a location agreed to by the consumer that protects their privacy		
2. Ensures specimen collection and the test itself are not conducted within the dispensing area, or in any area where food or drinks are consumed		
Criterion 4: The pharmacist undertakes appropriate measures to ensure the reliability of the results		
1. Uses screening tests that have been demonstrated to be appropriate and effective for the particular assessment		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Equipment calibration schedule and record (T5B). www.guild.org.au/qcpp
2. Performs all services and assessments in a manner consistent with the current relevant Australian professional and clinical guidelines and standards		
3. Applies a quality assessment process, including testing of blind samples, to establish that results produced are reliable and replicable		
4. Uses equipment that meets relevant Australian standards and is serviced regularly according to the manufacturers' recommendations		
5. Uses equipment that is calibrated according to the manufacturers' recommendations		
6. Maintains adequate documentation of all calibration and maintenance activities, which includes the date, the activity undertaken, and the name and signature of the person involved		
7. Uses an internal quality control procedure, where appropriate, for the screening service equipment by using a control sample from the manufacturers at the start and end of a session		
8. Maintains records of all screening services provided, including the batch numbers of all ancillary testing products, and signs off each test performed		
Criterion 5: The pharmacist uses a systematic operating procedure for conducting screening services		
1. Follows a procedure to identify consumers who would benefit from screening		• Appendix 10: Screening Record and Referral Form, p. 93
2. Provides the consumer with information to ensure they understand the nature and purpose of the test, and any significant risk involved in having or not having the test		

Criteria/Indicators	Self check: Yes/No/NA	Resources
3. Obtains informed consent from the consumer, or carer, before undertaking any screening tests		
4. Uses an established procedure to document all aspects of the service, including management of consumer information, privacy of files, and consent		
5. Undertakes and documents the consumer interview to ascertain the consumer's risk factors for chronic disease and to identify unhealthy life style choices as soon as possible		
6. Ensures that all measurements and data are in accordance with the systematic operating procedure		
7. Ensures that results are recorded in accordance with documented procedures		
8. Ensures collected samples are labelled clearly		
9. Communicates details of the service provided, including any limitations, and the fee payable by the consumer		
Criterion 6: The pharmacist follows a systematic operating procedure for providing results, counselling, and referrals		
1. Ensures that the explanation of results, and their significance and limitations, is based on current knowledge and provided in a timely manner		• Pharmaceutical Society of Australia. Self care fact cards. www.psa.org.au • HealthInsite. www.healthinsite.gov.au • National Prescribing Service. Patient leaflets and action plans. www.nps.org.au • Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy (P2I). www.guild.org.au/qcpp • Professional Practice Standard 3: Counselling, p. 20
2. Interprets test results while considering any medications the consumer might be taking, which could influence the results		
3. Provides test results to the consumer, or an authorised agent, in a sensitive manner		
4. Explains the relevance of the results in the context of the consumer's current conditions and/or risk factors, where applicable		
5. Discusses the results in the context of the consumer's overall health and lifestyle		
6. Has easy and immediate access to current information resources, and provides consumers with relevant reading materials		
7. Documents the key features of the explanation and recommended follow-up actions, including referrals, on the service record form		
8. Provides the consumer with a report outlining the results and recommendations arising from the screening test		
9. Establishes a network of health care professionals and primary care organisations to refer consumers to when needed		
10. Determines, in consultation with other health care providers, the referral criteria and best method for referral		
11. Discusses the referral process and the relevance of the referral with the consumer		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 7: The pharmacist ensures the result and referral forms, and follow-up letters (where required) are completed in a manner that facilitates further consumer contact should the need arise		
1. Documents recommendations, follow-up, and outcomes for consumers who are referred to other health care providers, where possible		• Appendix 10: Screening Record and Referral Form, p. 93
2. Provides the pharmacist's name and signature as well as the contact details for the pharmacy providing the clinical testing on all results, referral forms, and follow-up letters		
Criterion 8: The pharmacist implements an appropriate risk management strategy for the screening services provided		

1. Follows a documented procedure to manage spillages and contamination		• Pharmaceutical Society of Australia Clinical resource centre. www.psa.org.au
		  ◦ Infection control template procedure
		  ◦ Incident report form template
		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Incident register (T7C)
		  ◦ Incident report (T7D)

2. Uses appropriate containers for storage and disposal of contaminated clinical waste and sharps		
3. Segregates clinical waste prior to its disposal in an approved manner and time interval		
4. Diligently follows a documented infection control procedure		
5. Ensures pharmacy staff adhere to the infection control requirements		
6. Ensures that all necessary protective clothing, equipment, and containers for storage and disposal of contaminated clinical waste and sharps are available and used		
7. Documents spillages, contamination, needle-stick injuries, and other incidents		
8. Regularly assesses the suitability of the designated area, equipment, and facilities allocated to the provision of screening services		

Additional references

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Standard 17: Disease State Management

Standard

The pharmacist works with the consumer and other health care providers to systematically manage the consumer's disease state, optimise the consumer's health and wellbeing, raise awareness of risk factors for chronic disease states, and motivate and engage the consumer to accept responsibility for their own health.

Scope of this standard

- This standard serves as an overarching standard covering the principles of all disease state management (DSM) programs. These services may include smoking cessation, diabetes, asthma, weight management, and cardiovascular disease.
- DSM is a consumer-centred process that focuses on enabling consumers suffering from chronic conditions to participate in the management of their disease with the objective of reducing their disease-related risk factors. This can be achieved through monitoring, counselling, education, enhancement of self-management, and promotion of the quality use of medicines. The pharmacist must recognise the need for involvement in an ongoing cycle of care, assessment, intervention, monitoring/feedback, and assessment of consumer behaviour changes when providing DSM services.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard. Refer also to the Managing Pharmacy Practice, Counselling, Medication Review, Health Promotion, and Screening and Risk Assessment standards, where appropriate.
- Pharmacists should also refer to the relevant practice guidelines for specific DSM programs.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist fulfils their role in providing a DSM service		

1. Applies the principles of quality use of medicines of the National Medicines Policy		• Australian Government Department of Health and Ageing. www.health.gov.au
		  ◦ National Medicines Policy
		  ◦ Quality use of medicines
		  ◦ *Australian Guide to Healthy Eating*
		• Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change*. 2nd edn. New York: Guilford Press, 2002
		• Australian Government Department of Health and Ageing. Healthy weight website. Being active. www.healthyactive.gov.au
		• Australian Government. Every cigarette is doing you damage. The National Tobacco Campaign. www.quitnow.info.au
		• See Additional Information: Stages of Change box, p.75

2. Provides the consumer with details of the DSM service and the pharmacist's role in providing the service		
3. Provides counselling and education to raise consumer awareness of the implications of chronic disease, the value of preventive strategies, and the importance of appropriate medicine use		
4. Works with the consumer to address lifestyle changes that can have a positive impact on chronic disease, and/or improve the outcomes of medicines use		
5. Applies different motivational techniques and understands the 'Stages of Change Model'		

Criteria/Indicators	Self check: Yes/No/NA	Resources
6. Motivates and encourages consumers to accept responsibility for their own health, medical conditions, and appropriate use of medicines		• Prochaska JO, DiClemente CC. Transtheoretical therapy: toward a more integrative model of change. Psychotherapy: Theory, Research and Practice 1982;19:276–88
Criterion 2: The pharmacist establishes and maintains the relevant knowledge and skills to undertake the specific DSM service being provided		
1 Completes the appropriate level of training and/or credentialing required to deliver the service		
2 Maintains access to appropriate resources to support the services being provided		
3 Maintains a detailed knowledge of relevant therapeutic areas required to deliver the service		
4 Maintains the skills to operate equipment and perform the relevant clinical testing proficiently.		
5 Ensures staff authorised to assist in providing the DSM service are trained and competent		
Criterion 3: The pharmacist provides the DSM service in an environment that is appropriate and acceptable to the consumer		
1. Delivers the service in a location that protects the privacy of the consumer		
2. Ensures clinical tests are not conducted within the dispensing area, or in any area where food or drinks are consumed		
Criterion 4: The pharmacist uses appropriate equipment to deliver the service		
1. Uses equipment that meets relevant Australian standards and is serviced regularly according to the manufacturers' instructions		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Equipment calibration schedule and record (T5B). www.guild.org.au/qcpp • Pharmaceutical Society of Australia. Infection control template procedure. www.psa.org.au
2. Uses equipment that is calibrated according to the manufacturers' recommendations		
3. Uses appropriate containers for the storage and disposal of contaminated clinical waste and sharps		
Criterion 5: The pharmacist follows a documented procedure to collect consumer information		
1. Obtains informed consent from the consumer before collecting, storing, and sharing the consumer's details		• Society of Hospital Pharmacists of Australia. SHPA standards of practice for clinical pharmacy. J Pharm Pract Res 2005;35: 122–46 • Pharmaceutical Society of Australia. *Medication Profiling Service* [guidelines and standards]. www.psa.org.au • Rigby D. Adherence assessment tools: drugs don't work when they're not taken. Aust J Pharm 2007;88:32–3
2. Conducts consumer interviews that are appropriate to the specific condition, including assessing consumer knowledge of the disease state, symptoms, and gathering a social and family history		
3. Documents the consumer's relevant medical history, and ensures privacy of all consumer information		
4. Conducts any relevant physical assessments (such as weight and height measurements) and obtains and utilises available laboratory information		
5. Collaborates with the consumer's other health care providers to obtain, and also provide, additional relevant information		

Criteria/Indicators	Self check: Yes/No/NA	Resources
6. Assesses the consumer's adherence to their medications		
Criterion 6: The pharmacist works with the consumer and the consumer's other health care providers to develop a documented consumer care plan		
1. Reviews and interprets the consumer's health information objectively, and evaluates the consumer's current pharmacological, non-pharmacological, and self-care therapies and activities		• Appendix 11: Template Consumer Care Plan, p. 95 • Pharmaceutical Society of Australia. Self care fact cards. www.psa.org.au • HealthInsite. www.healthinsite.gov.au • Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy (P2J). www.guild.org.au/qcpp
2. Identifies and addresses the consumer's information needs		
3. Assists the consumer in gaining an understanding of their condition, and encourages the consumer to improve their health		
4. Works with the consumer and the consumer's other health care providers to establish realistic therapeutic and lifestyle goals		
5. Provides the consumer with a copy of their care plan		
6. Recommends pharmacological, non-pharmacological, and self-care plans that are consistent with current guidelines and desired health outcomes		
7. Documents all relevant communications with the consumer and the consumer's other health care providers		
8. Liaises closely with the consumer's other health care providers to address any issues identified and/or discuss suggested interventions		
Criterion 7: The pharmacist develops a systematic procedure to monitor and evaluate the consumer's progress against their consumer care plan and therapeutic goals		
1. Regularly assesses the consumer's care plan, motivation, adherence and progress, and develops a regular follow-up schedule, as necessary		• Appendix 11: Template Consumer Care Plan, p. 95
2. Provides evidence-based information and advice to inform the consumer care plan and to enable the consumer to achieve their therapeutic goals		
3. Conducts clinical assessment as required		
4. Assesses the safety and effectiveness of the consumer's therapy		
5. Monitors adverse reactions, interactions, and/or contraindications		
6. Recommends alternative modes of treatment and interventions in consultation with the consumer's other health care providers in situations where the desired outcomes are not being achieved		
7. Continues to collaborate with the consumer and the consumer's other health care providers for the benefit of the consumer		

Additional information: Stages of change

Consumers may find it difficult to make the necessary changes and to achieve their therapeutic goals despite the known health risks and consequences associated with their condition. Pharmacists need to provide a supportive environment at all times, and to adopt a sensitive and respectful attitude. Pharmacists should have a good understanding of Prochaska and DiClemente's Stages of Change Model, which draws on psychotherapy theories to explain the variations in a consumer's response to advice about changing behaviour.

Stages of Change Model

Stage	Behaviour	Implications for pharmacist intervention
Pre-contemplation	The individual is content with current behaviour, has no intention of changing, and is not considering change.	Listen and respond to questions. Attempts to persuade are unlikely to be successful.
Contemplation	The individual is thinking about the possibility of changing, but has made no plans to change.	Listen and respond to questions. Provide information.
Preparation	The decision has been made to change, and the person is getting ready to make the change.	Help with planning and goal setting.
Action	The change is implemented.	Encourage the consumer to return to the pharmacy to discuss progress. Aim to use a supportive approach.
Maintenance	The individual works to prevent relapse to the previous behaviour.	Continue using a supportive approach. Encourage discussion of possible problems that might lead to relapse. Give positive feedback.

Adapted from Prochaska JO, DiClemente CC. Transtheoretical therapy: toward a more integrative model of change. Psychotherapy: Theory, Research and Practice 1982;19:276–88.

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Standard 18: Harm Minimisation

Standard

The pharmacist provides opioid substitution and/or needle and syringe services to optimise therapeutic outcomes for drug-dependent consumers and to help reduce the harm associated with illicit drug use.

Scope of this standard

- This standard applies to the delivery of opioid substitution and needle and syringe programs aimed at reducing the morbidity and mortality associated with illicit drug use. This standard may also be applied to the provision of other supervised or restricted supplies, such as benzodiazepine withdrawal regimens.
- Needle and syringe programs involve the supply of sterile needles, syringes and other injecting equipment; the collection and disposal of used needles and syringes; and the provision of advice and information relevant to injecting drug users.
- Opioid substitution programs involve the provision of medicines, which are intended to reduce or eliminate illicit opioid use, along with support and advice on substance abuse.
- The principle of harm minimisation has formed the basis of successive phases of Australia's National Drug Strategy since its inception in 1985. The concept of harm minimisation is outlined in *The National Drug Strategy: Australia's Integrated Framework 2004–2009* and consists of three components:
  - supply reduction
  - demand reduction
  - reducing drug-related harm.
- Harm minimisation does not condone drug use; it aims to improve health, social, and economic outcomes for both the individual and the community, and encompasses a wide range of approaches, including abstinence-orientated strategies. Australia's harm minimisation strategy focuses on both licit and illicit drugs, and includes preventing anticipated harm and reducing actual harm.
- Pharmacists may find it useful to publicly display a one-page policy to inform other consumers and the community about local and national harm reduction strategies.
- Pharmacists have a duty of care to use their professional judgement when deciding whether to supply or decline supply to an obviously drug- or alcohol-affected person.
- This standard is to be applied in conjunction with the Fundamental Pharmacy Practice standard, as well as the Counselling and Dispensing standards. Refer also to the Health Promotion standard, where appropriate.

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 1: The pharmacist has the training and experience needed to provide harm minimisation services		

1. Has completed on-the-job training in providing opioid substitution therapies and/or needle and syringe programs		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Training plan (T15A)
		  ◦ Training record (T15B)

2. Undertakes regular education in the area of substance abuse and treatment		
3. Understands the objectives and principles of harm minimisation		

Criteria/Indicators	Self check: Yes/No/NA	Resources
Criterion 2: The pharmacist integrates harm minimisation services into pharmacy practice		
1. Prioritises harm minimisation services within the framework of other service demands		
2. Adapts workflow to facilitate the delivery of opioid substitution and/or needle and syringe services		
3. Ensures opioid substitution supply occurs discreetly to maintain consumer dignity		
4. Supplies and collects needles, syringes, and injecting equipment in a manner that acknowledges the consumer's dignity and so protects the safety of pharmacy staff and other consumers		
Criterion 3: The pharmacist uses appropriate equipment and resources to support and assist in the delivery of harm minimisation services		
1. Accesses the policies, guidelines, and relevant regulations governing the delivery of harm minimisation services		• Pharmaceutical Society of Australia. *Guidelines for Pharmacists Providing Opioid Pharmacotherapy Services*. www.psa.org.au
2. Ensures current substance abuse and treatment information resources are available to consumers and staff to support service delivery		
3. Provides consumers with drinking water and facilities to dispose of, or adequately clean, drinking cups		
4. Maintains access to an approved sharps container		
5. Uses appropriate equipment for providing opioid substitution pharmacotherapy doses to consumers. Appropriate equipment will include accurate dose dispensing and measuring devices (such as pumps and syringes) and containers for dosing (such as disposable or washable drinking cups, and containers with child-resistant closures for take-away doses)		
Criterion 4: The pharmacist follows a systematic dispensing and dosing procedure for providing an opioid substitution program		
1. Maintains a documented operating procedure for dispensing and dosing of opioid substitution therapy (including take-away doses)		• Pharmaceutical Society of Australia. Sample client/pharmacist agreement form. www.psa.org.au • Professional Practice Standard 5: Dispensing p. 28
2. Ensures the dispensing and dosing procedure document is available and displayed in the area where opioid substitution therapy is prepared		
3. Maintains a file with current photo identification for each consumer		
4. Maintains an accurate and unambiguous dosing record system		
5. Uses a pharmacist/consumer agreement form		
6. Ensures that dosing only occurs for a single consumer at a time		

Criteria/Indicators	Self check: Yes/No/NA	Resources
7. Documents any event where supply of a dose is declined		
8. Stores opioid substitution therapies and any prepared doses appropriately in an approved safe		
Criterion 5: The pharmacist liaises with the consumer's prescriber and/or other health care providers, when appropriate		
1. Records contact details of the consumer's prescriber and other relevant health care providers		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. Medical and other health professionals advice referral policy (P2I) www.guild.org.au/qcpp
2. Reports to the prescriber or other relevant health care providers any issues relating to the consumer's treatment, such as consecutive missed doses, erratic attendance, unusual behaviour by the consumer, or any other important information		
3. Documents any significant communication with the prescriber or other relevant health care providers		
4. Communicates or documents relevant consumer information for other pharmacists working in the pharmacy		
Criterion 6: The pharmacist assists the consumer with general health and medicines information		
1. Provides written and oral information appropriate to the consumer's needs		• Australian Drug Information Network. Alcohol and drug services. www.adin.com.au • Drug Info Clearinghouse. Alcohol and drug info. www.druginfo.adf.org.au • Centre for Education and Information on Drugs and Alcohol. Drugs and alcohol services. www.ceida.net.au • Pharmaceutical Society of Australia. Self care fact cards. www.psa.org.au • HealthInsite. www.healthinsite.gov.au • State Government of Victoria. Department of Health. DirectLine. Ph: 1800 888 236 www.health.vic.gov.au/doh
2. Provides the consumer with access to current sources of information about medicines and therapeutic devices, safe injecting techniques, and general health topics		
3. Maintains a current list of details for support services to refer consumers to as needed		
4. Refers consumers to relevant local support services and other health care providers when necessary		
5. Maintains a list of referral points for the collection of used needles and syringes, when this service is not provided by the pharmacy		
6. Provides information on possible injuries and complications that the consumer could experience, including significant drug interactions, major side effects, symptoms of overdose, and the effects of polydrug use and excessive alcohol intake		
7. Provides counselling specific to the harm minimisation service provided		
8. Records significant advice given in the consumer's file		
Criterion 7: The pharmacist ensures the safety of all pharmacy staff and the community when delivering harm minimisation services		
1. Explains the principles of harm minimisation to all staff		• Pharmaceutical Society of Australia. Infection control template procedure. www.psa.org.au

Criteria/Indicators	Self check: Yes/No/NA	Resources

2. Allows pharmacy staff, other than pharmacists, the option to not participate in harm minimisation services		• Pharmacy Guild of Australia. Quality Care Pharmacy Program. www.guild.org.au/qcpp
		  ◦ Opioid Substitution Program checklist (T3A)
		  ◦ Needle and Syringe Program checklist (T3D)
		• Department of Health. Section 23. Needlestick and other blood or body fluid incidents. In: *Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting*. www.health.gov.au

3. Ensures all pharmacy staff follow the documented procedures for the delivery of harm minimisation services		
4. Instructs all pharmacy staff on the potential risks and precautionary measures that should be taken when delivering the service		
5. Counsels and advises all pharmacy staff and consumers on the safe disposal of used needles and syringes		
6. Directs consumers using the harm minimisation service to place any used equipment in the pharmacy disposal units provided to reduce the risk of infection and needlestick injuries		
7. Maintains an appropriate system for the disposal of full sharps containers		
8. Ensures sharps containers are clearly labelled with appropriate warning labels/symbols and located in an area that cannot be easily accessed by unsupervised children		
9. Ensures all staff follow a systematic procedure in the event of a needlestick injury		
10. Practises general hygiene principles to limit the spread of infection by all staff		

Additional references

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Pharmaceutical Society of Australia. Guidelines for pharmacists providing opioid pharmacotherapy services. Canberra: PSA, 2004.

Pharmaceutical Society of Australia. Opioid substitution therapy. In: Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: PSA, 2009: 61–4.

Additional information: Harm minimisation

Harm minimisation is consistent with a comprehensive approach to drug-related harm. There is a balance between supply reduction, demand reduction, and harm reduction strategies.

- *Supply reduction strategies* disrupt the production and supply of illicit drugs, and the control and regulation of licit substances (e.g. age restrictions on alcohol and tobacco sales).
- *Demand reduction strategies* prevent the uptake of harmful drug use, including abstinence-orientated strategies and treatment to reduce drug use (e.g. 'Every cigarette is doing you damage' the National Tobacco Campaign, and pharmacotherapy).
- *Harm reduction strategies* reduce drug-related harm to individuals and communities (e.g. the provision of safe, clean injecting equipment).

This professional standard only refers to the concepts of harm and demand reduction at a basic, introductory level. A more comprehensive treatment of the subject is beyond the scope and intention of this document. However, pharmacists can obtain more detailed information from the information resources at the end of this standard.

Pharmacists should be aware of issues such as general health, street drugs, preparation and administration of injections, phlebitis ('track marks'), collapsed veins, burning pain on injection, 'dirty hits', abscesses, ulcers, cellulitis, gangrene, and endocarditis.

Safer injecting practices

Pharmacists should recommend that injecting drug users take note of the following recommendations.

- Always inject with the blood flow.
- Rotate injection sites.
- Use sterile new injecting equipment with the smallest bore needle possible.
- Do not share any equipment used in the injecting process (e.g. needles, syringes, cups, water, spoons, filters, and swabs).
- Mix powders with sterile water, and filter the solution before injecting.
- Remember tablets are not designed for injection, and the risk of problems caused by the injection of insoluble materials is high.
- Note that gel-containing capsules are also not designed for injection, and vein damage caused by gel capsule contents is common.
- Avoid injecting into infected areas.
- Do not inject into swollen limbs even if the veins appear to be distended.
- Avoid veins in the neck, groin, breast, feet, and hands as injection sites.
- Always dispose of equipment safely.
- Be aware that poor veins indicate a poor technique; try to see what is going wrong.
- Remember needles go blunt after one use, leading to increased risk of vein damage if used again.
- Do not inject while alone.
- Remember tolerance will be reduced after a period of abstinence (e.g. rehabilitation, detoxification, or imprisonment), making the effects of injecting drug use more difficult to predict.
- Be aware that obtaining drugs from a different dealwer, and/or using different batches, may mean a change in the strength or potency of the drug.
- Note that the use of multiple drugs may increase the risk of overdose and other negative effects.
- Be aware that there is an increased risk of a systemic infection caused by a dose first being 'stored' in the mouth later being injected.
- Learn basic principles of first aid and cardiopulmonary resuscitation so that you can help friends at times of crisis.

Many people who inject drugs regard community pharmacies as their preferred location for obtaining needles and syringes, and receiving advice and information on drug-related matters. The aim of a needle and syringe program is to:

- supply sterile needles and syringes
- discourage practices that lead to needles and syringes being shared or re-used
- promote the safer use of needles and syringes
- reduce the risk of transmission of blood borne viruses, in particular HIV and hepatitis B and C
- provide a mechanism to collect and dispose of used needles and syringes
- provide information and advice on aspects of harm reduction
- assist injecting drug users to achieve an improved quality of life, by improving their physical and psychological health and social functioning.

Opioid substitution pharmacotherapy has been used in Australia since 1969. It is recognised as an effective public health measure and a vital component of harm reduction. The main objectives of providing an opioid substitution program are to:

- assist individuals in reducing or eliminating illicit opioid drug use
- reduce the mortality and morbidity associated with illicit drug use
- reduce the risk of transmission of blood-borne viruses, in particular HIV and hepatitis B and C
- reduce the social costs of illicit drug use
- assist individuals in achieving an improved quality of life, by improving their physical and psychological health and social functioning.

Appendix 1: The Medicines Management Pathway

Adapted from Stowasser DA, Allinson YM, O'Leary KM. Understanding the medicines management pathway. J Pharm Pract Res 2004;34:293–6.

The medicines management pathway (Figure 1) has nine key steps and three system-wide background processes.[1] The steps are both cognitive and physical. Opportunities for error exist within each step, and as the processes are interdependent, they influence each other. The pathway is a closed loop, or cycle, as feedback on the effect of the medicine and the transfer of information relating to the previous steps influences future treatment decisions in the next cycle. The pathway is applicable to the use of all medicines, independent of the setting, the health professionals involved, and the funding source. It provides a framework to identify how steps are related, the potential for any errors, and thus, possible medication safety system improvements.

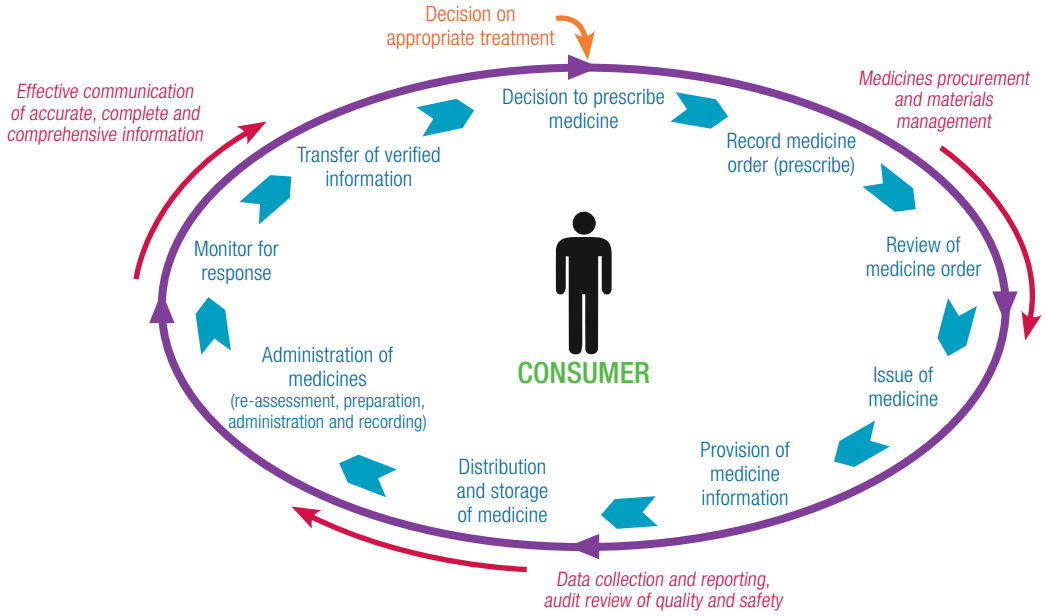

Figure 1. The medicines management pathway.[1]

In some circumstances, steps occur in parallel rather than in sequence; for example, an electronic prescribing system with decision support may simultaneously 'review the medicine order' at the 'record medicine order (prescribe)' step. On occasions, the steps may not occur in strict sequence, as when medicine information is provided as the medicine is ordered. The same person may be responsible for consecutive steps. Generally each step will be undertaken when medicines are used, although how the steps are undertaken may differ depending on the setting.

The consumer is the central focus of the pathway, with direct involvement in some or all of the steps (such as when self medicating). Depending on the pharmacy practice setting, pharmacists have newly developing and/or well established roles at all steps of the pathway.

Steps in the medicines management pathway

1. Decision on appropriate treatment and decision to prescribe medicine

The prescriber needs access to accurate, complete, and up-to-date consumer-specific information and consumer input to assess the most appropriate treatment option, considering both the best available evidence and the consumer's treatment goals. If the most appropriate option is the use of a medicine, the decision becomes the choice of the most appropriate, safe, and cost-effective medicine for that person. The decision may be influenced by treatment protocols, cost-effectiveness, and acceptability to the consumer, as well as the funding source. An example of a pharmacist undertaking this step is providing a recommendation for an over-the-counter medicine.

2. Record medicine order (prescribe)

The intention of the prescriber needs to be conveyed to others involved in the medicines management pathway. The medicine order (or prescription) needs to be clear, unambiguous and contain enough information to support the use of the medicine as intended. Therefore communication is required with the consumer, the person issuing the medicine (often a pharmacist), the person administering the medicine (the consumer or carer, or in the hospital setting, usually a nurse), and finally, the person assessing the impact of the use of the medicine.

3. Review of medicine order

The review of the order at this step provides a valuable safeguard for consumers and prescribers. Orders may be reviewed to ensure compliance with legislative requirements or funding by a third party (e.g. the Pharmaceutical Benefits Scheme), to optimise the use of the medicine prescribed, to verify and confirm the intention of the prescription, or to consider clinical appropriateness prior to dispensing or administration of the medicine, according to the information available to the health care provider. If an issue is identified, clarification is sought with the prescriber, and any proposed changes discussed and documented.

4. Issue of medicine

Issuing of medicines includes the processes of dispensing, manufacturing, or supply of medicines, and is usually undertaken by pharmacists or other endorsed providers (e.g. rural nurses). The correct medicine should be manufactured or selected, and it should be labelled fully and clearly. Where required, consumer-specific instructions are included to assist the person administering the medicine to understand the prescriber's intent, and a record of the issue is made.

5. Provision of medicine information

Appropriate consumer information about medicines, including how to store and use them correctly, improves medicine safety and the quality use of medicines. In addition, information on the appropriate preparation and administration of the medicine should be provided to persons involved in administering the medicine.

6. Distribution and storage of medicine

Once issued, medicines are distributed to the care delivery areas (e.g. the ward) within a residential or health care facility, or for local storage by the consumer or carer (at home or wherever the consumer resides). The method of medicines storage (such as using an imprest system or bedside locker) will depend on the needs of the consumer, and financial, physical, regulatory, and safety constraints.

7. Administration of medicine

The need for a medicine may be reassessed before administration; for example, as in the need for pain relief or symptom control. Therefore, this step encompasses reassessment of need, the selection of the correct medicine (dosage, route, and time), appropriate preparation of the medicine, and administration of the medicine to the correct person on each occasion. Where required, a record of the administration of the medicine is made.

8. Monitor for response

Consumers often monitor their response to medicines, particularly when self-medicating. Prescribers or other health professionals seek the consumer's opinion on the response or, where the response is not self evident, investigate the person's response to the medicine according to symptom control or investigative tests. Responses to medicines may be both positive and negative (such as in an adverse drug reaction or event).

9. Transfer of verified information

Information on the actual use of the medicine is crucial to assess the impact of the medicine, to assist with future decisions about care, and to enable the safe transfer of care, especially when another health care provider is involved in ongoing care. This includes information on:

- the medicine that was issued at transfer
- current treatment regimen (a complete and accurate list of ALL medicines), including the medicine, dosage, reason for use, and intended duration of therapy
- a description of changes to the therapy during the episode of care.

This communication step is crucial when the consumer's care is shared between health professionals and across the continuum of care. It is important that appropriate quality assurance steps are in place to ensure the accuracy, completeness, and timeliness of the information provided to the next health care provider.

System-wide background processes in the medicines management pathway

These processes occur on a 'system-wide', rather than on an individual consumer basis. Their impact is across the whole of the medicines pathway, with their ultimate focus being to ensure the quality use of the medicine for each consumer.

Medicines procurement and materials management

The timely access to high-quality medicines at a cost the individual and community can afford is crucial to the appropriate use of medicines. Medicines must be procured, stored, and distributed appropriately to ensure the safety of individual consumers and the environment (e.g. refrigerated medicines, cytotoxic medicines, etc.) and to ensure the effective use of resources.

Data collection and reporting, and audit review of quality and safety

Data on all aspects of the cycle is collected for reporting on a system-wide basis. In particular, data on the prescribing, issuing, and administration of medicines is collected as part of audit activity to support the quality use of medicines and to monitor medication safety. This process may also include the collection of data required for funding by third parties.

Effective communication of accurate, complete and comprehensive information

Effective communication is fundamental to achieve optimum outcomes for consumers along the whole medicines management pathway. For example, communication is needed to ensure that prescribers are aware of formulary prescribing, that consumers have medicines information and knowledge of the management plan, and that verified information is accurately communicated to the next health care provider.

The medicines management pathway in other guidelines

The medicines management pathway is also used in the Australian Pharmaceutical Advisory Council's *Guiding Principles to Achieve Continuity in Medication Management* document,[2] where the pathway is referred to as the 'medication management cycle'. The background to this document states:

> The health care continuum can be viewed as a series of cycles. Each cycle relates to an episode of care. For each episode of care, there is a corresponding medication management cycle.

Each cycle comprises the nine steps of the medicines management pathway and the three background processes. This document aims to achieve continuity of quality use of medicines in medication management when consumers move from one episode of health care to another. Pharmacists may obtain copies of this document from the National Medicines Policy Secretariat at: nmp@health.gov.au.

Application of the medicines management pathway

Identifying opportunities for error

Opportunities for consumer harm exist within the pathway and within each step. Therefore, an understanding of the pathway and the human factors associated with each step is necessary to ensure the safe, effective, and efficient use of medicines. The pathway can assist consumers and health professionals to understand their own role and how their actions can improve medicine safety.

Recent innovations in pharmacy practice

A detailed understanding of the medicines management pathway is essential to support the safe, effective, and efficient introduction of many initiatives including:

- the interpretation of the impact and applicability of medication safety projects
- the transfer of medicines information across the continuum of care
- the use of electronic prescribing systems with decision support within health services
- the use of barcode and other technologies to support safety improvements.

Relevance of the *Professional Practice Standards* to the medicines management pathway

The medicines management pathway allows pharmacists to gain an overview of what happens when medicines are used. It demonstrates the multiple opportunities for improvement in the systems and processes used in providing professional services.

Depending on the pharmacy practice setting, pharmacists may identify with newly developing and/or well established roles at all steps of the pathway.

Some standards are directly linked to one or other step of the pathway, while others support many steps, or even the whole of the pathway. Using the pathway can assist a better understanding of the output of the standards in terms of the quality of the consumer service that is delivered.

The Fundamental Pharmacy Practice standard relates closely to the three background processes of the medicines management pathway, and applies on a system-wide basis to all services provided by the pharmacist. The Managing Pharmacy Practice standard addresses the responsibility of some individuals for providing the material and human resources necessary to facilitate compliance by others with the Professional Practice Standards.

The Professional Practice Standards address some specialty services (including medication reviews and Dose Administration Aids Services) that represent localised cycles of care within the medicines management pathway. These specialty services may focus on a particular process, such as communication, reporting, or the provision of medicines, but pharmacists must also be familiar with other inter-related professional practice standards, and any regulatory and privacy issues.

The *Professional Practice Standards* provides a context for the pharmacists' contribution to the medicines management pathway and promote uniform safety and quality in pharmacy practice.

References

1. Stowasser DA, Allinson YM, O'Leary KM. Understanding the medicines management pathway. J Pharm Pract Res 2004;34: 293–6.
2. Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Canberra: Commonwealth of Australia, 2005. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-guiding

Appendix 2: Quality Use of Medicines and Practice Improvement

Quality use of medicines (QUM) means 'selecting management options wisely, choosing suitable medicines if a medicine is considered necessary and using medicines safely and effectively'.[1] QUM is one of the four central objectives of Australia's National Medicines Policy.[2] This policy advocates shared responsibility between governments, health care professionals, and consumers to achieve QUM.

'It is estimated that over 1.5 million Australians suffer an adverse event from medicines each year resulting in at least 400,000 visits to general practitioners and 140,000 hospital admissions.'[3] In 2005, the Australian Council for Safety and Quality in Health Care noted that 90% of safety problems were based in the system, and only 10% with the individual.[4] A systems approach to improving quality involves building layers of barriers to reduce the probability of identified risks occurring.

Maintaining a focus on continuous quality improvement is not only an effective means of improving the service provided to consumers, but is also the key to achieving efficiency and productivity gains. The goal of all reviews is to identify opportunities for improvement. It is important that reviews of processes are evaluated carefully, and the findings used to improve services. For example, regular audits of service records can identify rates of compliance with required documentation that, in turn, can indicate where documentation systems can be simplified. Surveys of consumers can indicate the degree of satisfaction with the service, as well as elicit suggestions for changing the service so that it will meet customer needs more effectively and so improve consumer outcomes. Further information on conducting quality reviews may be found in the PSA's *Guidelines for Managing Pharmacy Systems for Quality and Safety.*[5]

Investing time in improving the quality of pharmacy systems is an important task that can assist improvements in health outcomes. Unless there are changes and improvements in the systems used, there cannot be improvements in outcomes. While not all changes result in improvement, all improvements require change. It is important for pharmacists to weigh the value of any improvement using objective evidence. Pharmacists routinely practise evidence-based medicine, and the documentation recommended in these standards provides the evidence base for 'evidence-based quality practice improvement'.

The plan-do-study-act cycle

One model for quality improvement is the plan-do-study-act (PDSA) cycle[6] adopted by the National Primary Care Collaboratives Program. This cycle consists of the following steps:

Step 1 ***Plan*** – involves identifying the problem.

Step 2 ***Do*** – involves carrying out the plan, observing and recording data.

Step 3 ***Study*** – involves measuring or analysing the effects.

Step 4 ***Act*** – involves adjusting the activity of the next cycle based on the outcomes of this cycle.

This model adapts to pharmacy services at all levels of practice (see Figure 1).

This same cyclic approach may be used to improve individual cycles of care for consumers, or to improve organisational systems.

Figure 1. The plan-do-study-act cycle in pharmacy services.

Quality improvement activities

Examples of activities involved in the implementation of quality improvement include the following:

a) reviewing and updating educational material provided in the pharmacy, and noting and recording the popular topics

b) drawing up a calendar of health topics and activities for pharmacy staff

c) informing consumers, through flyers and leaflets, about future health campaigns

d) encouraging feedback from consumers and health professionals by distributing surveys or feedback forms after each health education/promotion activity, and analysing the responses

e) keeping a log of dispensing errors, analysing what factors may be attributable, and recording corrective actions already taken and/or future strategies to prevent recurrence

f) undertaking a random self-audit regularly (e.g. once a month) to assess timeliness of supply (e.g. recording the time of prescription receipt and the time of supply for every third prescription received)

g) maintaining a log of the extemporaneous preparations or the total number of items dispensed and analysing trends (e.g. how busy the pharmacy usually is on pension days or before school holidays); this analysis may be used to determine appropriate staffing levels for an anticipated workload

h) distributing standard written feedback forms to customers regularly, and recording any verbal feedback in a logbook

i) noting the types and numbers of enquiries received (including the subject involved and the enquirer), and the type of response provided (e.g. an on-the spot response, a response after consulting references, or requiring extensive research before answer)

j) recording the usual or average response time to a request for a professional service

k) keeping an audit trail to ensure ease in tracing the original enquiry in cases where follow-up information is required

l) providing feedback forms with written reports when reports are requested and/or supplied, and analysing any comments received from enquirers.

m) seeking external or peer review of the service supplied.

References

1. Australian Government Department of Health and Ageing. The national strategy for quality use of medicines. Plain English edition. Canberra: Commonwealth of Australia, 2002. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pdf-natstrateng-cnt.htm

2. Australian Government Department of Health and Ageing. National medicines policy 2000. Canberra: Commonwealth of Australia, 1999. Available at: www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm

3. Roughead L, Bedford G. Chapter 4. Medication safety: will adverse drug events be reduced? In: Windows into safety and quality in health care 2008. Sydney: Australian Commission on Safety and Quality in Health Care, 2008: 27–37. Available at: www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/com-pubs_MedSafety

4. Australian Council on Safety and Quality in Health Care. Achieving safety and quality improvements in health care. Sixth report to the Australian Health Ministers' Conference. Canberra: Commonwealth of Australia, 2005. Available at: www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/a-zpublicationsa-e

5. Pharmaceutical Society of Australia. Guidelines for managing pharmacy systems for quality and safety. Canberra: PSA, November 2002. Available at: http://psa.advsol.com.au/scriptcontent/Custom/MC_ShowPage.cfm?page=163

6. Australian Primary Care Collaboratives. The model for improvement. Available at: www.apcc.org.au/about_the_APCC/the_model_for_improvement

Appendix 3: The Health Promotion Planning Cycle

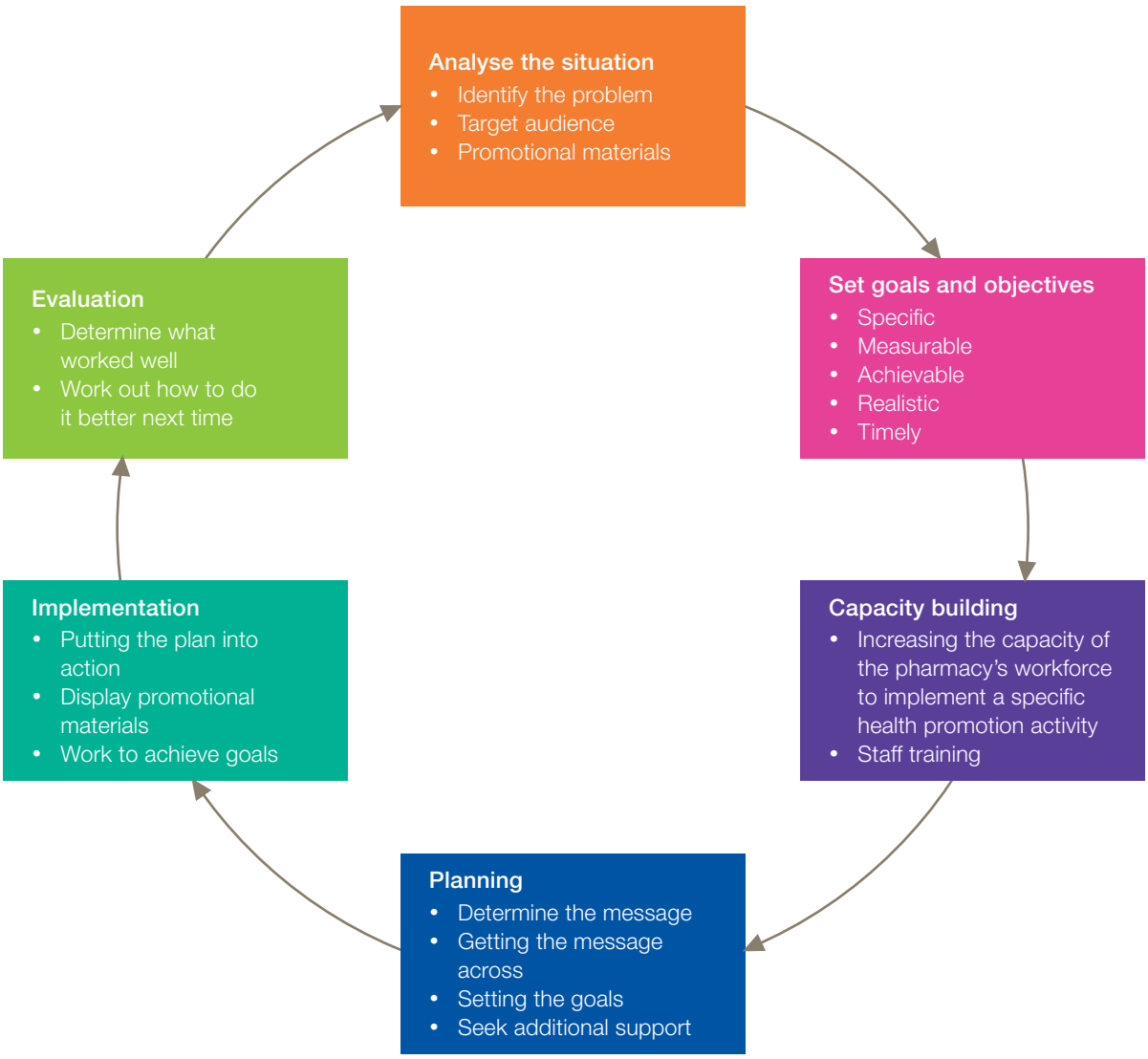

Figure 1. The health promotion planning cycle.

Adapted from Egger G, Spark R, Donovan R. Health promotion strategies and methods. 2nd edn. Sydney: McGraw-Hill, 2005.

When planning a health promotion activity, a structured approach can ensure the best outcomes. The steps in the health promotion planning cycle (shown above) can be used in planning a health promotion activity on any topic. Pharmacists should start by analysing the area they want to promote and the type of activity they would like to implement and then move on to setting goals and preparing the pharmacy for the delivery of the health promotion activity (including training staff). Further planning is then needed before implementing the activity. Once the health promotion activity is completed, it is important to always reflect and to identify how such activities could be improved in the future.

Appendix 4: Adherence Assessment Tool

The following modification of the Morisky scale[1] is a validated tool for assessing whether a consumer is unintentionally non-adherent with their medicines. It may assist the consumer to adhere with their medication regimen through increased awareness of their medicines.

First name	Family name
Address	
Date	Assessed by
Pharmacy details	

Ask the consumer

Question	Answer (score)	Patient's answer and score
1. Do you ever forget to take your medicines?	No (0) Yes (1)	
2. Are you always careful about taking your medicines?	No (1) Yes (0)	
3. When you feel better do you sometimes stop taking your medicines?	No (0) Yes (1)	
4 Sometimes, if you feel worse when you take your medicines, do you stop taking them?	No (0) Yes (1)	

Explanation of scores	
Total score of zero	Adequate adherence
Total score of 1–4	Inadequate adherence (partial adherence or non-adherence)
Other comments/notes	

1. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care 1986;24:67–74.

Appendix 5: Details of Local Health Care Providers

Below is a template table to be used to document the details of health care providers in the pharmacist's local area. This can be a quick reference tool for the pharmacist or pharmacy staff to use when referring consumers to other health care providers. The template is not an exhaustive list but is designed to be tailored to the needs of individual pharmacies.

Provider	Name of Provider	Contact Person	Phone	Address	Email
Aboriginal and Torres Strait Islander Health Services					
Community Nursing Services					
Dentist					
Diabetes Educator					
Dietician					
Early Childhood Clinic					
Family Counselling					
Family Planning Services					
General Practitioner					
General Practitioner					
General Practitioner					
General Practitioner					
General Practitioner					
General Practitioner					
Hospital					
Hospital					
Hospital – Aged Care and Rehabilitation Services					
Hospital Pharmacy					
Medical Specialist (e.g. dermatologist)					
Medical Specialist					
Medical Specialist					
Naturopath					
Occupational Therapist					
Optometrist					
Podiatrist					
Poisons Information Centre					
Psychologist					
Psychologist					
Speech Therapist					
Youth Counselling					

Appendix 6: Documenting Counselling Events and Interventions

Counselling involves the communication of information that will ensure the medicine used by the consumer has the desired therapeutic effect and the incidence of preventable adverse effects is minimised.[1] Documentation of counselling events and interventions provides a record that can be used by other pharmacists in the pharmacy to tailor their communication with the consumer when subsequently supplying medicines. Documentation can also be used as a risk management strategy to provide a record of evidence that an intervention has occurred.

This document provides guidance on what counselling issues may be important to record and how the information should be documented. This list is a guide only and some situations not identified in this list may also be of clinical significance and require recording. Pharmacists are reminded to use their professional judgement when deciding which issues are relevant to document.

Clinically important counselling issues to record	What to record
Difficulties communicating with the consumer/carer due to: • vision impairment • hearing impairment • language or cultural differences • cognitive impairment	• Reasons for the communication difficulty • Actions taken or methods used to overcome communication difficulty (e.g. use of a translation service) • Any follow up required or recommended
A consumer or carer refusing counselling	• Reasons for refusal • Any information provided
A consumer or carer possibly having difficulties with medicine adherence	• The adherence issue identified • The advice given to improve adherence • Any follow up required or recommended
The identification of a drug interaction	• The drug interaction identified • The advice given or action taken to resolve the drug interaction issue • Any follow up required or recommended
The identification of an adverse drug reaction	• The adverse drug reaction indentified • The advice given or action taken to resolve the adverse drug reaction • Any follow up required or recommended
An inadequate response to a medicine	• Details of the inadequate response to the medicine • The advice given or action taken to resolve the issue • Any follow up required or recommended
A cessation of a medicine	• Details of medicine ceased • Reasons for medicine being ceased
A change of dose	• Confirmation of change of dose • Reasons for change of dose (if known) • Any additional advice given relating to the change in dose and/or expected outcomes
A change of instructions for the consumer on a medicine	• Confirmation that the instructions have changed • Confirmation that consumer is aware of the new instructions

1. Sansom LN, ed. Australian pharmaceutical formulary and handbook. 21st edn. Canberra: Pharmaceutical Society of Australia, 2009.

Appendix 7: Indirect Supply Services: New Consumer Details/Change of Consumer Details Form

This is a template for pharmacists to use to gather all necessary information from new consumers who wish to access an indirect supply service or for consumers whose details have changed. The template is designed to be a guide and should be adapted to best suit the needs of the individual pharmacies.

New Consumer Details/Change of Consumer Details		Date
First name	Family name	Date of birth
Address		
Email address		Phone
Concession card number		Expires
Repatriation health card number		Expires Please circle colour: Gold / White / Orange
Medicare number		Expires
Safety net number		Expires
Emergency contact details		
Carer name and contact details (if applicable)		
GP name	Address	
Phone	Email	

Medication regimen (Include all prescription and non-prescription items – if more space is required, please attach on another sheet of paper)	**Directions for use** (If more space is required, please attach on another sheet of paper)
1.	
2.	
3.	
4.	
5.	
6.	

Medical history (e.g. medical conditions, physical disabilities – if more space is required, please attach on another sheet of paper)	Allergies
Consumer's preferred mode and time of delivery	
Relevant delivery details (e.g. security gates, pets, house, apartment, language difficulties, etc.)	
Information recorded by	

Appendix 8: Medicines that may be considered Unsuitable for Indirect Supply

There are a variety of reasons why medicines may be considered unsuitable for delivery, and pharmacists need to make a risk assessment to determine the suitability of a medicine for indirect supply based on the individual circumstances. There is a greater likelihood of error when the opportunity for face-to-face contact with the consumer is absent, and this should be taken into account when determining the appropriateness of medicines for indirect supply.

This list provides guidance on those medicines that may be unsuitable for indirect supply. Pharmacists may use this as a template to create their own list. The list should be reviewed and updated on a regular basis.

Category	Examples	Comments
Commonly misused medicines	Anabolic steroids, benzodiazepines, stimulants, appetite suppressants, pseudoephedrine, codeine, laxatives, eye drops, analgesics	• Need to prevent inappropriate supply • Ensure all documentation and details are accurate and authentic
Pharmacist Only Medicines (Schedule 3)	Analgesics, vaginal thrush treatments, emergency hormonal contraception	• Some jurisdictions require face-to-face contact between pharmacist and consumer (these may be supplied on prescription) • Need to consider ability to assess the therapeutic need without face-to-face contact and the risks involved with the use of Pharmacist Only Medicines
Medicines that require refrigeration	Eye drops, vaccines, thyroxine	• Need to ensure delivery arrangements are able to accommodate temperature/storage conditions of the medicines being delivered
Substances that are prohibited from commercial transport	Narcotics	• Confirm which medicines are prohibited from commercial transport with delivery companies
Medicines with a low therapeutic index	Warfarin, digoxin	• There is an increased risk of toxicity with such medicines; consider contacting the consumer via telephone to offer direct counselling

Appendix 9: Template Procedure for Consumer Admissions and Readmissions to Residential Care Facilities

This is a template procedure for pharmacists to follow upon receiving notification that a consumer has been admitted or readmitted to a residential care facility (RCF). The template is a guide and should be adjusted to best suit the needs of the individual pharmacies and the RCFs involved.

Procedure for consumer admission or readmission to a residential care facility	Person responsible for task	Tick when task completed
Record the admission/readmission notification received from the RCF (via fax, email, or phone), and refer on as needed		
Obtain, and record, consumer details from the RCF including: • name • Medicare and concession details (including expiry dates) • safety net details • GP name and contact details • details of previous pharmacy used by the consumer • billing details		
Obtain and review a copy of the consumer's medication chart		
Contact the consumer's previous pharmacy to obtain: • previous medication details • any prescriptions or medication held by the previous pharmacy When received, record details as necessary		
Compare consumer's RCF medication chart with previous medication details; record details as necessary		
Confirm any differences or changes in the medication chart with the consumer's GP		
Establish an electronic consumer profile in the dispensing software		
Create a billing account for the consumer		
Dispense prescriptions or obtain consumer's own medication from the RCF or previous pharmacy as needed		
Create an electronic consumer profile in the packing software		
Create a hard-copy file to store: • a copy of the consumer's medication chart and other details • prescriptions • records of packing, if applicable		
Print packing materials if applicable		
Supply the medication, according to the needs of the RCF (e.g. by using medication sachets, blister packs, or original packaging)		
Check repacked medication or original packs against the medication chart		
Deliver medication to the facility in a timely manner		

Appendix 10: Screening Record and Referral Form

This screening record and referral form is a template that pharmacists may wish to adapt and use when recording screening services. The form allows the details of the service provided to be documented and contains a tear-off referral form for consumers to take to another health care provider if required.

Screening record form

Date	
Name	Date of birth
Address	
Email	Phone

Medication regimen (Include all prescription and non-prescription items – if more space is required, please attach on another sheet of paper)	**Directions for use** (If more space is required, please attach on another sheet of paper)
1.	
2.	
3.	
4.	

Test(s) (e.g. blood glucose, blood pressure, cholesterol)

Test equipment details

Date	Test results	Need for referral	
		Yes	No
		Yes	No
		Yes	No
		Yes	No

Screening outcomes

Referred to	Date
Address	
Email	Phone
Pharmacist name	Pharmacist signature

Referral form

Date

Consumer name	Phone
Address	
Email	

Referred to	Phone
Address	
Test(s) conducted	
Test (s)results	
Reason for referral	

Pharmacy name	Phone
Address	
Email	
Pharmacist name	Pharmacist signature

Appendix 11: Template Consumer Care Plan

Below is a template consumer care plan for pharmacists to document the treatment aims for consumers receiving disease state management services. The care plan allows the details of each consultation and the goals for the consumer's treatment to be documented. A copy of the second page of the care plan should be given to the consumer so they have a record of their treatment goals and date of next consultation.

Consumer care plan			Date
First name	Family name		Date of birth
Address			
Phone	Email address		
Concession card number			Expires
Repatriation health card number			Expires (Please circle colour) Gold / White / Orange
Medicare number (the last digit corresponds to the number on the left of the name)			Expires
Safety net number			Expires
Emergency contact details			
Carer contact details (if applicable)			
Height	Weight	Waist circumference	Smoking (Please circle) No / Yes Number/day
GP name	Address		
Phone	Email		
Other health care providers			
Name	Address		
Phone	Email		
Name	Address		
Phone	Email		

Medication profile (Include prescription and non-prescription items and directions for use. If more space is required, please attach on another sheet of paper)	**Reasons for use** (If more space is required, please attach on another sheet of paper)	**Adherence check** (Refer to Appendix 4: Adherence Assessment Tool)
1. e.g. Diabex 500 mg 4 n	e.g. Type 2 diabetes	e.g. Good
2.		
3.		
4.		
5.		
6.		

Medical history (e.g. medical conditions, physical disabilities – if more space is required, please attach on another sheet of paper)	Allergies

Lifestyle review/Consumer self-management issues (e.g. exercise, diet, blood glucose measurements)

Clinical tests	Results					
	Date	Result	Date	Result	Date	Result
e.g. Blood pressure						
e.g Blood glucose						
e.g. Cholesterol						
e.g. Spirometry						
e.g. Peak flow						
e.g. Weight						

Issues identified/changes since last consultation

Treatment options **(e.g. pharmacological, non-pharmacological, lifestyle and self-care activities)**

1.

2.

3.

4.

5.

6.

Care plan goals **(Goals should be specific, measurable, achievable, realistic and timely)**

1.

2.

3.

4.

Care plan review (Please circle)	Weekly / Monthly / 3-monthly / 6-monthly	Date of next review
Referral required (Please circle) No / Yes	Referred to	Phone
	Address	
Pharmacist name	Pharmacist signature	
Consumer name	Consumer signature	

NOTE: Page 1 of the consumer care plan to be retained by the pharmacist. Give a copy of page 2 of the consumer care plan to the consumer.

Appendix 12: The History of the *Professional Practice Standards*

In late 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.

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]

In 1998, the Pharmacy Guild of Australia launched the Quality Care Pharmacy Program, 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' sin community pharmacy.

Separate to these standards, the PSA developed the first edition of the *Professional Practice Standards* with the AACP framework and the International Pharmaceutical Federation's *Standards for Quality of Pharmacy Services: Good Pharmacy Practice* guidelines[4] in mind. 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 in October 1999 and consisted of 11 standards.

As the role of pharmacists in health care delivery has expanded, the PSA has sought to add continuous quality improvement elements and to update the standards as required. In July 2001, the PSA published an interim update to the standards, followed by an additional eight standards in version 2 of the *Professional Practice Standards* released in October 2002.[6]

A second detailed review of the Professional Practice Standards in 2005 expanded the scope of the standards and developed the universal Fundamental Pharmacy Practice standard integral to all pharmacy services and all areas of practice. The *Professional Practice Standards*, version 3 was developed by the PSA through an extensive consultation process with key industry stakeholders and experts from across the profession. The *Professional Practice Standards*, version 3 was published in January 2006.[7]

Each review and subsequent edition ensures that the *Professional Practice Standards* continues to reflect current practice as pharmacists in Australia face a professional climate of dynamic change.

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Appendix 13: Project Participants

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The Pharmaceutical Society of Australia is grateful for the contribution of the following individuals and organisations to the *Professional Practice Standards*, version 4.

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Glossary

Term	Definition
Adverse drug reaction (ADR)	Any response to a drug that is noxious and unintended, and that occurs at doses normally used in man for prophylaxis, for diagnosis or therapy for disease, or for the modification of physiological function.[1]
Adverse drug event (ADE)	An event where a medicine is implicated as a causal factor. An ADE 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 ADEs.[2]
Carer	A person, either paid or unpaid, who has assumed a primary caring role for another person in the community or in their own home. This may include parents, guardians, children, and friends, as well as aboriginal health workers, nursing assistants, personal care assistants, and home and community care (HACC) workers.[3]
Complementary medicines	Medicines that are also known as 'traditional' or 'alternative' medicines. Examples include vitamins, minerals, nutritional and herbal supplements, aromatherapy, and homoeopathic products.[4]
Consumer	Any user or potential user of pharmacy services. This may include a carer, agent, or another individual who would normally assist the user in taking their medicines and/or using a therapeutic device. Other health care providers (such as medical practitioners and nurses) may also at times be users of pharmacy services.
Consumer care plan	A plan of systematic care outlined for the consumer that is provided by the pharmacist in collaboration with the consumer and other health care providers. It includes an accurate and comprehensive assessment of the consumer's health status, recommendations for pharmacological and non-pharmacological interventions, therapeutic goals that have been developed with the consumer, the provision of education and counselling, and regular follow ups to monitor the consumer's progress.
Controlled area	An area constructed and operated in a manner where some attempt is made to control the introduction of potential contamination and the consequences of accidental release of living organisms. At a minimum, the area should be maintained at a pressure negative to the immediate external environment and allow for the efficient removal of small quantities of airborne contaminants.[5]
Counselling	A two-way communication process between the pharmacist and the consumer in which the pharmacist ascertains the needs of the consumer and provides him or her with the information required to safely and effectively administer medicines and/or use therapeutic devices.
Cytotoxic drugs	Medicines used primarily in the treatment of cancer. They have deleterious effects upon cells and many have been found to be mutagenic, teratogenic, and carcinogenic.
Cytotoxic drug products	A specific term used to refer to cytotoxic drug formulations that are derived from the manipulation of commercially available cytotoxic raw materials (drug concentrates).
Dose administration aid (DAA)	Sealed, tamper-evident devices that allow individual doses to be packaged according to the prescribed dose schedule.[6]
Disease prevention	Processes designed to not only prevent the occurrence of disease, such as through risk factor reduction, but also to arrest the progress of a disease and to reduce its consequences once established.[7]

Term	Definition
Disease state management	A consumer-centred process that focuses on managing the health of consumers suffering from chronic conditions, with the objective of reducing risk factors through monitoring, counselling, education, enhancing consumer self-management, and the quality use of medicines.
Evidence-based information	Information that has been critically evaluated for its validity, importance, and relevance.
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.[8]
Hazardous materials	Products that can cause adverse health effects, such as severe poisoning, asthma, skin rashes, allergic reactions, allergic sensitisation, cancer, and other long-term diseases, from exposure to them and also cause physical effects, such as fire, explosion, release of hazardous gases, and corrosion. Hazardous materials may include many commonly found industrial, commercial, pharmaceutical, agricultural, and domestic chemicals.[9]
Health care providers	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).
Health literacy	The ability to understand and interpret the meaning of health information in any format (e.g. written, oral or electronic). Health literacy influences a consumer's ability to make sound health decisions in the context of daily life.[10]
Health promotion	The process of enabling people to both increase control over their health and to improve their health outcomes.[7]
Medicine	A formulated product or drug designed to deliver a therapeutic outcome or affect health when administered to a person or animal. Medicines include prescription and non-prescription products as well as complementary medicines.[11]
Medication	A medicine used by a specific consumer according to a particular dosing regimen.[11]
Medication action plan (MAP)	An ongoing plan for the use and management of medicines that is developed in collaboration with the consumer and/or their carer. A medication action plan is intended to support health care professionals and consumers and/or their carers in developing suitable strategies to manage the consumer's medications.[12]
Medication list	A current list of all of the consumer's current medicines. This list should be available and easily accessible to the consumer and all those involved in the consumer's care.[12]
Medicines Use Review (MUR)	A structured program that allows the consumer to have a face-to-face discussion with their pharmacist about the medicines they are taking, with the aim of: • helping the consumer to learn more about their medicines, what they are for, how they affect the body, and how to take them to get the most benefit • identifying any problems that the consumer is experiencing with their medicines • improving the effectiveness of the medicines, and ensuring that the most useful formulation is prescribed • supporting clinical and cost-effective prescribing, and encouraging the consumer not to waste, over-order, or stock-pile their medicines.
Medicines information	Written and/or oral information or advice about medicines and pharmacotherapy, in response to a request from other health care providers, consumers, or other groups or individuals such as media, policy makers, and lawyers. This information may be consumer-specific or general information promoting the safe and effective use of medicines.
Medicines information centre	A facility specifically designed for, and specialising in, the provision of medicines information by pharmacists. Examples may include hospital medicines information centres, the medical information departments of pharmaceutical companies, and online pharmacy services providing medicines information.

Term	Definition
Medicines information pharmacist	A pharmacist who is appropriately trained, and has demonstrated competency and knowledge in the provision of a medicines information service.
Medication profile	A complete and comprehensive summary of the medicines a consumer is currently taking. The profile includes key details about the consumer, the issuing pharmacy, and details for each medicine including active ingredient, brand name, strength, form, dose and directions for use, and other supplementary information (e.g. route of administration, indication, and special directions).[13]
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 consumer's understanding of the medication regimen.[14]
Monitoring	Refers to the regular measurement and assessment of specific clinical and social parameters to assist consumers undergoing treatment for, or at risk of, specific health conditions.
Non-prescription medicines	All medicines available for purchase by the public that do not require a prescription. Non-prescription medicines include, but are not limited to, Pharmacist Only Medicines (S3), Pharmacy Medicines (S2), unscheduled medicines, complementary medicines, and nutritional supplements.
Pharmacy practice	Pharmacy practice refers to any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. Pharmacy 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 have an impact on the safe, effective delivery of services in the profession, and/or use the pharmacist's professional skills.[15]

Pharmacist Only Medicines (S3)	Substances and preparations for therapeutic use that:
	• are substantially safe in use, but require professional advice or counselling by a pharmacist
	• the use of which requires a pharmacist's advice, management, or monitoring
	• are for ailments or symptoms that:
	  ◦ can be identified by the consumer and verified by a pharmacist
	  ◦ do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management.[16]

Pharmacy Medicines (S2)	Substances and preparations for therapeutic use that:
	• are substantially safe in use, but where advice or counselling is available if necessary
	• are for minor ailments or symptoms that:
	  ◦ can be easily recognised by the consumer
	  ◦ do not require medical diagnosis or management.[16]

Primary health care	Essential health care made accessible at a cost the country and community can afford, with methods that are practical, scientifically sound, and socially acceptable.[16]
Public health	The science and art of promoting health, preventing disease, and prolonging life through the organised efforts of society.[7]
Quality assurance (QA) program	A program of evaluation intended to ensure systems are working well, identify faults, suggest remedial action, and evaluate new systems. An effective QA program is an essential part of a pharmaceutical service. It should be included in every contract and be appropriate to the level of need.
Quality use of medicines (QUM)	Refers to 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.[17]
Residential care facility (RCF)	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).

Term	Definition
Risk assessment	A systematic process of organising information to support a risk decision being made within a risk management process. Risk assessment consists of the identification of hazards, and the analysis and evaluation of risks associated with exposure to those hazards.[18]
Screening	A public health service in which members of a defined population, who may not know they are at risk of a disease or its complications, undergo tests and/or are asked questions to identify individuals who may have the disease and who therefore require further more specific investigations. Such individuals are then referred to health care professionals for diagnosis.[19]
Pharmacy services	Professional services where pharmacists provide therapeutic goods, information, and advice about health and therapeutic goods, and any other aspect of consumer care.
Terminal sterilisation	Terminal sterilisation involves filling primary packaging containers with formulation, followed by thermal, ionizing, or chemical modes of sterilization.[20]
Therapeutic device	Any instrument, apparatus, appliance, material, or other article intended to be used for the diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury. Common therapeutic devices include nebulisers, spacers, bandages, blood glucose meters, blood pressure monitors, and pregnancy testing kits.
Therapeutic goods	Medicines and therapeutic devices.
Unscheduled medicines	Medicines which are exempt from scheduling under the provisions of the Standard for the Uniform Scheduling of Drugs and Poisons. Examples of unscheduled medicines include small packs of analgesics and most antacid and laxative products. The majority of complementary medicines can also be regarded as unscheduled medicines.

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The Professional Practice Standards version 4 has been endorsed by the following organisations at the time of publication.

The Pharmacy Guild of Australia

AACP
AUSTRALIAN ASSOCIATION OF CONSULTANT PHARMACY

Pharmaceutical Society of Australia

AUSTRALIAN PHARMACY COUNCIL

Pharmacy Board of Australia

PDA
PHARMACISTS' DIVISION OF APESMA