# Clinical Services Capability Framework Pharmacy Services

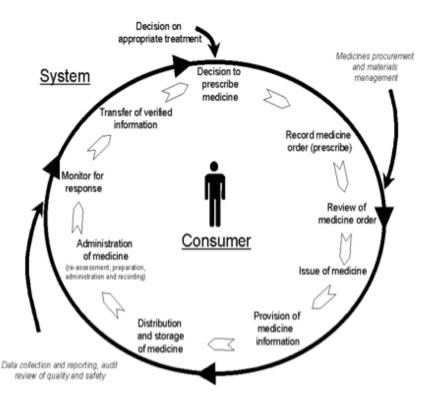


## Module Overview

Please note: This module must be read in conjunction with the Fundamentals of the Framework (including glossary and acronym list).

Pharmacy Services include a range of activities aimed at enhancing the safe and effective use of medicines to optimise patient outcomes. These activities include the procurement, manufacture and distribution of medicines, patient specific professional services and system wide operations such as teaching, training and research. The level and extent of Pharmacy Service provided by a health facility is determined by the complexity and acuity of its patients. Pharmacy Services are provided across the continuum including the community, hospital in the home and in hospital. Pharmacy Services must comply with relevant legislation and, for hospitals participating in Pharmaceutical Reforms, the Commonwealth's Pharmaceutical Reforms Program.

#### Figure 1: Medication management cycle



Adapted from: Journal of Pharmacy Practice and Research 2004; 34(4):294.

Medication management is 'a system of processes and behaviours determining the way medications are used or handled by patients and organisations'.<sup>1</sup> Medication management is multidisciplinary and collaborative, involves individuals and organisations, and includes all aspects of medication supply and use, as well as the management of those services. Medication management is centred on the consumer and their needs.

Australia's National Medicines Policy advocates better health outcomes for all consumers through the quality use of medicines and provides a framework for the delivery of Medication Services in Australia.<sup>2</sup> Service providers must observe the requirements of the Medication Safety Standard detailed in the National Safety and Quality Health Service Standards and also follow the Australian Pharmaceutical Advisory Council's (APAC) Guiding Principles to Achieve Continuity in Medication Management (July 2005)<sup>3,4</sup>. The APAC Guiding Principles describe the medication management cycle and its ten key components (Figure 1).

In order to minimise risk to patients and optimise health outcomes, Pharmacy Services play an integral role in supporting safe and effective medication management through the monitoring and review of all components of the medication management cycle. The Australian Council on Healthcare Standards and the International Pharmaceutical Federation's Consensus Statement on Hospital Pharmacy<sup>5</sup> outline key principles underpinning the provision of medication services. The Society of Hospital Pharmacists of Australia (SHPA) has also published a number of practice standards that support optimal medication use and contemporary pharmacy practice.

To ensure safe and effective medication use, and to prevent patient admission to hospital, the facility must:

- > ensure patients have timely access to medications they need
- > take an accurate and comprehensive history of a patient's medication regimen inclusive of recent changes<sup>6</sup>
- > review and assess that regimen against any prescribed regimen, medical conditions and admission plan (medication reconciliation<sup>7</sup>)

- > identify and act on potential problems (medication review<sup>2</sup>)
- > engage with patients to understand their desires and willingness to participate in medication care
- > provide correct and timely information about medications to patients inclusive of expected outcomes and timelines and what to do if these are not achieved (provision of counselling and building an agreed medication plan)
- > communicate the agreed medication plan to primary care providers.

Pharmacy service providers must also assess each patient's medication risk, and be trained and clinically skilled in making these assessments. Medication risk refers to the possibility of potential or actual harm from medication management. The service must be able to manage complex and unstable patients of different ages with comorbidities and/or complicated therapeutic needs as appropriate for the service level, or until transfer to a higher level service is available. As patient complexity and acuity and medication risk increases, the number of patients for whom a single pharmacist can provide clinical services decreases. This should be considered when determining appropriate staffing levels and pharmacist/pharmacy assistant ratios for all levels of service in conjunction with recommendations included in current SHPA Standards of Practice for Clinical Pharmacy Services.

Medication risk should include an assessment of medication complexity (preparation, monitoring, low therapeutic index, risk of adverse effects), use of APINCH medication, cost of medications and patient demographics such as English as a second language (ESL), older persons and co-morbidities. Management of patient medication risk, hospital avoidance, reduced length of stay and multidisciplinary teaching value should guide implementation of services in line with the CSCF.

## Service Infrastructure

Health services require information and communication technology software and equipment to facilitate the safe, legal and efficient delivery of medication services. Available equipment, depending on the level of service and information technology infrastructure, *may* include:

- > sufficient numbers of computers with reliable wireless internet connections
- > appropriate telecommunications equipment, if telehealth is part of a facility's service delivery strategy
- > wireless local area network, and requisite mobile devices and equipment to streamline work processes and day-to-day workflow.

Automation can also assist a facility in the safe, legal and efficient provision of medication services. Automation, depending on the level of service, may include:

- > automated dispensing devices
- > prepacking machinery
- > syringe loading machinery
- > smart infusion pump devices.

Security appropriate to the level of service may include:

- > CCTV
- > Restriction of access
- > Electronic access with associated recording of access
- > Duress alarms

## Service Networks

In addition to service network requirements outlined in the Fundamentals of the Framework, specific service network requirements include:

- > for some sites—access to remote pharmaceutical review (or telepharmacy) and medication services oversight, which are conducted by a pharmacist at a larger hospital and supported by nursing staff at a smaller site:
- > Levels 1 and 2 medication services primarily receive telepharmacy
- > Levels 3, 4, 5 and 6 medication services sites may provide telepharmacy to smaller sites where there is no on-site pharmacist
- > Levels 3 and 4 medication services may receive telepharmacy if a more complex patient presents and needs input from a senior pharmacist.

# Service Requirements

In addition to service requirements outlined in the Fundamentals of the Framework, specific service requirements include:

- > legislation requirements relating to extemporaneous and sterile (aseptic) dispensing and dispensing of antineoplastic drugs (i.e. service providers must comply with current regulatory requirements applying to their service level)
- > services preparing, compounding, manufacturing and repackaging medications (e.g. into dose administration aids or unit-of-use packs) follow guidelines and requirements of the Code of Good Manufacturing Practice, Pharmacy Board and relevant standards of the Pharmaceutical Society of Australia and Society of Hospital Pharmacists of Australia, and aspire to comply with the Therapeutic Goods Administration's relevant Australian standards, including AS1386:1989 Clean Rooms and Clean Workstations
- > access to appropriate facilities for cytotoxic reconstitution either on-site (if the health facility aspires to comply with AS4273, AS2567, AS2639 and AS/NZ ISO14644 and has appropriately trained staff) or access to an off-site provider (Therapeutic Goods Administration's Good Manufacturing Practice registered provider) for cancer-related medication services supporting clinical oncology and haematology services for supply of reconstituted cytotoxic products, and the service must comply with Safe Handling: Cytotoxic Drugs and Waste, SA Health.
- > use of guidelines and requirements of the Society of Hospital Pharmacists of Australia's relevant standards and Clinical Oncology Society of Australia's Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy
- > current editions of reference materials recommended by the Pharmacy Board of Australia be made available at every dispensary
- > occupational health and safety requirements, which services must consider in workplace design, equipment and procedures, particularly in relation to chemical management, manual handling and biological risks (e.g. sharps) while also complying with relevant legislation and standards
- > provide relevant clinical indicator data to satisfy accreditation and other statutory reporting obligations.
- > compliance with SA Health policy directives and guidelines that are referenced at:
  - <u>SA Health Policy Directives</u>
  - SA Health Policy Guidelines
  - SA Health Clinical Directives and Guidelines

# Workforce Requirements

The CSCF does not prescribe staffing ratios, absolute skill mix, or clerical and/or administration workforce requirements for a team providing a service, as these are best determined locally and in accordance with relevant industrial instruments. Where minimum standards, guidelines or benchmarks are available, the requirements outlined in this module should be considered as a guide only. All staffing requirements should be read in conjunction with the *Health Care Act 2008*, Awards and relevant Enterprise Agreements including, but not limited to:

- > SA Health Salaried Medical Officers Enterprise Agreement 2013
- > SA Health Visiting Medical Specialists Enterprise Agreement 2012
- > SA Health Clinical Academics Enterprise Agreement 2014
- > Nursing/Midwifery (South Australian Public Sector) Enterprise Agreement 2013
- > SA Ambulance Service Enterprise Agreement 2011
- > SA Public Sector Wages Parity Enterprise Agreement Salaried 2014

In addition to workforce requirements outlined in the Fundamentals of the Framework, specific workforce requirements include:

- > at all service levels staff must hold qualifications and any registration with professional bodies allowing them to provide these services under relevant statutory regulations
- > staff must be qualified and assessed as competent to deliver required services
- > staff must be qualified and assessed as competent in statutory requirements regarding the issue and storage management for the safe and quality use of medicines
- > processes must be in place to enable staff to establish and maintain their competencies or recency of practice in medication service provision; staff who dispense or supply medication must have competencies at least equal to those pharmacy support staff require—ideally a Certificate III or competence in relevant modules within the certificate qualification
- > sufficient staff and triage processes to provide timely services to patients based on medication risk and potential for harm, and adequate supervisory processes if pharmacy support staff have expanded roles
- > emerging pharmacist roles relating to other parts of the medication management cycle should be evaluated and, where beneficial, incorporated into a documented clinical governance process for inclusion in the medication services framework
- > where sites have access to robotics and automation to facilitate medication distribution and dispensing, staff using such technologies should be trained in optimal use of this equipment and software applications.

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service description	<ul> <li>provides services to ambulatory populations with low medication risk.</li> <li>not limited to rural and remote areas, and may include services provided in other community health centres.</li> </ul>	<ul> <li>provides limited ambulatory and inpatient clinical pharmacy service, and complies with relevant statutory regulations regarding provision and quality use of medications.</li> <li>able to provide medication service to adult and children with low medication risk.</li> <li>access to clinical pharmacy services and consultation from a contracted provider or Level 3 (or higher) service for patients with medication risk.</li> </ul>	<ul> <li>provides clinical pharmacy and distribution services on weekdays through on-site pharmacy or contracted service, and includes out-of-hours medication mechanism and access to pharmacist for emergency advice 24 hour/s.</li> <li>provides medication service to patients with medication risk.</li> <li>predominantly provided to inpatients and outreach services but may include limited hours of service to dispense medication to ambulatory patients.</li> </ul>	<ul> <li>provides clinical pharmacy and distribution services across 7 days through on- site pharmacy.</li> <li>provides on-site medication service to patients with medication risk (such patients likely to have complex and competing therapeutic needs, and multiple comorbidities that must be considered when optimising therapy).</li> <li>predominantly provided to inpatients and also to step down services.</li> <li>may host statewide medication information service.</li> </ul>	<ul> <li>provides services to patients up to very high medication risk level.</li> <li>capacity to act as referral service for very high-risk patients except those who need statewide senior clinical services, such as transplant, or most complex patients.</li> <li>provides clinical pharmacy and distribution services across 7 days and extended hours.</li> </ul>	<ul> <li>provides services for patients with highest level of medication risk.</li> <li>acts as referral service for all lower level services across the state, accepting referrals, including interstate, where applicable.</li> <li>clinical pharmacist dedicated to clinical unit is a senior practitioner with expertise in clinical area.</li> <li>accessed as statewide, organisational or institutional resource, and may be recognised at state and national level as providing highest level of service.</li> <li>provides clinical and distribution services across 7 days and 24 hours.</li> </ul>

Pharmacy Services Level 1	Level	2	Level 3	Level 4	Level 5	Level 6
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a         ctor if their needs       - a         tt opharmacist       - a         ttor if their needs       - a         aution regord       - a         aution regord       - a         aution reginand       - a         e and include       -	r Level 1, plus: dication services luding: independent medication reviews by pharmacist in collaboration with multidisciplinary team to identify and evaluate potential risks, and treating clinician to take action, wherever necessary access to regular pharmacist medication review for long-stay patients (not restricted to but including State aged care patients e.g. where facility has designated beds for nursing-home- type care) when there are changes to medications or to expected outcomes access to pharmacist review for patients triaged as having medication risk multidisciplinary process for transfer of verified medication information to healthcare provider/s continuing a patient's care on discharge (e.g. provision of discharge medication record to patient's nominated registered health practitioner/s). ensuring medication orders are legible and safe, including drug, form, route, dose and frequency	<ul> <li>As per Level 2, plus:</li> <li>medication services include: <ul> <li>independent medication review by pharmacist, including assessing medication therapy in line with current best available evidence</li> <li>identifying and investigating actual or potential drug-related problems, including drug-patient, drug-drug, drug-food or drug-disease problems</li> <li>determining and following course of action to resolve problems or minimise patient's medication risks</li> <li>engaging with the patient to determine an agreed medication action plan</li> <li>education for patients and their families about medication training), as required, to support patient care programs of other clinical services the facility provides.</li> </ul> </li> </ul>	<ul> <li>As per Level 3, plus:</li> <li>medication services including: <ul> <li>timely medication reconciliation for inpatients targeting points of entry into acute care system (e.g. via emergency department)</li> <li>proactive input into multidisciplinary team, such as influencing therapeutic decision- making in ward rounds or team meetings to effect changes to patient care</li> <li>medications and clinical services for inpatients, day patients and, where applicable, ambulatory patients in specialty clinics</li> </ul> </li> <li>Quality Use of Medicines Program, which includes: <ul> <li>development of local medication policy</li> <li>pharmacist participation in decisions made by LHN drugs and therapeutics committee, or equivalent, and where applicable, statewide networks</li> <li>ongoing drug utilisation evaluation program</li> </ul> </li> </ul>	<ul> <li>As per Level 4, plus:</li> <li>medication services include: <ul> <li>extended-hours service across 7 days with pharmacist accessible 24 hour/s</li> <li>teams of pharmacists or contracted pharmacists, including senior-level pharmacy practitioners, employed full time or located on-site and providing services under documented process</li> <li>dedicated clinical service may be provided to specific clinical service areas, particularly emergency department, perioperative services, rapid assessment medical units and chronic disease clinics (e.g. heart failure clinic).</li> </ul> </li> <li>basic, non-sterile, extemporaneous compounding possibly with batch manufacturing, and sterile, individually compounded products (e.g. chemotherapy including parenteral, targeted and oral chemotherapy) if use of these products falls within scope of practice of pharmacist or trained support staff providing supporting medication services.</li> <li>capacity to respond to requests for medicines information related to direct patient care in timely manner, either through medication service or service provided internally.</li> <li>On-site manufacturing facilities designed and maintained as per national standards</li> </ul>	As per Level 5, plus: > development of local medication management-related guidelines as part of its participation on local drugs and therapeutics committee with staff from Level 6 service participating in guideline development processes for statewide, organisational, institutional and/or national guidelines.

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service requirements	<ul> <li>providing basic medicines information to patients verbally and in writing (including information on how to take medicines, common side effects, and storage at home) within scope of practice of staff providing medication service, and staff access to pharmacist able to provide higher level services or specialist medicines information service if patients require more complex medicines information</li> <li>managing medication inventory (e.g. ordering, and rotating and controlling stock) which is supported by pharmacist oversight</li> <li>safely ordering with oversight from a contracted or Level 3 (or higher) Pharmacy service.</li> <li>distributing and storing medications in facility in accordance with legislative and non- legislative requirements, and relevant state drug policies and formulary.</li> </ul>	<ul> <li>medications for inpatients (supplied on basis of legal and safe written order) may be sourced from either regional hospital or by direct delivery via community pharmacy (where service agreements allow) or, alternatively, patients may use their own medications during admission where there are safe storage arrangements and processes in place for the use of these medications and their return to patients on discharge.</li> <li>medications for inpatients supplied using the SA Health statewide pharmaceutical contract where possible.</li> <li>medications for ambulatory and inpatients on discharge supplied on individual prescription from either community pharmacy, registered health practitioner, hospital or higher level service with documented processes in place for provision of medications requiring compounding.</li> <li>access to basic, non- sterile extemporaneous compounding through state-wide model if service is publicly provided.</li> </ul>	<ul> <li>monitoring treatment efficacy and patient response to therapy, including biochemistry, microbiological culture and sensitivities, and therapeutic drug monitoring, prioritising higher risk patients or patients taking higher risk drugs</li> <li>liaison with community health providers (e.g. medical practitioner [general practitioner] or community pharmacist) about medications, including transferring verified medication information (i.e. provision of discharge medication record).</li> <li>medication safety strategies that should include training and mechanisms to ensure competency of staff from all disciplines involved in medication management.</li> <li>service provided by on- site pharmacy (publically provided or contracted) with iPharmacy and PBS Reforms implementation and staffing in accordance with SHPA recommendations and as appropriate for patient acuity and LOS.</li> </ul>	<ul> <li>after-hours, on-call service for medication supply and clinical services, including medicines information 24 hour/s.</li> <li>services provided to inpatients, step down services such as Transition Care and Hospital in the Home and may be provided to ambulatory patients as part of specialty clinics (e.g. cardiac or pre-admission clinics, community mental health clinics—where they may operate in facility) and may have limited dispensing for ambulatory patients (for private facilities, where permitted by licence for pharmacy for the service)</li> <li>provision of medicines information to general or junior-level health professionals and senior / consultant—level medical staff, within scope of practice of pharmacist accessing and interpreting medicines information, as well as staff access to pharmacist at higher level services or medicines information service if access to information resources beyond those available at facility required or where answers to more complex medicines information questions required.</li> </ul>	<ul> <li>where other clinical services sponsor or participate in clinical medication trials, service has ability to provide management and support for medication clinical trials in terms of medication provision, trial documentation, quality assurance and operational advice (this service may also be provided for trials sponsored by pharmaceutical companies).</li> <li>service may actively participate undertake or participate in multidisciplinary research activities to contribute to evidence base for optimal medication management in addition to clinical trial management services and may involve local project development and implementation or participation in practice improvement initiatives or research projects sponsored by central organisations or external collaborators such as universities.</li> <li>where facility is training site for medical and nursing professions, service actively contributes to teaching programs sponsored by other clinical services and in collaboration with higher education providers.</li> </ul>	

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service requirements	<ul> <li>medications supplied on individual prescription from community pharmacy, primary health care clinic or higher level service.</li> <li>documented processes in place for providing medications requiring reconstituting.</li> <li>service operates within defined drug policy and guideline framework— which covers, for example, practices, charges for medications supplied after hours, use of patients' own medications, and drug usage or ordering— developed by higher level service or central organisation.</li> <li>where there is no pharmacist employed, on-site medication service oversight provided by pharmacist located elsewhere from a Level 3 (or higher) service (e.g. via telehealth) or through a documented process with community pharmacist or contracted service provider.</li> <li>links to other relevant services to support patients taking medications (e.g. Aboriginal and Torres Strait Islander medical services or community nursing services).</li> </ul>	<ul> <li>access to sterile, individual patient compounding including cytotoxic / chemotherapy and other medications sourced commercially from a registered TGA manufacturer or from a higher level of manufacturing facility.</li> <li>documented multidisciplinary processes for overseeing and monitoring drug utilisation, medication service provision and medication safety (e.g. drugs and therapeutics committee or equivalent) with local monitoring, including reporting on key performance indicators developed in collaboration with higher level service or central organisation, and having higher level service provide oversight and governance where these links exist.</li> <li>Periodic/regular visits (as appropriate for activity but at least monthly) from a contracted pharmacist, or pharmacist from a Level 3 Pharmacy Service (or higher) (may be via outreach pharmacy or telepharmacy or telepharmacy services) who oversees medication services, particularly to inpatients, which may involve documented process with community pharmacist.</li> </ul>	<ul> <li>medication distributed and stored by facility and, as required, to any lower level service that is safe, meets legislative requirements and assures quality of medicinal products (e.g. maintains cold chain).</li> <li>pharmacist accessible during designated business hours with documented processes in place to access medications and clinical services outside these hours (after-hours service may be provided by higher level service under documented process).</li> <li>access to relief / locum pharmacist services, as required.</li> <li>access to other multidisciplinary health professionals, as required.</li> <li>provision of medicines information to general or junior-level health professionals within scope of practice of pharmacist accessing and interpreting medicines information and, should access to information resources beyond those available at facility be required or where more complex medicines information questions need answering, staff have access to pharmacist able to provide higher level service or specialist medicines information.</li> </ul>	<ul> <li>may provide basic, non-sterile batch and extemporaneous compounding for distribution through state- wide model.</li> <li>access to sterile, individually compounded products including cytotoxic / chemotherapy and medications. If manufacture of these cytotoxic and chemotherapy is within scope of practice of pharmacist or trained support staff it may occur, providing:         <ul> <li>appropriately maintained facilities and equipment available</li> <li>staff undergo competency assessment in relevant practices</li> <li>documented processes in place for providing medications requiring more compounding or preparation.</li> </ul> </li> <li>may provide support for clinical trial medication distribution as part of limited clinical trial management service where other clinical services sponsor or participate in clinical medication trials.</li> </ul>		

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service requirements	<ul> <li>access in dispensary (either on-site or located off-site where services provided under service agreement) to computer hardware and software needed to meet statutory requirements for recording and dispensing medications and to support medication inventory management.</li> <li>access to communication technologies including:         <ul> <li>telehealth facilities where identified as means of providing medication services and oversight</li> <li>reliable internet connection with sufficient capacity to enable access to higher level medication information and support information systems.</li> </ul> </li> <li>access to print and online reference material, and published guidelines for medication management and medication information services.</li> <li>access to suitable medication distribution for supply of medications to maintain requisite medication inventory.</li> <li>medications may be sourced from regional hospital pharmacy or by direct delivery from contracted pharmacy.</li> </ul>	<ul> <li>Periodic visits from a pharmacy assistant to provide stock management services with professional oversight from a pharmacist.</li> <li>access to more specialised pharmacist support from higher level facility or central organisation (e.g. medication administration advice or specialty medicines information services).</li> <li>established documented processes and referral mechanisms for access to pharmacist support, and outreach or telehealth service from higher level service or community pharmacist.</li> <li>services may be provided predominantly by registered nurses or other health workers as authorised under legislation.</li> </ul>	<ul> <li>&gt; timely access to clinical information, including medical records and pathology results.</li> <li>&gt; timely access to print or online references recommended by Pharmacy Board of Australia, to published guidelines for medication management</li> <li>&gt; reliable access to dedicated desktop and/or laptop computer in ward / clinical area, or equivalent (e.g. electronic tablet), if wireless technology available.</li> <li>&gt; access to financial and/ or administrative support, as required (e.g. for drug claims and billing, if required by service).</li> <li>&gt; appropriate facilities, if non-sterile compounding undertaken by service.</li> <li>&gt; may have regional responsibilities across defined area, providing support and medication service oversight to lower level services through intermittent visits, via outreach pharmacy or telepharmacy services, or other means.</li> <li>&gt; may be recipient of telepharmacy services if more complex patients require input from specialist pharmacist or higher level service.</li> </ul>	<ul> <li>May provide statewide medicines information service, that:         <ul> <li>is provided by pharmacists trained in information retrieval and interpretation</li> <li>has broad resource base</li> <li>has dedicated work space</li> <li>has defined processes for referral and response, and quality assurance system</li> <li>supports operation of LHN &amp; state-level drugs and therapeutics committee and drug utilisation evaluation program by retrieving, critically appraising and summarising available best evidence, and by helping to develop local medication management-related guidelines.</li> </ul> </li> <li>timely access to print or online references for specialised medicines information resources reflecting nature and complexity of medicines information needs).</li> </ul>		

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service requirements	<ul> <li>&gt; service may be provided by pharmacist, nurse practitioner, authorised Aboriginal and Torres Strait Islander health worker or other health worker as authorised under regulation.</li> <li>&gt; ensuring medication management procedures are safe</li> <li>&gt; providing input and advice to Safety Learning System reports related to medications.</li> </ul>					
Workforce requirements	<ul> <li>As per module overview, plus: Medical</li> <li>may have access to medical practitioner for prescriptions.</li> <li>Nursing</li> <li>staffing levels in accordance with the relevant industrial instruments.</li> <li>access to registered nurse, nurse practitioner or other qualified nursing staff for facilities in rural and remote areas.</li> <li>Pharmacy</li> <li>outreach pharmacist either contracted or provided from a Level 3 (or higher) service for supervision and monitoring of services offered by facility.</li> </ul>	<ul> <li>As per Level 1, plus:</li> <li>&gt; where Level 2 service provided by higher level pharmacy service <ul> <li>medications may be supplied by higher level pharmacy</li> <li>pharmacy staff are involved in provision, supervision and monitoring of services provided</li> <li>pharmacy assistant visit on periodic basis</li> </ul> </li> <li>some Level 2 services outpatient medication supplies may be outsourced to community pharmacies or treating clinician with right of dispensing under documented process.</li> </ul>	<ul> <li>As per Level 2, plus:</li> <li>documented process in place with treating clinician for consultation if changes in patient's medication risk or presentation complexity beyond staff's scope of practice.</li> <li>Pharmacy</li> <li>services provided by on-site pharmacists supported by assistant staff, during business hours with documented processes for access to medications and pharmacy services after hours (i.e. higher level service may provide after-hours service under documented process).</li> </ul>	<ul> <li>As per Level 3, plus:</li> <li>Pharmacy</li> <li>sufficient number of employed pharmacists to provide services to patients, including timely action as per risk-based triage process.</li> <li>general or junior-level pharmacists mentored or clinically supervised by senior practitioner where applicable.</li> <li>process in place to enable pharmacists to establish and maintain their competencies in providing clinical and related medication services, including, where relevant, access to pharmacy clinical mentorship to support interns, new graduates and pharmacists.</li> </ul>	<ul> <li>As per Level 4, plus: Medical</li> <li>access to registered medical specialists, as required.</li> <li>Pharmacy</li> <li>pharmacists and support staff qualified and assessed as competent in providing services as part of competency process, including validation for any aseptic compounding processes.</li> <li>team of on-site pharmacists, including senior practitioners and pharmacists experienced in and aligned with clinical specialist services.</li> </ul>	As per Level 5, plus: Pharmacy > provided by team of: - pharmacists in training - junior- or general- level pharmacists - senior pharmacists in training - senior pharmacists with advanced knowledge and skills in specific Level 6 specialty area - pharmacists aligned with clinical specialist services, and supported by assistant staff including pharmacy assistants in training.

Pharmacy Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Workforce requirements	<ul> <li>access to (contracted or SA Health) pharmacist through documented processes.</li> <li>where services are provided by contracted or private service provider, service expectations are explicitly outlined in documented processes between facility and contracted/private service provider.</li> </ul>	<ul> <li>Pharmacy</li> <li>registered pharmacist to provide clinical services and oversee medication services.</li> <li>where service provided by community pharmacy or other third party provider, contracted provider is responsible for competency assessment and training of staff providing service under documented process.</li> </ul>	<ul> <li>pharmacists competent in statutory requirements regarding issuing and storing medications, drugs and poisons and, if required by service, non-sterile compounding.</li> <li>access to senior pharmacists.</li> <li>pharmacists with training and competency in less frequently used skills, such as basic extemporaneous compounding.</li> <li>Other</li> <li>pharmacy support staff accessible to ensure pharmacist best utilised to provide clinical service.</li> <li>sufficient trained pharmacy support staff accessible to perform support tasks, such as assisting with dispensing and medication distribution.</li> </ul>		<ul> <li>sufficient number of employed pharmacists to provide services to patients, including timely action as per risk-based triage process, and to cover services provided to clinics and emergency department at peak times (if service provided), including pharmacist leave cover and, if provided, outreach or remote pharmaceutical review services.</li> <li>where pharmacists provide medication services beyond facility, management should ensure access to sufficient pharmacist and support staff resources to cover expanded service while maintaining timely access to clinical and related services within facility(including availability of pharmacist/s for provision of remote pharmaceutical review (telepharmacy) or consultation from lower level services, if required).</li> </ul>	Senior pharmacists who form part of statewide network, and may be accessed as resource for statewide and, where relevant, interstate consultation if service is part of documented referral process (optional).
Specific risk considerations	Nil	Nil	<ul> <li>In addition to risk management outlined in the <i>Fundamentals</i> of the Framework, specific risk management requirements include:</li> <li>&gt; where service provided under documented process with community pharmacy or other private service provider, pharmacy or service provider, demonstrates compliance with recognised quality standards.</li> </ul>	As per Level 3, plus: > quality assurance program for validating and monitoring compounding processes <sup>8</sup> where provided.	Nil	

#### Legislation, regulations and legislative standards

In addition to what is outlined in the Fundamentals of the

<u>Framework</u>, medication services must comply with the following, and where a pharmacist provides medication services, there are further competencies and professional and clinical standards to which adherence is required. In the case where other clinicians (e.g. medical, nursing including Nurse Practitioners, paramedic or authorised Aboriginal and Torres Strait Islander Health Workers) provide medication services, their scope of practice must include competency in providing medication services to a standard ensuring consistent and safe medication management for the patient, in line with related pharmacist competencies.

These include but are not limited to:

- > Australian Government. National Health (Pharmaceutical Benefits) Regulations 1960. <u>www.comlaw.gov.au/series/F1996B02844</u>
- > Australian Standards including:
  - AS 1386-1989 (Clean rooms and clean workstations)
- AS4273-1999/Amdt 1-2000 (Design, installation and use of pharmaceutical isolators)
- AS2567-2000 (Laminar flow cytotoxic drug safety cabinets)
- AS2639-1994 (Laminar flow cytotoxic drug safety cabinets— Installation and use)
- AS/NZ ISO 14644.4:2002 (Clean rooms and associated controlled environments Design, construction and start-up).
- > South Australian Government. Controlled Substances (Poisons) Regulations 2011
- > South Australian Government. Medication Safety Standard 4, version 2. www.sahealth.sa.gov.au
- > South Australian Government. Safe Handling Cytotoxic Drugs and Waste. www.sahealth.sa.gov.au
- > The Standard for the Uniform Scheduling of Medicines and Poisons (SUSDP) published by the Commonwealth. <u>www.tga.gov.au/industry/schedulingpoisons-standard.htm#.Uwbj6FP6STA</u>
- > Workplace Health and Safety Regulation 2008, in particular, Part 16 Hazardous Substances, Division 3. Suppliers concerning Material Safety Data Sheets.

Non-mandatory standards, guidelines, benchmarks, policies and frameworks (not exhaustive & hyperlinks current at date of release of CSCF)

In addition to what is outlined in the Fundamentals of the Framework, plus:

- > Australian Government. National Medicines Policy. Canberra: Department of Health and Ageing; 2000. www.health.gov.au/
- > Australian Government. Department of Health and Ageing. Pharmaceutical Benefits Schedule. www.pbs.gov.au/pbs/home
- > Australian Pharmaceutical Advisory Council (APAC) guiding principles and guidelines
- > Clinical Oncological Society of Australia. Guidelines for the safe prescribing, dispensing and administration of cancer chemotherapy. COSA; 2008. www.cosa.org.au/publications/guidelines.aspx
- > Code of Good Manufacturing Practice (current edition).
- > Pharmaceutical Society of Australia (PSA) standards and guidelines.
- > PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments Pe010 2008.
- > The Pharmacy Guild of Australia. The Quality Care Pharmacy Program Standards (for Community Pharmacies). <u>www.qcpp.com</u>
- > The Pharmacy Board of Australia codes and guidelines. www.pharmacyboard.gov.au/Codes-Guidelines.aspx
- > The Society of Hospital Pharmacists of Australia (SHPA) Practice Standards and Guidelines (current editions). <u>http://www.shpa.org.au/Practice-Standards</u>
- > Various programs for the provision of training and competency assessment in medication services being delivered and in statutory requirements regarding the issue and storage of medicines.
- > Various processes for ensuring:
  - oversight and monitoring of drug utilisation, medication service provision and medication safety including reporting on key performance indicators that are developed in collaboration with a higher level service or central organisation
  - all required Material Safety Data Sheets are available and current (e.g. access to software such as Chem. Alert: extemporaneous products sourced from external providers are compounded according to Code of Good Manufacturing Practice Principles
  - processes to access quality assurance programs for validating and monitoring aseptic compounding
  - where service support is provided via a service level agreement with a community pharmacist, the pharmacist and pharmacy demonstrate compliance with relevant quality standards.
- > access to clinical governance (eg SAMAC and associated committees) to address medication safety and quality issues (e.g. reporting and action mechanism for adverse events and near misses).

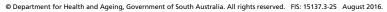
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- 2. Australian Pharmaceutical Advisory Council. Guiding Principles to Achieve Continuity in Medication Management. Guiding principle 5. APAC: 2005.
- 3. Australian Commission on Safety and Quality in Health Care (ACSQHC) (September 2011), National Safety and Quality Health Service Standards, ACSQHC, Sydney. http://www.safetyandguality.gov.au/our-work/medication-safety/
- 4. Stowasser DA, Allinson YM, O'Leary K Understanding the Medicines Management Pathway. J Pharm Pract Res 2004; 34(4):293–6.
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- 8. Australian Government. National Medicines Policy. Canberra: Department of Health and Ageing; 2000. www.health.gov.au/
- 9. Beaney AM. (ed). On behalf of NHS Quality Control Committee. Quality Assurance of Aseptic Preparation Services, 4th Edition. London: Pharmaceutical Press; 2006.

# For more information

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