

## Medication Handling in NSW Public Health Facilities

**Summary** Consolidates best practice principles on medication procurement, storage, prescribing, supplying, dispensing and administration at NSW public health facilities with the requirements of the NSW Poisons and Therapeutic Goods Act 1966 and the Poisons and Therapeutic Goods Regulation 2008, NSW Health policies and NSW Health directives relevant to medication handling. This policy also replaces IB2012\_009, IB2012\_008 and IB2010\_009

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**Applies to** Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Public Health Units, Public Hospitals, NSW Health Pathology, Cancer Institute

**Distributed to** Public Health System, Divisions of General Practice, Government Medical Officers, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Tertiary Education Institutes

**Audience** All clinical and allied health staff

### Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.

## MEDICATION HANDLING IN NSW PUBLIC HEALTH FACILITIES

### PURPOSE

This policy consolidates best practice principles on medication procurement, possession, storage, prescribing, dispensing, supplying, administering and recording at NSW public health facilities with the requirements of the NSW *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2008*, NSW Health policies and NSW Health directives relevant to medication handling.

The policy applies to all Public Health Organisation health facilities including hospitals, institutions, clinical services, outpatient clinics, community health centres, day centres and domiciliary services within the NSW Health system's jurisdiction, including where a public health service is contracted to a non-government organisation.

The policy can be used as the basis for individual public health facilities to develop detailed protocols and procedures specific to the local situation and circumstances, including a service contracted to a non-government organisation.

### MANDATORY REQUIREMENTS

By 1 March 2014, all public health facilities including hospitals, institutions, clinical services, outpatient clinics, community health centres and day centres at Public Health Organisations must implement this policy.

### IMPLEMENTATION

#### ROLES AND RESPONSIBILITIES

##### **NSW Ministry of Health:**

- Provide the mandatory requirements and standards to support implementation of the policy
- Evaluate implementation of the policy by Public Health Organisations.

##### **Clinical Excellence Commission:**

- Support implementation of the policy where applicable to medication safety.

##### **Chief Executives, Health Service Executives, Managers:**

- Assign responsibility, personnel and resources to implement the policy
- Provide line managers with support to implement the policy in their areas
- Ensure that local policies, protocols and procedures are in place at each facility to support implementation of the policy
- Report compliance with the policy to NSW Ministry of Health by 1 May 2014.

### **Drug and Therapeutics Committees:**

- Develop, approve and oversee the implementation of local policies, protocols and procedures where required
- Provide local oversight of the safe implementation of this policy.

### **Directors of Clinical Governance:**

- With other Executive members, ensure successful implementation of the policy within each Public Health Organisation.

## **REVISION HISTORY**

<b>Version</b>	<b>Approved by</b>	<b>Amendment notes</b>
November PD2013_043	Director General	New policy to consolidate and update PD2007_077 'Medication Handling in NSW Public Hospitals' and Section 3 of PD2005_105 'Medication Handling in Community-Based Health Services/Residential Facilities in NSW - Guidelines' which are now obsolete.

## **ATTACHMENT**

1. Medication Handling in NSW Public Health Facilities: Procedures

## Medication Handling in NSW Public Health Facilities



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**Issue date:** November-2013

PD2013\_043

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### 1 BACKGROUND

This policy consolidates best practice principles on medication procurement, storage, prescribing, supplying, dispensing and administration at NSW public health facilities with the requirements of the NSW *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2008*, NSW Health policies and NSW Health directives relevant to medication handling.

Best practice principles are adopted from recognised standards, such as those published by the Australian Commission on Safety and Quality in Health Care and the Commonwealth Department of Health.

The policy applies to all Public Health Organisation health facilities including hospitals, institutions, clinical services, outpatient clinics, community health centres, day centres and domiciliary services within the NSW Health system's jurisdiction (including where a public health service is contracted to a non-government organisation), defined as: -

- A. For each **Local Health District**; the respective public hospitals, public health institutions, public health services, and public health support services controlled by the Local Health District, as specified in Schedule 1 of the [Health Services Act 1997](#).
- B. For a **Statutory Health Corporation**; to the public hospitals health institutions, health services and health support services conducted by the Statutory Health Corporation, as specified in Schedule 2 of the [Health Services Act 1997](#), including facilities at which Justice Health & Forensic Mental Health Network provides health services.
- C. For an **Affiliated Health Organisation**; the respective hospitals, health institutions, health services and health support services controlled by the Affiliated Health Organisation, as specified in Schedule 3 of the [Health Services Act 1997](#).

The policy supersedes the content of: -

- a) NSW Health Policy Directive PD2007\_077 '*Medication Handling in NSW Public Hospitals*', and
- b) Section 3 of NSW Health Policy Directive PD 2005\_105 '*Medication Handling in Community-Based Health Services/Residential Facilities in NSW – Guidelines*' in relation to public community health centres and public day centres.

The policy can be used as the basis for individual public health facilities to develop detailed protocols and procedures specific to the local situation and circumstances, including where particular services are contracted to a non-government organisation.

The policy does not apply to medication handling and administration by paramedics and flight nurses employed by NSW Ambulance, which is instead mandated in a separate Medications Management Standard Operating Policy endorsed by the service's Chief Executive.

## 2 KEY DEFINITIONS

must	Indicates a mandatory action requiring compliance by staff at public health facilities, in accordance with a legislative requirement and/or a NSW Health policy or directive.
should	Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.
accountable medication	All Schedule 8 medications and or Schedule 4 Appendix D medications, as well as any non-Appendix D Schedule 4 medication directed by the chief executive (or delegate) of the facility to be accounted for in a register.
authorised person	A staff member authorised under protocols approved by the Drug and Therapeutics Committee to conduct a particular task at a facility in accordance with endorsements, notations and conditions on the person's registration as a health practitioner (where applicable) and the person's confirmed competence to complete the task.
authorised prescriber	<p>A person approved by the facility to prescribe medications, but only in accordance with any practice conditions imposed by the person's place of employment and the endorsements, notations and conditions on the person's health practitioner registration, as:</p> <ul style="list-style-type: none"> <li>• A <b>medical practitioner</b> registered by the Medical Board of Australia.</li> <li>• A <b>dentist</b> registered by the Dental Board of Australia as a dental practitioner.</li> <li>• A nurse registered by the Nursing and Midwifery Board of Australia with endorsement as a <b>nurse practitioner</b>, and also authorised under section 17A of the <i>Poisons and Therapeutic Goods Act 1966</i> by the Director General of Health (or delegate).</li> <li>• A midwife registered by the Nursing and Midwifery Board of Australia with endorsement as a <b>midwife practitioner</b>, and also authorised under section 17A of the <i>Poisons and Therapeutic Goods Act 1966</i> by the Director General of Health (or delegate).</li> <li>• An <b>optometrist</b> registered by the Optometry Board of Australia with endorsement to prescribe or supply a limited range of Scheduled medications.</li> <li>• A <b>podiatrist</b> registered by the Podiatry Board of Australia with endorsement to prescribe or supply a limited range of Scheduled medications.</li> </ul> <p>(Note: For the purpose of this Policy Standard, 'authorised prescriber' does not relate to a medical practitioner approved under the Commonwealth Therapeutic Goods Act 1989 to prescribe a Special Access Scheme medication nor to prescribe Pharmaceutical Benefits Scheme medications under the National Health Act 1953).</p>
facility, health facility	For the purpose of this Policy Standard, any hospital, clinic, institution, health service, or health support service controlled by a Local Health District, Statutory Health Corporation or Affiliated Health Organisation, as specified in Schedules 1 to 3 of the <a href="#">Health Services Act 1997</a> .

hospital, public hospital	For the purpose of this Policy Standard, a hospital designated as such by a Local Health District, a Statutory Health Corporation or an Affiliated Health Organisation.
medication	Used singularly throughout the Policy Standard to describe a drug, medicine, pharmaceutical preparation (including a compounded preparation), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing and a fluid for intravenous use. Includes Scheduled medication and unscheduled medication.
medication recalls coordinator	The person assigned by the health facility who is responsible for coordinating the prompt removal of medications which are the subject of a recall, and for keeping staff informed of current medication recalls as well as medication problem alerts.
patient care area	Any area, clinic or unit in a hospital, health facility, health institution, health centre, health service or health support service where patient treatment or care may be carried out. Includes a hospital ward, operating theatre, specialised treatment unit (for example haemodialysis, oncology, radiology, dental), day surgery unit, community health centre, domiciliary service, day centre, and facilities at which Justice Health & Forensic Mental Health Network provides health services.
Pharmacy Service	A service administered by a director of pharmacy which is responsible for the procurement, distribution, preparation and dispensing of medications as well as the delivery of clinical and other services as defined by the Society of Hospital Pharmacists of Australia. Includes a principal medication supply service (that is also not part of a patient care area) at a facility where no registered pharmacist is employed or contracted for whom the responsibility of the distribution of medications is assigned to the director of nursing or medical superintendent of the facility.
Scheduled medication	A medication containing a substance in the NSW Poisons List as; <b>Schedule 2</b> 'Pharmacy Medicine' (pharmacy 'over the counter' medication), <b>Schedule 3</b> 'Pharmacist Only Medicine' (pharmacist controlled 'over the counter' medication), <b>Schedule 4</b> 'Prescription Only Medicine'(also known as a 'restricted substance'), or, <b>Schedule 8</b> 'Controlled Drug' (also known as a 'drug of addiction').
Schedule 4 Appendix D medications	The subset of Schedule 4 medications that are known to be liable to abuse or misuse, and as such require additional requirements for storage in patient care areas. The medications include benzodiazepines (except a Schedule 8 benzodiazepine), anabolic-androgenic steroids, ephedrine, phentermine, phenobarbitone, thiopentone, and amylobarbitone and pentobarbitone when packed and labelled for injection.
Schedule 4 Appendix B medications	The subset of Schedule 4 Appendix D medications which require additional requirements for the prescriptions (but not medication chart orders) to include an interval for repeat dispensing and to be retained separately at the Pharmacy Service (other than with prescriptions for Schedule 8 medications). The medications include anabolic-androgenic steroids, and amylobarbitone and pentobarbitone when packed and labelled for injection.

### 3 GOVERNANCE

#### 3.1 The NSW Poisons and Therapeutic Goods Legislation

*The Poisons and Therapeutic Goods Act 1966* (NSW) and the *Poisons and Therapeutic Goods Regulation 2008* (NSW) regulates the procurement, possession, storage, prescribing, dispensing, supplying, administering and recording of both Scheduled and non-Scheduled medications in New South Wales at health facilities, and by health professionals and pharmaceutical wholesalers.

This legislation is administered by [Pharmaceutical Services Unit](#), Legal and Regulatory Services Branch of the NSW Ministry of Health.

#### 3.2 The Drug and Therapeutics Committee

Standard 4 of the [National Safety and Quality Health Care Standards](#) details the mechanisms for health service organisations to provide for the safe prescribing, dispensing, supplying, administering, storing, manufacturing, compounding and monitoring the effects of medications. Standard 4.1 provides for the development and implementation of governance arrangements and organisational policies, procedures and/or protocols for medication safety which are consistent with national and jurisdictional legislative requirements, policies and guidelines.

All Local Health Districts, and Affiliated Health Services and Statutory Health Corporations that provide patient care must ensure that all individual public health facilities must have access to at least one Drug and Therapeutics Committee (however named) which is adequately resourced for its role and responsibilities in promoting the safe, quality and rational use of medications.

The Committee/s will report to the Chief Executive of the public health organisation via a senior executive officer, such as the Director of Clinical Governance, in accordance with local protocols. The Committee/s will also report three monthly to the facility's clinical quality committee (however named), again in accordance with local protocols.

The Chief Executive must ensure each Drug and Therapeutics Committee is established with appropriate terms of reference that include integrated governance systems to promote patient safety and quality medication use and clearly articulate organisational and individual accountabilities throughout the organisation, and also that the committee's effectiveness is monitored.

NSW Therapeutic Advisory Group will support Chief Executives and the work of the Drug and Therapeutics Committees by promoting guiding principles for the roles and responsibilities of Drug and Therapeutics Committees to achieve effective medication governance. The Clinical Excellence Commission through the NSW Therapeutic Advisory Group will monitor the activities of the Drug and Therapeutics Committees state wide.

Each Drug and Therapeutics Committee will be responsible for the governance of quality and safe medication procurement, storage, prescribing, supply, administration and recording protocols and procedures at the facilities assigned to the Committee.

The Committee will, among other duties, be responsible for determining the range, number and quantities of medications to be made available in the facility through the approval of formularies, monitor medication use, and provide guidance all health workers in the rational use of medications and the treatment guidelines that apply in the facility.

The Drug and Therapeutics Committee should be multidisciplinary and include persons with relevant expertise in the safe, rational, high quality and cost-effective use of medications. The Committee should include representation from the facility's executive and the pharmacy, medical and nursing disciplines.

Subcommittees with relevant expertise for specific projects or aspects of the quality use of medicines, such as antimicrobial stewardship, paediatrics, venous thromboembolism prophylaxis and electronic medication management systems may also be appointed to assist the work of the Drug and Therapeutics Committee.

The functions of the Drug and Therapeutics Committee (or subcommittee where appropriate) include, for each facility assigned to the Committee: -

- The development and approval of medication protocols and procedures that support the quality, safe and cost-effective use of medicines, including all aspects of medication management within the facility, aligned with relevant NSW Health policies and directives.
- Assisting in the implementation of NSW Health policies concerning medications and medication management, including that for high-risk medicines in accord with NSW Health Policy Directive [PD2012\\_003 'High-Risk Medicines Management'](#).
- Formulary management, that is the evaluation and approval of medications for use in the facility, in accordance with NSW Health Policy Directive [PD2008\\_037, 'Medicine - Evaluation of Medicines for Use in Public Hospitals'](#), including the 'off-label use' ('unapproved use') of medications.
- Oversight of compliance with medication safety standards at the facility.
- The collation and analysis of medication incident reports. Where appropriate, this function may be delegated to a sub-committee of the Drug and Therapeutics Committee.
- The development and implementation of strategies for medication error prevention in accordance with the standards detailed in NSW Health Policy Directive [PD2005\\_608 'Patient Safety and Quality Program'](#).
- The design and approval of all specialty medication charts for use at the facility.
- The approval and review of standing orders for medication administration at the facility.
- The approval and review of nurse-initiated medications at the facility.
- The approval and oversight of the facility's electronic medication management system and other relevant technologies.

- Effectively communicating and monitoring all the Drug and Therapeutic Committee's decisions, protocols and procedures throughout the respective facility.

### 3.3 High-Risk Medications Management

All facilities must establish a high risk medications program, with systems for the management of the respective medications' storage and handling in accordance with NSW Health Policy Directive [PD2012\\_003 'High-Risk Medicines Management'](#).

The medications include (but are not limited to) the **APINCH** High-risk Medicine Groups: -

- Anti-infective agents, and
- Potassium and other electrolytes, and
- Insulin, and
- Narcotics (opioids) and other sedative agents, and
- Chemotherapeutic agents, and,
- Heparin and other anticoagulants.

Specific NSW Health Policy Standards are also included in [PD2012\\_003 'High-Risk Medicines Management'](#) for: -

- 'Vincristine Use', and
- 'Potassium Chloride Use', and
- 'Anticoagulation'.

Mandatory requirements in high-risk medications management are: -

- All facilities must maintain, as part of the program, a specific high-risk medications register, and
- All medications regarded as high-risk must be the subject of a local protocol, aligned with relevant NSW Health policy and prepared in consultation with relevant specialists and overseen by the Drug and Therapeutics Committee(s), and
- Each high-risk medicines protocol must include patient monitoring which is relevant and appropriate to therapy. This is to ensure a timely response to adverse events or side effects associated with the treatment, and
- All facilities should employ strategies to mitigate the risk of medications on the mandatory local high-risk medications register, and
- Adverse incidents involving high-risk medications should be reported in the facility's incident management system and regularly reviewed through quality management systems.

For a high-risk medication which is to be administered on a regular, but intermittent basis (for example, on one day per week), the Pharmacy Service must establish procedures to minimise the risk of dosing errors such as providing no more than one week's supply labelled for each individual patient.

Consideration should also be given for restricting high-risk medicines as imprest items only to patient care areas in which regular use is required.

### 3.4 Medication Safety Alerts, Recalls and Incident/Problem Reporting

#### 3.4.1 NSW Health Safety Alert Broadcasting System

NSW Health Policy Directive [PD2013\\_009 'Safety Alert Broadcast System Policy Directive'](#) details the NSW Health mechanism that provides a systematic approach to the distribution of patient safety information, including medication safety information.

The Safety Alert System includes three tiers of [Safety Alert Broadcast System Notifications](#), namely: -

- A Safety Alert.
- A Safety Notice.
- Safety Information.

Each safety alert broadcast notification specifies action to be taken by health facilities and services, the timeframe in which such action must occur, and the staff responsible for the action.

#### 3.4.2 Medication Recalls

A medication recall involves the removal of the medication from supply on the Australian market for reasons relating to the product's quality, safety or efficacy.

The medication recall process is administered by the Commonwealth Therapeutic Goods Administration (TGA) in co-operation with the particular product's sponsor (the Australian manufacturer or the distributor), as detailed in the Commonwealth's [Uniform Recall Procedure for Therapeutic Goods](#).

Medication recalls vary in the risk they pose to patient safety. A medication recall can occur because of a simple problem such as a minor labelling or packaging error, or a more serious problem such as an increase in unexpected side effects or adverse events. The TGA classifications for recalls are: -

**Class I** - When products are potentially life-threatening or could cause a serious risk to health.

**Class II** - When product defects could cause illness or mistreatment, but are not Class I.

**Class III** - When product defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

All facilities must respond effectively and promptly to any medication recall notification.

All facilities must establish internal procedures through the facility's executive to appoint a medication recalls coordinator who is responsible for: -

- Coordinating the prompt removal of medications which are the subject of a recall, and
- Keeping staff informed about medications subject to a recall, and
- Informing staff about medication problem alerts that require action other than the required removal of the medication from use, such as those alerts broadcast as NSW Health [Safety Alert Broadcast System Notifications](#) (see [section 3.4.1](#)).

Facilities may have a separate recalls coordinator for medical devices.

The medication recalls coordinator must ensure that medications which are the subject of a recall are removed from use in all locations in the facility (including 'hospital in the home' medications and medications brought into the facility by a patient) and the facility's medication recalls coordinator notified. Medications that have been transferred to another health facility must also not be overlooked, and that facility's medication recalls coordinator notified accordingly for appropriate action.

The medication recalls coordinator is responsible for notifying the NSW Ministry of Health Recalls Coordinator at [Pharmaceutical Services Unit](#) of any change to the email address assigned by the facility for the purpose of TGA medication recall notifications, and to provide for periods of absence, management of the appointment of a person to deputise as medications recalls coordinator.

### **System for Australian Recall Actions (SARA)**

The [System for Australian Recall Actions](#) (SARA) provides health care facilities, health care professionals, sponsors, wholesalers, retailers and consumers with access to information about recall actions occurring in Australia for therapeutic goods. The database is managed by the Therapeutic Goods Administration and holds information on recall actions that have been undertaken in Australia since 1 July 2012. (Note: The database includes recalls relating to therapeutic devices as well as medications).

### **Retention of Recall Records**

In accordance with NSW Policy Directive [PD2009\\_057 'Records Management'](#) and the [State Records Authority of NSW](#), records relating to the recall of medications are required to be retained at the facility for ten (10) years, and then are required to be stored as NSW State Archives. This includes policies for dealing with recall matters not related to individual issues, such as negotiation of jurisdiction and use of field staff, and recalls guidelines and procedure development.

### **3.4.3 Medication Incident Reporting**

As part of quality improvement programs in accordance with NSW Health Policy Directive [PD2005\\_608, 'Patient Safety and Clinical Quality Program'](#), facilities must have in place systems for medication incident reporting.

All staff must report incidents, including near-miss incidents, and probable adverse events associated with medication using the facility's incident management system detailed in Policy Directive [PD2007\\_061, 'Incident Management'](#). Where the incident

involves an individually patient-labelled medication obtained from the Pharmacy Service the detail of the incident should also be recorded in the patient's record in the Pharmacy Service computer dispensing system.

Staff should be made aware that the reason for collecting information on medication incidents is for the identification of system and process deficiencies that can be remedied. This is to ensure the highest standard of patient safety possible, further to a review of the incident by the Drug and Therapeutics Committee (or appropriate sub-committee) and appropriate action.

### Adverse Drug Reactions

Health professionals play an important role in monitoring the safety of medications by reporting any suspected adverse drug reactions (ADRs) to the [Therapeutic Goods Administration](#) (TGA). ADR reports contribute to the ongoing collection of information that occurs once health products are on the market.

Any suspected adverse drug reaction should be reported in accordance with any local reporting protocols and to the TGA using the '[Blue Card](#)' adverse reaction reporting form 'Report of Suspected Adverse Reaction to Medicines or Vaccines' either by post (pre-paid), facsimile, email or on-line.

#### 3.4.4 Medication Problem or Defect Reporting

All staff must be alert to the possibility of defects in the medications they handle, and must report any anomaly which may indicate a deficiency in the quality, safety or efficacy of the product to the facility's medication recalls coordinator.

Such problems could include incorrect or illegible product labelling, discolouration, cloudiness or incorrect tablets/capsules in a pack.

Any suspected or known problem or defect with a medication must be reported promptly in the facility's incident management system detailed in NSW Health Policy Directive [PD2007\\_061, 'Incident Management'](#) and also to the Commonwealth Therapeutic Goods Administration (TGA) since this may indicate a fault in a manufacturer's processes or be part of a wider problem and which may ultimately require a recall. The [TGA Medicine Problem Report Form](#) must be used for problem or defect reporting. Problems requiring urgent investigation must be reported immediately to the TGA by telephone on (02) 6232 8180.

Products which are suspected or known to be faulty must not be exchanged by a supplier or manufacturer without first establishing that the problem has been correctly reported to the TGA.

## 4 PRESCRIBING

### 4.1 Authorised Prescribers – General Limitations to Prescribing

The following staff are authorised to both issue a prescription for dispensing by a registered pharmacist, and order medication for administration on a medication chart, in accordance with any endorsements, notations and conditions included with the person's registration on the [Australian Health Practitioner Registration Agency](#) website as well as any condition on the person's employment at the facility: -.

**Medical Practitioner**, other than a Provisionally Registered Medical Practitioner (medical intern).

**Provisionally Registered Medical Practitioner ('Medical Intern')**, only for the prescribing to a patient while at the facility, and under the supervision of a medical practitioner. (Note: Medical students are not authorised to issue prescriptions or order medications on a medication chart).

**Nurse Practitioner**, in accordance with the medication list approved by the NSW Director General of Health (or delegate) under section 17A of the *Poisons and Therapeutic Goods Act 1966*.

(Note: Transitional Nurse Practitioners or Registered Nurses undertaking studies leading to endorsement as a Nurse Practitioner are not authorised to issue a prescription or order medications on a medication chart outside of standing orders approved by the Drug and Therapeutics Committee).

**Midwife Practitioner**, in accordance with the medication list approved by the NSW Director General of Health (or delegate) under section 17A of the *Poisons and Therapeutic Goods Act 1966*.

**Dentist**, for dental treatment only. While there is no restriction on a medication chart order for dental treatment, issuing a prescription for a Schedule 8 medication for an outpatient, or a patient on discharge from a hospital by a dentist is limited to: -

- A Schedule 8 medication included in the list of preparations that may be prescribed by participating dental practitioners for dental treatment only, set out in the current [Schedule of Pharmaceutical Benefits](#) issued by the Commonwealth Department of Health, or
- Pentazocine (not currently available in Australia as a proprietary preparation).

**Optometrist**, with endorsement on the person's registration by the Optometry Board of Australia to prescribe (and supply) specified Schedule 2, Schedule 3 and Schedule 4 medications for optometrical treatment only.

**Podiatrist**, with endorsement on the person's registration by the Podiatry Board of Australia to prescribe (and supply) specified Schedule 2, Schedule 3 and Schedule 4 medications for podiatry treatment only.

## 4.2 Restrictions on Prescribing Certain Schedule 4 Medications

Due to potential hazards with their use, the prescribing of certain Schedule 4 medications is restricted under the provisions of the Poisons and Therapeutic Goods Regulation 2008 to medical practitioners in accordance with the corresponding qualifications and/or conditions. However, in an emergency, an appropriately authorised person (such as a pharmacist, nurse or an authorised prescriber) may obtain a telephone, facsimile or email order from the approved prescriber (see [section 4.7.4](#) for prescriptions for pharmacist dispensing and [section 4.8.4](#) for medication chart orders).

The Schedule 4 medications with restricted prescribing rights are: -

### A. isotretinoin for oral use acitretin etretinate

Prescribing is generally restricted to a specialist dermatologist who is a current *Fellow of the Australasian College of Dermatologists*.

However, a patient admitted for unrelated treatment already being prescribed the medication by a specialist dermatologist and still undergoing treatment at the time of admission may be prescribed the medication on a medication chart by an authorised prescriber at the hospital for the term of the patient's inpatient stay.

Additionally, an authority to prescribe isotretinoin for oral use may be issued to a relevant specialist medical practitioner on a patient-by-patient basis for certain approved (non dermatological) medical treatments. Applications are to be forwarded by the specialist medical practitioner to the NSW Director General of Health through [Pharmaceutical Services Unit](#).

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*', or alternatively, with the individual authority reference number (RA.....) that has been issued to a particular prescriber by Pharmaceutical Services Unit.

### B. tretinoin for oral use

Prescribing is restricted to a specialist haematologist who is a *Fellow of the Royal Australasian College of Physicians* or a *Fellow of the Royal College of Pathologists of Australasia*, or both.

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*'.

**C. clomiphene  
cyclofenil**

Prescribing is restricted to a specialist who is either: -

- A *Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists* or a *Fellow of the Royal College of Obstetricians and Gynaecologists*, or
- A *Fellow of the Royal Australasian College of Physicians* and is practising endocrinology in a Specialist Endocrinology Unit.

However, a patient admitted for unrelated treatment already being prescribed the medication by a relevant specialist medical practitioner (as above) and still undergoing treatment at the time of admission may be prescribed the medication on a medication chart by an authorised prescriber at the hospital for the term of the patient's inpatient stay.

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*', or alternatively, with the individual authority reference number (CL.....) that has been issued to a particular prescriber by [Pharmaceutical Services Unit](#).

**D. follitropin beta  
luteinising hormone  
urofollitrophin**

Prescribing is restricted to a specialist endocrinologist who is a *Fellow of the Royal Australasian College of Physicians*.

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*'.

**E. dinoprost**

Prescribing is restricted to either: -

- A specialist who is either a *Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists* or a *Fellow of the Royal College of Obstetricians and Gynaecologists*, or
- A '*GP Obstetrician*', defined as a medical practitioner who is not a specialist obstetrician or gynaecologist but who has completed the *Diploma of the Royal Australian and New Zealand College of Obstetricians* after January 1992, or who has

completed the *Diploma of the Royal Australian and New Zealand College of Obstetricians* prior to 1 January 1992 and has attended a course approved by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists or Royal Australasian College of General Practitioners on the use of prostaglandins in obstetrics.

The prescribing must be in accordance with NSW Health Policy Directive [PD2010\\_064, 'Prevention, Early Recognition & Management of Postpartum Haemorrhage \(PPH\)'](#).

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*', or alternatively, with the individual authority reference number (PGT.....) that has been issued to a particular prescriber by [Pharmaceutical Services Unit](#).

### F. **dinoprostone (in any form)**

Prescribing is restricted to: -

- A specialist who is either a *Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists* or a *Fellow of the Royal College of Obstetricians and Gynaecologists*, or
- A '*GP Obstetrician*', defined as a medical practitioner who is not a specialist obstetrician or gynaecologist but who has completed the *Diploma of the Royal Australian and New Zealand College of Obstetricians* after January 1992, or who has completed the *Diploma of the Royal Australian and New Zealand College of Obstetricians* prior to 1 January 1992 and has attended a course approved by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists or Royal Australasian College of General Practitioners on the use of prostaglandins in obstetrics, or
- A Registrar in obstetrics in a hospital, subject to the following conditions;
  - The registrar is approved in writing by the Director of Obstetrics and Gynaecology to perform obstetrics, including the use of dinoprostone, provided that the hospital is equipped to carry out foetal and maternal monitoring and operative delivery, and
  - The registrar prescribes, supplies or administers the substance at all times in accordance with a written protocol for the use of the substance in the hospital that includes relevant warnings, contraindications, precautions and possible adverse reactions and which has been approved and signed by the Director of Obstetrics and Gynaecology.

The prescription or medication chart order must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutic Goods Regulation*', or alternatively, with the individual authority reference number (PGT.....) that has been issued to a particular prescriber by [Pharmaceutical Services Unit](#).

### 4.3 Requirements for Authority to Prescribe Certain Schedule 8 Medications

A NSW Health authority for the prescribing of Schedule 8 medications issued under the specific requirements at section 28 of the *Poisons and Therapeutic Goods Act 1966* is distinct from an authority issued by Medicare Australia for the prescribing of Pharmaceutical Benefits Scheme medications.

When prescribing a Schedule 8 medication, it is the responsibility of the prescriber to ensure they have obtained the appropriate NSW Health Schedule 8 medication prescribing authority, administered by the NSW Ministry of Health [Pharmaceutical Services Unit](#).

The specific circumstances for requiring a NSW Health authority are detailed in the Pharmaceutical Services Unit guideline [TG212 'Requirements for an authority to prescribe drugs of addiction under section 28 of the Poisons and Therapeutic Goods Act'](#) as: -

- A. For the central nervous system stimulants dexamphetamine and methylphenidate, either as: -
- The authority number issued to the prescriber by Pharmaceutical Services Unit on a patient by patient basis in the form '**XXXXXX-YY-20ZZ**' (where YY-20ZZ is the month and year during which the prescriber can last prescribe on the authority), or
  - A specialist medical practitioner who has been issued an approval under the Poisons and Therapeutic Goods Regulation 2008 that includes a reference number in the form '**S28CXXXXXX**', for prescribing in accordance with the associated NSW Ministry of Health approved criteria, or
  - A specialist medical practitioner who has been issued an approval under the Poisons and Therapeutic Goods Regulation 2008 that includes a reference number in the form '**CNSXXXXXX**', for prescribing in accordance with the associated NSW Ministry of Health approved criteria.
- (Note: At facilities at which Justice Health & Forensic Mental Health Network provides services, a medical practitioner cannot utilise his/her 'CNSXXXXXX' approval number and must instead obtain an individual authority number from [Pharmaceutical Services Unit](#) for each applicable patient).
- B. For any person who, in the opinion of the authorised prescriber, is a drug dependent person, as defined in the *Poisons and Therapeutic Goods Act 1966* as a person who has acquired, as a result of repeated administration of either a Schedule 8 medication or a prohibited drug (for example heroin, methylamphetamine, ecstasy), an overpowering desire for the continued administration of the substance.
- C. To a person for continuous treatment for a period exceeding two months of;
- Any Schedule 8 medication in injectable form, or

- Buprenorphine other than as transdermal patches, or
- Flunitrazepam (and alprazolam from 1 February 2014), or
- Hydromorphone, or
- Methadone.

### **Exemption for prescribing to a hospital inpatient**

In a hospital, an exemption to obtaining a NSW Health authority applies for the prescribing of any Schedule 8 medication to an inpatient for a period of up to 14 days following admission.

This provides for whether the patient was being prescribed the medication immediately prior to admission, or that the medication is being initiated in the hospital.

Following this 14 day period the authorised prescriber must hold or obtain the necessary authority from [Pharmaceutical Services Unit](#) in the particular circumstance as detailed above to provide for the continuing treatment of the patient with the Schedule 8 medication.

## **4.4 Consistent Prescribing Terminology**

The use of potentially dangerous abbreviations and dose expressions in the prescribing of medications is a critical patient safety issue and a major cause of medication errors.

The facility's Drug and Therapeutics Committee should ensure that endorsed standard prescribing terminology and abbreviations are used, consistent with the Australian Commission on Safety and Quality in Health Care ['Recommendations for terminology, abbreviations and symbols used in the prescribing and administration of medicines'](#) in all records, other related documents and electronic systems.

Additionally: -

- Medication names must not be abbreviated.
- The route for administration must be specified.
- Prescriptions for registered pharmacist dispensing and medication chart orders should be as the active ingredient 'generic'/substance name of the medication, except in specific circumstances when the ordering by the proprietary name ('trade name' or 'brand name') is authorised by the Drug and Therapeutics Committee.
- Oral liquid medications should be prescribed with the strength of the medication and both the quantity of the dose and the volume to be administered (in brackets), for example 'Xyz Mixture 5mg/mL, dose 10mg (= 2mL)'.

## **4.5 Prescribing of Medications for 'Off-label Use' and the Use of Unregistered Medications**

The appropriateness of the 'off-label use' of medications, also known as 'unapproved use', must be assessed by the authorised prescriber prior to prescribing.

In accordance with NSW Health Policy Directive [PD2008\\_037 'Medicine - Evaluation of Medicines for Use in Public Hospitals'](#), the facility's Drug and Therapeutics Committee must ensure that protocols and procedures are developed and implemented to provide for 'off-label use' of medication, whether this involves a variation in dosage, patient age for treatment, indication, or route of administration to that included in the medication's approved Product Information.

The Drug and Therapeutics Committee must also ensure that protocols and procedures are developed and implemented to provide for the use of 'unregistered medicines' (that is, medicines not included on the Australian Register of Therapeutic Goods). This should include provision for: -

- The circumstances requiring informed consent by the patient for the particular treatment, and
- The information provided to the patient on the treatment, and
- Monitoring and reporting of outcomes to treatment, including adverse events, and
- The ongoing supply of the medication following discharge from a hospital (as applicable).

### 4.6 Medications Used in Clinical Trials

A clinical trial involving a medication administered to or on humans must be approved by any committee involved in the approval of clinical trials at the facility including the human research ethics committee (however named), and also approved by, or notified, to (as applicable in the circumstances) the Commonwealth Therapeutic Goods Administration.

Detail on the ethical and scientific standards for the conduct of a medication clinical trial for human research is included in NSW Health Policy Directive [PD2010\\_055 'Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations'](#), which references the National Health and Medical Research Council '[National Statement on Ethical Conduct in Research Involving Humans](#)'.

Authorisation for the commencement of a human research project must be in accordance with NSW Health Policy Directive [PD2010\\_056 'Research - Authorisation to Commence Human Research in NSW Public Health Organisations'](#).

### 4.7 Issuing Prescriptions for Pharmacist Dispensing

#### 4.7.1 Prescriptions for Schedule 4 Medications (and Other Non Schedule 8 Medications)

A prescription (as opposed to a medication chart order) issued at a facility for a Schedule 4 medication must include: -

- a) The date the prescription is issued, and
- b) The patient's name, and

- c) The patient's address or patient care area (as applicable to outpatient/discharge or inpatient dispensing), and
- d) The medication's active ingredient/s, proprietary name (where applicable), form and strength, and
- e) The quantity of the medication to be supplied, and
- f) Adequate directions for use, including the dose, route for administration and frequency of administration, and
- g) The number of repeat supplies, if any, and
- h) For anabolic-androgenic steroids, an interval for repeat dispensing, and
- i) The endorsement required for the Schedule 4 medications with restricted prescribing rights listed in [section 4.2](#), and
- j) The authorised prescriber's signature, and
- k) The name, address and telephone number of the facility, and
- l) The name and the designation of the prescriber (for example, Resident Medical Officer, Staff Specialist, Nurse Practitioner) and the prescriber's contact telephone/pager number.

Items a) to i) must be in the prescriber's clear and legible hand writing, except where the prescription is computer-generated in accordance with Pharmaceutical Services Unit [TG184 'Criteria for Issuing Non-handwritten Prescriptions'](#) where the prescriber's signature only must be hand written.

Any dose that could be regarded as being dangerous or unusual must be confirmed in writing by underlining the dose and initialling the prescription in the margin.

Additionally, pre-printed patient 'addressograph' labels may be used on a prescription for a Schedule 4 medication when: -

- The prescription is for dispensing solely within a hospital and is endorsed 'For hospital use only', and
- The addressograph label includes the patient's name, address/patient care area and patient identification number (if applicable) and
- In accordance with local protocols, the prescriber confirms the details included on the addressograph label at the time of writing the prescription, for example by signing across both the addressograph label and the prescription or hand writing the patient's name under the addressograph.

When issuing a prescription for any other medication (except for Schedule 8 medication – see [section 4.7.2](#) below), applicable detail in accordance with that required for Schedule 4 medications (above) should similarly be incorporated on the prescription.

### 4.7.2 Prescriptions for Schedule 8 Medications

Pre-printed 'addressograph' labels containing the patient's name and address/patient care area must not be used on a prescription for a Schedule 8 medication.

In addition to requirements for a Schedule 4 medication prescription above in [section 4.7.1](#), a prescription for a Schedule 8 medication: -

- Must include the quantity being prescribed in both figures and words, and
- Must include an interval for repeat dispensing (if prescribed), and
- Must not include any other medication, including another form or strength of the same Schedule 8 medication, and
- In the case of dexamphetamine or methylphenidate prescribing, must include the NSW Health authority reference number issued to the prescriber (see [section 4.3](#)). This will be either;
  - As an individual reference number issued to the prescriber on a patient-by-patient basis in the form 'XXXXXX-YY-20ZZ', or
  - As a reference number in the form 'S28CXXXXXX' issued to a specialist medical practitioner for prescribing in accordance with the associated NSW Ministry of Health approved criteria, or
  - As a reference number in the form 'CNSXXXXXX' issued to a specialist medical practitioner for prescribing in accordance with the associated NSW Ministry of Health approved criteria.

Where the prescription is computer-generated in accordance with Pharmaceutical Services Unit [TG184 'Criteria for Issuing Non-Handwritten Prescriptions'](#) the prescriber must also hand write on the prescription (but only on the 'pharmacist/patient' form of a Pharmaceutical Benefits Scheme prescription) the following: -

- The name, strength, form and quantity (in both figures and words) of the medication, and
- The number of repeats (if prescribed), and the interval for repeat dispensing when prescribed, and
- Adequate directions for use, including the dose, route for administration and frequency for administration.

Any dose that could be regarded as being dangerous or unusual must be confirmed in writing by underlining the dose and initialling the prescription in the margin.

### 4.7.3 Discharge Medication Prescriptions and Discharge Summary

Discharge medications may be prescribed on: -

- a) A prescription issued by an authorised prescriber with the detail listed in [section 4.7.1](#) for Schedule 4 medications and [section 4.7.2](#) for Schedule 8 medications, or
- b) The 'discharge medicine' order section of the medication chart, or
- c) Where available, the removable 'discharge medicine' section on the patient's discharge summary, or
- d) An electronic discharge medication order that has been approved for use at the facility.

In relation to b), c) and d), for Schedule 8 medications the authorised prescriber must additionally issue a prescription in accordance with the requirements listed in [section 4.7.2](#).

At the time of discharge, the patient's medication regimen must be reviewed by an authorised prescriber as part of the patient's general review prior to leaving the facility.

The discharge summary should also identify changes to the medication regimen during the patient's stay and outline the reason/s for the changes wherever possible. If applicable, changes can be identified with reference to the '[Medication Management Plan](#)' form initiated for the patient at the time of admission as detailed in [section 4.8.2](#).

The discharge summary and any 'patient held' medication list prepared for the patient must be amended as changes are made to the discharge medications.

A legible copy of the discharge summary must be despatched or otherwise communicated to the patient's nominated general practitioner (or other primary care provider) as soon as possible.

#### **4.7.4 Emergency Verbal, Telephone, Facsimile and Email Prescription Orders for Pharmacist Dispensing**

In an emergency, an authorised prescriber may either verbally (face to face), by telephone, by facsimile or by email, direct a registered pharmacist to dispense a prescription for any Schedule 4 or Schedule 8 medication. Relevant details as listed in [section 4.7.2](#) for Schedule 8 medication and [section 4.7.1](#) for other medication must be included in the order to the registered pharmacist.

The authorised prescriber must: -

- a) Immediately issue a prescription, and
- b) Endorse the prescription with words that indicate the prescription has been issued in confirmation of a verbal, telephone, facsimile or email direction to the registered pharmacist, and
- c) Send the prescription without delay and within 24 hours to the registered pharmacist to whom the direction was given.

#### **4.7.5 Security of Prescription Pads and Forms**

Due to the risk of prescription forgeries on stolen prescription forms, all health facilities and authorised prescribers must ensure that prescriptions pads and forms are securely stored when not in immediate use. Prescription pads or forms must not be held within a patient care area Schedule 8 medication storage unit.

Prescription forms should include: -

- Unique, consecutive numbering of each form, and

- The words 'not valid for Schedule 8 drugs' (or the like) pre-printed or stamped on the form.

Strategies to support the security of prescription forms/pads should include consideration of: -

- Distribution through a centralised service such as the facility's Pharmacy Service, and
- The return of unwanted prescription pads to this service for destruction.

The theft of prescription forms/pads from the facility must be reported to [Pharmaceutical Services Unit](#). The report of a detected prescription forgery must additionally be reported to the local police.

Facilities must have procedures to maintain the security of user identity and passwords for the electronic medication management system (where approved for use) to prevent unauthorised access to medication ordering.

## 4.8 Medication Chart Orders in Patient Care Areas

### 4.8.1 Medication Charts and Medication Orders for Administration

The [National Inpatient Medication Chart \(NIMC\) standard](#) published by the Australian Commission on Safety and Quality in Health Care is adopted as policy in all NSW Health facilities.

The NIMC standard includes the Paediatric National Inpatient Medication Chart (PNIMC) which in addition allows for signatures for two staff members for each dose administered and provides a field for the calculation of weight based dosages. The PNIMC must be used in patient care areas approved by the Drug and Therapeutics Committee.

The facility's Drug and Therapeutics Committee must approve and review (annually or more frequently as deemed appropriate) the use of any specialty medication charts, including the appropriateness of the ongoing use of the chart in the particular patient care area.

The Drug and Therapeutics Committee must develop and implement protocols and procedures to ensure that only medication charts that have been approved by the Committee for a particular patient care area can be procured for use in that area.

Prescribers must ensure that medication orders are clear, legible and not open to misinterpretation.

Medication chart orders must be in accordance with the Australian Commission on Safety and Quality in Health Care ['Recommendations for terminology, abbreviations and symbols used in the prescribing and administration of medicines'](#).

A medication order on a medication chart must clearly specify: -

- The medication's active ingredient/s and/or proprietary name (where approved for use at the facility) with the strength, form and route of administration, and
- The indication for treatment (if applicable), and
- For a 'regular' medication;
  - The dose to be administered, and
  - The frequency and times for administration to the patient, and
  - The maximum number of doses or the maximum duration of treatment with the medication, (except where the prescriber's intention is for the duration of the medication chart), or
- For a 'when required' ('prn') medication;
  - The maximum individual dose, and
  - The maximum daily dose, and
  - The hourly frequency for administration to the patient, and
  - The maximum number of doses or the maximum duration of treatment with the medication (except where the prescriber's intention is for the duration of the medication chart), and
- The date of the medication order, or
  - Where applicable, the date and time of an amendment to the medication order, or
  - Where applicable, the date and time of ceasing a medication order prior to what was originally ordered, and
- The prescriber's name (printed), signature and contact telephone/pager number.

The reason for an amendment to, or cessation of a medication order should be documented in the patient's health care record, signed and dated by the prescriber with his/her name and contact telephone/pager number.

### 4.8.2 Medication Reconciliation

Facilities must implement formal processes for obtaining, verifying and documenting the patient's best possible medication history (including known allergies and previous adverse medication events) from at least two sources. This will include consideration of any medications brought in by (or with) the patient at the time of admission.

The national '[Medication Management Plan](#)' provides a standardised form for use by nursing, medical, pharmacy and allied health staff to improve the accuracy of information recorded on admission.

The use of a medication management plan (whether the national '*Medication Management Plan*' or otherwise), as part of the patient's health care record, must be in accordance with the facility's local protocols and procedures. Where considered appropriate in the individual patient circumstances, the plan should be used to record the medications being used prior to presentation at the facility, and for reconciling the patient's medicines on admission, intra-hospital transfer(s) and at discharge.

The list of current medications should be used to inform medication treatment decisions and should also be used for reference by prescribers preparing medication chart orders for a patient on admission.

Formal processes must also be implemented to compare the patient's documented medication history with their currently prescribed medications, taking into consideration their clinical condition. This includes matching the medications the patient *should* be prescribed to those that are *actually* currently prescribed.

Where there are discrepancies, these should be discussed with the previous prescriber/s then rectified either by adjusting the currently prescribed medications to reflect the intended treatment, or by documenting the reasons for the changes to the therapy in the patient's health care record.

Also, to ensure continuity of care when the care of the patient is transferred, for example, between hospitals or to home, a current and accurate list of medications, including reasons for medication changes, must be provided to the person taking over the patient's care.

Facilities must also implement formal processes for reviewing medications prior to transfer to ensure: -

- The appropriateness to continue each medication in the receiving area, and
- Essential medications withheld on admission are recommenced if clinically appropriate, and
- Any changes to the patient's medication regimen are identified and communicated to the person taking over the patient's care, together with the reason for the change.

### 4.8.3 Regular Review of Medication Orders

Facilities must establish systems and implement local protocols for the regular review of medication orders, as appropriate in the particular patient circumstances.

The Drug and Therapeutics Committee must ensure that procedures are in place to provide for the timely follow up by prescribers and registered pharmacists when medication orders have been highlighted for review.

The outcome of the follow up and any resulting medication changes must be documented in the patient's health care record.

### 4.8.4 Verbal, Telephone, Facsimile and Email Medication Orders

When an authorised prescriber is unable to present to complete a medication chart order, the order may be given verbally (face to face), or by telephone, facsimile or by email.

The person receiving such an order must be a person approved to administer or prescribe medication at the particular patient care area.

The authorised prescriber must provide: -

- The patient's name and relevant identifiers (as applicable), and
- The medication's active ingredient/s, proprietary name (where applicable), strength (where multiple strengths are available) and form (where multiple forms are available), and
- The dose to be administered, and
- The route for administration, and
- The frequency and times for administration, and
- The maximum number of doses or the maximum duration of treatment with the medication.

Due to the risk of misinterpretation, all orders received by telephone must be read back to the prescriber with the numbers as separate words, for example, as '*fifty milligrams, five zero milligrams*' for a 50mg dose.

In accordance with local protocols, as a further check, the prescriber should repeat the telephone or verbal (face to face) order to a second person as detailed in [section 7.7](#). This must be implemented for all Schedule 8 medications, high risk medications and intravenous medications. An exception to this is in the community setting where a second person is not available.

The authorised prescriber who orders a medication for patient administration verbally (face to face) or by telephone must confirm within 24 hours all doses administered either by: -

- Counter-signing the record of administration on the patient's medication chart and reviewing the patient as soon as appropriate in the circumstances of the case, or
- Sending written confirmation of the order by facsimile or email, and attending the facility to review the patient as soon as appropriate in the circumstances of the case.

An authorised person who orders a medication for patient administration by facsimile or email must attend the facility to review the patient as soon as appropriate in the circumstances of the case, re-write the current order for the medication on the medication chart and cancel the facsimile/email order accordingly.

These procedures must also be followed when the authorised prescriber is changing or ceasing a particular order on a medication chart. Additionally, the prescriber must document the reason for changing/ceasing the order in the patient's health care record when next at the facility.

Note: The requirements for the prescriber to attend the facility to review the patient do not apply to the medication order for a patient of Justice Health & Forensic Mental Health Network if confirmation of the order for administration is given in accordance with the requirements of the approved Justice Health & Forensic Mental Health Network protocol.

## 5 THE PHARMACY SERVICE

### 5.1 Responsibility

The director of pharmacy of the Pharmacy Service is responsible for the storage of all medications at the facility other than those that have been supplied to a patient care area.

However, the director of pharmacy is also responsible for overseeing and advising on the storage of medications in other areas of the facility including patient care areas and intravenous fluid stores.

Where no registered pharmacist is employed or contracted at the facility, the responsibilities of the director of pharmacy with regard to the storage and distribution of medications are assigned to the **authorised officer of the Pharmacy Service** at the particular facility, defined as: -

- a) The director of nursing of the facility (however named), or
- b) The medical superintendent of the facility (however named) appointed by the facility's chief executive officer (however named).

The range and quantities of medications held at the Pharmacy Service must include consideration of circumstances when a patient will present to the facility seeking a previously prescribed essential medication for which his/her supply has been unexpectedly exhausted.

In instances where a particular medication is not in stock at a facility and a replacement supply cannot be provided by or through the person's primary health practitioner, prior arrangements made through the Pharmacy Service may provide for the supply from a local community pharmacy.

Generally, a facility may enter into a service agreement with a community pharmacy for medication supply and other services. These arrangements must incorporate appropriate safety and accountability considerations, compliance with the relevant ordering and recording provisions of this Policy Directive and any licensing of wholesale supply required under legislation.

### 5.2 Medication Procurement

#### 5.2.1 Medication Purchasing

In accordance with the '*Procedures for Purchase and Supply of Pharmaceuticals*' detailed in NSW Health Policy Directive [PD2012\\_068 'Outpatient Pharmaceutical Arrangements and Safety Net Arrangements'](#), health facilities are required to purchase medications in accordance with the supply contracts arranged by the NSW State Contracts Control Board.

However, where a required medication is not available as a contract item, it may be purchased from a non-contract supplier.

The NSW Health Policy Directive PD2013\_023 '[Goods and Services Procurement Policy](#)' read in conjunction with the NSW Health '[Goods and Services Procurement Policy Manual](#)' provides further information regarding purchasing procedures.

Orders for medications may be placed with the supplier in writing, or by telephone, facsimile or electronic mail.

The order for a Schedule 8 medication must be approved by: -

- The director of pharmacy or a delegated registered pharmacist, or
- The authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted.

Particular care must be taken to ensure that stocks of substances known to be diverted for illicit use, including preparations containing pseudoephedrine, are maintained and supplied/used under the supervision of suitably qualified or delegated staff.

### 5.2.2 Deliveries to the Pharmacy Service

Medication deliveries that are received by a non Pharmacy Service staff member, such as by stores or administration staff, must be transferred to the Pharmacy Service immediately on arrival.

Where after-hours access to the Pharmacy Service is required for non Schedule 8 medication deliveries, this must be in accordance with a procedure approved by the Drug and Therapeutics Committee, and restricted to delegated nursing and/or medical staff.

After-hours deliveries of Schedule 8 medication(s) must be handled in accordance with the procedure detailed below in [section 5.2.3](#).

### 5.2.3 Receipting for Deliveries of Schedule 8 Medications

When a parcel containing a Schedule 8 medication is delivered to a facility the recipient at the facility must sign the courier's 'proof of delivery' document (either electronically or in hard copy) for the unopened sealed parcel.

With regard to an after-hours delivery of Schedule 8 medication, the procedure approved by the Drug and Therapeutics Committee must include the provision for a sealed parcel containing a Schedule 8 medication being stored unopened in an appropriate patient care area's Schedule 8 medication storage unit (for example the Emergency Department) pending the return of a registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted. The corresponding Schedule 8 drug register entry in the patient care area should be on a

separate page to all other medications, and recorded as, for example '*one unopened sealed package*', pending transfer to the Pharmacy Service.

When the Schedule 8 medication parcel is received at the Pharmacy Service, further to checking the contents against the original purchase order, a delegated registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted, must sign and date a receipt confirming the supply of the individual Schedule 8 medication(s), and forward this receipt confirmation by post or courier to the supplier within 24 hours of the delivery. A copy of the signed and dated receipt confirmation must also be retained at the Pharmacy Service.

The Schedule 8 medication(s) received at the Pharmacy Service must be immediately recorded in the corresponding Pharmacy Service drug register and locked in a Schedule 8 medication storage unit.

### 5.3 Medication Storage in the Pharmacy Service

#### 5.3.1 Medication Security and Access – General Provisions

The Pharmacy Service is an area requiring high security. For advice concerning the management of security issues in the Pharmacy Service, reference must be made to Chapter 18 'Security in Pharmacies' of NSW Health Policy Manual '[Protecting People and Property; NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies](#)'.

Access to the Pharmacy Service must be restricted to staff authorised by the director of pharmacy, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted. Protocols for authorising and auditing access to the pharmacy by keys or other means must also be implemented by the director of pharmacy/authorised officer of the Pharmacy Service.

#### 5.3.2 After-Hours Access to the Pharmacy Service

Entering the Pharmacy Service after hours should rarely be necessary. When required, access must be in accordance with procedures approved by the Drug and Therapeutics Committee and restricted to delegated senior nursing and/or medical staff. Such entry to the Pharmacy Service must not include access to Schedule 8 medications.

The facility's security officer may enter the Pharmacy Service after hours at times of an emergency, such as during a fire or an alarm sounding. Any keys or codes used for emergency access to the Pharmacy Service should be held under maximum security with the facility's security service.

Facilities must develop appropriate systems for recording every occasion of after-hours access to the Pharmacy Service, including documenting the purpose of this access.

### 5.3.3 General Medication Storage Requirements

All stocks of medications in the Pharmacy Service must be regularly checked to ensure proper storage conditions are met, including temperature control and security.

Storage temperatures must be consistent with the range specified on the manufacturers' labels (typically not above 25°C for 'general' storage, and 2-8°C for refrigerated storage), and monitored accordingly. In the event of temperature storage conditions falling outside those specified by the manufacturer, the director of pharmacy must evaluate the event and take appropriate action.

A system of stock rotation, monitoring of expiry dates, and quarantining and destroying expired stock must be in place.

Where additional access controls are deemed appropriate, local protocols approved by the director of pharmacy and the Drug and Therapeutics Committee may direct specific non-Schedule 8 medications to be stored separately in locked cupboards with restricted access by authorised staff members. Medications that could be considered for increased access controls through separate storage include benzodiazepines, propofol, methoxyflurane and the codeine phosphate 30mg compound preparations.

Also in accordance with local protocols, the procurement and supply of the medication may be recorded in a register as if it was a Schedule 8 medication.

### 5.3.4 Storage of Schedule 8 Medications

All Schedule 8 medications in the Pharmacy Service must be stored in a separate safe or vault apart from all other medications or goods (except cash or documents).

Where used, the safe must be firmly attached to a wall or to the floor and must comply, as a minimum with the requirements of clause 76 of the [Poisons and Therapeutic Goods Regulation 2008](#), 'Storage in Pharmacies'.

The safe/vault must be kept locked when not in immediate use.

Where a key is used to unlock the safe/vault, it must be retained by a registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted, on his/her person. After-hours, the key may be retained in a safe/key safe to which only a registered pharmacist/ authorised officer of the Pharmacy Service has access.

Where a code or combination is required to unlock the safe/vault, this must only be known to authorised registered pharmacists, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted.

Schedule 8 medications held at the Pharmacy Service pending the collection by, or delivery to a patient care area or an individual patient should be stored in the Schedule 8 medication safe/vault until collected or delivered.

### 5.4 Medication Supplies – General Provisions

#### 5.4.1 Preparation and Distribution Standards

NSW Health Policy Directive [PD2005\\_590 'Pharmaceuticals - Preparation in Hospital Pharmacy Departments in New South Wales'](#) details the principles for medication preparation, including quality management.

Standards for the preparation of medications must be in accordance with the Society of Hospital Pharmacists of Australia [SHPA Guidelines for Medicines Prepared in Australia Hospital Pharmacy Departments](#) to be read in conjunction with the Pharmaceutical Inspection Co-Operation Scheme [Guide to good practices for the preparation of medicinal products in healthcare establishments](#).

Aseptic preparation must not be undertaken at the Pharmacy Service without the appropriate standards for manufacturing and quality assurance as detailed in these guides, and must be by staff with the training, skills and demonstrated competency to complete the particular task.

The Society of Hospital Pharmacists of Australia [SHPA Standards of Practice for the Distribution of Medicines in Australian Hospitals](#) provides guidance on Pharmacy Service practices that: -

- Deliver medications to patients in a timely manner, and
- Support the lowest possible medication error rate, and
- Minimise the cost of medications stored throughout the facility, and
- Minimise wastage, and
- Minimise opportunities for misappropriation of medications, and
- Provide data on medication usage, and
- Identify unusual medication usage patterns.

[The Society of Hospital Pharmacists of Australia](#) also publishes practice standards relevant to the hospital setting on topics including: -

- Clinical pharmacy services.
- Investigational drugs services.
- Medication safety practices.
- Medication reconciliation.
- Palliative care pharmacy practice.
- Emergency medicine pharmacy practice.
- Mental health pharmacy practice.
- Critical care pharmacy practice.

- Clinical oncology pharmacy practice and the handling of chemotherapy drugs.
- Patient self-administration of medications.

Guidelines for pharmacy practice approved by the [Pharmacy Board of Australia](#) include those for the dispensing of medicines, specific practice issues and specialised supply arrangements.

Professional Practice Standards published by the [Pharmaceutical Society of Australia](#) are also directly relevant to the provision of high quality, reliable health care services and products from the Pharmacy Service, including those for: -

- Dispensing practices.
- Dose Administration Aids services.
- Extemporaneous dispensing.
- Compounding aseptic preparations.

The [National Safety and Quality Health Service Standards](#) published by the Australian Commission on Safety and Quality in Health Care include recommendations to promote the safe storing, manufacturing, compounding, dispensing, and distribution of medications at Standard 4 – Medication Safety.

### 5.4.2 Sensitisation Due to Occupational Exposure

All staff should be aware that allergy or sensitisation to pharmacological agents can occur through occupational exposure. Any symptoms experienced by a staff member that may be related to such exposure must be reported as soon as possible, and appropriate action taken.

NSW Work, Health and Safety legislation requires that all workplace risks, including those associated with the handling of pharmacological agents, be identified, assessed and controlled. NSW Health Policy Directive PD2013\_005 '[Work Health and Safety: Better Practice Procedures](#)' provides guidance on implementing the *Work Health and Safety Act 2011* and *Work Health and Safety Regulation 2011*.

Where available, reference should also be made to relevant NSW Health policies, directives, guidelines, Safety Data Sheets and [Work Health and Safety Information Sheets](#) in relation to specific agents.

The Pharmacy Service has a role in ensuring that the risk of sensitisation is reduced as far as practical when preparing medications including: -

- Avoiding unnecessary occupational exposure.
- The use of appropriate personal protective equipment (PPE) such as masks, gloves, gowns and respirators.
- Applying locally developed procedures specific to the situation to minimise exposure as far as possible.
- Taking prompt action where symptoms of allergy or sensitisation occur.

- Regularly reviewing local procedures for effectiveness.

### 5.4.3 Authorised Recipients of Pharmacy Service Medications

The Pharmacy Service is only authorised to supply medication to: -

- Patient care areas in public hospitals, public health facilities, health institutions, health services and health support services, either as imprest stock or as patient-labelled medication, and
- To inpatients of a hospital on discharge as patient-labelled medication, and
- To non-admitted patients/outpatients attending a public health facility as patient-labelled medication, and
- In an emergency, morphine ampoules to a NSW Ambulance paramedic (see [section 5.4.6](#)).

### 5.4.4 Patient Payment for Medications

In accordance with NSW Health Policy Directive [PD2012\\_068 'Outpatient Pharmaceutical Arrangements and Safety Net Arrangements'](#), pharmaceuticals are to be issued without charge as medically prescribed to inpatients and same day patients of the hospital irrespective of whether they are public or private inpatients.

Take home supplies of pharmaceuticals should not exceed 7 days' supply to patients when they are discharged from hospital, unless prior authority has been obtained from the Chief Executive, the Medical Administrator, or the Medical Administrator's nominee.

The provision, payment, and quantities of medications supplied to eligible outpatients and the provision of 'S100' Highly Specialised Drugs (see [section 5.4.5](#)) are also detailed in NSW Health Policy Directive [PD2012\\_068 'Outpatient Pharmaceutical Arrangements and Safety Net Arrangements'](#).

Certain high cost medications may also be available to outpatients at a free/subsidised cost in accordance with NSW Health Policy Directive [PD2005\\_395 'Drugs - Funding Arrangements for Outpatient Use of High Cost Drugs Not Funded by the Commonwealth'](#).

### 5.4.5 Highly Specialised Drugs Programs

The Australian Government provides funding for certain specialised medications as Pharmaceutical Benefits Scheme items under the Highly Specialised Drugs Programs provided for under Section 100 of the National Health Act 1953.

Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist

hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Detail on the Highly Specialised Drug on-line claiming provisions at included on the [NSW HealthShare Project Site](#).

### **A. The Highly Specialised Drugs (HSD) Program**

Under this program the Commonwealth Pharmaceutical Benefits Scheme funds an agreed list of highly specialised drugs for specified medical indications for use by outpatients and those patients attending day services in a public hospital. Details of the medications and the associated medical indications can be found on the [Commonwealth Department of Health and Ageing Section 100 – Highly Specialised Drugs Program website](#).

### **B. The Complex Authority Required Highly Specialised Drugs (CAR HSD) Program and Trastuzumab (Herceptin) Special Authority Program for Early Stage Breast Cancer**

All CAR HSD and Pharmaceutical Benefits Scheme trastuzumab (Herceptin) require prior approval from the Commonwealth Department of Human Services before dispensing to be eligible for funding as highly specialised drugs .

Detail on the approval process for these medications is available on the [Commonwealth Department of Human Services, Complex Authority Required Highly Specialised Drugs \(CAR HSD\) website](#).

Pulmonary Arterial Hypertension medications under the CAR HSD Program may only be prescribed by medical practitioners associated with Pulmonary Arterial Hypertension Designated Prescribing Centres which are listed on the [Pulmonary Hypertension Association website](#).

#### **5.4.6 Emergency Supplies Of Morphine to NSW Ambulance Paramedics**

In an emergency, a registered pharmacist may supply a NSW Ambulance paramedic with morphine 10mg/mL ampoules from the Pharmacy Service stock.

The registered pharmacist must obtain from the NSW Ambulance paramedic a copy of the person's paramedic authority issued by the NSW Ambulance as well as a written order and receipt for the supply, signed and dated by the paramedic, for retention at the Pharmacy Service.

Note: The supply of morphine ampoules to a NSW Ambulance paramedic must not be made by an Emergency Department staff member or any other patient care area staff member.

#### **5.4.7 Schedule 8 Medication Deliveries by a Facility Staff Member**

When Schedule 8 medication ordered by the registered nurse/midwife in charge of a patient care area is delivered to the patient care area by a facility staff member, this must

be under the direction of a registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted.

The package containing the Schedule 8 medication must be handed by the facility staff member to a registered nurse/midwife, who must sign and date a receipt confirming the quantity of the medication supplied. This receipt must be returned by the facility staff member to the Pharmacy Service for retention. A copy of this receipt must also be retained at the patient care area.

Alternatively, a registered nurse/midwife from a patient care area may collect Schedule 8 medication ordered from the Pharmacy Service by the registered nurse/midwife in charge of the patient care area. The registered nurse/midwife collecting the medication must sign and date a receipt confirming the quantity of the medication supplied, and again the receipt must be retained at the Pharmacy Service. A copy of this receipt must also be retained at the patient care area.

In both scenarios, the registered nurse/midwife receiving the Schedule 8 medication must immediately record the acquisition in the patient care area Schedule 8 drug register in accordance with [section 6.13.1](#), and immediately store the medications in the patient care area's Schedule 8 medication drug storage unit. A witness must be present to confirm both actions by the registered nurse/midwife and sign the relevant entry(s) in the patient care area drug register, in accordance with [section 6.13.2](#).

### 5.4.8 Schedule 8 Medication Deliveries by a Courier

When Schedule 8 medication is being delivered to a patient care area or health facility remote to the Pharmacy Service by a courier who is not a facility staff member: -

- The Schedule 8 medication must be packed by the Pharmacy Service separate to any other goods and the outside of the package must not indicate that it contains Schedule 8 medication, and
- The courier must sign and date a document to confirm he/she has collected the package, and this document be retained at the Pharmacy Service.

The courier must obtain a 'proof of delivery' receipt (either electronically or in hard copy) for the unopened sealed parcel from the person to whom the parcel is delivered. The courier must then arrange for this 'proof of delivery' receipt to be forwarded to the Pharmacy Service that supplied the medication.

The registered nurse/midwife who receives the medication at the patient care area must sign and date a receipt confirming the quantity of the medication(s) received. This receipt must be forwarded by the registered nurse/midwife to the Pharmacy Service within 24 hours, for retention at the Pharmacy Service. A copy of this receipt must also be retained at the patient care area.

## 5.5 Dispensing Patient-Labelled Medications

### 5.5.1 Orders for Dispensing Patient-Labelled Medications

#### Patient-labelled Medications for Inpatient or Clinic Administration

For inpatient or clinic use, dispensing of patient-labelled medications may be: -

- a) From the authorised prescriber's clear and legible order on the patient's medication chart either forwarded to the Pharmacy Service by facsimile, email (as a scanned copy) or another approved electronic form, or photocopied by a registered pharmacist, or
- b) On a prescription issued by an authorised prescriber, with the relevant details listed in [section 4.7.2](#) for Schedule 8 medications and in [section 4.7.1](#) for Schedule 4 medications and other non-Schedule 8 medications (see also [section 5.5.3](#) for the provision of a the verbal (face to face), telephone, facsimile or email order of an authorised prescriber).

The registered pharmacist dispensing a medication for an individual patient should review the medication order or prescription in the context of the patient's full medication regimen (where available) prior to the administration of a dose to the patient.

#### Discharge Medications

Discharge medications may be dispensed from: -

- a) A prescription issued by an authorised prescriber, with the relevant details listed in [section 4.7.2](#) for Schedule 8 medications and in [section 4.7.1](#) for Schedule 4 medications and other non-Schedule 8 medications (see also [section 5.5.3](#) for the provision of a the verbal (face to face), telephone, facsimile or email order of an authorised prescriber), or
- b) The 'discharge medication' order section of the medication chart either sighted then photocopied by the registered pharmacist, or forwarded to the Pharmacy Service by facsimile, email or another approved electronic form, or
- c) Where available, the removable 'discharge medicine' section on the patient's discharge summary, or
- d) A discharge medication order in an approved electronic form.

In relation to b), c) and d) for Schedule 8 discharge medication orders, the authorised prescriber must also issue a prescription with the detail required in [section 4.7.2](#). The registered pharmacist dispensing medication(s) for an individual patient should review the medication order or prescription in the context of the patient's full medication regimen (where available) prior to the medication(s) being handed to the patient (or patient's carer).

#### Outpatient Dispensing

Prescriptions for dispensing Schedule 4 medications and Schedule 8 medications for the use by outpatients must be in the form detailed in [section 4.7.1](#) and [section 4.7.2](#) for Schedule 4 and Schedule 8 medications respectively.

## 5.5.2 Schedule 8 Prescriptions – Additional Requirements

A prescription for a Schedule 8 medication cannot include any other medication, including another form or strength of the same Schedule 8 medication.

A registered pharmacist must not dispense a prescription for a Schedule 8 medication unless he/she: -

- a) Is familiar with the handwriting of the prescriber who issued the prescription, or
- b) Knows the patient for whom the medication is prescribed, or
- c) Has verified that the prescriber named on the prescription has actually issued the prescription. In the case where the prescriber is not contactable, a registered pharmacist may supply the Schedule 8 medication in a quantity sufficient for no more than 2 days' treatment pending verification with the prescriber purported to have issued the prescription.

## 5.5.3 Emergency Dispensing on a Verbal, Telephone, Facsimile or Email Order from an Authorised Prescriber

In an emergency, a registered pharmacist may dispense a prescription for any medication on the verbal (face to face), telephone, facsimile or email order of an authorised prescriber (see [section 4.7.4](#)).

In the case of a Schedule 4 or Schedule 8 medication order, the prescriber must send the prescription without delay (and within 24 hours) to the registered pharmacist to whom the direction was given. If this prescription is not received within 7 days, this fact must be reported by the registered pharmacist involved to the Director General of Health at [Pharmaceutical Services Unit](#).

## 5.5.4 Prescription Forgeries

Detected prescription forgeries for any medication must be reported to the local police and to [Pharmaceutical Services Unit](#).

## 5.5.5 Dispensing Re-Packaged Patient-Labelled Medications

Re-packaging for the purpose of dispensing medications labelled for the use of an individual patient must be in accordance with Part 2, sections 20 to 26 of the [Standard for the Uniform Scheduling of Medicines and Poisons](#).

Re-packed patient-labelled medications must include Child Resistant Packaging in accordance with the detail described in [section 5.5.6](#) and labelled in accordance with the requirements of [section 5.5.7](#).

## 5.5.6 Child Resistant Packaging

The Pharmacy Service must have a system in place to identify at the time of dispensing those medications requiring child resistant packaging. The Pharmacy Service must hold

adequate stocks of the complete range of containers that include a child resistant closure for the facility's purposes.

### Legislative Framework

[Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines](#) (TGO 80) specifies those medications that must be supplied in child resistant packaging and the situations and conditions under which they are exempt from these requirements.

[Therapeutic Goods Order No. 80A Amendments to Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines](#) (TGO 80A) amends TGO 80 with an additional list of medications that also require child resistant packaging.

TGO 80 specifies the standards that child resistant packaging must meet. TGO 80 also provides exemptions to the use of child resistant packaging, including (but are not limited to) the following medications: -

- To be used by, or administered to, a patient for treatment in a public hospital, private hospital, nursing home, dental hospital or dental surgery, or
- Intended to be administered by injection, or
- A solid or semi-solid (excluding solid dosage forms) preparation intended for application to the skin or mucous membrane, including transdermal patches, or
- A liquid or semi-solid preparation intended for application to the eye, ear or mucous membrane, and supplied in a container that;
  - has a nominal capacity of not more than 20 millilitres, or
  - is fitted with a restricted flow insert, or
- An individually wrapped powder, or
- A liquid preparation in spray presentation if;
  - the delivery device is engaged into the container in such a way that prevents it
  - from being readily removed, and
  - direct suction through the delivery device results in delivery of no more than one
  - dosage unit, and
  - actuation of the spray device is ergonomically difficult for young children to accomplish, or
- A paste, powder or gel for the cleaning of teeth.

Medications identified by TGO 80 and TGO 80A as requiring child resistant packaging, and are not exempted, must carry the appropriate warning flag or statement relating to child resistant packaging where they appear in pharmacy information systems (see below).

### Pharmacy Information Systems – Format of the Warning Flag and Statement for Child Resistant Packaging

The format of warning flags and statements for inclusion in pharmacy information systems has been determined in consultation with the NSW Medication Safety Expert Advisory Committee and the Pharmacy Improvement Program team at HealthShare NSW.

Child resistant closure warning flags and statements must conform to the following: -

- Location of the warning flag or statement;  
The warning flag and statement are intended to provide information for staff involved in the dispensing of the medications.

The warning flag or statement must be printed on labels produced by the pharmacy information system in order to be visible to all staff involved in the dispensing process. The warning flag or statement does not need to be printed on the main dispensing label used for the labelling of patients' medications and may be printed on any portion of the dispensing label. However, it must be positioned in such a way as to ensure that it is printed for all medications that it is associated with. It must not be obscured by other text or omitted for any reason. If this requires the warning flag or statement to have a unique field and space created for it on dispensing labels, such space must be created.

- Warning flag text;  
Where the warning flag appears it will be presented as the text '**KIDCAP**'.
- Warning statement text;  
Where the warning statement appears it will be presented as the text '**Child resistant packaging required**'.

Medications on the Hospital Pharmacy Product List that have been assigned the KIDCAP warning flag and associated warning statement (as defined by Therapeutic Goods Orders from time to time) can be found on the HealthShare webpages for the HPPL in the document entitled '[HPPL warning codes](#)'.

Users should check the site for the current list as updates are made regularly.

### **Settings Where Child Resistant Packaging Must Be Used**

All medications identified by TGO 80 and TGO 80A as requiring child resistant packaging, and are not exempted, must be supplied in child resistant packaging. This includes the supply by both a registered pharmacist and an authorised prescriber. Medications for use within the hospital and outside of the hospital that require child resistant packaging include, but are not limited to: -

- Outpatient dispensed medications, and
- Discharge medications, and
- Medications dispensed for day or weekend leave, and
- Emergency Department pre-packs of medication and in other situations where the medication may later be supplied to a patient for take-home use.

Labels generated by pharmacy information systems for medications used in these settings must carry the warning flag '**KIDCAP**' or the warning statement '**Child resistant packaging required**'.

However, in accordance with local protocols and circumstances approved by the Drug and Therapeutics Committee, a registered pharmacist can exercise discretion, in consultation with the authorised prescriber as appropriate, and not dispense the medication in child resistant packaging when the registered pharmacist and/or the authorised prescriber is of the opinion that the patient would suffer undue hardship through difficulty in opening the container.

In this case, adequate instructions in writing, and verbally where possible, must be given to the patient and/or the patient's carer (as applicable) about the potential risk if the medication is swallowed by a child.

### 5.5.7 Labelling of Dispensed Medications

Dispensed medications must be labelled in accordance with Appendix A to the [Poisons and Therapeutic Goods Regulation 2008](#), with: -

- a) The patient's name, and
- b) The medication's active ingredient/s, proprietary name (where applicable), form, strength and the quantity supplied, and
- c) Adequate directions for use including, where ordered, the instructions specified by the prescriber, and
- d) The Pharmacy Service's dispensing reference number, and
- e) The date of dispensing (unless that date is clear from the dispensing reference number), and
- f) The name and address of the hospital, and
- g) The words '**KEEP OUT OF REACH OF CHILDREN**' in red on a white background, and
- h) If the substance is intended for external use only, the words '**FOR EXTERNAL USE ONLY**' or the word '**POISON**' in red on a white background, and
- i) If the substance is supplied in the circumstances referred to in [section 5.5.3](#) on a verbal, telephone, email or facsimile order, the words 'EMERGENCY SUPPLY', and
- j) Any ancillary label/s required for the particular active ingredient/s with the associated warning statement.

In the case of a preparation for which a proprietary product or a standard Australian Formulary does not exist, registered pharmacists must ensure that the dispensed medication clearly indicates the strength of the preparation with the dose prescribed and any additional detail relevant to the formula used.

### 5.5.8 Mandatory Ancillary Labels and Warning Statements

The use of an ancillary label with the associated warning statement is mandated with dispensed medications for: -

#### 1. Specified Sedating Medications

The label on a container of the [specified sedating medications](#) listed in Appendix K to the [Standard for the Uniform Scheduling of Medicines and Poisons](#) must bear Warning Statement 39, 40 or 90. The warning must be immediately preceded by a symbol in the

form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red. The Warning Statements are: -

- No. 39** *'This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol', or*
- No. 40** *'This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery', or*
- No. 90** *'This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol'.*

## 2. Specified Stimulant Medications

The medications are: -

amphetamine  
chlorphentermine  
dexamphetamine  
diethylpropion  
ephedrine  
methylphenidate  
phentermine  
propylhexedrine

The label on a container of such a substance (being a substance that is represented as being for oral use by a person other than a child under 16 years old) must bear the words 'THIS MEDICATION (or MEDICINE) MAY AFFECT MENTAL ALERTNESS OR CO-ORDINATION OR BOTH. IF AFFECTED, DO NOT DRIVE A MOTOR VEHICLE OR OPERATE MACHINERY'.

The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

## 3. Quinine

The label on a container of quinine must bear the words 'WARNING - MAY BE FATAL TO CHILDREN'.

### 5.5.9 Unregistered Medications Used in Clinical Trials

A clinical trial drug which is not registered or listed on the Australian Register of Therapeutic Goods must be labelled, stored, prescribed and administered either: -

- a) Where the substance or a similar substance is currently included in the NSW Poisons List (or is exempt from the NSW Poisons List), in accordance with that Schedule (or exemption), or,
- b) Where there is no similar substance on the NSW Poisons List, as a Schedule 4 substance.

### 5.5.10 Records of Dispensing

A registered pharmacist must record the dispensing of patient-labelled medication by: -

- Entering the details in an approved computer dispensing system (such as 'iPharmacy'), or
- Writing the details in a prescription book, or
- Retaining the prescription, or a copy of the prescription or medication chart order (as applicable) in chronological order of the date on which the medications were dispensed.

The record of the dispensing of a patient-labelled medication must include: -

- a) The date on which the prescription or order was issued, and
- b) The patient's name, and address and/or patient care area, and
- c) The medication's active ingredient/s, proprietary name (where applicable, as supplied), strength, form and the quantity supplied, and
- d) Adequate directions for use including, where ordered, the instructions specified by the prescriber, and
- e) Where prescribed, the number of repeat supplies of the medication, and
- f) Where repeats are ordered for Schedule 8 or Schedule 4 Appendix B medications, the interval at which the medication may be repeat supplied, and
- g) The name and designation of the authorised prescriber, and the name, address and telephone number of the facility, and
- h) The unique reference dispensing number issued at the Pharmacy Service, and
- i) The date on which the medication was dispensed, and
- j) The name of the registered pharmacist who dispensed the medication.

Where a medication is dispensed as an 'EMERGENCY SUPPLY' on a telephone, email, or facsimiled order from an authorised prescriber in accordance with [section 5.5.3](#), the dispensing record must also include: -

- The date on which the substance was supplied, and
- The name of the registered pharmacist who dispensed the medication.

Irrespective of the recording system used, dispensed prescriptions for Schedule 8 and Schedule 4 Appendix B medications must be retained at the Pharmacy Service, and must be kept apart from all other prescriptions.

All dispensing records, as well as the (original) dispensed prescriptions for Schedule 8 and Schedule 4 Appendix B medications, must be retained at the Pharmacy Service and must be available for inspection on request by an authorised inspector of NSW Health or a NSW police officer.

## 5.6 Stock (Imprest) Supplies to Patient Care Areas

### 5.6.1 Requisitions for Imprest Medications

Imprest (non-patient labelled 'stock') medications may be supplied from the Pharmacy Service either: -

- With reference to the approved Imprest List for the patient care area, or
- On the clear and legible requisition of the registered nurse/midwife in charge of the patient care area where the medication is to be used, either as the original hand written (hard copy) order, by facsimile, by email or another approved electronic form, or
- From a clear and legible medication chart order by an authorised prescriber, either sighted then photocopied by the registered pharmacist (or the authorised director of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted) or alternatively forwarded to the Pharmacy Service by facsimile, email or another approved electronic form.

The range of medications and respective stock levels on an Imprest List must be set by agreement between the nurse/midwife in charge of the patient care area and the facility's director of pharmacy and regularly reviewed using a risk assessment approach in accordance with protocols approved by the Drug and Therapeutics Committee.

The Pharmacy Service must maintain a record of all supplies of impost medications to patient care areas.

### 5.6.2 Re-Packaging and Labelling of Imprest Supplies

Imprest medications supplied from the Pharmacy Service to patient care areas should preferably be in the manufacturers' original packs. These original packs do not have to be further labelled but supplementary labelling may be applied as deemed appropriate by the supplying registered pharmacist.

Re-packaging of medications must be carried out by, or under the supervision and checked by, a registered pharmacist before delivery to the patient care area.

The packaging of re-packed items must be in accordance with the provisions of Part 2, sections 20 to 26 of the [Standard for the Uniform Scheduling of Medicines and Poisons](#). **Child Resistant Packaging** must be included with all re-packed medication provided to the Emergency Department and in other situations where the medication may later be supplied to a patient for take-home use (see [section 5.5.6](#)).

Labelling of re-packed items for impost stock must include, as a minimum, the following details: -

- The medication's active ingredient/s, proprietary name (where applicable), form, strength and the quantity supplied, and

- If applicable, that the preparation is a Schedule 8 or Schedule 4 Appendix D medication, and
- The batch number and expiry date of the original pack, or the Pharmacy Service's batch number in the case of a Pharmacy Service manufactured preparation, and
- The words '**KEEP OUT OF REACH OF CHILDREN**' in red on a white background, and
- If the substance is intended for external use only, in red on a white background the words '**FOR EXTERNAL USE ONLY**' or the word '**POISON**', and
- The name and address of the facility, and
- Any applicable additional information included on the manufacturer's original pack.

### 5.7 Pharmacy Service Schedule 8 Medication Accountability

#### 5.7.1 Entries in the Schedule 8 Drug Register

The Pharmacy Service must record all transactions of Schedule 8 medications in a drug register.

The drug register must be a bound book with consecutively numbered pages. A separate page must be used for each form, each strength, and each brand of the Schedule 8 medication.

A 'signature register' should be maintained by the director of pharmacy with the name, signature, and health practitioner registration number of all staff authorised to access the Schedule 8 medication storage unit(s), and should be kept separate to the Schedule 8 drug register.

The record in the drug register must be made on the day the transaction occurred and must include: -

- The date of the transaction, and
- The name and address of the supplier from whom the medication was received or the name and address of the person to whom the medication was supplied, except;
  - In the case of dispensing to an in-patient only, the patient's identification number may be entered instead of the address, or
  - In the case of a supply to a patient care area, the name of the ward, unit, clinic or service, and
- The quantity of the medication received, supplied, or destroyed, and
- The balance of the medication after the transaction. With regard to repacked liquid medicines, overage (excess) to the physical balance in the Schedule 8 medication storage unit is accounted for by adjusting the balance upwards on the next available line of the page. Deficits must be recorded and reported in accordance with the procedure detailed in [section 5.9](#), and
- The prescription reference number in the case of a medication supplied on a prescription, or the supplier's invoice or reference number in the case of a medication obtained from a pharmaceutical wholesaler, and

- The name of the requisitioning registered nurse/midwife for imprest supplies, or the name of the authorised prescriber for patient-labelled medications, and
- The full and legible signature of the registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted, making the entry, and
- Where the Schedule 8 medication is destroyed, in accordance with the additional requirements detailed in [section 5.8.2](#).

A registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted, who makes an entry in the Schedule 8 drug register: -

- Must not make a false or misleading entry, and
- Must not make any alterations, obliterations or cancellations. That is, no lines may be drawn through entries, no entries scribbled out or crossed out in any way, nor numerals altered. If a mistake is made, the entry must be left as it is, marked with an asterisk, rewritten as corrected on the next line with a note explaining the error (signed and dated) also marked with an asterisk.

### 5.7.2 Schedule 8 Medication Balance Checks

A check of the balance of all Schedule 8 medications held in the Pharmacy Service must be made during March and September each year as a minimum, and at other times as deemed necessary by the director of pharmacy and approved by the Drug and Therapeutics Committee.

Opened containers of liquids should be decanted and measured by a registered pharmacist to obtain the physical balance on hand.

The balance must be recorded under the last entry for each medication, and signed and dated. It is not sufficient to make a single entry on one page of the drug register to cover the checks of all Schedule 8 medication stocks.

Any detected loss (deficit) must be reported to the NSW Ministry of Health Pharmaceutical Services Unit, as described in [section 5.9](#).

A delegated registered pharmacist or authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted who assumes control over the Schedule 8 medication stock for one month or more must, immediately on assuming control, perform a full balance check as described above.

## 5.8 Disposal/Destruction of Medications

### 5.8.1 Disposal of Medications – General Requirements

The Pharmacy Service must have processes to dispose of all expired, unusable unwanted medications in accordance with NSW Health Policy Directive [PD2005\\_132](#) '[Waste Management Guidelines for Health Care Facilities](#)'.

Expired, unusable or unwanted medication must not be collected for the purpose of donation for humanitarian relief, in accordance with the '[Australian guidelines for medication donations to developing countries](#)'.

### 5.8.2 Destruction of Expired, Unusable or Unwanted Schedule 8 Medications

The following staff may destroy expired, unusable, or unwanted Schedule 8 medications at the Pharmacy Service: -

- The director of pharmacy of the Pharmacy Service, or
- A registered pharmacist authorised by the director of pharmacy, or
- At a hospital where no registered pharmacist is employed/contracted, the authorised officer of the Pharmacy Service.

The destruction of Schedule 8 medication must be in the presence of a witness, being: -

- A registered pharmacist, or
- A registered medical practitioner or registered dentist, or
- A registered nurse/ midwife in charge of a patient care area that has been authorised by the facility's director of nursing for this purpose.

The corresponding Schedule 8 drug register entry recording the destruction must include the following: -

- The quantity of the particular Schedule 8 medication destroyed, and
- The date of the destruction, and
- The name, signature and health practitioner registration number of the person destroying the medication, and
- The name, signature and health practitioner registration number of the person who witnessed the destruction.

An authorised officer of the NSW Ministry of Health or a NSW police officer may also destroy or supervise the destruction of Schedule 8 medications at a Pharmacy Service, including recording the destruction in the Pharmacy Service drug register.

Schedule 8 medications must be destroyed in such a way that the medications are made unidentifiable (that is, not disposed of intact in the original labelled packaging), unrecoverable and unusable, and are not likely to cause undue damage to the

environment or pose a risk to any person. The director of pharmacy and/or the Drug and Therapeutic Committee may determine local protocols to achieve this requirement.

Recommended procedures for the destruction of Schedule 8 medications are detailed in [section 5.8.3](#).

### 5.8.3 Recommended Methods for the Destruction of Schedule 8 Medications

The destruction of Schedule 8 medications at the Pharmacy Service must be recorded in the drug register, as described in [section 5.7.1](#).

Where appropriate, the person destroying the medication should wear disposable gloves and/or a disposable mask.

After the destruction: -

- The containers and implements used in the destruction must be thoroughly washed, and
- Hands must be thoroughly washed with warm soapy water, and
- A final check of the area where the medications were destroyed must be conducted to make sure that no drug material has been inadvertently left on the floor, bench, sink or surrounding areas.

The packaging must also be destroyed or defaced. When separated from the medication being destroyed, cardboard packs and emptied foils should cut or torn, and the labels of emptied bottles, vials and bags defaced. All such material must then be disposed of in a suitable secured receptacle. Recommended procedures for the destruction of Schedule 8 medications are: -

#### A. Tablets, Capsules and Suppositories

1. Remove the medication from the foil, blister platforms or bottles and place in a mortar or other suitable strong container, taking care that no medication falls outside the container. Check each foil/blister platform/bottle carefully before discarding to make sure that no medication remains. Large capsules (for example *Kapano*® 100mg) may be pulled apart and the contents and shells placed in the mortar/container.
2. Crush the medication in the mortar/container with a pestle or similar implement, mixing with an adequate quantity of hot soapy water, methylated spirits, or methyl salicylate liniment or the like. Take care that no drug material is forced out of the container during this process.
3. Pour the resulting slurry onto absorbent material such as cat litter granules or shredded paper and dispose of in a 'clinical waste' bin or a [Return Unwanted Medicines \(RUM\) Project](#) bin.

#### B. Liquids

1. Pour the liquid onto absorbent material such as cat litter granules or shredded paper.

2. Dispose of in a 'clinical waste' bin or a [Return Unwanted Medicines \(RUM\) Project](#) bin.

### C. Powders and Granules

1. Mix the powder in a suitable container with an adequate quantity of hot soapy water, methylated spirits, or methyl salicylate liniment or the like.
2. Pour the resulting slurry onto absorbent material such as cat litter granules or shredded paper and dispose of in a 'clinical waste' bin or a [Return Unwanted Medicines \(RUM\) Project](#) bin.

Note: Additional caution must be taken when handling *MS Contin*® controlled release suspension - granules for reconstitution, as the granules contain an intense dye.

### D. Injectable Medications

Glass ampoules/small vials;

1. In most cases ampoules which are in a cardboard carton may be crushed in the manufacturer's pack, enclosed with newspaper. Alternatively, remove the ampoules/vials from the carton and enclose with newspaper.
2. Place the wrapped pack of ampoules/vials on a hard floor on additional newspaper and crush underfoot (wearing sturdy hard soled shoes), or with an implement such as a hammer.
3. Pick up the wrapped ampoules carefully and dispose of in a sharps container.

Plastic ampoules, plastic IV infusion bags and large vials;

1. Pour the contents onto absorbent material such as cat litter granules or shredded paper.
2. Dispose of in a 'clinical waste' bin or a [Return Unwanted Medicines \(RUM\) Project](#) bin.

### E. Transdermal Patches and Sublingual Film

1. Cut each sachet with the patch enclosed into several pieces.
2. Disperse in a small quantity of hot soapy water, methylated spirits, or methyl salicylate liniment or the like, then dispose of the solution in a sharps container.

Caution: Fentanyl patches, even after being used or when expired, contain sufficient fentanyl to cause life-threatening respiratory depression in an opioid-naïve person if absorbed. If during the destruction of fentanyl patches the active layer come into contact with the skin or other body surface, immediately wash off thoroughly with soap and water.

## 5.9 Reporting Lost or Stolen Accountable Medications

Accountable medications are defined as Schedule 8 medications and Schedule 4 Appendix D medications. However, medications such as propofol, methoxyflurane or the codeine phosphate compound preparations that are also accounted for in a register at the Pharmacy Service in accordance with local protocols must also be managed as accountable medications for the purpose of this section.

A registered pharmacist/authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted who detects the loss, theft or deficit of an accountable medication must immediately: -

- Report this fact to the facility's director of pharmacy, and
- Complete and submit a report in accordance with the facility's incident management system under the requirements of NSW Health Policy Directive [PD2007\\_061](#) '[Incident Management](#)'.

This includes all medication that cannot be supplied or used, such as the loss of liquid by spillage, and the loss in broken or damaged bottles and ampoules, but does not include medication that is intact but expired, unusable unwanted, and is instead destroyed in accordance with [section 5.8.2](#) for Schedule 8 medications and [section 5.8.1](#) for other accountable medications.

The registered pharmacist/authorised officer of the Pharmacy Service who detected loss, theft or deficit of the Schedule 8 medication must also immediately record the physical balance on hand in the Schedule 8 drug register with an explanatory note highlighting the deficit from the arithmetical balance.

The director of pharmacy must notify the NSW Ministry of Health at Pharmaceutical Services Unit immediately using the [on-line notification form](#).

This immediate notification to Pharmaceutical Services Unit should be marked on the form 'Initial Notification'. As soon as all notifiable details become available, such as when further investigation has been conducted, a follow-up notification should be submitted to Pharmaceutical Services Unit, again using the [on-line notification form](#).

The director of pharmacy must also: -

- Ensure that a full investigation of the loss, theft or deficit of the medication is conducted.
- With a confirmed theft, report the event to the local police.
- With confirmed misappropriation by a staff member, report the matter to the particular health practitioner's national registration board as well as to [Pharmaceutical Services Unit](#).

Where there is no apparent loss of medication, but a concern exists of possible, or admitted, misappropriation of medication by a staff member, this must similarly be reported to the director of pharmacy for further appropriate action, as detailed above. Failure to report these incidents may result in harm to a patient or to the member of staff, particularly where a possibility exists that this staff member is drug dependent and/or health impaired.

The Pharmacy Service can pro-actively prevent the misappropriation of medications by ensuring strict adherence to NSW Health and local protocols and procedures.

## 5.10 Reporting a Lost, Destroyed or Tampered Schedule 8 Drug Register

A registered pharmacist/authorised officer of the Pharmacy Service who detects that a drug register appears lost, destroyed, has had pages removed, or has tampered entries or pages must immediately report the matter to the director of pharmacy.

The director of pharmacy must immediately: -

- Notify the NSW Ministry of Health at [Pharmaceutical Services Unit](#) in writing of the known detail of the circumstances of the loss, destruction or tampering, and
- Arrange for a registered pharmacist to carry out a balance check of Schedule 8 medications involved, and enter the particulars in a new drug register, and
- Complete and submit an incident report in accordance with the facility's incident management system.

## 5.11 Retention Periods for Records, Prescriptions and Drug Registers

The following retention periods apply to records relating to dispensing and supply of medications by the Pharmacy Service, In accordance with NSW Policy Directive [PD2009\\_057 'Records Management'](#) and the [State Records Authority of NSW](#): -

- **2 years** for prescriptions (except 'Section 100' Highly Specialised Drugs Program prescriptions which are for 7 years), records of medication chart orders, requisitions, receipts/records of deliveries, inventory control records, manufacturing records and purchase orders for all medications and pharmaceuticals.
- **7 years** for drug registers, records relating to the supply of medications under the 'Section 100' Highly Specialised Drugs Program (including prescriptions and declaration forms), Special Access Scheme approvals and records relating to the organisation's compliance with mandatory or optional standards or with statutory requirements. This applies whether the drug is held or not at the Pharmacy Service.
- **10 years** for records relating to reports of lost or stolen Schedule 8 or Schedule 4 Appendix D medications, and Schedule 8 drug registers.
- **15 years** for clinical trial drugs **or** until the patient attains the age of 25 years of age, whichever is longer.

## 6 PATIENT CARE AREAS

### 6.1 Responsibility

The registered nurse/midwife in charge of a patient care area is responsible for the procurement and storage of all medications in that area. This person must ensure that the medications are stored in accordance with all legal requirements and that the correct provisions are met in relation to medication security, temperature control, stock rotation, and disposal of expired and unwanted medications.

Exceptions are provided in patient care areas where a registered nurse/midwife in charge is not employed, and the responsibility for the procurement and storage of medications is delegated to an appropriately authorised person (for example certain nuclear medicine departments, radiography departments, dental clinics, as applicable).

Patient care area medication management systems must include: -

- The range and quantities of medications stocked in each patient care area being appropriate for the needs of the area, and
- Storage in a manner that minimises medication error due to a mix-up between preparations, and
- A routine procedure of stock rotation and monitoring of expiry dates, with unwanted, unusable, or expired medications disposed of in accordance with [section 6.15.1](#) and also [section 6.15.2](#) for Schedule 8 medications, and
- Temperature storage consistent with the specifications on the manufacturers' packs.

Medications requiring refrigeration should be monitored with a temperature sensor that includes an audible alarm when the required temperature range (normally 2-8°C) is breached. Appropriate action following events when the storage temperature deviates from the manufacturer's nominated temperature range must be taken, further to the assessment of the risk by the director of pharmacy that the quality, safety and/or efficacy of the medication(s) has been compromised.

## 6.2 Medication Procurement By Patient Care Areas

### 6.2.1 General Provisions

Patient care areas may obtain medications either from: -

- The Pharmacy Service, either as imprest stock, or labelled for an individual patient in accordance with a medication chart order or prescription issued by an authorised prescriber, or
- Directly from a pharmaceutical wholesaler (commonly referred to as 'Vendor Managed Inventory'), in accordance with the protocol approved by the facility's director of pharmacy and Drug and Therapeutics Committee.

The Drug and Therapeutics Committee is responsible for formulary management at the facility's patient care areas, that is the evaluation and approval of medications for use throughout the facility in accordance with NSW Health Policy Directive [PD2008\\_037](#), '[Medicine - Evaluation of Medicines for Use in Public Hospitals](#)', including the 'off-label use' ('unapproved use') of medications for general, restricted or individual patient use.

Medications may be ordered by the registered/nurse midwife in charge of the patient care area or by an authorised prescriber on an (original) written order, facsimile, email or another approved electronic form.

### 6.2.2 Receipting Schedule 8 Medication Deliveries

Schedule 8 medication may be delivered to a registered nurse/midwife of the patient care area either: -

- a) By a facility staff member for Schedule 8 medication ordered from the Pharmacy Service, under the direction of a registered pharmacist, or the authorised officer at the Pharmacy Service where no registered pharmacist is employed/contracted, or
- b) By a courier arranged by the Pharmacy Service for transfers to a patient care area remote to the Pharmacy Service, or
- c) By a courier arranged by the pharmaceutical wholesale supplier in the case of deliveries directly from the wholesaler.

Alternatively, Schedule 8 medication ordered from the Pharmacy Service may be collected by a registered nurse/midwife from the patient care area.

The registered nurse/midwife who receives the Schedule 8 medication on behalf of the patient care area must provide to the Pharmacy Service/pharmaceutical wholesaler a signed and dated receipt confirming the quantity of the medication supplied. A copy of this receipt must also be retained at the patient care area.

Where Schedule 8 medication is delivered by a courier who is not a facility staff member, the person receiving the unopened sealed parcel must also sign and date a 'proof of delivery' receipt (either electronically or in hard copy) for the parcel.

The registered nurse/midwife who receives the Schedule 8 medication delivery must immediately enter the supply in the patient care area drug register in accordance with [section 6.13.1](#) and lock the medication in the Schedule 8 drug storage unit with a witness as described in [section 6.13.2](#).

Systems for the delivery, collection and transfer of Schedule 8 medications should include procedures designed to minimise the opportunities for misappropriation, for example: -

- By checking that tamper-evident seals are intact, and
- By conducting audits, in accordance with protocols approved by the Drug and Therapeutics Committee, of drug registers which includes checks against the signed and dated receipts of supplies to, and transfers from the patient care area.

### Transferring Schedule 8 Medications Between Patient Care Areas

Local protocols should detail the circumstances and procedures under which Schedule 8 medication may be transferred between patient care areas, including the need for this to only occur after-hours when the Pharmacy Service is not available. When transferring Schedule 8 medication for use in another patient care area, a signed and dated requisition and receipt must be provided by the registered nurse/midwife in charge of the patient care area obtaining the Schedule 8 medication.

This signed and dated requisition and receipt must be retained in the patient care area supplying the medication, and a copy retained at the patient care area obtaining the medication. The corresponding drug register entries detailing the transaction must be completed for both patient care areas concurrently, in accord with the detail included in [section 6.13.1](#). Arrangements should be made as soon as is practical to obtain subsequent supplies of the medication from the pharmacy.

### 6.2.3 Pharmacy Service Packs or Re-Packs

All medications must be stored in patient care areas in the same container as received from the Pharmacy Service. This applies to either the manufacturer's original pack, or a re-pack labelled by a registered pharmacist.

An exception is provided for medications required urgently in medical emergencies on emergency, resuscitation or anaesthesia trolleys, where rapid access is essential and the quantity held is minimal, and in accordance with a standard stock list appropriate for the purpose.

Re-packing must not occur outside of the Pharmacy Service, including the 'pooling' of medication from multiple containers into one container, re-labelling or over-labelling of containers, or re-packing from bulk stock into smaller containers.

### 6.2.4 Use of Patient's Own Medication and Complementary Medicines

A patient's own medication generally may only be used in the event that the patient care area does not have immediate access to the facility's stocks of the medication.

The medication must be obtained by the patient care area as soon as possible, and when received, the patient's own supply must be withdrawn from use.

Exceptions may be made in the case of specialised formulations for individual patients (such as paediatric patients), personal use items for self-administration (for example, eye drops and inhalers), clinical trial drugs, Special Access Scheme medications, non hospital formulary medications and complementary medicines. A registered pharmacist should verify the suitability for use of the medication in the particular circumstances, that is, without replacing the medication with Pharmacy Service stock.

The Council of Australian Therapeutics Advisory Group [Guiding Principles for the Use of Complementary and Alternative Medicines in Hospitals](#) provides guidance to facilities in the development of local protocols and procedures for the management and use of complementary and alternative medications (CAMs) alongside conventional medical or surgical treatments.

An exception is also provided for patients attending (non inpatient) day centres (see [section 7.10](#)) where the staff member is assisting the patient in self-administration.

The use of a patient's own medication in a patient care area must be specifically notated by an authorised prescriber as appropriate for use alongside the medication order on the medication chart.

When not returned to the patient for whatever reason, patient's own medications must be disposed of in accordance with [section 6.15.1](#) and [section 6.15.2](#) (for Schedule 8 medications), and must not be retained as stock for administration to other patients.

### 6.2.5 Methadone and Buprenorphine for Opioid Treatment Program Patients

Other than at public Opioid Treatment Program clinics or dosing points, due to security and safety issues, methadone syrup/liquid for the management of opioid dependence should be supplied to patient care areas from the Pharmacy Service as separate daily doses either as pre-packed and labelled doses or as individual patient labelled doses. However, local protocols may provide for specific high use patient care areas to obtain the manufacturer's 200ml pack size, including, but not limited to, drug detoxification units.

The oral buprenorphine tablet or film preparations Subutex® and Suboxone® (with naloxone) may be supplied to the patient care area in the original manufacture's pack, as registered pharmacist labelled re-packs, or labelled by the registered pharmacist for an individual patient.

Patient's own ('take-away') supplies of Opioid Treatment Program medications should not be administered to inpatients.

Patient's own ('take-away') supplies of Opioid Treatment Program medications handed over by the patient on admission must only be returned to the patient on discharge when both the patient's Opioid Treatment Program prescriber and dosing point have been advised accordingly.

## 6.3 Medication Storage in Patient Care Areas

### 6.3.1 Storage of Schedule 8 Medications

Stock levels of Schedule 8 medications should be kept to the lowest practical level in patient care areas.

All Schedule 8 medications must be stored in the Schedule 8 medication storage unit, including a patient's own Schedule 8 medication(s) and Schedule 8 medication(s) labelled for supply to a patient on discharge.

Schedule 8 medications must be stored apart from all other medications, except when stored with Schedule 4 Appendix D medications, and apart from all other goods (such as keys, cash, documents) in an appropriate Schedule 8 medication storage Unit.

A Schedule 8 medication storage unit must be a sturdy cabinet, preferably a metal safe, securely attached to the floor or a wall and kept locked when not in immediate use. The lock should be a five lever lock, or have a locking mechanism which provides at least

equivalent security. Consideration should also be given for the security of the Schedule 8 medication storage unit(s) to include closed circuit television (cctv) monitoring.

When new facilities are built, or existing facilities renovated, any remaining wooden Schedule 8 cupboards should be upgraded with the installation of metal safes.

Where a key is used to access the Schedule 8 medication storage unit, transfer of the custody of the key must be strictly controlled, including being kept separate to all other keys.

The registered nurse/midwife in charge of the patient care area should hold the Schedule 8 medication storage unit key/s during his/her work shift, and hand the relevant key to each registered nurse/midwife or authorised prescriber requesting access to the Schedule 8 medication storage unit as required. When the particular task is completed, the registered nurse/midwife or authorised prescriber must immediately return the key to the registered nurse/midwife in charge of the patient care area.

However, in the case of a Schedule 8 medication storage unit within an operating theatre, a delegated registered nurse/midwife in charge or an authorised prescriber (such as an anaesthetist) should hold the key on behalf of the registered nurse/midwife in charge.

Provision must also be made for when the registered nurse/midwife currently in charge of the patient care area is unavailable, for example during meal breaks, by handing the key/s to a delegated registered nurse/midwife.

In accordance with local protocols, when a patient care area is closed for any purpose, any keys to that area's Schedule 8 medication storage units should be either: -

- a) Stored in a metal torch and drill resistant key safe, securely attached to the wall or floor of the patient care area, or
- b) Handed over to the registered nurse/midwife in charge of the facility, or
- c) Handed over to the facility's Nursing and Midwifery Administration for securing in a safe or a key safe, or
- d) Handed over to the facility's security service for securing in a safe or a key safe.

Any spare keys to a patient care area Schedule 8 medication storage unit should be retained in a safe or key safe at the facility's Nursing and Midwifery Administration.

A code or combination required to unlock the Schedule 8 medication storage unit must only be provided to a registered nurse/midwife or an authorised prescriber, in accordance with local protocols. Regular changing of this code or combination is required, also in accordance with local protocols.

Schedule 8 medications must not be transferred to medication trolleys for administration during a medication round, except where provided for in accordance with protocols approved by the facility's Drug and Therapeutics Committee. Where this practice is

approved, at the conclusion of the medication round the Schedule 8 medication packs must be returned to the Schedule 8 medication storage unit.

Patient care areas that are routinely closed over short periods of time (for example on weekends) must be securely locked to prevent unauthorised access. When a patient care area is closed for longer periods, the Schedule 8 medication packs should be sealed with tamper evident tape or in tamper evident packs, and transferred in accordance with local protocols to another appropriate patient care area Schedule 8 medication storage unit or to the Pharmacy Service.

### 6.3.2 Storage of Schedule 4 Appendix D Medications

Schedule 4 Appendix D medications must be stored apart from all other medications and goods (such as keys, cash and documents), except: -

- When stored in the Schedule 8 medication storage unit, or
- When stored on an emergency trolley, anaesthetic trolley, or operating theatre trolley. In these cases, Schedule 4 Appendix D medications must be kept at minimal levels and the trolleys kept in a locked room when the patient care area is closed, with access only by authorised persons.

Where Schedule 4 Appendix D medications are stored apart from Schedule 8 medications, this must be in a separate safe or cupboard securely attached to the premises, and which is kept securely locked when not in immediate use. This can include but is not limited to the 'Schedule 8 drug cabinet within a Schedule 4 Appendix D drug cupboard' model.

A code or combination required to unlock the Schedule 4 Appendix D medication storage unit must only be provided to a staff member authorised to access the medication. Regular changing of this code or combination is recommended, in accordance with local protocols.

Where the same key is used to access both Schedule 4 Appendix D and Schedule 8 medications, this key must be kept separate from all other keys (other than another key used to access a separate Schedule 8 medication storage unit).

Where Schedule 4 Appendix D and Schedule 8 medications are stored in the same storage unit, the procedures for the custody of the Schedule 8 medication storage unit key must be followed as detailed in [section 6.3.1](#). This will restrict access to the key to a registered nurse/midwife or an authorised prescriber.

Where provided for under local protocols approved by the facility's Drug and Therapeutics Committee, Schedule 4 Appendix D medication packs may be moved to a medication trolley for the purpose of administering doses during a medication round. At the conclusion of the medication round, the Schedule 4 Appendix D medication packs must be returned to the Schedule 4 Appendix D medication storage unit.

### 6.3.3 Storage of Unscheduled, Schedule 2, Schedule 3 and Non-Appendix D Schedule 4 Medications

Medications in Schedule 2 (*Pharmacy Medicine*), Schedule 3 (*Pharmacist Only Medicine*), non-Appendix D Schedule 4 medications and unscheduled medications must be stored out of patient and public access, preferably in a locked room or a locked cabinet securely attached to the wall or floor of the premises, with the following exceptions: -

- a) On a medication trolley used for medication rounds, which should be kept in a locked room when not in use, or
- b) On an anaesthetic trolley or operating theatre trolley which is kept in a locked room when not in use, or
- c) Minimal quantities of medications on an emergency trolley, or
- d) In a secure cabinet (such as a bedside cabinet), including that used for patient self-administration in an approved program, in situations for which it may be impractical to attach the cabinet to the wall or floor of the premises. (Note: Schedule 8 medications must not be included in a bedside storage unit for self-administration. Local protocols should determine whether Schedule 4 Appendix D medications are included for patient self-administration and if so, provide for the requirement for these medications to be stored apart from the other medications).

The key, code or combination used to unlock the room, cabinet, or trolley must only be provided to a registered nurse, registered midwife, an enrolled nurse, or authorised prescriber, as approved by the registered nurse/midwife in charge of the patient care area. In accordance with local protocols approved by the facility's Drug and Therapeutics Committee, the registered nurse/midwife in charge of the patient care area may also approve access to the room, cabinet or trolley by Pharmacy Service staff members.

#### **Separately Stored Non-appendix D Schedule 4 Medications**

In accordance with local protocols approved by the Drug and Therapeutics Committee specific non-appendix D Schedule 4 medications may be stored in separate (discrete) medication storage areas with similarly separate key, code or combination access to all other medications to minimise the likelihood of misappropriation. Examples of medications that may be considered for separate storage include propofol, methoxyflurane and the Schedule 4 codeine phosphate compound preparations.

Non-appendix D Schedule 4 medications that are also accounted for in a register at the patient care area in accordance with local protocols as described in [section 6.14](#) must also be managed as accountable medications, with any loss, theft or deficit reported to Pharmaceutical Services Unit in accordance with the procedure detailed in [section 6.16](#).

### 6.3.4 Storage of Medications in Automated Dispensing Cabinets

Separate to the requirements detailed in sections 6.3.1 to 6.3.4, the facility's Drug and Therapeutics Committee may approve the use of (electronic) automated dispensing

cabinets at particular patient care areas. Approval by the facility's Drug and Therapeutics Committee is also required for the size and type of the automated dispensing cabinets used in each patient care area.

The use of automated dispensing cabinets in patient care areas should include the following: -

- The automated dispensing cabinet(s) must be securely attached to the wall or floor of the patient care area in a manner approved by the facility's security service.
- An alarm monitoring system approved by both the facility's Drug and Therapeutics Committee and security service should be included to detect and alert any tampering or unauthorised movement of the automated dispensing cabinet(s).
- Consideration for the security of the automated dispensing cabinet(s) to include closed circuit television (cctv) monitoring.
- The automated dispensing cabinet system should be evaluated against the Core Processes detailed in the Institute for Safe Medication Practices ['ISMP Medication Self Assessment for Automated Dispensing Cabinets'](#) to confirm the safe and quality use of the system.
- Separation of Schedule 8 and Schedule 4 Appendix D medications from all other medications is required in accordance with [section 6.3.1](#) for Schedule 8 medications and [section 6.3.2](#) for Schedule 4 Appendix D medications.
- Medications must be stored in the automated dispensing cabinet in the packs received from the Pharmacy Service.
- Electronic access to the particular medications in the automated dispensing cabinets must be restricted to staff members authorised to administer those medications and approved by the registered nurse/midwife in charge of the patient care area. However, in accordance with local protocols approved by the facility's Drug and Therapeutics Committee, Pharmacy Service staff members may be permitted access to the cabinets for the purpose of stocking medications, other than Schedule 8 medications.
- Schedule 8 medication stocking must be completed by a registered nurse/midwife with a witness (second person) authorised by the registered nurse/midwife in charge of the patient care area.
- Each staff member must be assigned unique electronic access to the respective medication receptacles within the automated dispensing cabinet that the person is authorised to access.
- The use of an authorised 'second person' to witness medication administration must include that person logging into the automated dispensing cabinet system to access the particular medication required.
- All access events by staff members must be recorded and retained in the automated dispensing cabinet system for the purpose of audits.
- The automated dispensing cabinet system must include back-up provisions to access medications in the case of a power failure or electronics malfunction.
- The implementation of protocols for conducting regular audits to detect unauthorised use, review the safety of the system and review the efficiency of the system.

## 6.4 Principles for the Safe Storage of Accountable Medications

Schedule 8 medications and Schedule 4 Appendix D medications are defined collectively as 'accountable medications'. The NSW Health Safety Notification '[Safe Storage of Accountable Medicines - Safety Information 003/11](#)' details the review that should be completed at patient care areas of accountable medication facilities and practices to minimise the chances of selection error. Other medications that are also accounted for in a register at the patient care area in accordance with local protocols as described in [section 6.14](#) may also be managed as accountable medications for the purpose of this section.

The review applies to accountable medication storage units in inpatient ward areas, operating suites and emergency departments, and includes safes where Opioid Treatment Program medications are stored.

Actions to minimise risks associated with storing and handling accountable medications include the following: -

- Accountable medications being stored in accordance with a) [section 6.3.1](#) for Schedule 8 medications, b) [section 6.3.2](#) for Schedule 4 Appendix D medications, and c) [section 6.3.4](#) for non Schedule 4 Appendix D medications that are accounted for in a register at the patient care area in accordance with [section 6.14](#) and stored separately to all other medications.
- Regular review of the range and quantity of accountable medications, with;
  - An annual review of usage and frequency of ordering using pharmacy information system reports.
  - Minimisation of the range of strengths and quantity of each medication routinely stocked.
  - Establishing an agreed list of routinely stocked medication and quantities, and adding this list to pharmacy inventory computer systems.
- Checking the facility's incident management system reports to identify incidents or near misses including those that may have resulted from selection error, and identify high risk medications stocked that may require further consideration including;
  - High potency medications such as hydromorphone.
  - Unusual strengths or routes of administration.
  - Multiple strengths of the same medication.
  - Look alike or sound alike preparations, such as the 'contins'.
  - Similar manufacturer packaging.
  - Bulky items, such as one litre bottles.
  - Oral liquids, as it may be difficult to perform balance checks.
- Reviewing controls based on risk assessment, for example;
  - Identifying items which should not be routinely stocked, but should instead be dispensed for individual patients and returned to the Pharmacy Service when no longer in use.
  - Separate shelf locations for items prone to mix-up, such as oxycodone , hydromorphone and morphine preparations. Due to the number of incidents

relating to errors involving hydromorphone being administered instead of morphine, and vice versa, consideration could be given to storage in different Schedule 8 medication storage units, particularly in high use areas.

- Redesigning accountable medication storage units, such as increasing capacity, separated storage of Schedule 8 and Schedule 4 Appendix D medications, or separate storage for large volume preparations.
- Labelling medication storage units with the included contents.
- Maintaining separate, clearly labelled drug registers for items prone to mix-up.
- Matching the order of medications in drug registers to the shelf order in the storage units.
- Reviewing workflow by;
  - Ensuring authorised persons are not accessing a Schedule 8 medication storage unit alone.
  - Ensuring two person checks can be performed with both people sighting the original medication order at the time of the selection and preparation of the prescribed dose, and both being present for the administration of the dose and the discarding of any unused portion.
  - Ensuring oral/enteral dispensers are in use for oral liquids.
  - Checking for clutter, and reviewing signage.
  - Adding a workbench underneath drug storage units to reduce spillage and breakage.
  - Eliminating the location of waste bins from under drug storage units to reduce potential losses.
- Labelling of shelves and medications with;
  - The inclusion of suggested order quantities.
  - The inclusion of warning labels for high risk preparations, applied to shelf labels and/or to individual products.
  - The use of 'Tall Man' lettering.

Medication storage areas are to be considered in the development or redevelopment of clinical areas for medication safety, as well as for routine storage/access requirements.

Considerations in the redesign should include: -

- Reviewing number of patients, patient case mix, and therefore medication requirements which may inform different storage requirements.
- Increasing the size of medication storage units that are routinely supplied, depending on the anticipated volume of medication to be stored.
- Considering the appropriateness of the use of automated drug cabinets, in accordance with legislative and NSW Health policy requirements.
- Ensuring adequate bench space surrounding the medication storage units, and positioning in a low traffic area.
- Ensuring medication storage units are accessible without undue bending or reaching.
- Reviewing the proximity of the sink and waste disposal unit to the medication storage units.

- Ensuring larger metal safes have floor reinforcement or supports.

### 6.5 Procedural Units/Operating Theatres Stock Management – Additional Considerations

Systems must be established to minimise misadventure associated with medication supply and use in procedural units and operating theatres.

Systems should include: -

- The regular review of requests for non Imprest List medications by the registered nurse/midwife in charge of the unit with the registered pharmacist and attending authorised prescribers, for the purpose of additional medications being included on the Imprest List, and
- Assessment and verification by a registered pharmacist of the suitability for use of additional imprest medications before being placed into stock, and
- Separated storage of imprest and non-imprest (patient-labelled) medications, and
- Unused patient-labelled medications being returned to the Pharmacy Service in accordance with local protocols, and
- A registered nurse/midwife checking all stock on receipt to identify any variation from the current medication packs, pack sizes or proprietary names, and
- Protocols to notify staff when new medications, or variations to existing medications, are introduced, and
- Protocols to regularly review medication storage units to confirm the suitability (including size and design) for the unit's purposes.

### 6.6 Radiopharmaceuticals – Additional Considerations

Nuclear Medicine Departments must be licensed under the requirements of the [Australian Radiation Protection and Nuclear Safety Agency](#) (ARPANSA).

The NSW Radiation Control Act 1990 and Regulation 2003 regulate the use of radioactive substances and radiation equipment in NSW, as detailed on the [NSW Environmental Protection Authority](#) website.

Good Radiopharmacy Practice is covered in the ARPANSA Radiation Protection Series (RPS) 14.2 Safety Guide for Radiation Protection in Nuclear Medicine. The corresponding Code of Practice, RPS14, has been gazetted in NSW under the Radiation Control Regulation 2003 and is enforceable by law in NSW. RPS14 and RPS14.2 cover all aspects of radiopharmaceutical use including justification of the procedure, optimisation of the activity, safe administration, storage requirements, protection of carers and members of the public, and waste disposal.

Chapter 23 'Security of Radioactive Substances' of NSW Health Policy Manual '[Protecting People and Property: NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies](#)' details the that standards must be implemented unless a risk assessment determines another control is more appropriate.

## 6.7 After-Hours Inpatient Medication Store Supplies

To minimise the need to access the Pharmacy Service after hours, where appropriate, a separate medication store may be used to access medications for inpatient use that are currently unavailable in a particular patient care area.

The store should be stocked by the Pharmacy Service with an appropriate range of medications, either in the manufacturers' original packs, or re-packed and labelled by a registered pharmacist for inpatient use. The store must not include Schedule 8 or Schedule 4 Appendix D medications.

The medication store should be located in a convenient, supervised area and must be locked when not in immediate use.

The store must only be accessed after hours and only by nursing, midwifery or medical staff in accordance with a protocol approved by the Drug and Therapeutics Committee. The protocol should include the maintenance of a register to track the date and time each staff member accesses the store.

Any removal of stock from this store must be recorded, including, as a minimum: -

- The date and time, and
- The name, strength, form and quantity of the medication removed, and
- The name of the patient, and
- The name of the patient care area where the medication was used, and
- The name of the staff member removing the medication.

## 6.8 Emergency Department After-Hours Medication Store Supplies

To accommodate situations when the Pharmacy Service is unavailable, the Emergency Department should have access to medication stocks of essential medications for supply to a patient by an authorised prescriber, or by a registered nurse/midwife in a remote area facility in the circumstances provided for in [section 6.12](#).

The use of this store will minimise the need to access the Pharmacy Service after hours, as detailed in [section 5.3.1](#).

The separate after-hours medication store should contain adequate stocks of the medications most likely to be prescribed for non-admitted patients requiring immediate treatment upon leaving the facility.

The range and quantities of medications held at the after-hours medication store must include consideration of circumstances when a patient will present to the facility seeking a previously prescribed essential medication for which his/her supply has been unexpectedly exhausted.

In instances where a particular medication is not in stock at a facility and a replacement supply cannot be provided by or through the person's primary health practitioner, prior arrangements made through the Pharmacy Service may provide for the supply from a local community pharmacy.

The store must not include Schedule 8 or Schedule 4 Appendix D medications. In the rare circumstances that such medications will be required, procurement should be from the stocks held in the Emergency Department storage units.

The medications dispensed by an authorised prescriber must be recorded in full in the patient's medication record. Individual health facilities may require an additional record for stock control purposes in accordance with local protocols.

The authorised prescriber must label the medication with: -

- a) The date of supply, and
- b) The patient's name, and
- c) The name, strength, form and quantity of the medication supplied, and
- d) Adequate directions for use, and
- e) The words '**KEEP OUT OF REACH OF CHILDREN**' in red on a white background, and
- f) The name, address and telephone number of the hospital, and
- g) If the substance is intended for external use only the words '**FOR EXTERNAL USE ONLY**' or the word '**POISON**', in red on a white background, and
- h) If applicable, the ancillary label with the associated warning statement required for the particular medication (see [section 5.5.8](#)).

A supply of 'blank' labels with the name, address and telephone number of the facility, the words '**KEEP OUT OF REACH OF CHILDREN**' in red on a white background and the required the ancillary label with the associated warning statement required for the particular medication (at h) above) is recommended for this purpose.

### 6.9 Medication Kits for Home Visits

A patient care area such as a community health centre or clinic may hold a range of medications in a locked bag or box that can be taken for domiciliary care services such as 'Hospital in the Home', then immediately returned to the patient care area.

The list of medications and the quantities stored in this medication kit should be approved by the Drug and Therapeutics Committee.

Maintenance of the stock levels in the medication kit is the responsibility of the registered nurse/midwife in charge of the patient care area. The kit must be kept in a locked room or cupboard at the centre or clinic when not in use, and which may be with other non-Appendix D Schedule 4 medications held at the facility.

If the kit needs to be kept in the car during a home visit, this should be locked in the boot of the car.

The staff member carrying the kit must consider the potential for the medications to be subjected to temperatures in excess of that stated on the medication packs, and storage in an insulated container (such as an esky) could be used accordingly.

The kit should not routinely include Schedule 4 Appendix D medications or Schedule 8 medications. Where these medications may be required for a particular patient visit, they may be added to the kit from the stocks held at the health facility on a visit-by-visit basis, then returned to the respective patient care area's storage unit(s). Facilities are required to retain a record of the transfers, as well as the associated administration, of Schedule 4 Appendix D and Schedule 8 medications procured for the kit. Entries documenting Schedule 8 medication transfers, supplies and administrations must be recorded in a separate Schedule 8 drug register maintained for each kit. Corresponding entries documenting the Schedule 8 medication transfers to the kit must also be recorded in the patient care area's Schedule 8 drug register.

Medications administered from the kit must be in accordance with local protocols and procedures and may either be nurse-initiated medications ([see section 7.5](#)), or ordered by an authorised prescriber either on a medication chart or as a telephone, facsimile or email order to the staff member (see [section 7.3](#)). The administration must be recorded on the medication chart (as applicable) as if the medication was administered in a patient care area.

Medications must not be collected from patients during home visits for return to and disposal at the patient care area, but instead be taken by the patient or patient's carer to a community pharmacy for disposal under the [Return Unwanted Medicines Project](#).

Chapter 16 'Working in the Community' of NSW Health Policy Manual '*Protecting People and Property: NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies*' details standards for staff working in the community such as that carried out in patients' homes, within community health centres and public venues such as schools or community halls and in mobile units.

### 6.10 Disaster Packs Supplies

NSW Health Policy Directive [PD2009\\_080 'NSW Health Response Team Medical Equipment Kit'](#) details the required medications in 'Disaster Packs' for use in the medical response to a mass casualty situation resulting from an incident or disaster.

Prepared packs, which may include Schedule 8 medications, must be stored in a locked room or cabinet, with access limited to authorised personnel only. A suitable person, such as the registered nurse/midwife in charge of the adjacent patient care area or the director of pharmacy must be appointed as being responsible for ensuring secure storage of the packs, and for the maintenance of the medications held in the packs.

### 6.11 Discharge Medications and Patient's-Own Medications

A registered nurse/midwife, enrolled nurse (in accordance with local protocols approved by the facility's Drug and Therapeutics Committee), authorised prescriber or pharmacist may provide medications to a patient, or the patient's carer, on the patient's discharge from the patient care area as: -

- a) Discharge medication, either previously dispensed by the Pharmacy Service, or labelled and recorded by an authorised prescriber in accordance with [section 6.8](#), and
- b) The medications surrendered by the patient to the patient care area on admission.

All supplies must be recorded in the patient's health care record as having been provided to the patient (or the patient's carer). Also, all Schedule 8 medications supplied must be recorded in the patient care area drug register in accordance with [section 6.13.1](#) with a witness as described at [section 6.13.2](#).

Patients should be asked to provide consent for his/her patient's own medications that have been ceased since admission to be retained at the patient care area for destruction.

Hospitals must develop appropriate systems for the supply of medications to patients at discharge to ensure continuity of care between the hospital and the community in accordance with NSW Health Policy Directive [PD2011\\_015 'Care Coordination: Planning from Admission to Transfer of Care in NSW Public Hospitals'](#), with additional information provided in the Commonwealth Department of Health and Ageing ['Guiding principles to achieve continuity in medication management'](#).

Such systems must include the following: -

- Planning for a patient's discharge, temporary leave, or transport to another point of care, including the arrangement of medication supplies during the Pharmacy Service opening hours so that an adequate quantity of medication is dispensed to ensure continuity of care until the patient is able to obtain future supplies. Where a dispensed supply from the Pharmacy Service has not been arranged and the Pharmacy Service is closed, an authorised prescriber may dispense the medication appropriately packed and labelled with full directions for use, and
- The dispensing registered pharmacist taking into account the individual needs of the patient, for example those with visual impairment or may experience difficulty in opening certain containers, and
- The prescriber reviewing the patient's medication prior to authorising discharge medication, where applicable in conjunction with the *'Medication Management Plan'* form (or equivalent, in accordance with local protocols) initiated for the patient at the time of admission described in [section 4.8.2](#). This includes checking the patient's own medications scheduled for return to the patient to exclude conflict with the discharge supplies being provided by the Pharmacy Service, and
- Accurate information on the patient's medication being communicated to the patient's general practitioner (or primary care provider as applicable) as soon as possible, and

- Written information being provided to all patients that require an understanding of how to take their medication when they go home, and of any changes to their medication regimen since admission. This may include a medication(s) Consumer Medicines Information and/or locally published information pertaining to the treatment.

### 6.12 Additional Supplies by Registered Nurses

#### 6.12.1 Emergency After Hours Supply By Registered Nurses – Rural and Remote Areas

Registered nurses are authorised by an instrument issued under the Poisons and Therapeutic Goods Regulation 2008 to supply emergency medications other than Schedule 8 medications to outpatients attending a rural or remote hospital when the Pharmacy Service is unavailable AND an authorised prescriber is not present at the facility, in accordance with the following requirements: -

- The registered nurse is employed by the Local Health District, and
- An authorised prescriber is unable to attend to supply the medication to the patient, and
- An authorised prescriber has authorised the supply (dispensing) of the medication to the patient for emergency use by telephone, facsimile, or email, and
- The patient is in immediate need of the medication and a community pharmacy nor hospital Pharmacy Service is available in close proximity at that time, and
- The medication is included on the list (with the associated quantity) of medications which may be supplied for emergency patient supply as determined by the Drug and Therapeutics Committee, and
- The registered nurse records the details of the medication order received from the prescriber and the quantity of medication supplied to the patient in the patient's health care record, and
- Where possible, the prescriber's telephone order is confirmed by a second person (registered nurse or enrolled nurse), and
- The medication is supplied in the unopened packs provided by the Pharmacy Service, appropriately pre-labelled by a registered pharmacist with the usual dose and directions for use for the medication, and with an area for the registered nurse to enter the full name of the patient and the date the medication is supplied, and
- Where the medication is a paediatric mixture requiring the calculation of the dose for the individual patient, the authorised prescriber must calculate the dose according to the weight of the patient, and then specify the actual dose amount for the nurse to enter on the medication label, and
- The labelled medication is checked by the second person who confirmed the prescriber's telephone order (where applicable).

### 6.12.2 Supply of Tenecteplase Under the Pre-Hospital Thrombolysis Program to NSW Ambulance Paramedics

In accordance with specified conditions approved for the purpose of the Pre-Hospital Thrombolysis Program the registered nurse in charge of the Emergency Department or other approved patient care area of a public hospital, or his/her delegate, may supply a tenecteplase 50mg vial to a NSW Ambulance paramedic at the time of patient handover to replace a tenecteplase 50mg vial administered to the patient.

## 6.13 Patient Care Area Schedule 8 Drug Register

### 6.13.1 Records in the Schedule 8 Drug Register

The registered nurse/midwife in charge of the patient care area is responsible for ensuring that a record is kept of all Schedule 8 medication transactions in a drug register. The drug register must be in the form of a bound book with consecutively numbered pages that cannot be removed or replaced without trace.

A separate page must be used for each form, strength and brand of Schedule 8 medication.

A 'signature register' should be maintained by the registered nurse/midwife in charge of the patient care area with (where possible) the names and signatures of the authorised persons eligible to access the Schedule 8 medication storage unit(s). The signature register should be kept under the control of the registered nurse/midwife in charge of the patient care area, and apart from the Schedule 8 drug register. Authorised persons could include a registered nurse/midwife or authorised prescriber assigned to the patient care area or a registered pharmacist.

An authorised person must include the following details relevant to each Schedule 8 medication transaction in the drug register: -

- The date and time of day, and
- In the case of medications received into stock, the name of the source (for example the Pharmacy Service), and the quantity received, and
- In the case of a medication which is supplied to a patient (for example as discharge medication or returned 'patient's own medication') or administered to a patient, the patient's name, the name of the prescriber, and the amount supplied or administered as;
  - For liquids, in millilitres (mL), or
  - For solid dosage forms, as discrete units, for example 1 or 0.5 with tablets (if the medication is suitable to be given as a part tablet), or
  - For ampoules, as discrete units, (for example 1 or 0.5) OR as the dose (for example 10mg or 5mg) in accordance with local protocols approved by the Drug and Therapeutics Committee, and
- The amount discarded, where only a portion of the medication (tablet or injection) is administered, as above, and

- The amount destroyed, in the case of the destruction of a medication which is expired, unusable or unwanted, with the additional requirements for recording the destruction as detailed in [section 6.15.2](#), and
- The balance remaining in the drug register after the transaction. Overage (excess) of liquid medication compared is accounted for by adjusting the balance upwards with an additional entry on the next available line on the drug register page. (Note: Liquids should not be decanted for measuring by anyone other than a registered pharmacist, however, accurate reconciliation of the balance on hand should occur each time a new bottle is opened). Any deficit must be recorded and reported in accordance with procedure described in [section 6.16](#), and
- The full and legible signature of the person making the entry, either receiving, administering, discarding, destroying, or carrying out a balance check, and
- The full and legible signature of the **witness** to the transaction, as described in [section 6.13.2](#).

The authorised person making an entry in a patient care area drug register: -

- Must not make any false or misleading entry, and
- Must not make any alterations, obliterations or cancellations. That is, no lines may be drawn through entries, no entries scribbled out or crossed out in any way, nor numerals altered. If a mistake is made, the entry must be left as it is, marked with an asterisk, rewritten as corrected on the next line (and countersigned by the second person) with a note explaining the error (signed and dated by both staff members) also marked with an asterisk.

Where the Schedule 8 medication is being administered to a patient temporarily transferred from another patient care area, this should be noted by the administering person in the patient's health care record for the purpose of future reference, as well as for Schedule 8 medication audit purposes.

### **Drug Register Recording of Schedule 8 Medication Transfers Between Patient Care Areas**

Local protocols should detail the circumstances and procedures under which Schedule 8 medication may be transferred between patient care areas, including the need for this to only occur after-hours when the Pharmacy Service is not available.

The transfer of Schedule 8 medications between patient care areas must be by a registered nurse/midwife from each patient care area in accordance with the procedure detailed in [section 6.2.2](#), with the Schedule 8 medications being provided by the supplying patient care area on a signed and dated requisition and receipt completed by the registered nurse/midwife in charge of the patient care area obtaining the Schedule 8 medication.

An example of the appropriate entries in the corresponding drug registers is provided below: -

*Supplying Patient Care Area Drug Register (Ward A1)*

Date	Time received or given	Patient's Name	Amount Received	Amount given	Balance	Signature of administering person	Signature of person supervising, authorising or witnessing administration	Name of prescriber
02/05/13	1050	Alex Patient		1	100	<i>Ann Min</i>	<i>Bree Smith</i>	Dr I Max
02/05/13	1100	Transferred to Ward B2		50	50	<i>Col Nurse</i>	<i>Dee Nurse</i>	

*Receiving Patient Care Area Drug Register (Ward B2)*

Date	Time received or given	Patient's Name	Amount Received	Amount given	Balance	Signature of administering person	Signature of person supervising, authorising or witnessing administration	Name of prescriber
2.5.04	1050	Ian Patient		50	NIL	<i>Jack Jons</i>	<i>TimToms</i>	Dr G Jay
2.5.04	1100	Transferred from Ward A1	50		50	<i>Dee Nurse</i>	<i>Col Nurse</i>	

**6.13.2 Witness to Schedule 8 Medication Transactions**

The witness to a Schedule 8 medication transaction must be a person who is fully familiar with Schedule 8 medication handling and recording procedures. This would include a registered nurse or registered midwife, an authorised prescriber, a registered pharmacist, and any other person authorised by the registered nurse/midwife in charge of the patient care area to complete this task, such as an enrolled nurse.

The witness must be present during the entire procedure, that is: -

- The removal and replacing of the medication from the Schedule 8 medication storage unit, and
- The preparation of the medication (as applicable), such as drawing up into a syringe, and
- The discarding and rendering unusable any unused portion of the medication (as applicable) and
- The recording in the Schedule 8 drug register, and
- The transfer to the patient, and
- The administration to the patient.

**6.13.3 Balance Checks in the Schedule 8 Drug Register**

The registered nurse/midwife in charge of the patient care area must ensure that the balance of Schedule 8 medications recorded in the drug register is checked against the physical balance in the Schedule 8 medication storage unit(s) at least once every 24 hours.

In high usage patient care areas a Schedule 8 medication balance check should be done during, or at the change of, each shift, in accordance with local protocols approved by the Drug and Therapeutics Committee.

A registered nurse/midwife who assumes control over the Schedule 8 medication stock as the person in charge of a patient care area for a period of one month or more must also conduct a full balance check at the time of the handover.

Each routine balance check must be carried out by a registered nurse/midwife with a witness as described in [section 6.13.2](#) and recorded in the drug register on the relevant page for each Schedule 8 medication. The entry must state the quantity of medication actually held at the time of the balance check. Liquids should be decanted for measuring by a registered pharmacist.

Where there is a discrepancy between the drug register balance and the physical balance in the Schedule 8 storage unit, this must be recorded and reported in accordance with the procedure described in [section 6.16](#).

### 6.13.4 Schedule 8 Drug Register Audits

In addition to balance checks, regular audits of patient care area Schedule 8 drug registers at intervals approved by the Drug and Therapeutics Committee must be conducted to confirm records are meeting legislative and policy requirements and also to detect any possible misappropriation.

Where an area of non-compliance or concern is revealed, appropriate steps must be instituted to rectify the issue.

Audits should: -

- Be performed by two staff members authorised under local protocols to perform the task, one of which must be independent of the patient care area's nursing/midwifery staff, and
- Include checks of entries recording stock received against the patient care area and Pharmacy Service records, and
- Check and verify signatures for the purpose of detecting forgeries, and
- Verify the drug register contents page against the corresponding drug register pages, and
- Verify the 'carried forward' balances, and
- Verify that the routine 24 hour balance checks (or more frequently in accordance with local protocols) have been conducted, and
- Verify that the Schedule 8 medications that have been found to be lost or stolen, including broken ampoules, have been reported and recorded in accordance with the procedure described in [section 6.16](#), and
- Review the frequency of broken ampoules and discarded portions of ampoules and tablets, and
- Review the presence of altered, obliterated and cancelled entries, and

- Include a selection of patient medication chart checks against the respective Schedule 8 drug register entries.

### 6.14 Additional Accountable Medication Recording in a Register

In order to minimise the risk of misappropriation, in accordance with local protocols approved by the Drug and Therapeutics Committee, the chief executive of the facility may direct certain medications in addition to Schedule 8 medications to be recorded in a register, and also if directed, with a witness to the transaction (as if it was a Schedule 8 medication).

This may apply particularly in areas of high usage of medications known to be abused or misused, such as in operating theatres and recovery wards.

Where used, the register should be separate to the Schedule 8 drug register.

Typical medications that may be additionally recorded in a register are: -

- The Schedule 4 Appendix D benzodiazepines, particularly midazolam.
- Propofol.
- Methoxyflurane.
- The Schedule 4 codeine phosphate compound preparations.

### 6.15 Disposal of Expired, Unwanted or Unusable Medications

#### 6.15.1 Disposal of Medications – General Requirements

Unwanted medications in patient care areas include: -

- Expired, contaminated or damaged medication, and
- Patient-own medications not returned to the patient, and
- Partly used packs no longer required for use.

Unwanted medications that are not in the manufacturer's original immediate container (blister platform, foil, or sealed bottle/vial, as applicable) must not be returned to the Pharmacy Service for the purpose of re-supply.

Each patient care area must have Drug and Therapeutics Committee approved protocols and procedures for the disposal of unwanted medications, which also must be in accordance with NSW Health Policy Directive [PD2005 132, 'Waste Management Guidelines for Health Care Facilities'](#).

The specific requirements for the destruction of Schedule 8 medications are detailed in [section 6.15.2](#). For other medications, local protocols will direct either the disposal at the patient care area, or return to the Pharmacy Service for disposal.

### 6.15.2 Destruction of Expired, Unusable or Unwanted Schedule 8 Medications

Expired, unusable, or unwanted Schedule 8 medications must: -

- Remain recorded in the Schedule 8 drug register with the useable medication of the same type (except for patient's own Schedule 8 medication which must remain where initially entered in the drug register), and
- Remain stored in the Schedule 8 medication storage unit at the patient care area pending destruction by a registered pharmacist, or the authorised officer of the Pharmacy Service at a facility where no registered pharmacist is employed/contracted with a registered nurse/midwife acting as the witness to the destruction.

The expired, unusable or unwanted Schedule 8 medications must be included in the routine stock checks pending destruction, with a process for securing and identifying these medications from the useable stock of the same medication in the Schedule 8 medication storage unit, such as storage in a sealed, clear container, with the description and quantity of the medication enclosed written on the container.

A record of the destruction of the medication must be made in the patient care area drug register, signed and dated by the registered pharmacist/authorised officer of the Pharmacy Service destroying the medication and with the registered nurse/midwife witness also signing the drug register, in accordance with the detail listed in [section 6.13.1](#).

The recommended procedures for destroying the various forms of Schedule 8 medications are detailed at [section 5.8.3](#).

## 6.16 Reporting Lost or Stolen Accountable Medications

Accountable medications are defined as Schedule 8 medications and Schedule 4 Appendix D medications. However, non Appendix D Schedule 4 medications that are also accounted for in a register at the patient care area in accordance with local protocols as described in [section 6.14](#) must also be managed as accountable medications for the purpose of this section.

(Note: The reporting requirements detailed in this section do not apply to an accountable medication that is intact but expired, unusable or unwanted and is instead disposed of in accordance with [section 5.8.1](#) for non Schedule 8 medications or destroyed in accordance with [section 5.8.2](#) for Schedule 8 medications, nor to the unwanted portions of ampoules and tablets discarded at the time a dose is prepared).

The person who detects the loss, theft, or deficit of an accountable medication must: -

- Immediately report this fact to the registered nurse/midwife in charge of the patient care area, and

- Complete and submit a report in accordance with the facility's incident management system under the requirements of NSW Health Policy Directive [PD2014\\_004](#) '[Incident Management Policy](#)'.

This includes all medication that cannot be supplied or used such as: -

- Loss of liquid by spillage, and
- Loss in broken or damaged bottles and ampoules, and
- Loss is believed to be attributed to the irretrievable amount retained in the measuring apparatus used (such as the repeated measuring of small dosing using a syringe which is associated with discarding of a small quantity in the 'dead space' of the syringe).

The person who detects loss, theft, or deficit of a Schedule 8 medication must also immediately record the physical balance on hand in the Schedule 8 drug register in accordance with [section 6.13.1](#) with a witness as described in [section 6.13.2](#), with an explanatory note highlighting the deficit from the arithmetical balance.

Following the receipt of a verbal report (in the first instance) of the loss, theft or deficit of an accountable medication the registered nurse/midwife in charge of the patient care area must immediately (and within 24 hours) report the loss, theft or deficit to the facility's director of pharmacy, as well as the director of nursing at the facility (however named).

The director of pharmacy must then immediately notify the NSW Ministry of Health Pharmaceutical Services Unit using the [on-line notification form](#).

This immediate notification to Pharmaceutical Services Unit should be marked on the form 'Initial Notification'. As soon as all notifiable details become available, such as when further investigation has been conducted, a follow-up notification should be submitted to Pharmaceutical Services Unit, again using the [on-line notification form](#).

Other required actions by the director of nursing at the facility (however named) are: -

- Ensuring that a full investigation of the loss, theft or deficit of the medication is conducted.
- With regard to a confirmed theft, report the event to the local police.
- With confirmed misappropriation by a staff member, report the matter to the particular health practitioner's national registration board and to [Pharmaceutical Services Unit](#).

Where there is no apparent loss of medication, but a concern exists of possible, or admitted, misappropriation of medication by a staff member, this must similarly be reported through to the director of nursing at the facility (however named) for further appropriate action, as detailed above. Failure to do this may result in harm to a patient or to the member of staff, particularly where a possibility exists that this staff member is drug dependent and/or health impaired.

Personnel in patient care areas can pro-actively prevent the misappropriation of medications by ensuring strict adherence to NSW Health and local protocols and procedures.

### 6.17 Reporting a Lost, Destroyed or Tampered Schedule 8 Drug Register

A registered nurse/midwife at a patient care area who detects that a drug register appears lost, destroyed, has had removed pages, or has tampered entries or pages must immediately report the matter to the registered nurse/midwife in charge of the patient care area.

The registered nurse/midwife in charge of the patient care area must immediately: -

- Complete and submit a report in accordance with the facility's incident management system and the requirements of NSW Health Policy Directive [PD2007\\_061, 'Incident Management'](#), and
- Notify the director of pharmacy and the director of nursing (however named).

The director of pharmacy must then immediately (and within 24 hours) notify [Pharmaceutical Services Unit](#) in writing immediately detailing the known circumstances of the loss, destruction or tampering.

A balance check of all Schedule 8 medications stock must be performed and entered in a new drug register in accordance with the detail included in [section 6.13.1](#) with a witness as described in [section 6.13.2](#).

(Note: The disposal of a Schedule 8 drug register after the required retention period of 7 years is not reportable).

### 6.18 Retention of Records

The following retention periods apply to records relating to the procurement, prescribing, administration and supply of medications in patient care areas in accordance with NSW Policy Directive [PD2009\\_057 'Records Management'](#) and the [State Records Authority of NSW](#): -

- **2 years** for medication charts, medication requisitions and purchase orders, receipts and records of medication deliveries, and inventory control records.
- **7 years** for Schedule 8 drug registers.

## 7 ADMINISTERING MEDICATION

### 7.1 Who May Administer Medication?

Facilities must ensure that staff members administering medications have appropriate qualifications, training, and demonstrated current competency. Responsibility for

ensuring appropriately qualified and trained clinicians rests with the lead clinician in each department.

Competency to administer medications is included in the qualifications of medical practitioners, dentists, nurse practitioners, midwife practitioners, registered nurses, registered midwives and enrolled nurses, but only in accordance with any practice conditions imposed by the person's place of employment and the endorsements, notations and conditions on the person's registration.

Other appropriately trained and accredited staff members may be authorised to administer certain medications and/or diagnostics agents within their context of practice at the particular facility in accordance with local protocols. Examples (which includes allied health professionals) are: -

- Pharmacists.
- Dental therapists.
- Physiotherapists.
- Orthoptists.
- Radiographers (contrast).
- Nuclear medicine technologists (radiopharmaceuticals, contrast).
- Certified anaesthetic technicians.
- Cardiopulmonary technicians certified as clinical perfusionists.
- Health care employees to non-inpatients at a day centre, for the purpose of assisting the patient to self-administer the medication.

A trainee or student in any category must be directly supervised by the appropriate authorised person when administering any medication or diagnostic agent.

In accordance with local protocols, facilities must ensure all persons authorised to administer medicines have completed training that addresses the necessary competencies and relevant workplace safety and infection control practices in completing specific tasks, and as appropriate be re-assessed and re-accredited for the tasks. A higher level of skill may be needed for the safe administration of an individual medication or class of medication, or for carrying out certain clinical functions, such as intravenous administration. The level of medical back-up required should also be considered relevant to each clinical situation and according to best professional practice guidelines.

## 7.2 Medication Administration Orders

A medication order by an authorised prescriber authorises the administration of unscheduled, Schedule 2, Schedule 3, Schedule 4, and Schedule 8 medications to a patient.

This medication order may be in the form of a: -

- A prior written order on an individual patient's medication chart or anaesthetic record in accordance with [section 4.8.1](#), or

- An approved electronic order, or
- A standing order in accordance with [section 7.4](#), or,
- A verbal, telephone, facsimile or email order in accordance with [section 7.3](#).

### 7.3 Administering from a Verbal, Telephone, Facsimile or Email Medication Order

When an authorised prescriber is unable to write directly into a medication chart order, the order may be given verbally (face to face), or by telephone, facsimile or email, as detailed in [section 4.8.4](#).

The person receiving such an order must be an authorised person to administer the particular medication in that patient care area.

Due to the risk of misinterpretation, all orders received by telephone must be read back to the prescriber, with numbers in figures and words (for example, *50mg: fifty milligrams, five zero milligrams*).

In accordance with local protocols, as a further check, the prescriber should repeat the telephone order to a second person. This must be implemented for all Schedule 8 medications, high risk medications and intravenous medications. An exception to this is in the community setting where a second person is not available.

When a person administers a medication from a verbal/telephone order, the administration must be recorded on the medication chart in the 'Telephone Orders' section.

The prescriber must confirm within 24 hours all doses administered on a verbal/telephone order either by: -

- Counter-signing the record of administration, and attending to review the patient as soon as appropriate in the circumstances of the case, or
- Sending written confirmation of the order via facsimile or email for inclusion on the patient's medication chart.

When a person administers a medication from a facsimile or email order, this order must be attached to patient's medication chart for the purpose of recording the ongoing treatment, until such time as the order is included with the other medication orders on the patient's medication chart by an authorised prescriber.

If verbal or telephoned orders are not confirmed by the prescriber in writing, by facsimile, or by email within 7 days, the facility is required to report this in writing to [Pharmaceutical Services Unit](#).

Where a prescriber's telephone instruction is to cease a medication, the person receiving the instruction may endorse the medication chart accordingly with the words 'ceased as per phone order', the prescriber's name, the staff member's name and signature, and the date and time. A corresponding entry should also be made in patient's health care record, including the reason given for ceasing the order.

Note: The above requirements do not apply to the medication order for a patient of Justice Health & Forensic Mental Health Network if confirmation of the order for administration is given in accordance with the requirements of the approved Justice Health & Forensic Mental Health Network protocol.

### 7.4 Standing Orders

Standing orders provide authorisation by an authorised prescriber for the administration (or supply for administration where applicable) of medication without a patient-specific written order in specific clinical and emergency situations.

Authorising the use (and subsequent recording) of specific medications will vary according to the context. Facilities must identify the appropriate governance, identify and manage the risks of misadventure, and approve the relevant protocols.

All standing orders must be approved by the Drug and Therapeutics Committee and be in the form of a written instruction, signed and dated by an appropriate senior medical officer. A standing order must be consistent with the respective medication's approved Product Information, evidence-based clinical practice guidelines and other relevant NSW Health policies and directives. Each standing order must be reviewed every 12 months, and re-approved as appropriate.

A standing order must contain sufficient detail for the information of staff administering the medication (or supplying for administration where applicable) including the medication's form, strength, dose, route of administration, frequency of administration, indications and contraindications for use (including possible interaction with other medications) as well as any restriction on the categories of staff who may administer (or supply where applicable) the medication.

When a medication is administered according to a standing order, the details must be recorded on the patient's medication record, or anaesthetic record where applicable.

#### **Standing Orders for Emergency Treatment**

An authorised prescriber must confirm the administration by countersigning the record of the administration within 24 hours.

#### **Standing Orders for Dosage Adjustments Only**

Standing orders for protocols in which doses are adjusted according to an approved set of clinical criteria may include insulin or infusions of inotropes. Dose adjustments must be recorded in the patient's medication record. An authorised prescriber must confirm the administration by countersigning the record of the administration within 24 hours.

#### **Individual Prescriber Standing Orders**

An individual prescriber's standing order authorisation provides for administration of medication to his/her patients only. Examples may include medicines and fluids administered peri operatively or for analgesia during labour at the specific request of an

individual prescriber, which also includes the requirement this person to countersign the patient's medication record (as applicable in the circumstance) within 24 hours.

### Standing Orders for Routine Procedures and Programs

In the absence of an authorised prescriber, medication administration (or supply for administration where applicable) during routine procedures and under certain programs conducted at or by a facility may be carried out under a standing order within the particular context of the administering/supplying person's practice (see also [section 7.1](#) 'Who May Administer Medication'). Examples include: -

- Agents administered by anaesthetic technicians.
- Agents administered by clinical perfusionists.
- Contrast administered by radiographers.
- Radiopharmaceuticals and contrast administered by nuclear medicine technologists.
- Vaccines by accredited registered nurse/midwife vaccinators for the purpose of a vaccination program.
- Registered nurses/midwives for a public health emergency response.

Local protocols should determine whether the particular procedure or program requires that an authorised prescriber must confirm the administration/supply by countersigning the record of the administration/supply.

### 7.5 Nurse/Midwife Initiated Medication

The list of medications that may be administered without an authorised prescriber's standing order must be approved by the Drug and Therapeutics Committee. The list must not include any Schedule 4 or Schedule 8 medications.

Written protocols for the nurse/midwife initiated medication must accompany this list and provide sufficient detail to nursing and midwifery staff to make informed decisions prior to administration.

A record of the administration must be made in the 'nurse initiated medicines' section of the patient's medication record.

An enrolled nurse may administer 'nurse-initiated' medication according to local policy and procedures which have been approved by the Drug and Therapeutics Committee. The enrolled nurse must confirm verbally with their supervising registered nurse prior to the administration that the medication is appropriate and safe for the patient.

It is important for nursing and midwifery staff to remain aware that: -

- Minor ailments may be symptoms of other more serious diseases or may be adverse reactions to medication already prescribed, and
- Nurse-initiated medication may interact with the patient's prescribed medication, and
- The maximum daily recommended dose of the medication must not be exceeded.

A nurse-initiated medication should not be administered on a continual and/or ongoing basis unless it is reviewed and ordered by an authorised prescriber.

### 7.6 Principles for Safe Medication Administration

Safe and accurate medication administration requires the 5 Rights ('the 5 R's') of: -

- ✓ The Right **Patient**, and
- ✓ The Right **Drug**, and
- ✓ The Right **Dose**, and
- ✓ The Right **Time**, and
- ✓ The Right **Route**.

The following principles should be observed on every occasion that an appropriately authorised staff member administers a medication: -

- The staff member administering the medication must refer directly to the prescriber's order on the medication chart, which must be clear, legible and not open to misinterpretation.
- If the staff member considers a medication order is unclear or ambiguous, or is concerned that the order may be incorrect or inappropriate for the particular medical condition, the staff member must contact the prescriber for clarification before administering the dose.
- Telephone orders must be written on the patient's medication record at the time the order is given, then read back to the authorised prescriber, as detailed in [section 7.3](#).
- A strict process should be followed for verifying the identity of the patient. The patient's allergies/previous adverse drug reactions must also be checked before administering.
- The same person should select, prepare, administer and record the administration. This involves;
  - Reading the medication order, and
  - Checking the dose, form and route of administration of the medication and the time for administration, and
  - Preparing the medication including checking the medication's name, strength, form, route of administration and expiry date against the medication order, and
  - Re-checking at the point of administration to the patient with the patient's identification, known allergies and other appropriate patient parameters, and
  - Documenting the administration, and
  - Monitoring the effect of the medication (as applicable), and
  - Requesting further supplies of the medication as needed.
- Proper and complete entries on the medication chart must be made in accordance with the recommendations in the National Inpatient Medication Chart (NIMC) standard as detailed in [section 4.8.1](#).
- Medications are to be administered, or prepared for administration, directly from the container supplied by the Pharmacy Service.
- Care must be taken to minimise the risk of occupational exposure to hazardous agents.

- Doses must be prepared for only one patient at a time, immediately before the intended use.
- Medications should be prepared for immediate administration to a single patient and not retained for later use due to the risks of contamination, potential instability, potential mix-up with other medications and to maintain security of the medication.
- Medication storage areas and medication trolleys must not be left unlocked unless in immediate use.
- Anaesthetic technicians must only administer medicines under the direct supervision of an anaesthetist.
- The inclusion of a second person check before certain medications are administered (other than by an authorised prescriber) in accordance with local protocols as described in [section 7.7](#).
- Careful reading of the label and verifying the name, strength form and route of administration of the medication against the medication order, and any warning statements on the label, for example, 'FOR INTRAVENOUS ADMINISTRATION ONLY', to avoid selecting the wrong preparation. NSW Health ['Safety Notice 006/09 - Wrong Route Errors with Oral Medication'](#) details actions that can prevent wrong route medication errors.
- **Injectable medications and associated lines and catheters** must be labelled to identify the correct route of administration and be colour coded according to target tissue in accordance with NSW Health Policy Directive [PD2012\\_007 'User applied Labelling of Injectable Medicines, Fluids and Lines'](#), with the person administering the medication verifying that the line is correctly labelled by referencing back to the source pack.
- Injections must not be shared between patients ('multi-dosed'), except where provided for in NSW Health Policy Directive [PD2007\\_036 'Infection Control Policy'](#) for multi-dose vials where there is no other alternative available on the Australian pharmaceutical market.
- Where possible, a collapsible squeeze tube/bottle or a pump pack should be used to dispense lotion or cream from a multi-dose container. Where used, the pump pack should be disposed of with the container.
- In accordance with NSW Health Policy Directive [PD2007\\_036 'Infection Control Policy'](#) open **multi-dose lotion or cream in tubes/pots/containers** must only be used for an individual patient's use.
- **Oral or enteral dispensers** must be used for administration of liquid medicines by routes other than injection, with reference to NSW Health Policy Directive [PD2012\\_006 'Safe Administration of Liquid Medicines by Routes other than Injection'](#).
- Oral medications must be witnessed as having been consumed by the patient.
- Medications must not be left by a patient's bedside for administration at a later time.
- **Unwanted portions of ampoules and tablets** must be discarded at the time the dose is prepared. For Schedule 8 medications, the procedures detailed at [section 7.9](#) must be followed.
- Medication orders must be regularly reviewed by an authorised prescriber in accordance with a timeframe that is appropriate in the particular circumstances.

- **Clinical handover** must address ongoing medication issues and identify actions and monitoring that need to occur in accordance with NSW Health Policy Directive [PD2009\\_060 'Clinical Handover - Standard Key Principles'](#).

Due to serious incidents occurring in relation to the administration of certain Schedule 8 medications, specific information on the selection, handling and/or administration is provided in Safety Notices listed on the [Safety Alert Broadcast System Register](#). Safety Notices pertaining to Schedule 8 medication selection, handling and/or administration include but may not be limited to: -

- ['Safety Notice 011/10 - Medication Incidents Involving Hydromorphone \(Opioid\)'](#), to be read in conjunction with ['Safety Alert 004/11 - Hydromorphone: High-risk analgesic'](#), in identifying risks and implementing strategies to minimise the likelihood of a hydromorphone administration error.
- ['Safety Notice 004/08 - Oxycodone \(Revised\)'](#), which includes strategies on reducing mix-ups relating to the wide range of strengths and variable rates of release of available oxycodone preparations, as well as with similar named morphine preparations.
- ['Safety Notice 005/06 - Safe Use of Fentanyl Skin Patches'](#), in relation to the safe prescribing and administration of fentanyl transdermal patches, as well as the education of patients and carers about handling and use of the patches.

### 7.7 Second Person Checks Prior to Administration

A second person check should be used before certain medications are administered (other than by an authorised prescriber) as determined by relevant NSW Health policies and local protocols and procedures, and must include as a minimum (and in all situations where practicable): -

- Doses administered by injection, and
- Doses administered to children up to their 16th birthday, and
- Contrast administered by a radiographer, with the second person check by an authorised prescriber or registered nurse. If the person administering is an authorised prescriber or registered nurse in medical imaging, the radiographer may be the second person checking, and
- Radiopharmaceuticals for diagnostic purposes administered by a Nuclear Medicine radiation technologist/scientist, and
- Radiopharmaceuticals for therapeutic purposes administered by a Nuclear Medicine radiation technologist/scientist, and
- All Schedule 8 medications, with the second person being the 'witness' described in [section 6.13.2](#).

The second person checking the preparation and administration of a medication is responsible for: -

- Confirming the identity of the patient, and
- Confirming the selection of the correct medication and fluid, and

- Confirming that the dose is appropriate and the calculations are correct, and
- Confirming that a rate limiting device such as an infusion pump has been correctly set, and
- Countersigning the administration on the medication chart against that of the administering person.

Local protocols should include processes to confirm the suitability of individual staff members to act as a second person checking the preparation and administration of the medications specific to the patient care area.

### **Domiciliary care and patient transfers**

When medications for injection are to be administered by a nurse/midwife to a patient in a domiciliary care setting such as 'Hospital in the Home', or when a patient is in transit from a health facility, the second person check must occur within the health facility. The person administering an injection must re-check the medication against the medication order at the time of the administration.

## **7.8 Administration by Injection – Additional Considerations**

Facilities must develop additional protocols and procedures for the administration of medications by injection using a multidisciplinary approach including medical, nursing, pharmacy, infection control staff and workplace safety personnel. [The Australian Injectable Drugs Handbook](#) offers concise, referenced information for nurses and registered pharmacists preparing medicines for administration by injection.

All protocols and procedures for the administration of medications by injection must be consistent with NSW Health policies, and be approved and regularly reviewed by the Drug and Therapeutics Committee. Local policy should include the requirement for a second person to check the preparation and administration of injectable medication (wherever practicable), in accordance with [section 7.7](#) above.

Labelling is to be with the standard NSW Health label set in accordance with NSW Health Policy Directive [PD2012\\_007 'User applied Labelling of Injectable Medicines, Fluids and Lines'](#).

### **Cytotoxic Medications**

Cytotoxic medication solutions for injection must be prepared, administered and disposed of by appropriately accredited staff members.

Where available, reference should also be made to relevant NSW Health policies, directives, guidelines and [Work Health and Safety Information Sheets](#) in relation to specific agents.

### **Administration of Epidural Anaesthesia or Analgesia**

Epidural administration must be governed by protocols and procedures developed by the facility. Nursing and midwifery staff who are required to reload or adjust epidural infusions

subsequent to the initial dose must have completed additional appropriate training and be accredited to administer medication via this route.

Recommended safety practices are detailed in the NSW Health [‘Safety Notice 010/10 - Correct identification of medication and solutions for epidural anaesthesia and analgesia’](#).

### Safe Use of Midazolam

The use of midazolam has been associated with some dosing errors, resulting in over-sedation of the patient receiving treatment. The NSW Health [‘Safety Notice 022/099 - Safe use of midazolam’](#) details strategies for reducing midazolam related incidents and the management of over-sedation with an affected patient.

### Single Use Injections

When only a portion of dose is required for a patient, the unused balance must be discarded. The discarding of part doses of Schedule 8 injections is detailed in [section 7.9](#).

### Multi-dose injections

Medications supplied in multi-dose ampoules or vials must only be used in accordance with NSW Health Policy Directive [PD2007\\_036 ‘Infection Control Policy’](#) and for exclusive use of a single patient. An exception is provided in [PD2007\\_036 ‘Infection Control Policy’](#) for multi-dose vials where there is no other alternative available on the Australian pharmaceutical market.

### Labelling of injections and lines

Injectable medications and associated lines and catheters must be labelled to identify the correct route of administration and be colour coded according to target tissue in accordance with NSW Health Policy Directive [PD2012\\_007 ‘User applied Labelling of Injectable Medicines, Fluids and Lines’](#), using the standard NSW Health label set.

### Additions to intravenous fluids

Additions of medications to intravenous fluids should be made under controlled environmental conditions where possible, or else prepared immediately prior to administration using aseptic technique.

## 7.9 Discarding Partly Used Schedule 8 Medications

All patient care area procedures involving Schedule 8 medications by an authorised person must be with a witness as described in [section 6.13.2](#), other than those conducted by an anaesthetist in an operating theatre.

### Part Tablets or Ampoules

Where only a portion of a dose form of a Schedule 8 medication is required for administration, the unused portion must be rendered unusable and discarded in the presence of the witness to the administration.

A separate entry recording the discard must be made in the drug register on the next available line following the record of the administration.

Any unused portion of an injectable medication must not be discarded in the original container, but drawn up into a syringe and the contents expelled into a sharps container in the presence of the witness.

The discarding of any unused portion of a Schedule 8 medication by an anaesthetist must also be recorded in the patient's anaesthetic record.

### **Partially used infusions**

Any remaining Schedule 8 medications in replaced or discontinued infusions (for example, intravenous, epidural, or patient controlled analgesia preparations) must be discarded in the presence of a witness in a safe manner that renders the drug unrecoverable.

The quantity of the discarded portion must be recorded in the patient's health care record (as applicable in the circumstance), signed and dated by the registered nurse/midwife and countersigned and dated by a witness to the procedure.

For a syringe driven device, the syringe graduations provide for the measurement of the discard. For an infusion device it is accepted that only the arithmetically calculated amount can be recorded as discarded. However, if there is an apparent discrepancy between the arithmetic amount and the physical residue, the registered nurse/midwife must report this to the registered nurse/midwife in charge of the patient care area for further appropriate action.

### **Used Schedule 8 transdermal patches**

Special attention must be applied to the discarding of Schedule 8 (fentanyl, buprenorphine) transdermal patches that have been removed from a patient's skin.

Fentanyl patches, even after being used or when expired, contain sufficient fentanyl to cause life-threatening respiratory depression in an opioid-naïve person if absorbed. If in the disposing of fentanyl patches the active layer come into contact with the skin or other body surface, immediately wash off thoroughly with soap and water.

Particular care must be taken to ensure that a Schedule 8 transdermal patch is not left in the patient's clothes/bed linen or dropped onto the floor, thereby providing the opportunity for someone, such as a child, to swallow the patch.

The used transdermal patch must be removed in the presence of a witness, even if the patch is not to be replaced.

Discarded transdermal patches must be folded in half so that the medication is trapped within the adhesive surface, then disposed of in a 'sharps' container. The time of the discarding must be recorded in the patient's health care record, signed and dated by the registered nurse/midwife and countersigned and dated by the witness to the procedure.

Where a Schedule 8 transdermal patch is found to be missing from the patient, this must be treated as a loss and reported immediately in accordance with [section 6.16](#).

### **Partially Used Fentanyl Lozenges**

Partially used fentanyl lozenges must be disposed of by a registered nurse/midwife in the presence of a witness in a 'sharps' container.

The discarding should be recorded in the patient's health care record, signed and dated by the administering registered nurse/midwife and countersigned and dated by the witness.

## **7.10 Patient Self-Administration and Time-Critical Medications**

All self-administered medication must be ordered on a medication chart by an authorised prescriber with the other medication orders, with an annotation identifying that the medication is for self-administration. A record must be made of each dose taken on the patient's medication chart by the authorised person attending to the patient.

Medications may include those dispensed for the patient in a dose administration aid (see [section 7.11](#)).

The Drug and Therapeutics Committee should establish processes for self-administration by patients on medication regimens requiring strict adherence to a schedule where delays in dosing may adversely affect patient care (such as Parkinson's Disease and diabetes).

### **Patient Training and Education Programs**

The Drug and Therapeutics Committee should implement a formal patient education program for patients about whom a treating clinician is concerned may not be able to manage his/her own medications in the community after leaving the facility without being given detailed instruction and training.

These programs should include, as a minimum, protocols for appropriate patient selection, assessing the appropriateness of the inclusion of the medications in a dose administration aid (see [section 7.11](#)), practical education and training, assessment of the patient's acquired knowledge and capacity to self-manage his/her medications, and monitoring of the ongoing self-use by the patient while the patient is at the facility.

### **Non-Inpatient Day Centres**

Staff may assist a patient self-administering the patient's-own medications in a non-inpatient day centre, further to the authorised prescriber who completes the medication chart confirming that: -

- a) The medication is current, and
- b) The dosage stated on the pharmacy dispensing label is current.

If there is any doubt, the original prescriber must be contacted to clarify the medication order.

## 7.11 Dose Administration Aids

Dose administration aids should not be used for the routine administration of medications, other than as an option to residential aged care patients at a hospital or Multipurpose Service for whom medications are obtained through the Pharmaceutical Benefits Scheme or as 'private' prescriptions in accordance with local protocols approved the Drug and Therapeutics Committee. Dose administration aids may also be used in patient care areas to train or assess a patient's ability to self-medicate (see [section 7.10](#)).

Additionally, patients may present to day centres with medications packed in a dose administration aid (see [section 7.10](#)).

Dose administration aids may comprise blister packs, plastic 'packettes' (sachets) or 'dosette boxes'. The packing and labelling, with the inclusion of the required warning and precautionary labels, must be checked by a registered pharmacist prior to the supply for patient administration. Detail on the requirements relating the supply of dose administration aids by registered pharmacists is included in the Pharmacy Board of Australia *'Pharmacy Guidelines on specialised supply arrangements'*.

A registered nurse may only fill a 'dosette box' compliance aid for the purpose of educating a patient on how to fill the container him/herself, and only from individual packs that have been dispensed and labelled by a registered pharmacist.

The facility's Drug and Therapeutics Committee is responsible for establishing the circumstances for the use and type of a dose administration aid, and the criteria for assessing patient suitability for use, with particular consideration of: -

- Strategies for managing changes to therapy and how to identify dose administration aid packed medication on the medication chart.
- The need for child resistant packaging for certain medications in accordance with [section 5.5.6](#), although blister packaging of medication is recognised as child resistant.
- The need for a moisture-proof container for some medications, and the protection of individual doses from contamination (sealed packs provide this protection).
- The possibility of spillage and a consequential mix-up of medication, especially for a person with visual impairment or poor manual dexterity.
- The self-administration of 'time critical' medications (see [section 7.10](#)).

## 8 ATTACHMENT

### 8.1 Implementation Checklist

<b>LHD/Facility:</b>			
<b>Assessed by:</b>		<b>Date of Assessment:</b>	
<b>IMPLEMENTATION REQUIREMENTS</b>	<b>Not commenced</b>	<b>Partial compliance</b>	<b>Full compliance</b>
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		
6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<u>Notes:</u>		