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**Patient Matters**

**CHAPTER 20 - PHARMACEUTICAL MATTERS**

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MEDICATION HANDLING IN NSW PUBLIC HEALTH FACILITIES (PD2013_043)


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.
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’
b) Section 3 of NSW Health Policy Directive PD2005_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.

KEY DEFINITIONS

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<th>must</th>
<th>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.</th>
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<td>should</td>
<td>Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.</td>
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<td>accountable medication</td>
<td>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.</td>
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<td>authorised person</td>
<td>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.</td>
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| authorised prescriber  | 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:  
  • A medical practitioner registered by the Medical Board of Australia.  
  • A dentist registered by the Dental Board of Australia as a dental practitioner.  
  • A nurse registered by the Nursing and Midwifery Board of Australia with endorsement as a nurse practitioner, and also authorised under section 17A of the Poisons and Therapeutic Goods Act 1966 by the Director-General of Health (or delegate).  
  • A midwife registered by the Nursing and Midwifery Board of Australia with endorsement as a midwife practitioner, and also authorised under section 17A of the Poisons and Therapeutic Goods Act 1966 by the Director-General of Health (or delegate.)  
  • An optometrist registered by the Optometry Board of Australia with endorsement to prescribe or supply a limited range of Scheduled medications.  
  • A podiatrist registered by the Podiatry Board of Australia with endorsement to prescribe or supply a limited range of Scheduled medications.  
  (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.) |
| 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 Health Services Act 1997. |
| 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;

Schedule 2 ‘Pharmacy Medicine’ (pharmacy ‘over the counter’ medication),
Schedule 3 ‘Pharmacist Only Medicine’ (pharmacist controlled ‘over the counter’ medication),
Schedule 4 ‘Prescription Only Medicine’ (also known as a ‘restricted substance’), or,
Schedule 8 ‘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, phenetermine, 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.

GOVERNANCE

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.

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 PD2015_029 High Risk Medicines Management Policy.
- 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.
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 *PD2015_029 High-Risk Medicines Management Policy*.

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

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

Specific NSW Health Policy Standards are also included in *PD2015_029 High-Risk Medicines Management Policy* for:

- ‘Vincristine Use’
- ‘Potassium Chloride Use’
- ‘Anticoagulation’.

Mandatory requirements in high-risk medications management are:

- All facilities must maintain, as part of the program, a specific high-risk medications register.
- 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).
- 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.
- All facilities should employ strategies to mitigate the risk of medications on the mandatory local high-risk medications register.
- 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.

**Medication Safety Alerts, Recalls and Incident/Problem Reporting**

**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.

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.
- Keeping staff informed about medications subject to a recall.
- 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.

Medication Incident Reporting

As part of quality improvement programs in accordance with NSW Health Policy Directive PD2005_608 Patient Safety and 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 PD2014_004 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.

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 PD2014_004 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.
PRESCRIBING

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. 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.

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*.
   - 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*. 

194(28/11/13)
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.
- 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 and Management of Postpartum Haemorrhage.

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.
- 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.
- 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.
  - 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.
20. PHARMACEUTICAL MATTERS

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.

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

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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.

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)’.

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

Issuing Prescriptions for Pharmacist Dispensing

 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.
b) The patient’s name.
c) The patient’s address or patient care area (as applicable to outpatient/discharge or inpatient dispensing).
d) The medication’s active ingredient/s, proprietary name (where applicable), form and strength.
e) The quantity of the medication to be supplied.
f) Adequate directions for use, including the dose, route for administration and frequency of administration.
g) The number of repeat supplies, if any.
h) For anabolic-androgenic steroids, an interval for repeat dispensing.
i) The endorsement required for the Schedule 4 medications with restricted prescribing rights listed in section 4.2
j) The authorised prescriber’s signature.
k) The name, address and telephone number of the facility.
I) 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’
- The addressograph label includes the patient’s name, address/patient care area and patient identification number (if applicable)
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.

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.
- Must include an interval for repeat dispensing (if prescribed).
- Must not include any other medication, including another form or strength of the same Schedule 8 medication.
- 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’.
  - 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.
  - 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.
- The number of repeats (if prescribed), and the interval for repeat dispensing when prescribed.
- 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 initalling the prescription in the margin.

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.

b) The ‘discharge medicine’ order section of the medication chart.

c) Where available, the removable ‘discharge medicine’ section on the patient’s discharge summary.

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.

**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.

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.

c) Send the prescription without delay and within 24 hours to the registered pharmacist to whom the direction was given.

**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.
- 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.
- 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.

Medication Chart Orders in Patient Care Areas

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.
- The indication for treatment (if applicable).
- For a ‘regular’ medication:
  - The dose to be administered.
  - The frequency and times for administration to the patient.
  - 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).
- For a ‘when required’ ('prn’) medication:
  - The maximum individual dose.
  - The maximum daily dose.
  - The hourly frequency for administration to the patient.
  - 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).
- The date of the medication order:
  - Where applicable, the date and time of an amendment to the medication order.
  - Where applicable, the date and time of ceasing a medication order prior to what was originally ordered.
- 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.

**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.
- Essential medications withheld on admission are recommenced if clinically appropriate.
- 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.

**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.
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).
- The medication’s active ingredient/s, proprietary name (where applicable), strength (where multiple strengths are available) and form (where multiple forms are available).
- The dose to be administered.
- The route for administration.
- The frequency and times for administration.
- 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.

THE PHARMACY SERVICE

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)
- 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.

**Medication Procurement**

**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 **PD2014_005 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.
- 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.
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.

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.

Medication Storage in the Pharmacy Service


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.
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.

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.

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.

Medication Supplies – General Provisions

Preparation and Distribution Standards

NSW Health Policy Directive *PD2015_007 Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services* 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.
- Support the lowest possible medication error rate.
- Minimise the cost of medications stored throughout the facility.
- Minimise wastage.
- Minimise opportunities for misappropriation of medications.
- Provide data on medication usage.
- 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 drug.s
- 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.

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.


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.

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).

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.

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 are 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.
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.

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.

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.
- 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.
Dispensing Patient-Labelled Medications

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.

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).

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.

c) Where available, the removable ‘discharge medicine’ section on the patient’s discharge summary.

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.

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

b) Knows the patient for whom the medication is prescribed
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.

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 with 7 days, this fact must be reported by the registered pharmacist involved to the Director-General of Health at Pharmaceutical Services Unit.

Prescription Forgeries

Detected prescription forgeries for any medication must be reported to the local police and to Pharmaceutical Services Unit.

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.

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.
- Intended to be administered by injection.
20. PHARMACEUTICAL MATTERS

- A solid or semi-solid (excluding solid dosage forms) preparation intended for application to the skin or mucous membrane, including transdermal patches.
- 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;
  - is fitted with a restricted flow insert.
- An individually wrapped powder.
- 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.
  - direct suction through the delivery device results in delivery of no more than one dosage unit.
  - actuation of the spray device is ergonomically difficult for young children to accomplish.
- 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.
20. PHARMACEUTICAL MATTERS

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.
- Discharge medications.
- Medications dispensed for day or weekend leave.
- 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.

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.
b) The medication’s active ingredient/s, proprietary name (where applicable), form, strength and the quantity supplied.
c) Adequate directions for use including, where ordered, the instructions specified by the prescriber.
d) The Pharmacy Service’s dispensing reference number.
e) The date of dispensing (unless that date is clear from the dispensing reference number).
f) The name and address of the hospital.
g) The words ‘KEEP OUT OF REACH OF CHILDREN’ in red on a white background.
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.
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’.
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.
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’.

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).

b) Where there is no similar substance on the NSW Poisons List, as a Schedule 4 substance.

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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’).
- Writing the details in a prescription book.
- 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.

b) The patient’s name, and address and/or patient care area.

c) The medication’s active ingredient/s, proprietary name (where applicable, as supplied), strength, form and the quantity supplied.

d) Adequate directions for use including, where ordered, the instructions specified by the prescriber.

e) Where prescribed, the number of repeat supplies of the medication.

f) Where repeats are ordered for Schedule 8 or Schedule 4 Appendix B medications, the interval at which the medication may be repeat supplied.

g) The name and designation of the authorised prescriber, and the name, address and telephone number of the facility.

h) The unique reference dispensing number issued at the Pharmacy Service.

i) The date on which the medication was dispensed.

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.

- 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.

Stock (Imprest) Supplies to Patient Care Areas

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.

- 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.

- 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 imprest medications to patient care areas.

**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 imprest 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.
- If applicable, that the preparation is a Schedule 8 or Schedule 4 Appendix D medication.
- 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.
- The words ‘KEEP OUT OF REACH OF CHILDREN’ in red on a white background.
- 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.’
- The name and address of the facility.
- Any applicable additional information included on the manufacturer’s original pack.

**Pharmacy Service Schedule 8 Medication Accountability**

**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.
20. PHARMACEUTICAL MATTERS

- 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.
  - In the case of a supply to a patient care area, the name of the ward, unit, clinic or service.
- The quantity of the medication received, supplied, or destroyed.
- 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.
- 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
- The name of the requisitioning registered nurse/midwife for imprest supplies, or the name of the authorised prescriber for patient-labelled medications.
- 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.
- 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.
- 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.

**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.
Disposal/Destruction of Medications

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’.

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.
- A registered pharmacist authorised by the director of pharmacy.
- 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.
- A registered medical practitioner or registered dentist.
- 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.
- The date of the destruction.
- The name, signature and health practitioner registration number of the person destroying the medication.
- 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.

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.
- Hands must be thoroughly washed with warm soapy water.
- 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 *Kapanol®* 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.
20. PHARMACEUTICAL MATTERS

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.

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.
• 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.

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.

**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.
- 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.
- Complete and submit an incident report in accordance with the facility’s incident management system.

**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.

**PATIENT CARE AREAS**

**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.
- Storage in a manner that minimises medication error due to a mix-up between preparations.
- 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.
- 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 be compromised.

Medication Procurement By Patient Care Areas

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.
- 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.

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.

b) By a courier arranged by the Pharmacy Service for transfers to a patient care area remote to the Pharmacy Service.

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.
- 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.

### 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.
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.

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.
Medication Storage in Patient Care Areas

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.

b)    Handed over to the registered nurse/midwife in charge of the facility.

c)    Handed over to the facility’s Nursing and Midwifery Administration for securing in a safe or a key safe.

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.

**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.
- 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.
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.

b) On an anaesthetic trolley or operating theatre trolley which is kept in a locked room when not in use.

c) Minimal quantities of medications on an emergency trolley.

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.

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).
20. PHARMACEUTICAL MATTERS

- 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.

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 section 6.14 and stored separately to all other medications 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.

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

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 that standards must be implemented unless a risk assessment determines another control is more appropriate.

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

**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.
b) The patient’s name.
c) The name, strength, form and quantity of the medication supplied.
d) Adequate directions for use.
e) The words ‘KEEP OUT OF REACH OF CHILDREN’ in red on a white background.
f) The name, address and telephone number of the hospital.
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.
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 ancillary label with the associated warning statement required for the particular medication (at h) above) is recommended for this purpose.

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.

**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.

**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

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.

- 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.

- 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.

- 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.

- 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.

**Additional Supplies by Registered Nurses**

**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.
- An authorised prescriber is unable to attend to supply the medication to the patient.
- An authorised prescriber has authorised the supply (dispensing) of the medication to the patient for emergency use by telephone, facsimile, or email.
- 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.
- 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.
- 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.
- Where possible, the prescriber’s telephone order is confirmed by a second person (registered nurse or enrolled nurse).
- 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.
- 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.
- The labelled medication is checked by the second person who confirmed the prescriber’s telephone order (where applicable).
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.

Patient Care Area Schedule 8 Drug Register

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.
- In the case of medications received into stock, the name of the source (for example the Pharmacy Service), and the quantity received.
- 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).
  - 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).
  - 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.
- The amount discarded, where only a portion of the medication (tablet or injection) is administered, as above.
- 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.
- 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.
20. PHARMACEUTICAL MATTERS

- The full and legible signature of the person making the entry, either receiving, administering, discarding, destroying, or carrying out a balance check.
- 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.
- 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)

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Time received or given</th>
<th>Patient’s Name</th>
<th>Amount Received</th>
<th>Amount given</th>
<th>Balance</th>
<th>Signature of administering person</th>
<th>Signature of person supervising, authorising or witnessing administration</th>
<th>Name of prescriber</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5.04</td>
<td>1050</td>
<td>Ian Patient</td>
<td>50</td>
<td>NIL</td>
<td></td>
<td>Jack Jonas</td>
<td>TimToms</td>
<td>Dr G Jay</td>
</tr>
<tr>
<td>2.5.04</td>
<td>1100</td>
<td>Transferred from Ward A1</td>
<td>50</td>
<td>50</td>
<td></td>
<td>Dee Nurse</td>
<td>Col Nurse</td>
<td></td>
</tr>
</tbody>
</table>

**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.

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

**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.

**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.
- Include checks of entries recording stock received against the patient care area and Pharmacy Service records.
- Check and verify signatures for the purpose of detecting forgeries.
- Verify the drug register contents page against the corresponding drug register pages.
- Verify the ‘carried forward’ balances.
- Verify that the routine 24 hour balance checks (or more frequently in accordance with local protocols) have been conducted.
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.

Review the frequency of broken ampoules and discarded portions of ampoules and tablets.

Review the presence of altered, obliterated and cancelled entries.

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

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.

Disposal of Expired, Unwanted or Unusable Medications

Disposal of Medications – General Requirements

Unwanted medications in patient care areas include:
- Expired, contaminated or damaged medication.
- Patient-own medications not returned to the patient.
- 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.

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).
• 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.

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.
• Submit a report in accordance with the facility’s incident management system under the requirements of NSW Health Policy Directive PD2014_004 Incident Management.

This includes all medication that cannot be supplied or used such as:
• Loss of liquid by spillage.
• Loss in broken or damaged bottles and ampoules.
• 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.

**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 PD2014_004 Incident Management
- 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.)
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.

ADMINISTERING MEDICATION

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.

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.
- An approved electronic order.
- A standing order in accordance with section 7.4.
- A verbal, telephone, facsimile or email order in accordance with section 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.
- 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.
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 perfusionist.s
- 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.

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.
- Nurse-initiated medication may interact with the patient’s prescribed medication.
- 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.

Principles for Safe Medication Administration

Safe and accurate medication administration requires the 5 Rights (‘the 5 R’s’) of:

- The Right Patient
- The Right Drug
- The Right Dose
- The Right Time
- 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.
  • Checking the dose, form and route of administration of the medication and the time for administration.
  • Preparing the medication including checking the medication’s name, strength, form, route of administration and expiry date against the medication order.
  • Re-checking at the point of administration to the patient with the patient’s identification, known allergies and other appropriate patient parameters.
  • Documenting the administration.
  • Monitoring the effect of the medication (as applicable).
  • 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.

**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.

• Doses administered to children up to their 16th birthday.

• 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.

• Radiopharmaceuticals for **diagnostic** purposes administered by a Nuclear Medicine radiation technologist/scientist.

• Radiopharmaceuticals for **therapeutic** purposes administered by a Nuclear Medicine radiation technologist/scientist.

• 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.
- Confirming the selection of the correct medication and fluid.
- Confirming that the dose is appropriate and the calculations are correct.
- Confirming that a rate limiting device such as an infusion pump has been correctly set.
- 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.

**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.

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.

**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.

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.

**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’s *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.
20. PHARMACEUTICAL MATTERS

- 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).
PURPOSE

This Information Bulletin is to provide guidance on tenecteplase replacement in public hospitals for NSW Ambulance Paramedics.

KEY INFORMATION

The Pre-Hospital Thrombolysis (PHT) program is part of the State Cardiac Reperfusion Strategy (SCRS) that is being progressively implemented by the Local Health Districts (LHD) with support from the Agency for Clinical Innovation (ACI) in collaboration with NSW Ambulance.

As part of the PHT program, NSW Ambulance paramedics administer intravenous tenecteplase to eligible patients with ST Elevation Myocardial Infarction (STEMI) prior to the patient arriving at the hospital.

In accordance with an Authority issued under the Poisons and Therapeutic Goods Regulation 2008 (NSW), a registered nurse in charge (or his/her delegate) of the Emergency Department (ED) of a public hospital that receives a patient following pre-hospital administration of thrombolytic therapy, is permitted to supply a NSW Ambulance paramedic with one vial of tenecteplase 50mg from ED stock, at the time of patient handover (i.e. 1:1 replacement) to restock the Ambulance Medication kit.

A record of the supply of tenecteplase from the ED, signed and dated by the nurse in charge of the ED (or his/her delegate) and the NSW Ambulance paramedic, must be kept for accountability over the movement of prescription medicines and audit purposes.

The replacement vial must be unused and in its original packaging and should have at least six (6) months shelf life prior to the expiry date.

Replacement should occur even if the hospital only holds one vial of tenecteplase 50mg in stock. In such cases, the Local Health District (LHD) and hospitals will determine how the hospital stock will be replaced according to their local pharmaceutical supply policies.

Processes to facilitate the replacement of tenecteplase provided to paramedics by the ED will be established locally.

In most cases, the patient receiving the pre-hospital tenecteplase would have received tenecteplase at that hospital if the PHT program was not in place (or at another hospital within the same LHD).

These replacement arrangements apply only to tenecteplase that has been used for a patient. Expired stock will not be replaced, nor will any other medication used by paramedics.

The procurement, storage, recording, handling and supply of tenecteplase by a hospital must be in accordance with the NSW Ministry of Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities.
20. PHARMACEUTICAL MATTERS

ALPRAZOLAM UP-SCHEDULING TO SCHEDULE 8 (IB2013_064)

PURPOSE

To inform staff at public health organisations of the up-scheduling of alprazolam preparations from Schedule 4 to Schedule 8 of the NSW Poisons List from 1 February 2014.

KEY INFORMATION

In response to the increasing illicit use of alprazolam and evidence of physical and psychological symptoms of alprazolam dependence, alprazolam is to be up-scheduled from Schedule 4 to Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons on 1 February 2014.

Consequently, alprazolam will become a Schedule 8 drug (drug of addiction) on the NSW Poisons List as of 1 February 2014.

The up-scheduling of alprazolam to Schedule 8 will apply to all forms and preparations of alprazolam. Currently available alprazolam brands include; Alprax, Alprazolam Sandoz, Alprazolam-GA, Chemmart Alprazolam, GenRx Alprazolam, Kalma, Ralozam, Terry White Chemists Alprazolam, and Xanax (now discontinued by the sponsor).

From 1 February 2014, all alprazolam preparations must be procured, receipted, stored, ordered, prescribed, supplied, administered, recorded and destroyed in the same manner as all other Schedule 8 medications, both at the Pharmacy Service and in patient care areas.


Alprazolam preparations in original packaging labelled as a Schedule 4 preparation (‘Prescription Only Medicine’) may be supplied or administered after 1 February 2014. However, the pack must either be:

a) Labelled as a dispensed medicine with a patient’s name by a registered pharmacist or authorised prescriber (for example medical practitioner or nurse practitioner).
b) Re-labelled by a registered pharmacist with the signal heading ‘Controlled Drug’ in the case of an imprest supply to a patient care area.

When prescribing alprazolam to an inpatient in a public hospital, no authority is required for a course of treatment of alprazolam up to a maximum of 14 days. The prescriber must then obtain the necessary authority under the NSW Poisons and Therapeutic Goods Act 1966 from the Ministry of Health’s Pharmaceutical Services Unit.

See TG212 ‘Requirements for an authority to prescribe drugs of addiction under Section 28 of the Poisons and Therapeutic Goods Act’ (attached) for more information.
APPROVAL PROCESS OF MEDICINES FOR USE IN NSW PUBLIC HOSPITALS
(PD2016_033)

PD2016_033 rescinds PD2008_037

PURPOSE
This policy establishes a standard process for the approval of medicines and their use for listing on hospital formularies, or for individual patient use.

MANDATORY REQUIREMENTS
All public hospitals in NSW must have a formally constituted, multidisciplinary Drug and Therapeutics Committee in place, or have access to a Local Health District or Speciality Health Network Drug and Therapeutics Committee. The Drug and Therapeutics Committee is responsible for governing the medication management system, and ensuring the appropriate, safe, effective and cost-effective use of medicines in the health facility, Local Health District or Speciality Health Network.

All public hospitals in NSW must have a hospital formulary. Prescribers working within public hospitals in NSW may only prescribe medicines included in the relevant hospital formulary and in accordance with this policy.

Each Local Health District or Speciality Health Network must develop and implement local procedures based on the process outlined in this policy.

IMPLEMENTATION

NSW Clinical Excellence Commission is responsible for:
- Monitoring the implementation of this policy.

Chief Executive is responsible for:
- Assigning responsibility, personnel and resources to implement and comply with this policy.

Director of Clinical Governance is responsible for:
- Reporting the status of the policy implementation to the NSW Clinical Excellence Commission by returning the Implementation Checklist (Attachment 4.2) within six months of publication of the policy.

Drug and Therapeutics Committee is responsible for:
- Undertaking approval process of medicines for use in the hospital as outlined in this policy
- Communicating formulary decisions and any related safety requirements to relevant clinicians and medication-related governance committees
- Informing the NSW Therapeutic Advisory Group of formulary and Individual Patient Use (IPU) decisions, as required by this policy.

Clinical Staff who are responsible for submitting formulary applications must:
- Follow the approval process set out by this policy.
1. ABOUT THIS DOCUMENT

This policy establishes a standard process for the approval of medicines for listing on public hospital formularies, or for individual patient use (IPU). All NSW public hospitals must follow this process for:

- Medicines that are registered or listed on the Australian Register of Therapeutic Goods that have not yet been added to the formulary
- Use of registered or listed medicines in a manner that is not included in, or is disclaimed in, the approved product information for that medicine
- Use of medicines that are not registered or listed on the Australian Register of Therapeutic Goods.

The process set out in this policy, does **not** apply to:

- Medicines supplied through Medicines Access Programs (refer to the Council of Therapeutic Advisory Groups (CATAG) document on *Managing Medicines Access Programs: Guiding Principles for the governance of Medicines Access Programs in Australian hospitals*).
- The approval of medicine use for research purposes. Use of medicines for research purposes must be referred to the relevant Human Research Ethics Committee (refer to NSW Health Guidelines on Human Research Ethics Committees).

1.1 Related documents

NSW Health Policies:
- **Conflicts of Interest and Gifts and Benefits**
- **Drugs – Funding Arrangements for Outpatient Use of High Cost Drugs Not Funded by the Commonwealth**
- **Medication Handling in Public Health Facilities**
- **Pharmaceuticals – Preparation in Public Health Facility Pharmacy Services**

NSW Health Information Bulletin:
- **NSW Hospital Peer Groups 2016**

- Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals
- Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals
- Position statement for the use of complementary and alternative medicines
- Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines.
### 1.2 Key definitions

| **Biosimilar** | A biosimilar is a subsequent molecular (‘follow on’) variant of an already registered off-patent biological medicine (the innovator biologic) that:  
| | • Has a demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies  
| | • Has been evaluated by the Therapeutic Goods Administration (TGA) according to its guidelines and other relevant European Union guidelines adopted by the TGA.  
| | A biosimilar is not a generic version of the innovator biologic and is not considered to be bioequivalent\(^{(1)}\). |

| **Drug and Therapeutics Committee (DTC)** | The group with delegated responsibility for governance of the medication management system and for ensuring the appropriate, safe, effective and cost-effective use of medicines in the health facility, Local Health District or Speciality Health Network\(^{(2)}\).  
| | For further information on the role and operation of DTCs, refer to:  
| | • CATAG document on *Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals*  
| | • NSW Health Policy on *Medication Handling in Public Health Facilities*. |

| **Drug Use Evaluation** | A cyclical process where reviews of medication use are followed, where necessary, by strategic interventions with the aim of improving patient care and appropriate use of resources\(^{(3)}\). |

| **Hospital Formulary** | A hospital specific list of medicines and related information approved by the DTC. It includes, but is not limited to, medicines and medicine-associated products or devices, medication charts, medication use policies, important ancillary drug information, decision-support tools, and facility guidelines\(^{(4)}\). |

| **Individual patient use (IPU)** | The use of a medicine by an individual patient outside the hospital formulary regulations\(^{(4)}\). |

| **Medication** | Used singularly throughout this Policy to describe a drug, medicine, pharmaceutical preparation (a medicine presented as a completed formulation following a process of compounding or reconstituting), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing and a fluid for intravenous use.  
| | The term includes scheduled medication and unscheduled medication. |
### Off-label medicine use

The use of a medicine other than that specified in the TGA-approved product information including when the medicine is prescribed or administered:

- For another indication
- At a different dose
- Via an alternate route of administration
- For a patient of an age or gender outside the registered use\(^5\).

See **1.3 Definitions of categories and conditions for off-label medicine use**

### Special access scheme (SAS)

Arrangements which provide for the import and / or supply of a non-TGA approved therapeutic good for individual patient use\(^6\).

### Unregistered medicine

An unregistered medicine is a medicine or dosage form that is not currently approved for use in Australia and hence is not entered on the Australian Register of Therapeutic Goods\(^7\).

### 1.3 Definitions of categories and conditions for off-label medicine use\(^5\)

#### Routine use

Refers to medicines routinely used off-label where:

- High quality evidence supports such use
- There is a favourable benefit / harm ratio for the intended off-label use.

#### Exceptional use

Refers to off-label use of medicines where:

- There is low or very low quality evidence
- The potential benefits may be greater than the potential harms for the specific individual circumstances that meet pre-specified criteria (such as a serious or rare condition and / or no other effective or safe alternative therapy).

Approval is patient specific.

#### Conditional use

Refers to off-label use of medicines where:

- The quality of evidence is low to moderate however there is reasonable justification for use in certain types of patients
- A DTC-approved protocol or NSW Health Policy / Clinical Guideline guides the therapy
- Evidence development is required with systematic reporting of effectiveness and safety outcomes to the DTC and relevant clinicians
- There is regular review of continued therapy for an individual and group of patients.

Approval applies to a specific group of patients.

See CATAG document, *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*, for further information on categories and conditions including for Research or Investigational Use.

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308(10/08/16)
2. PROCEDURES

All medicines and their use must be approved by the Drug and Therapeutics Committee (DTC) before they can be added to the hospital formulary or for IPU.

All DTCs must have a process in place for regular review of the hospital formulary. The timeframe for review is determined by the DTC.

All public hospitals in NSW must have a hospital formulary. Prescribers working within public hospitals can only prescribe medicines that are listed in the relevant hospital formulary or in accordance with this Policy.

The DTC must have a process in place for non-hospital formulary medicines (such as those prescribed in the community and continued in hospital) with regard to the approval for use, supply during hospitalisation and discharge, monitoring and reporting of use to the DTC.

Members of DTCs and others who may be involved in the approval of applications must disclose any perceived or actual conflicts of interest (see NSW Health Policy on Conflicts of Interest and Gifts and Benefits). There must be full disclosure of any significant relationship (financial or otherwise) between the clinician, who request hospital formulary addition or approval of individual patient or patient group use, and the supplier of the product or other significant party.

2.1 Submission processes for hospital formulary and IPU medicines

2.1.1 Submission processes for hospital formulary approval

DTC’s approval is required for any hospital formulary listing of a medicine and its use. All medicines, which are under consideration by the DTC for addition to the hospital formulary or variation to an existing hospital formulary listing, must undergo an evaluation process that:

- Critically evaluates the best available patient-based research evidence to support the inclusion on to the formulary. The level of evidence required concerning effectiveness will depend on the specific medicine and the circumstances in which it is proposed to be used. Sufficient evidence regarding the safety spectrum of the medicine will be required to establish an acceptable benefit / harm ratio for the given clinical circumstances (see CATAG document on Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines)
- Clearly defines the objectives of formulary addition or update of listed indication(s) with respect to the delivery of patient care including a broad perspective on the scope of the health problem and the expected impact of this change
- Assesses the medicine costs (including costs associated with the use of the medicine such as need for extra resources) and related direct and indirect costs associated with the potential harms and benefits of a new medicine in comparison with existing therapies, including non-pharmacological therapies where appropriate
- Assesses the requirement of a specific medicine protocol in order to standardise and guide judicious, appropriate, effective, safe and cost-effective medicine use
- Assesses the requirement for any specific training, qualifications, skills or competencies to prescribe, dispense or administer the medicine
- If applicable, considers organisational and electronic medication safety requirements.

308(10/08/16)
The DTC must have a standard process to guide decision making when evaluating a medicine for hospital formulary listing. The NSW TAG DTC decision algorithm for evaluation of medicines can be used for this purpose.

The DTC must have a standard process for evaluating biological or biosimilar medicines for hospital formulary listing (see CATAG document on Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals).

The clinician(s) requesting the hospital formulary addition must complete:

- A hospital formulary submission form for the DTC. The formulary submission should include the objective of formulary addition or indication update
- Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapies and common and serious adverse effects.

It is recommended that hospitals use the NSW Therapeutic Advisory Group (TAG) template and tools for hospital formulary submissions: Formulary submission template, Prescribing protocol template and Supplementary information template.

There are additional considerations for hospital formulary submissions for off-label or unregistered medicines (see 2.1.3 Use of off-label or unregistered medicines for requirements).

2.1.2 Application-process for IPU approval

Approval for IPU of specific medicines is required when a therapeutic need exists for a medicine which would not otherwise be available on the hospital formulary.(4)

The DTC must have a standard process to guide their decision-making when evaluating a medicine for IPU.

The clinician(s) requesting use of a medicine for IPU should complete:

- The relevant IPU application form for the DTC
- Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapy, common and serious adverse effects.

It is recommended that hospitals use the NSW TAG template and tools: IPU application template and Prescribing protocol template and Decision Algorithm for evaluation of medicines for IPU approval.

There are additional considerations for IPU applications for off-label or unregistered medicines (see 2.1.3 Use of off-label or unregistered medicines for requirements).

Multiple IPU requests for the same medication / indication

The DTC must develop and maintain a system to track IPU approvals. High use of a specific IPU medicine should prompt a formulary submission. In these cases, the DTC should advise the applicant when it is appropriate to make a formulary submission and the submission's requirements.

There may be circumstances involving high use IPU medicines where ongoing DTC oversight of use is required, for example, the use of expensive IPU medicines. In these circumstances the clinician and DTC may consider the development of a streamlined IPU approval form for that medicine and its use. Examples of some streamlined IPU approval forms are available on the NSW TAG website.
2.1.3 Use of off-label or unregistered medicines

Prescribers considering use of a specific medicine (hospital formulary or IPU) in an off-label manner, or use of an unregistered medicine, should follow a systematic process (see Attachment 4.1) to assist with their assessment on whether such use is justified and whether they should proceed with an application to the DTC for formulary addition or IPU.

All medicines that are under consideration for off-label or unregistered use must undergo an evaluation process.

The DTC must have policies and protocols for off-label use of medicines and use of unregistered medicines. Policies and protocols must address:

- Consent and documentation requirements as outlined in Table 1, Patient consent and other documentation requirements for off-label and unregistered medicines
- Patient’s and / or carer’s involvement in any decision-making regarding off-label medicine use
- Medicine information for clinicians, patients and / or their carer
- Monitoring and reporting of outcomes to treatment, including adverse events
- Ongoing supply of medicines following discharge from hospital
- Any TGA requirements for use of the unregistered medicine including patient / carer consent and prescriber and hospital reporting requirements
- Any requirement of specific training, qualifications, skills or competencies.

Where a patient’s own medicine is an unregistered medicine, and was commenced prior to hospital admission, prescribing whilst an inpatient must be subject to the IPU approval process.

Off-label medicines

The CATAG Guiding Principles for the quality use of off-label medicines should be used to support decision making by health professionals, consumers and DTCs in their evaluation, approval and use of off-label medicines.

Unregistered medicines

All medicines that are under consideration for unregistered use must undergo an evaluation process that considers, in the first instance, the use of an alternative registered product in accordance with its approval by the TGA. Unregistered medicine use should only be considered when the approved use of a registered medicine does not address the clinical needs of the patient(s).

DTCs should have processes in place that evaluate and manage the risk that may be associated with the use of unregistered medicines, such as those obtained under Schedule 5A of the Therapeutic Goods Regulation 1990 (CTH), Section 19A of the Therapeutic Goods Act 1989 (CTH) and via the Special Access Scheme (SAS).

Conditional registration of a product may occur under Section 19A of the Therapeutic Goods Act 1989 (CTH), for example, during times of medicine shortage. Use of these replacement products should be evaluated by the DTC to ensure appropriate, safe, effective and cost-effective use.

308(10/08/16)
Table 1: Patient consent and other documentation requirements for off-label and unregistered medicines\(^{(5)}\)

<table>
<thead>
<tr>
<th>Off-label medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine use</td>
</tr>
<tr>
<td>• Follow usual processes for patient consent to therapy with provision of information and discussion</td>
</tr>
<tr>
<td>• This should occur as part of routine clinical care and does not require additional measures.</td>
</tr>
<tr>
<td>Exceptional use</td>
</tr>
<tr>
<td>• Approval is patient specific</td>
</tr>
<tr>
<td>• Written informed consent should be obtained</td>
</tr>
<tr>
<td>• Reasons for use should be documented in the medical record</td>
</tr>
<tr>
<td>• The prescriber should conduct a detailed discussion about uncertainty of benefits and harms with use of the medicine with the patient and / or carer.</td>
</tr>
<tr>
<td>Conditional use</td>
</tr>
<tr>
<td>• Written informed consent should be obtained</td>
</tr>
<tr>
<td>• Reasons for use should be documented in the medical record</td>
</tr>
<tr>
<td>• Approval of use is conditional on further monitoring and assessment of effectiveness and safety</td>
</tr>
<tr>
<td>• Detailed discussion about these aspects with the patient and / or carer as well as the benefit / harms of available alternatives and potentially sharing information with others is required.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unregistered (unlicensed) medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Written informed consent is required</td>
</tr>
<tr>
<td>• Refer to the TGA website for specific requirements.</td>
</tr>
</tbody>
</table>

### 2.2 Management of applications

All applications (hospital formulary and IPU), including urgent out of session applications and the outcome of all applications, must be recorded by the DTC.

The approval of a medicine for hospital formulary inclusion must include the active ingredient, strengths, dosage forms, indications and any restrictions; for example, by prescriber, indication or duration of therapy.

**Notification of application outcomes**

All applicants (for hospital formulary or IPU) must be informed of the outcome of their application together with details of approved use, including indications of use, any prescribing restrictions and any monitoring and reporting requirements.

The DTC must have a mechanism for reviewing applications and decisions, should an applicant wish to appeal the DTC decision or provide further relevant information.

Processes must be in place for communication of relevant DTC decisions to all relevant clinicians and medication related governance committees.
**Urgent applications**
In circumstances where use of a specific medicine is required urgently to prevent or minimise harm to a patient, there must be a procedure in place that complies with the formulary application process, to facilitate rapid assessment of the IPU application by a DTC delegate. The circumstances and details of such approvals must be clearly documented and reported for review at the next DTC meeting.

In circumstances of medication shortage or recall of medicines, the DTC must have a process in place to facilitate rapid assessment and approval of an alternative medicine. Formulary application processes must be followed.

**2.3 Review of DTC approved medicines**
DTC must have a formulary review process in place.

**Monitoring and reporting**
Processes must be in place for monitoring and reporting outcomes of medicines use to inform systems improvements. Drug Use Evaluation or other clinical quality audit processes should be utilised. Drug Use Evaluation should be included as a standing agenda item for the DTC meeting.

**Medication incident reporting and adverse drug reaction reporting**
In addition to the usual reporting using the facilities incident management system and the TGA’s Australian Adverse Drug Reaction Reporting System, incidents associated with the use of medicines, including suspected adverse drug reactions, must be reported to the DTC for review, evaluation and appropriate action. The evaluation should include the review of any associated clinical protocol for use of the medicine.

**2.4 Communication of hospital formulary decisions to other health services**
In order to facilitate communication of DTC decisions to the DTCs of other NSW hospitals, Local Health Districts and Speciality Health Networks, the NSW TAG maintains a register of DTC decisions for NSW public hospitals. The register is accessible in the members’ section of the NSW TAG website to authorised personnel including DTC members.

The DTCs of the following hospitals (or LHDs that include the following hospitals), should inform NSW TAG of all hospital formulary and IPU decisions, and other DTC decisions as per the template provided to hospitals by NSW TAG:

- Principle referral hospitals (A1)
- Paediatric specialist hospitals (A2)
- Ungrouped acute – tertiary referral hospitals.

(see NSW Health Information Bulletin on *NSW Hospital Peer Groups 2016*).
REFERENCES

308(10/08/16)
4. ATTACHMENTS

Assessing appropriateness of off-label medicine use

The diagram below is reproduced, with the permission from the Council of Australian Therapeutic Advisory Groups, Darlinghurst, from the document: Rethinking medicines decision making in Australian Hospitals. Guiding principles for the quality use of off-label medicines.

Note: This policy does not cover the ‘Research or Investigational Use’ pathway.

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Diagram:

![Diagram of assessing appropriateness of off-label medicine use](image)
## 4.2 Implementation checklist

<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Not commenced</th>
<th>Partial compliance</th>
<th>Full compliance</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The DTC has a standard process in place for evaluating a medicine for formulary listing.</td>
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<td></td>
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<tr>
<td>2. Formulary applications include an application form and a written clinical protocol where appropriate.</td>
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<tr>
<td>3. The DTC has a standard process for reviewing formulary and IPU applications and decisions where necessary.</td>
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<tr>
<td>4. There are medication specific policies or protocols available for off-label medicine use and unregistered medicine use.</td>
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<tr>
<td>5. The DTC has a standard process in place to facilitate rapid assessment of IPU applications.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. All applications (formulary and IPU) including urgent out-of-session applications, and the outcome of all applications are recorded by the DTC.</td>
<td></td>
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</tr>
<tr>
<td>7. Processes are in place for monitoring and reporting outcomes of medicines use to the DTC.</td>
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PHARMACEUTICALS – PREPARATION IN NSW PUBLIC HEALTH FACILITY
PHARMACY SERVICES (PD2015_007)


PURPOSE

This policy consolidates best practice principles for the preparation of pharmaceuticals by, or on behalf of, NSW public health facility Pharmacy Services.

The policy applies to Pharmacy Services at all NSW Public Health Organisations, including where:
a) The provision of the Pharmacy Service to the Public Health Organisation is contracted to a non-government provider, and
b) A contracted provider supplies compounded or reconstituted pharmaceutical preparations to the Public Health Organisation.

MANDATORY REQUIREMENTS

By 1 April 2015 all NSW 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.

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.

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.

1 BACKGROUND

Public health facility Pharmacy Services must not dispense compounded or reconstituted pharmaceutical preparations unless the Director of Pharmacy has confirmed there are appropriate standards of training, skill, facilities, and preparative and quality assurance procedures in place to provide a high level of confidence that the preparations are of a consistently high quality standard.
In accordance with NSW Health Policy Directive Medication Handling in NSW Public Health Facilities pharmaceutical preparations at NSW public hospitals must be formulated in accordance with the Society of Hospital Pharmacists of Australia SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments (2010) which references the Guide to good practices for the preparation of medicinal products in healthcare establishments published by the Pharmaceutical Inspection Co-Operation Scheme under the Pharmaceutical Inspection Convention (PIC/S, 2008) as the standard for medicines prepared in Australian Hospital Pharmacy Departments (Services).

The Society of Hospital Pharmacists of Australia also publishes practice standards relevant to the preparation of pharmaceuticals in various clinical settings which should be implemented where possible (see webpage at http://www.shpa.org.au/Practice-Standards), including for:

- Investigational drugs services.
- Palliative care pharmacy services, and
- Safe handling of cytotoxic drugs.

Additionally, the Pharmacy Board of Australia ‘Guidelines for the dispensing of medicines’ (available at http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx) includes guidance on appropriate professional pharmacist practice for extemporaneous dispensing (compounding).

**KEY DEFINITIONS**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>must</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>should</strong></td>
<td>Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.</td>
</tr>
</tbody>
</table>
| **ingredients of animal or human origin** | Any component derived from animals or humans that is contained in, or involved in the manufacture of, the pharmaceutical preparation, including but not limited to:  
- cell lines,  
- embryonated chicken eggs,  
- materials used in cell culture media,  
- deer velvet antler,  
- amino acids, and  
- some excipients such as gelatin. |
| **pharmaceutical preparation** | For the purpose of this policy, a medication presented as a completed formulation following a process of compounding or reconstituting, for a purpose that may or may not be an approved indication;  
a) Compounded pharmaceutical preparation – extemporaneously manufactured using ingredients which may or may not be on the Australian Register of Therapeutic Goods (ARTG).  
b) Reconstituted pharmaceutical preparation – prepared for administration via a process of mixing pharmaceutical products with other ingredients. This would include pre-filled syringes with one or more ingredients, intravenous fluids with added electrolytes, Total Parenteral Nutrition solutions and parenteral oncology medications. |
| **Pharmacy Service** | For the purpose of this policy, a service administered by a Director of Pharmacy responsible for the procurement, distribution, preparation and dispensing of medications as well as the delivery of clinical and other pharmacist practice services. |
| **public health organisation** | As defined under the Health Services Act 1997, a local health district, statutory health corporation or affiliated health organisation (in respect of its recognised establishments and services). |
PRINCIPLES

Approval for the Use of Pharmaceutical Preparations

Public health facility Pharmacy Services should not supply a pharmaceutical preparation not listed or registered on the Australian Register of Therapeutic Goods (ARTG) when a similar or a substantially similar product on the ARTG is available.

NSW Health Policy Directive PD2008_037 Medicine - Evaluation of Medicines for Use in Public Hospitals describes the role of the Drug and Therapeutics Committee in the evaluation and approval of all pharmaceuticals added to a facility’s formulary.

Quality Management

To produce a consistently safe and effective product, irrespective of its scale or complexity, for every patient, the Director of Pharmacy of a Pharmacy Service supplying compounding and/or reconstituting pharmaceutical preparations should implement a quality management system which incorporates the elements in the SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments pertaining to:

- Personnel
- Premises and equipment
- Production of preparations
- Documentation
- Quality control
- Contracted services, such as the reconstitution of chemotherapeutic agents
- Complaints and product recalls, and
- Self audits.

PREPARATION, STORAGE, SUPPLY AND HANDLING OF PRODUCTS

Sourcing Completed Pharmaceutical Preparations

Where a preparation is not available as an ARTG registered/listed commercial product and the Director of Pharmacy determines that the Pharmacy Service does not meet the principles in the SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments to formulate the preparation (compound or reconstitute), the preparation must be obtained from either:

a) Another NSW public health facility Pharmacy Service, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, or

b) A community pharmacy, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, or

c) An Australian manufacturer appropriately licenced under the Commonwealth Therapeutic Goods Act 1989 to manufacture pharmaceuticals in accordance with the Good Manufacturing Practice for Medicines.

Sourcing Ingredients of Animal or Human Origin

The Director of Pharmacy must implement procedures to ensure that ingredients of animal or human origin are not included in preparations unless the product is on the ARTG. Exception is provided for the use of non-ARTG products where appropriate steps have been taken by the pharmacist, under a protocol approved by the Director of Pharmacy, that the evaluation of the material confirms there is a minimal risk of any disease transmission.

The information from the Therapeutic Goods Administration (TGA) to sponsors of ARTG medications on the use of material of animal or human origin in ‘Guidance 10: Adventitious agent safety of medicines’ (TGA August 2013) may assist pharmacists in confirming the safe inclusion of such materials in pharmaceutical preparations – see for example reference to the European Pharmacopoeia (Ph. Eur.) Chapter 5.2.8, ‘Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products’.

Packing, Labelling, Recording of Pharmaceutical Preparations

Pharmaceutical preparations prepared by or on behalf of the Pharmacy Service must be supplied (when for imprest stock) and dispensed (for a particular patient) in accordance with the packing, labelling and recording requirements in section 5 of NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities, including where the product requires child resistant packaging (in section 5.5.6).

The labelling should also include the name and contact details of the source of a compounded or reconstituted pharmaceutical preparation.

Assignment of Expiry Dates

The Pharmacy Service must assign an appropriate expiry date to compounded or reconstituted preparations and recommend corresponding storage conditions.

Once it has been confirmed that the Pharmacy Service can supply the preparation with a consistently high level of quality assurance, including sterility where appropriate, the limiting factor for assigning the expiry date for use will be the stability of the preparation. The expiry date allocated to a preparation may be varied according to the circumstances, within the limits of the estimated stability.

Accordingly, the Director of Pharmacy of the Pharmacy Service must implement procedures to ensure that:

a) The preparation is chemically and physically stable for the recommended period included on the label, and

b) Appropriate storage facilities are used to maintain the quality of the preparation over that period.

Pre-filled syringes for immediate use

Pharmacists must confirm there is no incompatibility arising from the contact of a compounded or reconstituted pharmaceutical preparation with the materials of the syringe plunger and barrel used to administer the product.

When a preparation in a pre-filled, single-use syringe intended for immediate use is supplied to a patient care area the appropriate staff member must be alerted accordingly.
Storage of Pharmaceutical Preparations

Compounded or reconstituted products should be stored for the shortest possible period prior to administration.

Where not required for immediate use, preparations must be stored in accordance with the requirements in PD2013_043 Medication Handling in NSW Public Health Facilities both at the Pharmacy Service (in section 5) and the patient care area (in section 6).

Temperature storage conditions must be monitored both at the Pharmacy Service and at the patient care area where the preparation is to be used.

For a preparation used to treat a patient in their home, the pharmacist should, where possible, confirm that appropriate storage is available and that the patient is educated accordingly. The use of a temperature monitoring device should also be recommended to the patient.

Discarding and Destruction of Expired, Unusable or Unwanted Pharmaceutical Preparations

Expired, unusable or unwanted preparations must be destroyed in accordance with the requirements PD2013_043 Medication Handling in NSW Public Health Facilities at the Pharmacy Service (section 5.8) and the patient care area (section 6.15).

Where only a part of the prepared unit dose of the product (for example, capsule, ampoule, infusion) is required for administration, the unwanted portion must be discarded in a manner that is safe to the public and renders the preparation unusable. Further information on discarding part units of Schedule 8 preparations is in section 7.9 of PD2013_043 Medication Handling in NSW Public Health Facilities.
MANAGEMENT OF OPIOID DEPENDENT PERSONS ADMITTED TO HOSPITALS IN NEW SOUTH WALES (PD2006_049)


This policy directive applies to the management of opioid dependent persons in public or private hospitals.

1 INTRODUCTION

From time to time, opioid dependent persons are admitted to hospitals for the treatment of acute or life threatening medical conditions or injuries or for the management of drug toxicity or withdrawal.

In such cases the prescribing of opioid drugs, including methadone or buprenorphine, may need to be considered. However, without prior proper investigation of the patient’s history and physical condition, the immediate prescribing of an opioid drug may be contraindicated.

The policy addresses both the clinical and legal issues of prescribing drugs of dependence for opioid dependent persons and has been prepared to assist medical practitioners in dealing with this situation by outlining the procedures to be followed.

In short, the policy provides for the management of opioid dependent persons:
1. who are on an opioid treatment program and who have been admitted to a hospital for the treatment or assessment of:
   - a medical condition and need to continue with their authorised methadone or buprenorphine dose, or
   - a painful medical condition and need to continue with their authorised methadone or buprenorphine dose together with such opioid analgesics as are necessary to control pain. In such cases, there should be a clearly identifiable cause of pain or other strong clinical indication requiring analgesia.

2. who are not on an opioid treatment program and who have been admitted to a hospital for the treatment or assessment of a medical condition, and require opioid treatment where:
   - controlling withdrawal symptoms with opioids is a necessary part of the management of a serious medical condition, and/or
   - there is a clearly identifiable cause of pain or other strong clinical indication requiring analgesia.

This policy should be brought to the attention of all hospital staff involved in the management of inpatients who are opioid dependent persons. Additionally, each hospital should ensure that protocols or mechanisms exist for obtaining expert advice on a 24 hour basis on the clinical management of opioid dependent persons.

2 LEGAL RESTRICTIONS ON THE PRESCRIBING OF DRUGS OF ADDICTION TO DRUG DEPENDENT PERSONS

Under the provisions of Section 28 of the Poisons and Therapeutic Goods Act 1966 the authority of the NSW Department of Health is required to prescribe for or supply to a drug dependent person\(^1\) any drug of addiction (listed in Schedule 8 of the Poisons List\(^2\)).

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\(^1\) A ‘drug dependent person’ means a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug.
Therefore, a medical practitioner may not prescribe or supply any drug of addiction (listed in Schedule 8 of the Poisons List) for a person who, in the practitioner’s opinion, is a drug dependent person without the prior authority of the NSW Department of Health. The intent of this legislation is to prevent drug dependent persons from “shopping around” to obtain drugs and consequently receiving treatment from more than one medical practitioner concurrently.

In order to facilitate the management of persons admitted to hospitals in New South Wales, an exemption to the above requirement allows a medical practitioner to prescribe a drug of addiction, for up to 14 days, to a person who is an inpatient in a public or private hospital, without the need to obtain authority from the Department to do so, even when the patient is known or suspected to be a drug dependent person.

3 CLASSIFICATION OF THE OPIOID DEPENDENT PERSON

Opioid dependent persons fall into the following distinct categories:

1. On NSW Opioid Treatment Program (methadone or buprenorphine), and
   1.1. Not requiring additional opioids for analgesia, or
   1.2. Requiring opioid analgesia
2. Not on NSW Opioid Treatment Program and
   2.1. Requiring opioids to manage withdrawal, and/or
   2.2. Requiring opioids to manage pain

4 TREATMENT OF AN IN-PATIENT CURRENTLY ON AN OPIOID TREATMENT PROGRAM

These are persons for whom a medical practitioner holds an authority to prescribe methadone or buprenorphine for the treatment of opioid dependence under the NSW Opioid Treatment Program.

After verifying the patient’s identity, contact must be made with both the authorised prescriber and the opioid treatment dosing point, i.e. the place where the patient attends for dosing, to confirm the current actual dose and the date & time of the last dose, including any take-away doses given. It is important to establish these facts as administration of a dose of an opioid drug may lead to overdose if the patient has received a dose recently or the wrong dose is given.

If there is any difficulty in obtaining details of the authorised prescriber from the patient, Pharmaceutical Services Branch may be contacted during office hours on (02) 9391 9944 for assistance.

(a) Not requiring additional opioids for analgesia

Provided that there is no medical contraindication to the administration of an opioid, methadone or buprenorphine should be continued in hospital. It must be prescribed by the patient’s hospital medical practitioner in accordance with the dosage regimen prescribed by the patient’s authorised methadone or buprenorphine prescriber.

Methadone, in oral liquid form, is administered as a once daily dose. Buprenorphine is a sublingual tablet and may be administered as a daily, second daily or third daily dose. The patient’s authorised prescriber should be advised of the approximate length of stay in hospital in order to prevent the patient being exited from the program through ‘non-attendance’.

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When the patient is discharged, the authorised prescriber and the opioid treatment dosing point must be informed in advance of the discharge to ensure that appropriate arrangements are in place for the patient’s continuation on the program.

**Note:** Patients on methadone or buprenorphine are unlikely to exhibit withdrawal symptoms until at least 24 hours after the last dose was administered. In the event that withdrawal symptoms occur and neither the authorised prescriber nor the opioid treatment dosing point can be contacted (e.g., after-hours), the objective signs of withdrawal should be managed, until such time as contact can be made with the prescriber or opioid treatment dosing point, as follows:

Methadone - the patient should be administered 30mg methadone orally. If required, further doses of 5mg may be given, titrated against observable signs of withdrawal, up to a maximum daily dose of 40mg.

Buprenorphine - the patient should be administered 4 mg of buprenorphine sublingually with further doses of 2mg, titrated against observable signs of withdrawal. (Note: the maximum dose of buprenorphine on any day should not exceed 32mg.)

**(b) Requiring opioid analgesia**

Administration of opioid analgesia to persons on a methadone or buprenorphine program must be carried out in consultation with a local Drug and Alcohol specialist. Where contact cannot be made with a Drug and Alcohol specialist, advice on clinical management can be obtained (24 hours a day) from the NSW Drug and Alcohol Specialist Advisory Service, on 9361 8006 (Sydney Metro) or 1800 023 687 (Outside Sydney)

(i) **Patient is on a methadone program**

Methadone should be administered as in (a) above and additional opioids may be prescribed to relieve pain. If analgesia is not achieved with normal dosage regimens, consultation must be undertaken with the patient’s authorised methadone prescriber or a local Drug and Alcohol specialist.

(ii) **Patient is on a buprenorphine program**

Patients maintained on buprenorphine will have a diminished response to opioids prescribed for analgesia, i.e. patients on buprenorphine who suffer severe acute or chronic pain will require higher doses of opioid analgesia than individuals not on buprenorphine treatment. This is because of the ‘blocking’ effect of the buprenorphine on full opioid agonists.

Generally, if acute or sub-acute analgesia is required, a temporary increase in the buprenorphine dose may provide the additional analgesic cover. Where additional opioid analgesia is required, non-opioid analgesic options should be considered and either used alone or in concert with additional opioid analgesia (e.g. morphine), the dose of which should be titrated according to clinical response.

Patients who develop chronic pain, which does not respond to buprenorphine, may require transfer to methadone. Drug and Alcohol specialist advice on a safe transfer between treatments should be sought if this course is contemplated. The dose of analgesic should be closely monitored if buprenorphine is reduced or stopped. This is because there is the potential for over-sedation, or even overdose, from a high opioid dose as the buprenorphine levels reduce (with a corresponding reduction in the ‘blocking’ effects of buprenorphine). Where the buprenorphine treatment is stopped completely, the dose of opioid will need to be closely monitored every day for at least 4 - 5 days after the last buprenorphine dose and will probably have to be reduced over time, to avoid an overdose. If in doubt, Drug and Alcohol specialist advice should be sought to ensure safe and effective treatment of pain.
When the patient is discharged, the authorised prescriber and the opioid treatment dosing point must be informed, in advance of the discharge, of the dose and the date of last dose in hospital to ensure that appropriate arrangements are in place for the patient’s continuation on the buprenorphine or methadone program.

If there is a need to continue opioid analgesia, the patient’s authorised buprenorphine or methadone prescriber should be advised in addition to their general or treating practitioner.

5 TREATMENT OF AN IN-PATIENT DRUG DEPENDENT PERSON NOT CURRENTLY ON AN OPIOID TREATMENT PROGRAM

(a) Where Opioid Analgesia IS NOT Required But Symptoms Of Withdrawal Are Evident.

Wherever possible, withdrawal symptoms should be symptomatically treated with non-opioids only.

However, opioids (i.e. methadone in oral liquid form, or buprenorphine sublingual tablets) may be used to treat withdrawal symptoms where:

(i) withdrawal symptoms could reasonably be expected to interfere with the optimum medical management of the patient, or
(ii) the patient is suffering from a serious or life-threatening illness and the patient’s premature self-discharge before completion of therapy would prejudice optimum management.

Where methadone is prescribed for the treatment of withdrawal to a person not on an opioid treatment program, 10mg to 20mg per day, in oral liquid form, should be administered in divided doses. The dose may be gradually increased, by 5mg increments titrated against objective signs of withdrawal, to a maximum daily dose of 40mg. The dose may be combined into a single daily dose when stabilized. Doses should not be increased above 40mg daily unless consultation has taken place with a specialist in the management of drug dependence. Patients should be advised that this treatment does not constitute entry to the methadone program. Entry to this program must be through approved prescribers.

An alternative strategy is to use buprenorphine sublingually in a dose of 2mg every two to four hours if required to control withdrawal symptoms on day 1. On day 2, the total dose for day 1 should be given as a single dose, and then reduced by 2mg per day thereafter. This is a simpler form of withdrawal management and withdrawal is achieved more rapidly than with methadone. A Drug and Alcohol specialist should be consulted to facilitate this schedule. Patients should be advised that this treatment does not constitute entry to the buprenorphine program. Entry to this program must be through approved prescribers.

All patients given methadone or buprenorphine to allay symptoms of withdrawal from opioids should be slowly withdrawn from methadone or buprenorphine prior to discharge from hospital wherever possible. Where it is not possible to complete the withdrawal in hospital or where it is considered appropriate to extend the use of methadone or buprenorphine after discharge, arrangements for continuation should be made following consultation with an approved prescriber. This should be done well in advance of the patient’s discharge.

(b) Where Opioid Analgesia IS Required

Tolerance to drugs may necessitate higher doses and/or greater frequency of administration in some cases to achieve satisfactory analgesia compared to an opioid naive patient with a similar condition.
Therefore, for acute problems with a clear diagnosis (e.g. trauma), opioid analgesia, within normal dosage regimens, should be provided in the first instance; above normal dosage or unduly prolonged prescribing should take place only after consultation with a specialist in the management of drug dependence. If contact cannot be made, advice on clinical management can be obtained (24 hours a day) from the NSW Drug and Alcohol Specialist Advisory Service, on 9361 8006 (Sydney Metro) or 1800 023 687 (Outside Sydney).

- FURTHER INFORMATION

Advice regarding the nearest approved methadone or buprenorphine prescriber can be obtained from the Pharmaceutical Services Branch of the NSW Department of Health (phone (02) 9391 9944).

General information may be obtained from the Duty Pharmaceutical Adviser, Phone (02) 9391 9944 or at the Branch website - [http://www.health.nsw.gov.au/publichealth/pharmaceutical/](http://www.health.nsw.gov.au/publichealth/pharmaceutical/)

DOSING FACILITIES IN PUBLIC HOSPITALS FOR PATIENTS ON OPIOID TREATMENTS SUCH AS BUPRENORPHINE AND METHADONE (PD2006_052)

This policy directive is to advise Area Health Service Chief Executives of their responsibility to ensure the availability of dosing points in public hospitals for patients on an opioid treatment program.

1. Background

1.1 The role of opioid pharmacotherapies in the drug treatment system

Maintenance treatment using opioid agonist pharmacotherapies (methadone and buprenorphine) is an essential component of a comprehensive drug treatment system and thus of a health care system.

1.2 The structure of the opioid treatment system

The opioid treatment program is delivered by a combination of (a) medical practitioners authorised to prescribe methadone and buprenorphine, (b) case management services at dosing points and (c) dosing or delivery systems to provide the doses on a regular basis (often daily) to patients.

There are four categories of dosing points.
1. Public, specialised drug treatment service, often within or on the grounds of public hospitals or community health centres.
2. Private, specialised drug treatment services.
3. Community pharmacies that are authorised to dose.
4. Other locations within public hospitals without special-purpose drug treatment services, for example the use of hospital pharmacies or other appropriate facilities to dose a medium number of patients.

1.3 The roles of public opioid treatment services

The roles of public specialised opioid treatment services are essentially:

(a) to initiate opioid pharmacotherapy treatment and to maintain treatment for complex cases;
(b) to substitute where necessary for other dosing facilities; and
(c) to support community pharmacies.
2. The role of public hospitals in the opioid treatment

Depending on the ready availability and accessibility of specialised drug treatment facilities and dosing pharmacies, the primary purpose of dosing methadone and buprenorphine in public hospitals is to supplement other dispensing facilities.

Public hospital pharmacies or appropriate locations within the hospital will provide dosing facilities for a limited number of patients on the opioid treatment program where there are no other dosing facilities available and accessible.

3. Occupational Health and Safety Issues

Public Hospital dosing points must comply with safe practice and environment standards as per routine hospital accreditation.

Public hospital dosing facilities are required to ensure the safety of clients, staff and visitors and the secure storage of drugs in line with the Poisons and Therapeutic Goods Act (1966) and Regulation (2002). The Hospital Pharmacist will comply with standard hospital dosing requirements. Specific requirements include:

- Sufficient physical, electronic and procedural safety.
- Dosing equipment to be operated only by appropriate staff.
- Appropriate level of support and education for staff.
- Appropriate waste management of expired medication, and used bottles and labels.

4. Issues with Implementation

In view of the importance of the opioid treatment program and the responsibilities of the public health system to make provision for opioid pharmacotherapy treatment services, every public hospital must be prepared to provide methadone and buprenorphine dosing services.

It is the responsibility of the hospital to demonstrate to the Area administration and NSW Health through the Centre for Drug and Alcohol that:

- it has established and operates appropriate dosing facilities; or
- there is an unreasonable cost or burden in establishing dosing facilities; or
- it is not necessary or appropriate for the service to be provided.

It is anticipated that there may be minor costs associated with the establishment of methadone and/or buprenorphine dosing points in public hospitals, primarily to ensure appropriate dispensing facilities, safety and storage of Schedule 8 drugs.

Hospitals may need to ensure initial staff training, ongoing support and education to ensure competency and behavioural management strategies to manage this particular patient group. The capacity to dose at hospital pharmacies or the appropriate location within the hospital should be augmented by services such as case management, clinical review and clinical support. Area based drug and alcohol services should ensure that such support is available and accessible. The Area Health Service Director of Drug and Alcohol should be consulted regarding the provision of support and education.

Further information may be obtained by contacting Mr Mark Anns, Centre for Drug and Alcohol, by telephone 02 9424 5752 or by e-mail manns@doh.health.nsw.gov.au
1. PREAMBLE

1.1 In February 2006, Cabinet endorsed the development of a protocol between the NSW Departments of Health and the NSW Department of Community Services (DoCS) to facilitate exchange of information between these agencies where methadone is being made available to DoCS clients.

1.2 This protocol facilitates inter-agency exchange of information to assist DoCS casework staff to assess whether a child or children under 16 years of age is/are at a risk of harm due to a person’s misuse of opioids while participating in an opioid treatment program. It complements and has been developed in the context of a number of key policies including the NSW Drug and Alcohol Services Plan, the NSW Interagency Guidelines for Child Protection Interventions 2006 and the Interagency Guidelines for the early intervention, response and management of drug and alcohol misuse.

1.3 Participation in an opioid treatment program is considered a positive treatment option for individuals struggling with ongoing illicit opioid use. The focus of this protocol is information sharing to facilitate determination of whether, in specific cases, misuse of drugs supplied on the treatment program, and/or other circumstances in the household, combine to create inadvertent or deliberate risk of harm to children.

1.4 Accidental ingestion of takeaway doses of methadone by children or deliberate dosing of children by adults can be fatal. Takeaway doses of buprenorphine also present potential risk of harm to children. These risks are not confined to young children. The nature of the risk varies according to the age of the child. While accidental ingestion or deliberate dosing of methadone is a high risk for young children (under the age of six), risk of self-administration and experimentation increase with age and are most likely in adolescence.

1.5 Opioid treatment therapies involving methadone and buprenorphine are a medically accepted way of treating heroin addiction. Over thirty years of clinical experience and research has established that methadone is highly effective at retaining people in treatment, suppressing heroin use and associated crime, and reducing the risk of overdose and HIV. Research also confirms that buprenorphine treatment is effective in achieving these objectives. The most appropriate opioid treatment medication for a client is a clinical decision made by the prescribing practitioner and will reflect a wide range of factors related to the history of the client’s drug use and treatment and other medical conditions. The effective treatment of opioid dependence is a long-term issue. Any reduction in dose or withdrawal from treatment must be monitored by the prescriber and conducted gradually.

1.6 Buprenorphine is increasingly used as an alternative to methadone in opioid treatment programs. The pharmacological characteristics of buprenorphine differ from methadone. The different characteristics of buprenorphine allow it to be consumed sublingually (under the tongue) in tablet form. As it can take between 2 and 7 minutes for the drug to be absorbed, it is thought to be unlikely that a child would be able to save the tablet in their mouth for long enough to absorb it. In contrast to methadone there have been no reported deaths of children from an overdose of buprenorphine in Australia and it is considered by the medical community to be a safer drug than methadone. However, there is insufficient evidence to provide assurance that buprenorphine is safe if ingested by children. When a client on buprenorphine is to be given takeaways, a combination formula is used, buprenorphine-naloxone. The combined product is designed to reduce the likelihood of clients injecting or diverting takeaway medication.
1.7 The NSW Department of Health authorises health practitioners to prescribe opioid treatment to persons registered on an opioid treatment program. Prescribers can be either public (career medical officers, registrars, drug and alcohol staff specialists, drug and alcohol nurse practitioners, visiting medical officers) or private (general practitioners, drug and alcohol nurse practitioners, psychiatrists).

1.8 In New South Wales approximately 60% of clients on opioid treatment receive their prescriptions from a private prescriber. The dispensing of the medication is most commonly provided through public or private outpatient clinics, community pharmacies and local hospitals (particularly in rural areas).

1.9 Prescribers are issued with NSW Health clinical guidelines relating to their role in methadone and buprenorphine treatment. The NSW Clinical Guidelines for the Treatment of Opioid Dependence recently revised by the NSW Department of Health include an updated chapter on takeaways that was revised in consultation with DoCS. These Guidelines specify the contraindications to providing methadone and buprenorphine takeaway doses, including current child welfare issues or DoCS involvement of children under 16 in a household.

2. RELEVANT LEGISLATION AND DOCUMENTS

2.1 The client information disclosed to DoCS under this protocol relates to the safety, welfare and wellbeing of a child or children and is provided in accordance with the Children and Young Persons (Care and Protection) Act 1998. The NSW Health Privacy Manual, Version 2 identifies health information disclosed in this manner as exempt from privacy provisions of the Health Records and Information Privacy Act 2002.

2.2 The sections of the Children and Young Persons (Care and Protection) Act 1998 that are relevant to this protocol are outlined below.

- Section 24 of the Children and Young Persons (Care and Protection) Act 1998 provides for a person to report to DoCS where he or she has reasonable grounds to suspect a child is at risk of harm. Reports made under this section in good faith are protected, and cannot generally be used against the reporter in litigation or formal disciplinary action.

- Section 27 of the Children and Young Persons (Care and Protection) Act 1998 imposes a mandatory obligation on health service providers (including medical practitioners) to notify DoCS if in the course of their work, they form reasonable grounds to suspect a child is at risk of harm.

- Section 248 of the Children and Young Persons (Care and Protection) Act 1998. This section allows DoCS to require a “prescribed body” to provide DoCS with information relating to the safety, welfare and wellbeing of a particular child or young person or a class of children or young persons. Public health organisations under the Health Services Act (such as area health services) and organisations that provide health services to children are prescribed bodies.

2.3 Health Privacy Principle 11 of the Health Records and Information Privacy Act 2002 provides personal health information can only be disclosed for the purposes for which it was collected, or other purposes recognised by the Act. These include release with consent, release where there is a serious risk of harm to a person and release authorised by a law (such as the Children and Young Persons (Care and Protection) Act 1998).
2.4 Under Section 28A of the *Poisons and Therapeutic Goods Act 1966* practitioners must apply to the Director-General to be approved as a prescriber of methadone and buprenorphine for the purpose of treating opioid dependent individuals in the state of New South Wales. Approvals are subject to several conditions one of the conditions being to follow conditions specified in the *NSW Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Treatment (2006).*

2.5 Reporting requirements for prescribers employed in Area Health Services are also covered in NSW Health documents, Policy Directive PD2013_007 *Child Wellbeing and Child Protection Policies and Procedures for NSW Health.*

3. **OBJECTIVE**

3.1 This protocol facilitates the sharing of information between the NSW Department of Health’s Pharmaceutical Services Branch (PSB), opioid treatment prescribers and DoCS child protection casework staff concerning persons who are registered to receive opioid treatment (methadone or buprenorphine).

3.2 Information shared under this protocol is intended to assist DoCS to assess the risk of harm to children that arises due to their potential exposure to methadone or buprenorphine that is dispensed to registered opioid treatment clients so that the appropriate child protection responses may be initiated, where necessary.

3.3 The NSW Department of Health and DoCS have key roles in ensuring that DoCS child protection casework staff are adequately informed about the benefits and risks of standard treatments for opioid dependence and are able to obtain accurate information from prescribers to assist with assessment of risk of harm to children where concerns are reported in relation to opioid dependent persons.

4. **TARGET CLIENT GROUP**

4.1 Children under 16 years of age [as defined in the *Children and Young Person (Care and Protection) Act 1998*] who are at a risk of harm due to their relationship with a person undergoing opioid treatment.

4.2 The two categories of children are covered under this agreement are:
   a. Children subject to current DoCS involvement where there is an open case plan; and
   b. Children, whether known to DoCS or not, who become known to a prescriber through the prescriber’s contact with a client in opioid treatment.

5. **GENERAL ROLES AND RESPONSIBILITIES**

5.1 The requirements to be discharged by public prescribers in sharing child protection information with DoCS in accordance with this protocol are based on the general obligations on NSW Health staff:
   a. To make a report to the DoCS Helpline where he or she has reasonable grounds to suspect a child or young person is at risk of harm in accordance with sections 24 and 27 of the *Children and Young Persons (Care and Protection) Act 1998,* and
   b. To provide DoCS with information relating to the safety, welfare or wellbeing of a child or young person when directed to do so by DoCS under section 248 of the *Children and Young Persons (Care and Protection) Act 1998.*
5.2 For private prescribers the obligations on reporting to DoCS are based on:

- Conditions imposed on their authority to prescribe under the *Poisons and Therapeutic Goods Act 1966* and associated regulations that require prescribers to comply with the *NSW Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Treatment (2006)*, including to provide to DoCS casework staff information relevant to possible risk of harm to children as required under this protocol; and/or

- The general requirement on private prescribers who work in an incorporated practice that provides services wholly or partly to children to comply with sections 27 and 248 of the *Children and Young Persons (Care and Protection) Act 1998*.

5.3 NSW Health will review any unreasonable non-compliance by private sector prescribers to the reporting requirements in this protocol. This may result in a prescriber’s authorisation to prescribe methadone and buprenorphine being revoked.

5.4 DoCS is responsible for assessing risk of harm to children covered by this protocol.

6. **ROLES AND RESPONSIBILITIES RELATED TO CHILDREN SUBJECT TO CURRENT DOCS INVOLVEMENT**

6.1 Where DoCS has an open case plan suggesting a parent or carer’s misuse of an opioid or opioid treatment, including takeaway methadone or buprenorphine, DoCS will request information from PSB under section 248 of the *Children and Young Persons (Care and Protection) Act 1998* to establish current or recent participation in the opioid treatment program on the basis that in these circumstances the information is relevant to the safety, welfare and wellbeing of the child or young person.

6.2 In accordance with section 248, PSB will provide information to DoCS on whether the subject of the query is registered on the opioid treatment program or was registered for opioid treatment 30 days prior to the date of the request.

6.3 PSB will also provide DoCS with contact details of the current prescriber or most recent prescriber for those who are not on the program but were on the program in the 30 days prior to the request.

6.4 Following receipt of information that the subject of the request is not on the program and has not been on the program in the 30 days prior to the request, DoCS casework staff will pursue enquiries about opioid and/or other drugs through relevant section 248 enquiries of Area Health Services.

6.5 Many adult clients will have had treatment provided by the Area Health Services, not only in relation to opioids, but also for treatments relating to other drug or alcohol problems. The PSB database only holds information relating to schedule 8 drugs.

6.6 Following receipt of information that the subject of the request is on the program or has been on the program in the 30 days prior to the request, DoCS will contact the prescriber to request further information. This information request will focus on establishing whether there may be risk of harm concerns for a child or children as a result of the person’s opioid treatment, particularly where takeaway doses are involved. Specifically, DoCS will request the following information:
The prescriber’s knowledge about the client’s compliance with treatment;
• Whether the prescriber has sighted or examined a client’s child/children in the preceding three months, the reasons for the examination and any associated concerns for the child/children’s health and safety;
• Any recent observations that may indicate that the client’s parenting is compromised;
• Any current concerns the prescriber has for the health and safety of a child/children based on knowledge of the client, the client’s compliance with their treatment regime and/or any other issues that may impact on the safety of the child/children.

6.7 Questions for DoCS casework staff to ask of the prescriber during their initial query are at Attachment A. This is to alert prescribers to the information that will be pertinent to caseworker inquiries about their clients.

6.8 Following contact by DoCS, the prescriber will conduct an assessment of the most recent treatment review and determine whether another review is necessary (as per the NSW Clinical Guidelines for the Treatment of Opioid Dependence 2006).

6.9 In reviewing the appropriateness of takeaway doses the prescriber should always include dialogue with the dispenser (in most cases, a pharmacist). The dispenser may occasionally observe children, who attend dosing with the client and may be able to provide additional information as to the stability of the client. The outcome of any review, including dialogue with the dispenser should be documented.

7. ROLES AND RESPONSIBILITIES RELATING TO CHILDREN NOT SUBJECT TO DoCS INVOLVEMENT

7.1 The prescriber will conduct a normal review of the person’s treatment regime (as per the NSW Clinical Guidelines for the Treatment of Opioid Dependence 2006), including dialogue with the dispenser (in most cases, pharmacist).

7.2 A prescriber who has a reasonable concern (based on their regular review of the person’s current social circumstances) that a child/children under 16 years of age is/are at a risk of harm due to an adult’s misuse of opioids.

   a. Make a report to the DoCS Helpline
   b. Identify him or herself as a prescriber, and
   c. Provide to DoCS all relevant information that will assist DoCS to make an assessment of the risk of harm for the subject child or children. Provide to the DoCS caseworker all information about the person that may impact on a child’s safety, welfare and well-being, based on their knowledge of the client and their compliance or non-compliance with their treatment regime.

7.3 DoCS will review any report received from a prescriber in accordance with existing practices.

7.4 A prescriber contacted by DoCS in response to a report will provide the caseworker with any additional information they have that is relevant in assisting the caseworker to complete an assessment of any child at risk concerns.
8. **MONITORING, REPORTING AND EVALUATION**

8.1 DoCS and the NSW Department of Health will monitor the operation of the protocol.

8.2 The protocol is to be formally reviewed and evaluated by DoCS in conjunction with the Department of Health no later than two years after the date of commencement. The results of this review will be reported to the respective Directors-General within 3 months of the completion of the review. A particular focus of this review will be the effectiveness of the protocol in responding to the issues identified by the Cabinet decision that authorised its development.

**GLOSSARY**

**Mandatory Reporter**

A person who as part of their professional or paid work or as the supervisor/manager of a person who as part of their professional or paid work, delivers health care, welfare, education, children’s services, residential services or law enforcement to children or young persons.

Mandatory reporters are required under Chapter 3, Part 2, section 27 of the Act to make a report to DoCS if they suspect that a child is at risk of harm as detailed in Chapter 3, Part 2, section 23 of the Act.

Any prescriber who is not a mandatory reporter within the scope of the Act is required by directive of the Health Minister to report risk of harm under the terms of this protocol.

**Mandatory Report**

A report made to DoCS, usually via the Helpline to convey a concern about a child or young person who may be at risk of harm. The circumstances of risk of harm are outlined in Chapter 3, Part 2, sections 23, 24, 25 and 27, Chapter 7, Part 2, sections 120, 121 and 122 of the Act.

**Risk of harm**

Risk of harm is present if there are current concerns that a child or young person may suffer physical, sexual, psychological and/or emotional harm as a result of what is being done or not done by another person, often an adult responsible for their care. Risk of harm is defined in Chapter 3, Part 2, and section 23 of the Act.

**Open case plan**

A report on a child or young person has been allocated to a DoCS’ caseworker for further assessment.

**PSB Database**

An electronic database primarily used to issue authorities to medical practitioners to prescribe drugs of addiction (schedule 8) as required under section 29 of the Poisons and Therapeutic Goods Act 1966. This includes authorities to prescribe methadone or buprenorphine under the NSW Opioid Treatment Program, narcotic analgesic for the treatment of chronic pain, stimulants for the treatment of ADHD, etc.
20. PHARMACEUTICAL MATTERS

Diversion/diverted dose

The misuse of a prescribed drug, most commonly for selling or injecting

Takeaway dose

A dose of methadone or buprenorphine to be taken in an unsupervised setting, usually at home. Takeaway doses are only provided after careful assessment of the client’s stability.
### Attachment A

**Typical questions for DoCS Caseworkers to Ask Prescribers**

<table>
<thead>
<tr>
<th>Factors that may impact on parenting and/or risk of harm</th>
<th>Prescriber Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client prescribed takeaway doses? Which treatment is prescribed - methadone or buprenorphine? How long has the client been on takeaway doses? When was the last review? Did the review consider impacts on any children the person may be caring for? Did the review identify any issues of concern?</td>
<td>Any risk of harm concerns identified</td>
</tr>
<tr>
<td>Are there any current issues with the client’s compliance with treatment? If yes, please describe these issues. Is the client prescribed any other medication? If so, what?</td>
<td></td>
</tr>
<tr>
<td>In the last 3 months, have you sighted or examined the child or siblings of the child about whom DoCS has a report?</td>
<td></td>
</tr>
<tr>
<td>Are there any observations you have made in the last three months, which may indicate that parenting is compromised, eg. occasions when the child/ren looked ill, neglected, stressed or was/were otherwise behaviourally demanding? How did the client interact with the child/ren? Was the client aware of the child’s needs?</td>
<td></td>
</tr>
<tr>
<td>What is the client’s behaviour like at prescriber practice/dosing site (i.e. no aggressive/threatening behaviour towards staff/others reported)</td>
<td></td>
</tr>
<tr>
<td>Has the client indicated whether there are any significant life events impacting upon them at this time (eg. relationship breakdown, pregnancy, grief or loss, legal issues, lack of housing)</td>
<td></td>
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<tr>
<td>Does the client present with any other mental/physical health needs?</td>
<td></td>
</tr>
<tr>
<td>Do you have any information about the client’s current: Employment/education or training Accommodation status</td>
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</tbody>
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RAPID OPIOID DETOXIFICATION - GUIDELINES (GL2011_009)


PURPOSE

The purpose of NSW Health Guidelines on Rapid Opioid Detoxification is to provide information on a procedure which may be conducted in private health facilities, licensed for Rapid Opioid Detoxification (ROD) as per the Private Health Facilities Regulation 2010 under the Private Health Facilities Act 2007. In accord with the regulation, Rapid Opioid Detoxification Class private health facilities must comply with the Drug and Alcohol Withdrawal Clinical Practice Guidelines - NSW.

KEY PRINCIPLES

ROD is not currently conducted NSW’s public sector nor is it likely to be in the foreseeable future unless in the context of a clinical trial, thus the key principles of these guidelines are to ensure patients undertaking ROD procedures in a private health facility licensed for the purpose of ROD:

1. have been well informed of the treatment they are undertaking including potential risks and alternative treatment options;
2. have been advised verbally and in writing that rapid opioid treatment and naltrexone implants are still experimental treatments;
3. are advised verbally and in writing that naltrexone implants used in Australia have not been approved by the relevant regulatory authorities;
4. can competently provide signed, informed, consent to treatment;
5. have been satisfactorily assessed as appropriate for the treatment; and
6. are adequately monitored and supported during and post treatment.

The guidelines align with the Private Health Facilities Regulation 2010 under the Private Health Facilities Act 2007 which provides the recommended standards for the settings in which ROD is undertaken ensuring they are appropriately and adequately equipped. Refer section 4.1.7.

Further, the guidelines provide Public Hospital Emergency Departments and the like with appropriate recommendations on how to best manage patients who present post ROD treatment with complications and/or those who present in medical settings who are in continued treatment with naltrexone (including those with naltrexone implants).

USE OF THE GUIDELINE

As per the Private Health Facilities Regulation 2010 (amended) under the Private Health Facilities Act 2007, compliance with the NSW Health Guidelines on Rapid Opioid Detoxification is a condition of a private health facility license for the purpose of ROD.

In addition these guidelines provide recommendations for clinical staff in medical settings such as Public Hospital Emergency Departments and the like for the management of patients who may present post ROD procedures with complications and/or patients presenting who are in continued naltrexone treatment (including naltrexone implants).

FUNDING ARRANGEMENTS FOR OUTPATIENT USE OF HIGH COST DRUGS NOT FUNDED BY THE COMMONWEALTH (PD2005_395)

A number of high cost drugs prescribed in NSW for outpatient usage are not funded through the Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme, or Section 100 of the National Health Act and may be subject to the provisions of this Circular. The responsibility for defining the high cost drugs that are subject to these funding arrangements is delegated by NSW Health to the NSW Therapeutic Advisory Group (NSW TAG), in consultation with Directors of Pharmacy and Drug Committees of tertiary units.

The NSW TAG defines High Cost Drugs for the purposes of these arrangements as medicines which:

1. are not listed for subsidy on the Schedule of Pharmaceutical Benefits under either Section 85 or Section 100 of the National Health Act, and
2. incur acquisition costs equivalent to or more than $500 per week per drug per patient (subject to annual review by NSW TAG), and
3. require particular expertise for management of patient care.

And which:

4. are being used in accordance with the Approved Product Information, or
5. are being used in a manner that is supported by high quality clinical evidence

Therapy with high cost drugs not funded by the Commonwealth should only be initiated in tertiary units (principal or major referral hospitals) with the approval of the hospital Drug Committee. Where the patient being treated at the tertiary unit resides in another Area, the initiating Area Health Service should inform the Area Health Service (or the appropriate hospital Drug Committee with delegated authority) in which the patient resides. This enables queries or clarifications regarding the clinical indications for the drug to be discussed and resolved between the Areas prior to the transfer of costs.

The Area Health Service of the unit initiating therapy is responsible for financing the cost of the drugs for twelve months from the date of discharge from the episode during which the therapy was commenced, or for twelve months from the date of commencement if therapy was initiated on a non-inpatient basis. After twelve months the responsibility for financing passes to the Area of residence of the patient. Notification and billing should occur at an Area level between CEOs.

To avoid duplication of supplies, the Area initiating treatment should give the Area of residence details of the therapy including the patient’s initials, address, date of birth, date of commencement, quantity and cost of the drug at least three months prior to the transfer of funding responsibility. Notification of intention to bill should be made by way of a standard notification form developed by NSW TAG (available on the NSW TAG web site: http://www.nswtag.org.au).

These arrangements should not be used to cover:

1. Drugs that are being used in the context of a formal research protocol;
2. Drugs that are being used in “exceptional” circumstances (as described in NSW Health Department IB2004/15: Off-Label Use of Medicines and Use of Medicines Obtained under the Commonwealth Personal Importation Scheme in NSW Public Hospitals);
3. Drugs that are being used under the Special Access Scheme.
In such circumstances, the patient should continue to attend the hospital where the research or exceptional use was approved, unless new approvals are obtained via the local hospital and/or service provider. Financing of such therapy remains the responsibility of the hospital that has facilitated approval for such use.

For the purpose of this circular, outreach clinics are considered part of their original tertiary unit. However, the responsibility for supply and funding of drug therapy prescribed as a result of outreach clinic consultations is the responsibility of the Area Health Service in which the outreach clinic is located, unless such drug therapy has been specifically identified under the outreach service agreement.

These arrangements do not apply to financing outpatient chemotherapy cycles.

NSW TAG may be contacted at nswtag@stvincents.com.au.

NSW CLINICAL GUIDELINES: TREATMENT OF OPIOID DEPENDENCE (GL2018_019 and abbreviated version GL2018_018)

GL2018_019 rescinds GL2006_019

The Guidelines provide clinical guidance and policy direction for opioid agonist treatment in NSW. They align with national directions and recommendations, and incorporate the latest international clinical evidence.


ACCREDITATION OF COMMUNITY PRESCRIBERS – S100 HIGHLY SPECIALISED DRUGS FOR HIV AND HEPATITIS B (PD2019_005)

PD2019_005 rescinds PD2013_055

PURPOSE

The purpose of this Policy Directive is to detail the NSW Health requirements for the accreditation and authorisation of non-affiliated medical practitioners or nurse practitioners to prescribe Highly Specialised Drugs (HSD) under section 100 (s100) of the Commonwealth National Health Act 1953 for the treatment of Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV). S100 HSD are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the s100 HSD Program also provides for non-affiliated medical practitioners and nurse practitioners to be accredited to prescribe s100 HSD used in the treatment of HBV and HIV. With the introduction of new direct acting antiviral (DAA) treatments for Hepatitis C, it is now out of scope for inclusion as an s100 Highly Specialised Drug requiring accreditation and authorisation of community prescribers. In March 2016 the new DAAs for Hepatitis C were listed on the Pharmaceutical Benefits Scheme. The DAAs are now available on both the General Schedule (S85) and under the HSD Program (S100). Medical practitioners or nurse practitioners experienced in treating Hepatitis C, or in consultation with a specialist experienced in treating Hepatitis C, can now prescribe DAAs under General Schedule (S85) and prescriptions can be dispensed through community pharmacies.
MANDATORY REQUIREMENTS

A non-affiliated medical practitioner or nurse practitioner may only prescribe HSDs for HBV and HIV if they are authorised as a community prescriber as outlined in this policy.

IMPLEMENTATION

1. The Ministry of Health will appoint approved clinical authorities who will:
   1.1 Convene a Clinical Advisory Committee/s with sufficient specialist experience and knowledge to adjudicate applications for community prescribing accreditation in the areas of HBV and/or HIV.
   1.2 Recommend to the Ministry of Health applicants the Clinical Advisory Committee/s have assessed as having suitable grounding and experience for community prescribing with reference to any relevant clinical standards, treatment guidelines, models of care and government directives.
   1.3 Periodically adjudicate community prescribers’ ongoing suitability for community prescribing accreditation, with reference to recent clinical practice, continuing professional development (CPD), and links with appropriate specialists and specialist treatment facilities.
   1.4 Annually, or on request, provide the Ministry of Health with a copy of the register of community prescribers who continue to be suitable for community prescribing accreditation in accordance with item 1.3. The register shall include at least the following fields: Title, First Name, Last Name, Practice Address, Post Code, Phone, Email, Provider Type, Affiliated Specialist and Specialist Treatment Facility.
   1.5 Maintain a register of accredited community prescribers.

2 The Ministry of Health is required to:
   2.1 Provide a mechanism for community prescriber and training programs that reflect relevant clinical standards, treatment guidelines, models of care and government directives.
   2.2 On the basis of recommendations made by an approved clinical authority (per items 1.2 and 1.4 above), authorise community prescribers to prescribe HSD.
   2.3 Notify community prescriber applicants of the outcome of their applications.
   2.4 Oversight execution of a declaration that outlines the terms of the community prescriber program.
   2.5 Annually issue a list of authorised HBV and HIV community prescribers to NSW public hospital pharmacy departments.

3 Local Health Districts are required to:
   3.1 Ensure that all HSD prescribing, dispensing and claiming is done in line with Commonwealth and State requirements for the HSD Program, including establishing appropriate audit processes.
1. BACKGROUND

1.1 About this document

Highly Specialised Drugs (HSD) are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the HSD Program also provides for non-specialist medical practitioners and nurse practitioners to be accredited to prescribe s100 HSDs used in the treatment of HBV and or HIV for dispensing at a public hospital pharmacy department.

1.2 Key definitions

Affiliated medical practitioner: refers to a staff hospital specialist or visiting or consulting specialist of a hospital with HBV or HIV facilities.

Approved clinical authority: refers to a committee or organisation recognised by the Ministry of Health under this policy as having sufficient medical expertise to assess community prescribing accreditation applications.

Community prescriber: refers to a medical practitioner or nurse practitioner accredited and authorised to prescribe HSDs in accordance with this policy.

1.3 Legal and legislative framework

The HSD Program is a joint initiative of the Australian Government and the states and territory governments. The Program operates under section 100 of the National Health Act 1953 (Cth). Section 100 allows for special arrangements to be made for the supply of drugs that, because of their clinical use or other special features, are restricted to supply through public and private hospitals that have appropriate specialist facilities.

A medical practitioner or nurse practitioner, who is not affiliated with an appropriate specialist unit at a public or private hospital, may only prescribe HSDs with the approval of the state or territory.

Patients must be under appropriate medical care. They must also be an eligible person under the Health Insurance Act 1973 (Cth). An eligible person must be:

- an Australian resident;
- a person covered by a Reciprocal Health Care Agreement, or
- an eligible overseas representative.

2. PRESCRIBING

2.1 HSD Prescribing for HBV or HIV Medications

To write HSD prescriptions, a prescriber must be a medical practitioner issued with a PBS prescriber number and meet at least one of the following:

2.1.1. A visiting or consulting hospital medical specialist practitioner affiliated with a recognised specialist treatment facility.

2.1.2. An accredited community prescriber authorised by the Ministry of Health to prescribe HBV medication as outlined in Section 2.2 of this policy.
2.1.3. An accredited community prescriber authorised by the Ministry of Health to prescribe oral HIV medication as outlined in Section 2.3 of this policy.

2.1.4. A hospital medical practitioner or community general practitioner in exceptional situations where it is impractical to obtain a prescription for HBV or HIV medication from the treating specialist and where that specialist medical practitioner has provided written agreement for the prescription to be issued.

2.2 HBV Community Prescribing (Shared Care)
Authorisation to prescribe maintenance drug treatment for HBV may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.2.1 The applicant has:
   a) completed appropriate training and assessment requirements;
   b) demonstrated equivalent prior experience;
   c) current authorisation as a HBV community prescriber by another Australian State or Territory participating in the HSD Program.

2.2.2 The applicant demonstrates preparedness to participate in relevant continuing professional development (CPD).

2.2.3 There is evidence of an agreement to participate in shared care with a treating specialist associated with a recognised hospital viral hepatitis treatment facility. The applicant and his/her patients have full and timely access to the services of a nominated public hospital viral hepatitis treatment facility.

2.3 HIV Community Prescribing
Authorisation to prescribe oral agents for the treatment of HIV other than by specialists may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.3.1 The applicant has:
   a) completed appropriate training and assessment requirements OR
   b) demonstrated equivalent prior experience OR
   c) current authorisation as a HIV community prescriber by another Australian State or Territory participating in the HSD Program.

2.3.2 The applicant demonstrates preparedness to participate in relevant CPD.

2.3.3 The applicant can demonstrate an established link with a specialist in HIV, located within a recognised specialist HIV treatment facility approved by the Ministry of Health.

FURTHER INFORMATION
Further information on training courses, eligibility criteria and application procedures are available from approved clinical authorities. At the time of publication, the approved clinical authority for HBV and HIV community prescribing is:

Australasian Society for HIV, Viral Hepatitis and Sexual Health
Locked Mail Bag 5057
DARLINGHURST NSW 1300
Telephone: (02) 8204 0700
Facsimile: (02) 9212 2382
ashm.org.au

Further information about the HSD Program is available from Medicare Australia at:
medicareaustralia.gov.au/provider/pbs/highly-specialised-drugs/
HIGHLY SPECIALISED DRUGS PROGRAM - GUIDELINES FOR UNDERTAKING CLINICAL TRIALS

The purpose of this circular is to advise hospitals of guidelines recommended by the Highly Specialised Drugs Working Party in determining economical appropriateness of clinical trials on their premises.

The Highly Specialised Drugs Working Party (HSDWP) is a committee of Commonwealth, State and Territory officials established under the Australian Health Ministers’ Advisory Council (AHMAC) to advise on funding aspects of certain highly specialised drugs.

The HSDWP has recently been discussing ways to assist in ensuring the cost effectiveness of major new drugs supplied through public hospitals. The HSDWP appreciates that clinical trials often carried out in public teaching hospitals have short term cost implications for the hospitals and, in the longer term, can influence the use and cost of the drugs after marketing approval.

The PBS system provides a mechanism for negotiating reasonable costs for PBS listed drugs. There is, however, no such mechanism for public hospitals involved in clinical trials to influence the eventual purchase price of innovative drugs that are prescribed by clinicians but are not listed on the PBS.

In view of this, AHMAC has requested that the HSDWP advise State/Territory Health Departments of Working Party recommendations aimed at allowing the purchaser control over the conditions of supply. The HSDWP has developed guidelines covering economic matters for use by public hospitals in considering whether it is appropriate for a clinical trial to be conducted on its premises. Such considerations should commence at the earliest possible stage when sponsors approach specialists to make applications to the hospitals institutional ethics committees to conduct drug trials.

The guidelines recommended by the HSDWP are:

1. Sponsors of products intended for clinical trials should be required to provide a firm indication of the product price following eventual marketing approval. Presently, many sponsors refuse to specify, at the trial stage, the subsequent purchase price or price range for the drug. Sponsors should provide hospitals with information on the potential financial implications of maintaining patients on their products if the clinical trial demonstrates acceptable safety and efficacy and marketing approval is obtained.

2. Sponsors should be expected, when appropriate, to design clinical trials to include gathering of data on the value for money of the drug for the use under investigation.

3. Sponsors should undertake to meet all the reasonable direct and indirect costs to hospitals in conducting clinical trials. Over recent years there has been a tendency for sponsors not to meet all the legitimate costs of conducting drug trials. At times, companies provide only the drug without any other financial assistance for the trial.

4. Sponsors should undertake not to introduce any “administration fees” in the period following a drug trial and leading up to registration for marketing, or be prepared to justify any fee.
Some manufacturers do not, or are slow, in seeking marketing approval and have introduced “administration fees” for the supply of drugs under the Special Access Scheme (SAS) following the conclusion of clinical trials. These are solely determined by the manufacturer and in many cases are equivalent to the intended product price after marketing approval.

It should be noted that the Therapeutic Goods Administration is considering placing a limit on the volume of a product’s use under the Special Access Scheme to prevent the Scheme being used as an alternative to marketing.

5. Sponsors should undertake to pay hospitals for preparing individual case reports for products provided through the Special Access Scheme. Some suppliers require ongoing patient profiles during treatment.

6. Unregistered products used in clinical trials cannot be promoted by the sponsor. Hospital staff should be made aware of the code of conduct of the Australian Pharmaceutical Sponsors Association. By this code, the Industry self-regulates promotion of pharmaceutical products. Any infringement of the code should be reported to:

   Secretary
   Code of Conduct Subcommittee
   Australian Pharmaceutical Manufacturers Association
   Level 2, 77 Berry Street
   NORTH SYDNEY NSW 2060

POLICY ON THE AVAILABILITY OF DOSING PLACES FOR RELEASED INMATES ON SUBSTITUTION PHARMACOTHERAPIES, AND CRITERIA FOR PLACING INMATES OF CORRECTIONAL CENTRES ON SUBSTITUTION PHARMACOTHERAPIES (PD2005_313)

This circular is to advise Area Health Service Chief Executive Officers of the existence of policy covering the availability of dosing places for inmates released from correctional centres on substitution pharmacotherapies, and the existence of criteria for placing inmates of correctional centres on substitution pharmacotherapies.

Policy on the availability of dosing places for released inmates on substitution pharmacotherapies

Right to Access

Released inmates (clients) should have access to public dosing and case management in the Area Health Service within which they are released:

- regardless of where the client started on a pharmacotherapy program (in a correctional centre or in the wider community);
- regardless of whether the client had a public or private point of entry (if the client started on a pharmacotherapy program in the wider community);
- the released client should be maintained in public dosing until clinically stable and assessed as suitable for private sector dosing. The client should be advised of this process;
- where no convenient public dosing points exist, or where it is not in the best interests of the client to be publicly dosed, then the Area Health Service should:
  - take responsibility for identifying and arranging alternative treatment for the client;
  - discuss the client’s requirements with Corrections Health;
- clients released to the community should be continued on the pharmacotherapy they were engaged on. Subject to review, Area Health Services have the responsibility of arranging the provision of that pharmacotherapy where possible.
Prescribing

Initially prescription is usually provided by Corrections Health as public prescribers and therefore the Area Health Service to which the client is released should provide case management.

- Area Health Services should assist clients to find a non-Corrections Health Service prescriber.
- Where a non-Corrections Health Service prescriber has not been found within one month then the Area Health service generally has responsibility for prescribing for that client.
- Every Area Health Service should have the capacity to prescribe (and provide) buprenorphine.

Criteria for placing inmates of correctional centres on substitution pharmacotherapies

There are a number of potential reasons for placing inmates of correctional centres on substitution pharmacotherapies, including the reduction of the risks associated with illicit drug use in jail (specifically injected drugs) and the risk of relapse to drug use on release, with the possibility of death by overdose or return to criminal behaviour as consequences.

However, any decision to engage inmates in substitution pharmacotherapies must consider the community context from which they came and to which they will return. Clinicians considering placing inmates on substitution pharmacotherapies should therefore consider a range of issues, including the community availability of dosing places, as outlined in the criteria below.

Consistent with NSW Methadone Maintenance Treatment guidelines and the NSW Policy for the Use of Buprenorphine, methadone and buprenorphine treatment is indicated in people who meet the diagnostic criteria for opioid dependence.

In a corrections setting, evidence of opioid dependence may be that the inmate went through withdrawal on entry to the correctional centre. Alternatively, the inmate may have a long history of opioid use, with episodes of treatment or other verifiable risk of harms associated with opioid use.

Guidelines also stipulate that the informed consent of the patient to commence substitution pharmacotherapy treatment is required. The inmate must therefore be informed of the nature of the treatment and its consequences.

Once clinical assessment has been performed, verifying that these preconditions are met, the following criteria should then be used to assess the suitability of inmates for pharmacotherapies:

1) Inmates who have been on pharmacotherapies previously are suitable to be put back on pharmacotherapies following a favourable clinical assessment.

2) People without a history of treatment:
   o Are generally assessed post withdrawal;
   o Are put on pharmacotherapies according to priority (HIV+, pregnant or Hepatitis B carrier). These priorities are the same as those that apply in community settings;
   o If they do not fit one of the priorities above then the community situation must be considered as part of the assessment (i.e. the capacity of the likely community based dosing clinic to which the inmate will be released, the availability of buprenorphine dosing places). The clinician should communicate and negotiate with the Area to determine these issues, where possible.

Inmates who are not on pharmacotherapies are at greater risk of relapse/overdose on release. Discharge planning for these inmates on release should be considered at the time of assessment.

Further information may be obtained by contacting Mr Simon Johnston, Drug Programs Bureau by telephone 02 9391 9286 or by e-mail sijoh@doh.health.nsw.gov.au.
HIGH-RISK MEDICINES MANAGEMENT POLICY (PD2015_029)


PURPOSE

This policy sets out the requirements for the safe management and the use of high-risk medicines within NSW Health facilities. It defines the requirements for establishing a high-risk medicine program that includes the development of a specific high-risk medicines register and the strategies to mitigate the risks associated with those medicines.

This policy also includes individual policy standards for the following high-risk medicines: hydromorphone, methotrexate (oral), neuromuscular blocking agents, paracetamol, potassium (intravenous), vincristine and anticoagulants. These standards describe the minimum requirements to reduce specific risks with these medicines.

MANDATORY REQUIREMENTS

- All public health facilities must maintain a high-risk medicines program in accordance with the NSW Health Policy on Medication Handling in NSW Public Health Facilities.
- All public health facilities must maintain as part of the high-risk medicines program, a specific high-risk medicines register. The specific high-risk medicine register must include medicines used locally within the facility identified to be at ‘high-risk’ of misadventure.
- Local protocols must be developed for all identified high-risk medicines specified on the register. The protocols are to be developed in consultation with relevant specialists and overseen and approved by the District or Health Service Drug and Therapeutics Committee(s) (however named). Protocols must include a timeframe for review.
- Each high-risk medicine protocol must include patient monitoring which is relevant and appropriate for the patient’s clinical circumstances. This is to ensure a timely response to adverse events or side effects associated with drug treatment.
- All public health facilities should employ strategies to mitigate the risk of medicines on the mandatory local high-risk medicines registers.
- Adverse incidents involving high-risk medicines must be reported in the facility incident information management system and reviewed through local quality management systems.

248(13/08/15)
IMPLEMENTATION

NSW Clinical Excellence Commission
- Monitors trends of medicine related incidents.
- Monitor implementation of the High-Risk Medicines Management Policy.

Chief Executives
- Assign responsibility, personnel and resources to implement the policy.

Directors of Clinical Governance
- Ensure systems are in place to:
  - Implement the mandatory high-risk medicine policy and standards.
  - Monitor compliance with the high-risk medicine management policy and standards.
- Report implementation of this policy to the NSW Clinical Excellence Commission by returning the Implementation Checklist (Appendix 4.3) within 12 months of publication of the policy.

Drug and Therapeutics Committees
- Maintain a current high-risk medicines register for each location, facility or group of facilities. Develop a strategy for a review of medicines included on the register.
- Ensure medication safety is a key consideration in all formulary decisions and that when a medicine which is considered to be high-risk is added to the formulary, then it is included in the high-risk medicines register.
- Review reports on high-risk medicine incidents, policy compliance rates and formulate corrective action if indicated.
- Refer issues requiring corrective action to the Local Health District Clinical Council and associated Quality Committees.
- Refer medicines with specific identified safety risks through the NSW Therapeutic Advisory Group to the Medication Safety Expert Advisory Committee for consideration of approval to be included as a Policy Standard in the High-Risk Medicines Management Policy.

Heads of Department
- Assign responsibility for implementation of the high-risk medicine policy and standards.
- Ensure products and devices that support high-risk medicines safety strategies are available.
- Ensure service and models exist to facilitate compliance with safe practices in managing high-risk medicines.
- Support high-risk medicines monitoring activities.

Clinical staff involved in medication management
- Comply with this policy and the policy standards for high-risk medicines.
- Follow the local high-risk medicine protocols.
- When prescribing and supplying high-risk medicines, give clear advice to ensure safe administration.
- Maintain knowledge base relevant to area of practice.

1. INTRODUCTION

This policy sets out the requirements for the high-risk medicines register and standard management of the specified high-risk medicines. It addresses risks associated with prescribing, dispensing and administration of high-risk medicines.
This Policy supports requirements for Standard 4 (Medication Safety) of the National Safety and Quality Health Service Standards. Although most medicines have a wide margin of safety, a few drugs have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these high-risk medicines may not be more common than those from other groups but their consequences can be significant.

1.1 Related Documents

This Policy is to be read in conjunction with the following NSW Health Policies:

- Incident Management Policy
- Medication Handling in NSW Public Health Facilities
- Safe Administration of Liquid Medicines by Routes other than Injection
- Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services
- Prevention of Venous Thromboembolism
- User applied Labelling of Injectable Medicines, Fluids and Lines

1.2 Key Definitions

<table>
<thead>
<tr>
<th>Must</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should</td>
<td>Indicates a recommended action that should be followed unless there are sound reasons for taking a different course of action.</td>
</tr>
<tr>
<td>Activated partial thromboplastin time (aPTT)</td>
<td>An indicator for measuring the efficiency of both the intrinsic (now referred to as the contact activation pathway) and the common coagulation pathway. It is used in conjunction with prothrombin time which measures the extrinsic pathway.</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Any agent used to prevent the formation of blood clots including oral agents, such as warfarin or a non-vitamin K oral antagonist anticoagulant (NOAC), and other medications which are injected into the vein or under the skin such as heparin.</td>
</tr>
<tr>
<td>Bridging anticoagulant therapy</td>
<td>The administration of a short-acting anticoagulant, including subcutaneous low-molecular-weight heparin or intravenous unfractionated heparin, during interruption of oral anticoagulant therapy.</td>
</tr>
<tr>
<td>Dose error reduction software</td>
<td>Infusion device software that is capable of alerting the user to unsafe dose limits and programming error if standard concentrations and dose limits have been programmed into the pumps library.</td>
</tr>
<tr>
<td>Hepatotoxicity</td>
<td>The capacity of a drug, chemical, or other exposure to produce injury to the liver.</td>
</tr>
<tr>
<td>Hypokalaemia</td>
<td>Lower than normal blood concentration of potassium.</td>
</tr>
<tr>
<td>High-Risk Medicine</td>
<td>High-Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant.</td>
</tr>
<tr>
<td>International Normalised Ratio (INR)</td>
<td>The INR is the ratio of the prothrombin time to a normal (control) sample. It is used to monitor the effects of warfarin.</td>
</tr>
<tr>
<td>Minibag</td>
<td>A small volume intravenous infusion bag, usually containing 50 or 100 mL of sterile fluid.</td>
</tr>
</tbody>
</table>
The standard inpatient medication charts (adult and paediatric) used in NSW public hospitals to promote standardisation and consistency in documentation of the prescription and administration of medications.

A minimum standard of systematic appraisal of all aspects of patients’ medication management conducted or supervised by a qualified and suitably trained health professional (ideally a pharmacist) acting as part of a multidisciplinary team. It includes objective review of medication prescribing, dispensing, distribution, administration, monitoring of outcomes and documentation of medication related information in order to optimise Quality Use of Medicines.

Intravenous solutions prepared in a regulated compounding facility with full labelling and expiry dating.

The second person checking the preparation and administration of a medication is responsible for:
- Confirming the identity of the patient.
- Confirming the selection of the correct medication and fluid.
- Confirming that the dose is appropriate and the calculations are correct.
- Confirming that a rate limiting device such as an infusion pump has been correctly set.
- Countersigning the administration on the medication chart against that of the administering person.

(Refer to NSW Health Policy on Medication Handling in NSW Public Health Facilities for further information on requirements for second person checks).

A second person check for high-risk medicines must be conducted using independent double check principles. That is, clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the medicine before administering it to the patient.

Use of a combination of lower and upper case letters to highlight the differences between look-alike drug names, helping to make them more easily distinguishable.

Refers to the individualisation of dosage by maintaining plasma or blood drug concentrations within a target range (therapeutic range or window).

The suspension of activity immediately before commencing a procedure by the team or single operator involved in the procedure to undertake a final verification of the correct patient, procedure, site, drug and route of administration. For the purposes of administering cytotoxic chemotherapy, all doses should be checked by a second person with the appropriate training and skills.

2. **STANDARDS**

All public health facilities must have a high-risk medicines management program in place, which includes systems for the management of the respective medications’ handling in accordance with NSW Health Policy on Medication Handling in NSW Public Health Facilities.

The high-risk medicines program must include the following minimum elements.

2.1 **A High-Risk Medicines Register**

A High-Risk Medicines Register consists of a list of drugs or drug groups used within the health facility considered to be at ‘high-risk’ of misadventure. The register must be maintained at each facility or group of facilities. The “A PINCH” table (in Appendix 4.1) lists some essential medicine groups or medicines to be considered for inclusion in the high-risk medicines register. The “A PINCH” table is not an exhaustive list, there may be other medicines used within the facility that are considered to be high-risk.
The District or Health Service Drug and Therapeutics Committee (however named) is responsible for:
- Assessing and determining the medicines to be included in the register.
- Maintaining the register and associated protocols.

Before a new medicine is placed on the local health facility formulary by the District or Health Service Drug and Therapeutics Committee, the potential for error with that medication should be investigated in the literature. If the assessment identifies that there is a high risk of death or serious harm to the patient if the medicine is inadvertently selected, misused, prescribed or administered incorrectly, the medicine must be included in the High-Risk Medicine Register with an appropriate protocol developed.

Protocols are to be prepared in consultation with relevant specialists, aligned with NSW Health Policy on Medication Handling in NSW Public Health Facilities, and approved by the District or Health Service Drug and Therapeutics Committees.

Protocols are to clearly articulate:
- Responsibilities for the prescribing and administration of high-risk medicines.
- Additional considerations for high-risk patient groups such as paediatric, pregnant and elderly patients.
- Additional considerations for patients with conditions that may affect drug excretion or metabolism such as renal or hepatic impairment.
- Additional patient monitoring, for example, clinical observations, required to ensure a timely response to adverse events or side-effects associated with the treatment.
- Therapeutic drug monitoring requirements, including laboratory tests and dose amendment.
- Whether doses should be rounded off to the nearest whole number or dosage unit when appropriate and possible.
- Any specific training, qualifications, skills or competencies required to prescribe or administer the medicine.
- Specific storage requirements to minimise selection error.
- Patient and/or carer information or education requirements.

Processes must be in place to notify relevant clinical staff of changes to the register and the associated protocols.

2.2 Standards for prescribing and administering high-risk medicines

The following standards for prescribing and administering high-risk medicines apply:
- Accurate patient weight should be documented on the medication chart for all patients.
- The route of administration must be clearly identified. The use of multiple routes of administration in the one prescription should be avoided for the same medicine (for example, intravenous/oral).
- Where required, strengths of medicines must be clearly visible in terms of the dosage unit or dose per volume of liquid, for example, mg per mL.
- The prescriber should complete the ‘Indication’ for use box on the National Inpatient Medication Chart (NIMC) for high-risk medicines.
- Where Electronic Medication Management systems are in use, the indication for use should be documented according to local Electronic Medication Management guidelines.
- Dose adjustments must be considered when prescribing for patient groups such as overweight, obese or underweight patients, and patients with existing clinical conditions (such as renal or hepatic impairment) that may affect drug metabolism and excretion.
• Therapeutic guidelines should be followed where dosing is complex and duration of therapy substantially increases the risk of toxicity, for example aminoglycosides.
• Where a second person check or witness is required according to NSW Health Policy on Medication Handling in NSW Public Health Facilities, this policy, or local protocol, the check should be conducted using independent double check principles. That is, clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the medicine before administering it to the patient\(^1\). For domiciliary care and patient transfers refer to NSW Health Policy on Medication Handling in NSW Public Health Facilities.
• Medication reconciliation processes should be prioritised for these patients.

2.3 Strategies to minimise risk with high-risk medicines

The District or Health Service Drug and Therapeutics Committee must develop strategies related to high-risk medicine handling.

At a minimum, strategies related to high-risk medicines handling must include:
• Access to pre-measured medicine doses in a form that requires minimal manipulation prior to administration.
• Access to standardised concentrations of medicines in solution.
• Mechanisms to ensure mechanical infusion devices default to the safest setting.
• Alerting clinicians in clinical handover to the use of any high-risk medicines.
• Use of shelf reminders, checklists and alerts and, where possible, these should be built into information technology systems.
• Specific storage or practice requirements (see Appendix 4.2).
• A regular review of local and wider system incidents and near-misses and the use of prospective analysis and re-design of systems to prevent reoccurrence of the same errors.

2.4 References


3. INDIVIDUAL HIGH-RISK MEDICINE MANAGEMENT STANDARDS

The following policy standards outline the minimum actions required to mitigate identified risks for particular medicines or groups of medicines. They do not contain clinical guidance on therapeutic use. These standards do not preclude the District or Health Service Drug and Therapeutics Committees from including additional actions to mitigate risk or inclusion of clinical guidance on therapeutic use in locally developed protocols.

3.4 Anticoagulants

Anticoagulant medicines are used extensively in clinical practice. They act through targeting a number of different proteins that may limit or prevent thrombus formation. Anticoagulant medicines have a narrow therapeutic index and over or under anticoagulation can result in significant adverse patient outcomes\(^1\).
Errors involving anticoagulant medicines can include:

- Duplication of therapy. For example, ordering pharmacological venous thromboembolism (VTE) prophylaxis for patients who are receiving therapeutic anticoagulation.
- Use of a therapeutic dose when a prophylactic dose was intended and vice versa.
- Failure to adjust an anticoagulant dose according to patient factors. For example, haematology parameters, biochemistry, estimated creatinine clearance, age.
- Incorrect protocol use. For example, administration of a concentration of unfractionated heparin solution contrary to the protocol resulting in administration of an incorrect dose.
- Incorrect use following discharge. For example, inadequate patient and/or carer education for patients being discharged on anticoagulants resulting in adverse events. This standard outlines the minimum actions required to mitigate risks associated with anticoagulant use. This standard does not contain clinical guidance on anticoagulant medicine use.

3.1.1 Standards

**Risk mitigation strategy**

District or Health Service Drug and Therapeutics Committee protocols must include the following anticoagulants where they are in use: unfractionated heparin, warfarin, low molecular weight heparin and non-vitamin K antagonist oral anticoagulants (NOAC).

District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following information:

- The requirement for recording accurate patient weight (where practical) for all patients receiving anticoagulant therapy.
- Instructions for estimating renal function.
- Evidence-based dosing guidelines and guidance for prescribing (see Prescribing).
- Managing anticoagulation in patients:
  - With absolute or relative contraindications to anticoagulation.
  - With previous coagulation problems, for example; bleeding, heparin induced thrombocytopenia (HIT).
  - With bleeding risk, for example, planned surgery, platelet dysfunction.
  - Who are pregnant or breastfeeding.
- Monitoring for and the management of HIT.
- Monitoring for thrombocytopenia or for any new or extending thrombosis in patients receiving or recently discontinued from heparin.
- Management of bleeding in patients receiving anticoagulant medicines including referral processes.
- Instructions for switching to and from other anticoagulant medicines.
- Instructions (or reference to the local peri-operative guidelines) for managing anticoagulants during the perioperative period including:
  - Medical circumstances where bridging anticoagulation therapy is indicated.
  - Timing of stopping and restarting of anticoagulant medicines where required.
  - Perioperative management of patients receiving antiplatelet therapy.
  - Timing of neuraxial anaesthesia and regional block placement, as well as the removal of neuraxial and nerve catheters in patients receiving anticoagulant therapy.
  - The need for specific consideration of individual patient and procedural risk of bleeding.
- Any specific training, qualifications, skills or competencies required to prescribe or administer anticoagulants.
- Requirements for patient and/or carer education (see Patient information/education).
Additional protocol requirements for specific anticoagulants

Intravenous unfractionated heparin

Where possible intravenous unfractionated heparin protocols should be standardised within facilities and Local Health Districts. Where it is not possible to standardise, protocols must address how risks associated with patient transfer between and within facilities will be mitigated.

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Indications for intravenous unfractionated heparin.
- Clinical areas where intravenous unfractionated heparin may be used.
- Instructions for unfractionated heparin dose calculation, including advice on preferred use of actual body weight, ideal body weight or medically approved adjusted body weight in dose calculations.
- Recommended loading doses to be used for each indication.
- Explicit doses and corresponding infusion rates for each indication.
- Requirements for monitoring coagulation status.
- Therapeutic range for activated partial thromboplastin time (aPTT) (in consultation with local laboratory).
- Dose adjustments based on aPTT results.
- Procedures for reversal of anticoagulation.

Warfarin

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following information.

- Guidelines for dosing, taking into account:
  - Bleeding risk factors.
  - Patient age.
  - International Normalised Ratio (INR) results.
  - Presence of medical problems. For example, heart failure, liver disease, severe infection, recent major surgery, reduced oral intake, nutritional status and concomitant interacting medication.
- The timing of blood collection for INR testing.
- The management of a high INR result in patients receiving warfarin whether or not they are bleeding and instructions for warfarin reversal.

Prescribing

- The prescriber must determine if a female of child bearing age is pregnant or breastfeeding. If there is any doubt, a pregnancy test should be ordered.
- The indication for anticoagulation and therapeutic targets where appropriate, must be documented in the health care record. Details should include the anticoagulant name, dose, intended duration of therapy, timeframe for review and whether anticoagulation is newly initiated or a continuation of previous therapy.
- When assessing VTE risk, the prescriber must ascertain if the patient is already receiving any other anticoagulant medicines.
- Where Electronic Medication Management systems are in use, anticoagulant prescribing should be according to local protocol.

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Where National Inpatient Medication Charts (NIMC) are in use, any dedicated sections for warfarin, VTE Prophylaxis and Regular Medicines must be used for anticoagulant medicine prescribing according to the Australian Commission on Safety and Quality in Health Care NIMC User Guide.

In adult patients creatinine clearance should be estimated using the Cockcroft-Gault formula prior to initiating renally excreted anticoagulants.

**Storage and supply**
- Where unfractionated heparin solutions are required, commercially prepared pre-mixed solutions must be used wherever possible.
- Where ampoules of concentrated unfractionated heparin injection are available as imprest stock, a single strength should be available.

**Administration**
- A second person check is required for administration of warfarin and parenteral anticoagulants.

**Patient monitoring**
- Instructions for monitoring patients for bleeding must be recorded in the patient health care record. For example, laboratory tests, clinical observation requirements and actions to be taken.
- Patients on anticoagulants who fall are at an increased risk of bleeding and serious trauma including brain injury and will require close observation and monitoring according to local post-fall guide.

**Pharmaceutical review**
- Where possible all patients receiving an anticoagulant medicine should have a pharmaceutical review.

**Patient information/education**
- Patients and/or their carer who are discharged home on anticoagulant therapy should be provided with verbal and written information on their medication.
- Information and education should address:
  - Name and dose of anticoagulant.
  - Intended duration of therapy and timeframe for specialist review.
  - How to identify bleeding, who to contact and action to be taken.
  - What to do in the case of a missed dose.
  - Instruction for any laboratory testing and review.
  - Any medication or food interactions and other lifestyle factors that influence therapy.
  - Any specific storage and administration instructions.
- Patients and/or their carer must be given the opportunity to discuss anticoagulant therapy with a health practitioner.
- Patients on warfarin should be provided with either a warfarin booklet for tracking warfarin therapy and results, or an update to an existing warfarin book to record INR results during the hospital stay.
- Provision of anticoagulant education should be documented in the health care record and/or in the designated section on the NIMC.
- Professional Health Care Interpreters should be utilised for patient education for patients and/or carers who are not fluent in English or who are Deaf.
3.1.2 References

1. Therapeutic Guidelines LTD. *eTG Complete* 2014.

3.2 Hydromorphone

Hydromorphone is a potent opioid frequently used to treat moderate to severe, acute or chronic pain. Hydromorphone is 5 to 7 times more potent than morphine\(^1\). Because of its high potency, errors with this medicine may result in serious adverse patient outcomes.

Incidents involving confusion between morphine and hydromorphone have occurred, including fatal incidents involving inadvertent administration of hydromorphone instead of morphine. Hydromorphone is available in a variety of strengths and formulations (short acting and long acting). Dose calculation errors using the high-concentration injectable hydromorphone can result in an overdose.

This standard outlines the minimum actions required to prevent prescription and administration errors. This standard does not contain clinical guidance on therapeutic use of hydromorphone.

3.2.1 Standards

**Risk management strategy**

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of the following:

- Starting doses of hydromorphone for opioid naïve patients and those with risk factors such as asthma, obstructive sleep apnoea or those receiving other medications that can potentiate the effects of hydromorphone\(^1\).
- A schedule for frequency and type of clinical observations for all patients receiving hydromorphone, with:
  - A mechanism for immediate escalation of care if respiratory depression is evident.
  - The frequency of clinical observations required for patients newly prescribed hydromorphone, or for when a hydromorphone dose has been increased.
- Advice regarding the opioid conversion tool to be used for converting opioid doses to or from hydromorphone.

**Prescribing**

- For patients admitted to a facility who are already receiving hydromorphone, the dose of hydromorphone should be confirmed where possible with a reliable source such as the patient’s community pharmacist, general practitioner or medical specialist prior to prescribing.
- To reduce the risk of hydromorphone being confused with morphine, prescribers should also include in the order the trade name of the hydromorphone preparation, for example: hydromorphone Dilaudid.
- Opioid conversion tools should be consulted when converting opioid doses to or from hydromorphone.

**Storage and supply**

- Where possible, hydromorphone should be stored in a separate Schedule 8 medication storage unit from morphine. In clinical areas where there is only one Schedule 8 medication storage unit, hydromorphone must be separated from morphine by storing these medicines on different shelves and by placing all hydromorphone medicines in a distinctive coloured bag or container.
• Where possible, an additional sticker using Tall Man Lettering stating ‘HYDROMorphone’ should be applied to all inpatient hydromorphone packets and bottles. The sticker must not obscure original packet or bottle labelling.

• The following precautions should be taken in supplying hydromorphone to clinical areas:
  o Hydromorphone should not be stored in clinical areas where use is infrequent. In these circumstances, the required product should be individually issued per patient, and returned to pharmacy at the end of the patient care episode.
  o High-concentration formulations of injectable hydromorphone (10 mg per mL) should not routinely be stored in clinical areas outside of palliative care units. In circumstances when high-concentrations are required, the product should be individually dispensed per patient, and removed at the end of the patient care episode.

• Naloxone injection must be available for reversal in clinical units wherever hydromorphone is used.

Administrations
• In addition to witnessing requirements, a second person check must be employed when administering hydromorphone.

Pharmaceutical review
• Where possible, a pharmaceutical review should be completed for patients receiving hydromorphone prior to administration of the first inpatient dose with specific attention on the appropriateness of the agent for the indication, the dose prescribed in view of the patient’s comorbidities and other medicines prescribed, particularly other opioids.

Patient information/education
• Patients and/or their carer should be provided with relevant education and written information regarding hydromorphone with particular attention to adverse-effects and how they should be managed.
• Professional Health Care Interpreters should be utilised for patient education for patients and/or carers who are not fluent in English or who are Deaf.
• For inpatients prescribed hydromorphone, the patient’s family and/or carer should be advised to alert the patient’s nurse if they have concerns regarding a change in the patients’ condition including an unexpected decrease in their level of consciousness or other adverse-effects associated with hydromorphone.

Staff education
• Local protocols must address any specific training, qualifications, skills or competencies required to prescribe or administer hydromorphone.
• All medical officers, pharmacists, nurses (and midwives where relevant) should receive education on hydromorphone safety.

3.2.2 References


3.3 Methotrexate (Oral)

Oral methotrexate is used in the treatment of autoimmune or inflammatory disorders such as rheumatoid arthritis and severe psoriasis\(^1\). Methotrexate is also used in the treatment of malignancies as part of specialised protocols.
Oral methotrexate is usually taken as a **single dose once a week** (however, occasionally, in order to improve tolerance in some people, the total weekly dose is taken in divided doses at 12 hourly intervals up to a maximum of 3 doses per week).

The once a week dosage regimen is unusual compared to other medicines and has led to errors occurring with the use of oral methotrexate since clinicians and patients are much more familiar with daily dosing of medicines.

Catastrophic adverse events associated with methotrexate toxicity can occur following daily administration of oral methotrexate when weekly administration was indicated or intended.

This standard outlines the minimum requirements for the safe prescribing, storage and handling, and administration of oral methotrexate. This standard does not contain clinical guidance on therapeutic use of methotrexate (oral).

### 3.3.1 Standards

**Risk management strategy**

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Recommended patient monitoring standards.
- Education of staff regarding risks associated with the use of oral methotrexate.
- Patient involvement in the checking processes prior to prescribing and administering.

**Prescribing**

- The medication history taken on admission must include when the last dose of methotrexate was taken. Prescribers must refer to the medication history when prescribing methotrexate.
- Methotrexate must be written in full. Abbreviations such as MTX must not be used.
- When a weekly dose is prescribed, the prescriber must clearly specify on the medication chart or prescription that:
  - Methotrexate is to be given once a week, written in full and not abbreviated.
  - The day on which the drug is to be administered.

**Example:** Methotrexate 5 mg orally once a week on TUESDAY

- Patients admitted on oral methotrexate, should continue to have their methotrexate prescribed on the day that they normally take their dose unless there is rationale for changing. On discharge, the patient and/or their carer must be informed when their next dose of methotrexate is due.
- The prescriber must cross out the days on the medication chart when methotrexate is not to be administered.
- Where Electronic Medication Management Systems are in use, mechanisms should be built in to prevent inadvertent daily administration of methotrexate.
- As methotrexate can be prescribed at more frequent dosage intervals for some indications in haematology and oncology, the prescriber must include the indication for treatment in all orders or prescriptions for oral methotrexate. This should alert pharmacists and nurses to any potential prescribing errors where once a week dosing was intended.
Storage and supply
- As methotrexate tablets are available in two strengths (2.5 mg and 10 mg), Pharmacy Departments must take special precautions to minimise dispensing errors. Such precautions may include use of warning signs on shelves and separation of stock.
- Methotrexate tablets must not be available in wards as imprest stock or in the ‘After Hours’ Supply.
- In hospitals where after-hours medications are obtained through access to the Pharmacy Department directly, methotrexate tablets should be stored in a location in the Pharmacy Department that prevents after-hours access.
- All methotrexate orders must be reviewed by a pharmacist. Prior to supply being made, the pharmacist must confirm the dosage schedule is appropriate and clearly written.
  - For patients admitted at times when the pharmacy department is closed strategies must be in place to ensure pharmacist review of methotrexate orders occurs. For example, deferring administration of methotrexate until a pharmacist has reviewed the medication order.
  - For small rural hospitals where there are limited or no pharmacy services on site strategies must be put in place to ensure pharmacist review. These might include faxing the medication chart to the nearest Base Hospital or Procedural Hospital Pharmacy Department for review of the order during opening hours and using courier services to deliver methotrexate when required.
- Methotrexate must be dispensed for individual patients from a medication chart order or prescription. The label must state the dose and day of the week it is due and include a cytotoxic warning.
- Pharmacy Departments should supply only the amount required for the weekly dose, preferably on the day it is due.
- To reduce the risk of accidental daily dosing the patient’s own supply should not be used.

Administration
- Nurses administering methotrexate must have an understanding of methotrexate, its uses, normal dosing schedule and adverse effects to safely administer methotrexate to inpatients.
- Nurses should confirm with the patient and/or their carer the day of the week on which the patient’s dose is due, the normal dose and when it was last taken prior to administering a dose of methotrexate.
- Methotrexate must not be administered from an order that does not meet the criteria for a methotrexate order described in Prescribing.
- Where a medication order is unclear, or the nurse has reason to query the dose, he or she must contact the prescriber or a pharmacist for clarification prior to administration.

Pharmaceutical review
- A pharmaceutical review should be completed for patients receiving methotrexate.

Patient monitoring
- Clinical staff must be able to recognise patients with potential symptoms that may be signs of methotrexate toxicity or intolerance.

Patient information/education
- All patients receiving methotrexate, and/or their carer, should be provided with information and education by the prescriber and/or pharmacist and provided with a copy of the Consumer Medicine Information leaflet for methotrexate.
Information and education should include:

- Emphasis on the once a week dosage by naming the day of the week (when a weekly dose is prescribed). It should be stressed that additional doses of the medicine must not be taken ‘as needed’ for symptom control.
- Actions to be taken if a dose is missed.
- Information on the importance of regular monitoring tests, symptoms of toxicity and the need for early intervention if such symptoms appear.
- Emphasis on the similar appearance of methotrexate and folic acid tablets (if the patient is also on this supplement) and the difference in dosage of the two medicines.
- Emphasis on confirming with the administering nurse the day of the week on which their dose is due, their normal dose and when it was last taken prior to taking a dose of methotrexate.

Nursing staff should also be equipped to provide information and education on methotrexate to patients.

Patients and/or their carer should also be provided individual written information on their dosage regimen that specifies the patient’s dose and day of the week for taking the medicine.

Professional Health Care Interpreters should be utilised for patient education for patients and/or carers who are not fluent in English or who are Deaf.

Other considerations

- In addition to the above specific precautions for the use of oral methotrexate, staff should remain aware, when handling this drug, of the work health and safety procedures that apply to the handling of any cytotoxic drug and related waste.

3.3.2 References


3.4 Neuromuscular Blocking Agents

Neuromuscular blocking drugs produce skeletal (including respiratory) muscle relaxation, and are used to facilitate endotracheal intubation and control of the airway, to allow mechanical ventilation and to prevent reflex muscle contraction.

Neuromuscular blocking agents are considered high-risk medicines because inadvertent use in patients without the availability of medical staff skilled in airway support can lead to respiratory arrest, permanent harm, or death.

Serious incidents have occurred involving inadvertent administration of a neuromuscular blocking agent to a patient instead of a sedative.

Identified contributing factors to incidents involving neuromuscular blocking agents include:

- Look-alike packaging and labelling.
- Sound-alike medicine names.
- Drug administration after extubation.
- Use of pre-prepared unlabelled syringes.
- Unsafe storage, particularly small quantities in refrigerators.
- Use in clinical areas where clinical staff may be unfamiliar with the drugs and their action.
This standard outlines the minimum requirements for the safe handling of neuromuscular blocking agents. This standard does not contain guidance on therapeutic use of neuromuscular blocking agents.

3.4.1 Standards

**Risk management strategy**
The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:
- Any specific training, qualifications, skills or competencies required to prescribe or administer neuromuscular blocking agents.
- Specific neuromuscular blocking agent storage requirements.
- Any additional equipment required, for example, use of ‘red plunger’ syringes.
- Statement that ventilator support is present during and after administration and whilst these medicines have an effect.
- Minimum requirements for patient responsiveness prior to extubation.

**Storage and supply**
Supply of these agents must be limited to only those critical care areas where there is a clinical use and patients are ventilated and monitored.

Neuromuscular blocking reversal agents must be available in clinical areas where these agents are used and stored.

In clinical areas where a small number of doses are kept refrigerated to support cardiopulmonary resuscitation, specially identified secure storage must be used.

Warning labels should be applied to stored medication including intubation packs to identify them as containing neuromuscular blocking agents.

**Administration**
Once prepared, labelling must comply with the appropriate standards for anaesthesia or User-applied Labelling of Injectable Medicines, Fluids and Lines Policy.

A second person check should be used prior to administration of neuromuscular blocking agents (refer to recognised practice guidelines, for example, Australian and New Zealand College of Anaesthetists Guidelines3).

3.4.2 References

3.5 Paracetamol

Paracetamol is an effective analgesic and antipyretic and is well tolerated. In children and adults paracetamol is indicated as first line therapy for mild to moderate pain and symptoms of fever4. Paracetamol may be considered a high-risk medicine for certain population groups at risk of hepatotoxicity.

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Adverse events associated with paracetamol toxicity have been associated with:

- Concomitant administration of intravenous paracetamol and oral paracetamol.
- Accidental overdose through ongoing administration of regular and PRN paracetamol.

This standard outlines the minimum requirements for the safe handling of paracetamol. This standard does not contain guidance on therapeutic use of paracetamol.

### 3.5.1 Standards

**Risk management strategy**

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Any specific training, qualifications, skills or competencies required to prescribe or administer paracetamol.
- Any restrictions to limit use of intravenous paracetamol, for example, only to be used where patients are nil by mouth, or only to be prescribed by clinicians in anaesthesia, intensive care and pain management.

**Prescribing**

- Dose adjustments must be considered when prescribing for underweight patients, patients with existing clinical conditions (such as renal or hepatic impairment) and any other factors that may affect drug metabolism and excretion.
- Paracetamol (and/or paracetamol combination products) should be ordered in only one section of the medication chart. Ordering in both the regular and as required ‘PRN’ sections of the chart may potentially lead to overdose.
- Orders must be expressed in milligrams (mg) or grams (g) per dose.
- Orders should only specify a single route, that is; oral or rectal or intravenous.
- The maximum duration of therapy should be included on all intravenous orders.
- Orders for intravenous paracetamol should be reviewed every 24 hours.
- Orders should be written using the active ingredient drug name. However where a brand name is used on the order the active ingredient term ‘paracetamol’ or ‘contains paracetamol’ should be documented adjacent to the brand name.

**Prescribing and administration**

- When prescribing or administering paracetamol (including nurse/midwife - initiated paracetamol), clinicians must ascertain if paracetamol has been recently ingested, check that no other formulations of paracetamol are concurrently being prescribed or administered, and that the administration of the dose will not exceed the safe maximum daily dose of paracetamol (from all sources including combination paracetamol/codeine combinations).
- In circumstances where dose is calculated based on patient weight, for example, paediatric patients, the dose must not exceed the maximum recommended paracetamol dose.
- A second person check is required for administration of intravenous paracetamol and all doses administered to paediatric patients.

**Patient information/education**

- Patients and/or their parents or carers being discharged on paracetamol should be provided with specific information and education regarding paracetamol administration. They should also be counselled that many over-the-counter products recommended for cold, cough, headache etc. may also contain paracetamol and should not be taken concurrently.
- Professional Health Care Interpreters should be utilised for patient education for patients and/or carers who are not fluent in English or who are Deaf.
3.5.2 References


3.6 Potassium (Intravenous)

Potassium salts are administered intravenously to address hypokalaemia in patients who cannot receive the electrolyte orally or when rapid replacement is required. Potassium chloride is the most commonly used salt, with phosphate and acetate less often used.

Incidents involving administration of intravenous potassium can result in fatal patient outcomes. Adverse incidents related to intravenous potassium use can include:

- Too rapid intravenous infusion of a potassium chloride infusion related to failure to use a rate limiting device such as an infusion pump, or incorrectly programing an infusion pump.
- Administration of a bolus of concentrated potassium chloride (for example, potassium chloride 10 mmol in 10 mL) as a result of a selection error. For example, mistakenly selecting a potassium chloride ampoule instead of a sodium chloride 0.9% ampoule when preparing an intravenous flush.
- Failure to adequately mix a potassium chloride concentrate that has been added to an infusion prior to administration can result in the patient receiving a bolus of concentrated potassium chloride solution.

This standard outlines the minimum actions required to mitigate risks associated with intravenous potassium. This standard does not contain clinical guidance on therapeutic use of potassium (intravenous).

3.6.1 Standards

Risk mitigation strategy

The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- Any specific training, qualifications, skills or competencies required to prescribe or administer intravenous potassium salts.
- Instructions for preparation and administration practices for intravenous potassium chloride and other concentrated potassium salts.
- Recommended infusion rate, infusion pump requirements and associated clinical monitoring. The maximum recommended rate in adults of intravenous potassium administration is 10 mmol per hour.
- Recommendations regarding concentrations of administration and solutions for use in children (where applicable). Facilities should refer to NSW Health Guideline on Standards for Paediatric Intravenous Fluids.
- Supply and handling of concentrated potassium salts injections, including a list of clinical areas permitted to stock potassium chloride ampoules.
- Availability and storage of pre-mixed potassium chloride intravenous solutions, including a list of clinical areas permitted to stock potassium chloride 40 mmol per 100 mL minibags.
- Those clinical areas which are deemed appropriate for providing the patient care (including cardiac monitoring) required for administration of intravenous potassium at rates greater than 10mmol per hour.
Prescribing

- Oral potassium chloride should be the first choice for treatment of hypokalaemia if this route of administration is available.
- Consideration must be given to each patient’s potassium intake from all sources, for example, enteral and parenteral nutrition, oral intake and supplementary fluids.
- Orders for intravenous potassium salts must be expressed in millimoles (mmol) not milligram per litre (mg/L) or percent (%).
- Where clinically feasible, prescribers must limit orders for intravenous potassium chloride to the commercially prepared pre-mixed solutions available at their facility.
- The name of the potassium salt should be used for intravenous potassium orders. For example, potassium chloride.
- Chemical abbreviations must not be used for intravenous potassium orders.
- Orders for intravenous potassium salts must have the rate, route, dilution and administration instructions fully specified on the intravenous infusion medication chart. Orders without instructions for dilution and infusion rate are not complete and must not be accepted for either dispensing or administration.
- The infusion rate or time period must be included. Orders must not contain directions to give intravenous potassium as a ‘bolus’ or ‘stat’ dose.

Storage and supply

Pre-mix solutions

- Pre-mixed potassium chloride infusion solutions must be clearly differentiated from other intravenous fluids, for example, through use of colour coded over-pouches and labelling.
- The concentration for pre-mix solutions must be expressed in millimoles (mmol) per final volume.
- Pre-mixed, small volume intravenous solutions (minibags) containing potassium solutions must not have an additive port or, if intravenous potassium solutions are prepared in-house, the additive port must be capped.
- Where non-commercially available concentrations are required, a pharmacy-based compounding service should be used where available (see NSW Health Policy on Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services).
- In circumstances when a pre-mixed potassium chloride solution cannot be used and a pharmacy-based compounding service is not available, intravenous potassium solutions are to be prepared in the clinical area by staff using aseptic technique. Where this is routinely undertaken, District or Health Service Drug and Therapeutics Committee endorsed protocols must address the risks of supply and handling of concentrated potassium ampoules.
- Pre-mixed potassium chloride intravenous infusion solutions must be clearly labelled and separated from other, same size, commercial intravenous solutions (for example, sodium chloride 0.9% solution).
- Storage locations for pre-mixed solutions must be clearly identified throughout each facility.

Ampoules

- Potassium chloride ampoules should not be available as ward stock unless included in the District or Health Service Drug and Therapeutics Committee approved list of authorised clinical areas. Ampoules of other concentrated potassium salts (for example, potassium dihydrogen phosphate) should not be available as ward stock and only be available through pharmacy departments.
- Potassium chloride ampoules must not be placed on resuscitation trolleys due to the risk of inadvertent bolus administration.
- If required, potassium ampoules of strength greater than 1 mmol per mL, must only be kept in the pharmacy, clearly segregated from other strengths.
Critical care areas or operating suites

- In critical care areas or operating suites, where higher concentrations and doses of potassium are considered necessary:
  - A risk assessment should be performed to determine whether it is appropriate to keep ampoules as a stock item and if so, a District or Health Service Drug and Therapeutics Committee approved protocol for safe preparation and use must be in place.
  - The range of concentrated potassium injection/infusion salts available should be limited and should not exceed 1 mmol per mL.
  - Ampoules must be physically separated from ampoules of similar appearance and packaging, for example, in a separately identified and coloured box, and retained in original packaging until immediately prior to use.
  - Commercially prepared, pre-mixed, concentrated, small-volume solution (for example, 40 mmol per 100 mL minibag) should be available.

Administration

- When a patient is ordered an intravenous potassium solution, commercially prepared pre-mixed intravenous potassium chloride solutions must be used wherever possible.
- If a potassium salt is added to an intravenous solution, the solution must be fully mixed by inverting and agitating the solution immediately prior to administration. Concentrated solutions of potassium must never be added to an intravenous solution container in the hanging position as inadequate mixing is likely and a potential potassium bolus dose may result.
- A rate limiting device such as an infusion pump must be used for all potassium containing infusions. Wherever possible this should be a ‘smart’ pump using a pre-programmed infusion protocol. Dose error reduction software, where implemented, must be turned on and not bypassed while potassium is being infused.
- The maximum recommended concentration of potassium for administration via peripheral infusion lines in adults is 40 mmol per L unless using a commercially prepared pre-mixed solution (for example, potassium chloride 10mmol per 100 mL that has been made isotonic). Solutions stronger should be infused via a central venous access device.
- A second person check is required for the administration of all intravenous potassium solutions.

3.6.2 References


3.7 Vincristine

Vincristine is a neurotoxic, antineoplastic drug of the vinca alkaloid group.

Accidental administration of vincristine via the intrathecal route almost always results in central nervous system dysfunction and death.

This policy outlines the minimum actions required to prevent accidental intrathecal administration of vincristine. This document does not contain clinical guidance on therapeutic use.
3.7.1 Standards

Risk management strategy
The District or Health Service Drug and Therapeutics Committee must approve any local protocols and ensure inclusion of:

- A statement that only staff specifically trained and experienced in cancer treatments may prescribe, prepare, dispense or administer vincristine to patients.
- Procedures that segregate chemotherapy administered by the intrathecal route from all other doses given by other routes. For example:

  Pharmacy requires confirmation from the clinician that all intrathecal chemotherapy administration has been completed prior to releasing intravenous vincristine for the same patient due on the same day.

  OR

  If possible, choose a protocol which schedules administration of intravenous chemotherapy on different days from chemotherapy administered by the intrathecal route.

Storage and supply

- Doses of vincristine must be prepared in and administered from a minibag not a syringe\(^1\).
- All vincristine preparations, including outer wraps, must be labelled with a prominent warning label such as, “FOR INTRAVENOUS USE ONLY – CAN BE FATAL IF GIVEN BY OTHER ROUTES”. The outer wrap must also state, “Do not remove covering until moment of injection”.

Separate supply, delivery and administration of intrathecal medication

- If chemotherapy is prescribed for intrathecal administration in the Operating Suite, only the intrathecal chemotherapy is to accompany the patient to the Operating Suite. No other chemotherapy including intravenous chemotherapy is to be sent.

Administration

- Vincristine must only ever be administered intravenously.
- A time out checklist and a second person check must be employed prior to administering vincristine to ensure:
  - The correct patient name, drug, dose and route have been checked on the bag label.
  - It is being connected to a positively identified (correctly labelled) intravenous line.
  - It is being administered by the intravenous route.

Other considerations

- Procedures must be followed that ensure safe administration techniques and stringent monitoring. Despite dilution, vincristine remains a vesicant.
- In addition to the above specific precautions for the use of vincristine, staff should remain aware, when handling this drug, of the work health and safety procedures that apply to the handling of any cytotoxic drug and related waste.

3.7.2 References

4. APPENDICES

4.1 ‘A PINCH’ – HIGH-RISK MEDICINE GROUPS

This table is available with links to further information at the Clinical Excellence Commission website: http://www.cec.health.nsw.gov.au/programs/high-risk-medicines

This list is not intended to be exhaustive and will be the basis of a dynamic register at each site to suit local formularies.

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<td>P: Potassium and other electrolytes</td>
<td>Injections of potassium, magnesium, calcium, hypertonic sodium chloride</td>
</tr>
<tr>
<td>I: Insulin</td>
<td>All insulins</td>
</tr>
<tr>
<td>N: Narcotics (opioids) and other sedatives</td>
<td>Hydromorphone, oxycodone, morphine</td>
</tr>
<tr>
<td></td>
<td>Fentanyl, alfentanil, remifentanil and analgesic patches</td>
</tr>
<tr>
<td></td>
<td>Benzodiazepines, for example, diazepam, midazolam</td>
</tr>
<tr>
<td></td>
<td>Thiopentone, propofol and other short term anaesthetics</td>
</tr>
<tr>
<td>C: Chemotherapeutic agents</td>
<td>Vincristine</td>
</tr>
<tr>
<td></td>
<td>Methotrexate</td>
</tr>
<tr>
<td></td>
<td>Etoposide</td>
</tr>
<tr>
<td></td>
<td>Azathioprine</td>
</tr>
<tr>
<td>H: Heparin and anticoagulants</td>
<td>Warfarin</td>
</tr>
<tr>
<td></td>
<td>Enoxaparin</td>
</tr>
<tr>
<td></td>
<td>Rivaroxaban, dabigatran, apixaban</td>
</tr>
<tr>
<td>Other</td>
<td>High-risk medicines identified at Local Health District/Facility/Unit level which do not fit the above categories</td>
</tr>
</tbody>
</table>
4.2 EXAMPLES OF DOSE SPECIFIC SAFETY MEASURES THAT CAN BE APPLIED TO HIGH-RISK MEDICINES

<table>
<thead>
<tr>
<th>Transdermal patches</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Confirmation from the prescriber should be sought if multiple patches are to be applied.</td>
</tr>
<tr>
<td>• The time of application, site of application and time of removal should be documented on the medication chart.</td>
</tr>
<tr>
<td>• Transdermal patches should not be exposed to extremes of temperature.</td>
</tr>
<tr>
<td>• Transdermal patches should not be cut.</td>
</tr>
<tr>
<td>• Transdermal patches containing opioids should be securely disposed of for example, in sharps bin.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modified release oral medicines, for example, slow release formulations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• These formulations should not be dissolved, divided (unless scored) or crushed prior to administration.</td>
</tr>
<tr>
<td>• Pharmacy department should be contacted for advice on an alternative formulation or dose preparation if a patient has difficulty swallowing.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicines inhaled using devices:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure the patient understands and is able to use the devices correctly.</td>
</tr>
<tr>
<td>• Ensure the device settings are correct for each medicine delivery.</td>
</tr>
<tr>
<td>• Ensure use of the correct dose form and strength.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parenteral fluids:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• When available, high-risk medicines are purchased in a form closest to the dilution and strength in which they are to be administered so as to minimise opportunity for error in ward-based preparation. Pre-mixed infusion of fluids of high-risk medicines are to be used in preference to those locally prepared.</td>
</tr>
<tr>
<td>• The need to vary from pre-mixed infusion strengths is clearly indicated and documented in the patient’s healthcare record.</td>
</tr>
<tr>
<td>• Infusion pumps with intelligence activated (Smart pumps) are to be used, where available, to screen for dose, dilution and rate of administration. Intelligence checks are not to be by-passed without obtaining the clinical expertise of a senior clinician.</td>
</tr>
</tbody>
</table>
### HIGH-RISK MEDICINES MANAGEMENT IMPLEMENTATION CHECKLIST

<table>
<thead>
<tr>
<th>REQUIREMENTS</th>
<th>IMPLEMENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Facilities have a High-Risk Medicines Register in place.</td>
<td>Fully □  Partially □  Not □</td>
</tr>
<tr>
<td>Reason partially/not implemented:</td>
<td></td>
</tr>
<tr>
<td>2 A mechanism is in place for assessing safety of new medicines being</td>
<td>Fully □  Partially □  Not □</td>
</tr>
<tr>
<td>considered for the facility drug formulary.</td>
<td>Reason partially/not implemented:</td>
</tr>
<tr>
<td>3 A plan, including a time-line, for completion of local high-risk medicine</td>
<td>Fully □  Partially □  Not □</td>
</tr>
<tr>
<td>protocols in accordance with high-risk medicines standard requirements has</td>
<td>Reason partially/not implemented:</td>
</tr>
<tr>
<td>been developed.</td>
<td></td>
</tr>
<tr>
<td>4 A mechanism is in place to alert relevant clinicians to changes to the</td>
<td>Fully □  Partially □  Not □</td>
</tr>
<tr>
<td>high-risk medicines register.</td>
<td>Reason partially/not implemented:</td>
</tr>
<tr>
<td>5 A strategy is in place for review of protocols currently included in the</td>
<td>Fully □  Partially □  Not □</td>
</tr>
<tr>
<td>High-Risk Medicines Register.</td>
<td>Reason partially/not implemented:</td>
</tr>
</tbody>
</table>
IMPLEMENTATION OF BARCODE SCANNING IN NSW PUBLIC HOSPITAL PHARMACY DEPARTMENTS (IB2014_048)

PURPOSE

To provide information to NSW public hospital pharmacy departments on the implementation of barcode verification in the dispensing process.

KEY INFORMATION

Product selection errors made during the dispensing process can cause adverse drug events leading to patient harm, prolonged hospitalisation and wasted resources.

The implementation of barcode scanning (verification) during dispensing is a patient safety initiative that is known to reduce the rate of product selection errors.

The implementation of barcode verification is supported by the following professional pharmacy bodies and is required under the National Safety and Quality Health Service Standards (Criterion 4.5.2):

- The Pharmacy Board of Australia recommends the use of barcode scanning by pharmacists in all settings and is revising the Guidelines for dispensing of medicines to strengthen their position on the use of barcode scanning;
- The Pharmaceutical Society of Australia (PSA) endorses the use of barcode scanning to verify the selection of correct medicines in its Professional Practice Standard 5: Dispensing;
- The Society of Hospital Pharmacists of Australia (SHPA) encourages the use of barcode scanners even where legislation does not mandate the practice.

Recommendations

It is strongly recommended that all public hospital pharmacy departments implement barcode verification in dispensing processes.

The following actions will be essential for successful implementation and require advanced planning:

- Directors of pharmacy departments (and/or their delegates) oversee the redesign of the dispensary workflow to incorporate barcode scanning into the dispensing process.
- Barcode verification is incorporated into the dispensary workflow such that it acts as a checking process, rather than a product selection process.
- The requirement to use barcode verification is incorporated into pharmacy department protocols and procedure manuals.
- All pharmacy staff members are made aware of the need to use barcode scanning during dispensing, and undergo appropriate training to do so (see Staff Education).
- Barcode scanning is used just prior to attaching the label to the medicine.
- Regular and routine monitoring of the rate of barcode scanning in the dispensing process. Where scanning rates are low, underlying reasons should be analysed and appropriate remedial action/s are undertaken.

The only exclusion to these recommendations is the dispensing of medication packs that do not include an appropriate barcode. This may be because they are:

- Supplied as a part of a trial or study.
- Obtained under the Special Access Scheme (SAS).
- Extemporaneously prepared (i.e. those that are outsourced from external manufacturers, and those prepared locally).
Staff Education

All pharmacy staff involved in the dispensing process including pharmacists, pharmacy technicians and pharmacy interns, should be provided with education and training on how to use barcode scanning to verify product selection during the dispensing process.

The implementation of barcode scanning in public hospital pharmacy departments is expected to be incorporated in the next iteration of NSW Health Policy Directive PD2013_043 ‘Medication Handling in NSW Public Health Facilities’.

Resources


The following professional standards can also be accessed online:

- SHPA Practice Standards: Standards of Practice Guidelines for Hospital Pharmacy Outpatient Services – 2006 [Read-only PDF] [http://www.shpa.org.au/Practice-Standards](http://www.shpa.org.au/Practice-Standards)
CHANGES TO PRESCRIBING AND DISPENSING OF BOTULINUM TOXIN AND GROWTH HORMONE (IB2015_049)

PURPOSE

From 1 September 2015, new arrangements will be in place to govern the supply of Pharmaceutical Benefit Scheme subsidised growth hormone and botulinum toxin.

This information bulletin provides further detail on the practical implications of the new arrangements for NSW public hospitals.

KEY INFORMATION

GROWTH HORMONE

PBS Changes to prescribing and dispensing

- From 1 September 2015, the way PBS subsidised growth hormone (somatropin) is prescribed, dispensed and accessed is being amended by the Commonwealth to better align with other PBS arrangements.
- Currently, prescribers make a written application to the Commonwealth Department of Health to prescribe growth hormone.
- From 1 September 2015, prescribers will make a written application to the Commonwealth Department of Human Services – Medicare under the PBS Written Authority system.
- Prescriber eligibility criteria will remain unchanged (i.e. the eligible medical practitioner must hold a specialist qualification for the condition).
- Medicare will notify the prescriber of the outcome and the prescriber will be responsible for notifying the patient’s parent/carer of the outcome of the application.
- Approved PBS authority prescriptions will be used by the patient’s parents/carers to obtain growth hormone supplies at the pharmacy of their choice – the Commonwealth Department of Health will no longer manage the ordering and monitoring of growth hormone supplies.
- Patients will be able to present authorised prescriptions to any PBS-approved pharmacy.

Important practical arrangements and implications for NSW Public Hospitals

- NSW Health is not a signatory to the Pharmaceutical Reforms and therefore under the new arrangements NSW public hospital pharmacy departments are not able to claim the Commonwealth reimbursement for an authorised PBS prescription for growth hormone.
- In NSW this means, when providing a service to a privately referred non-admitted patient, an authorised PBS prescription is provided to the patient/carer who then presents the script to a community or private hospital pharmacy where the supplies will be ordered, delivered and dispensed to the parent/carer.

Co-payments

- Normal PBS patient co-payments will now apply.

For further information, please view the following FAQ link developed by the Commonwealth:
http://www.pbs.gov.au/info/general/changes-to-certain-s100-programs
KEY INFORMATION

BOTULINUM TOXIN

PBS Changes for prescribers and hospital pharmacies
- Section 100 Botulinum Toxin Program is being modified by the Commonwealth to align with other PBS arrangements, using PBS prescriptions and s94 Hospital Pharmacy coordination points.
- All changes to the Botulinum Toxin Program will take effect from 1 September 2015.
- Prescribers will no longer need to register with the Commonwealth, but specialists will be restricted, by specialty, to prescribing for specific indications. Details are in the Criteria for Availability in the PBS Schedule.
- Only s94 (PBS-eligible) hospital pharmacies will be able to claim reimbursement.
- Community pharmacies are not included in this program.
- Botulinum toxin, and related products, will continue to be listed in the PBS Schedule under s100 Botulinum Toxin.

Important practical arrangements and implications for NSW Public Hospitals
- NSW Health is not a signatory to the Pharmaceutical Reforms and as such NSW public pharmacies will not be able to claim PBS reimbursement for botulinum toxin from 1 September 2015.
- In NSW, when providing a service to a privately referred non-admitted patient, prescribers will have two options. The prescribers may either come to an arrangement directly with a s94 pharmacy or with a third party with appropriate arrangements in place, to dispense, deliver and claim reimbursement of the PBS botulinum toxin.
- The private hospital will claim reimbursement online via PBS Online.
- Importantly, the prescriber must arrange with the s94 pharmacy or alternative supplier the appropriate transportation and provision of the toxin so that the patient has no involvement in the transportation.
- Under no circumstances are patients to be in possession or involved in the transport of the botulinum toxin.

Co-payments
- Normal PBS patient co-payments will now apply to botulinum toxin dispensed at a s94 pharmacy.

An indicative botulinum toxin supply diagram follows.

For further information, please view the following FAQ link developed by the Commonwealth:

Botulinum toxin supply after 1st September

Potential PBS eligible

- Privately referred non-admitted patient

Yes

Does patient have a current referral?

No

PBS ineligible

Public patient

PBS use?

PBS supported

YES

Dr emails/faxes Third Party order form

Dr posts valid Authority prescription to third party

Botulinum toxin stock to patient sourced from third party & paid by PBS

PBS supported

NO

Hospital pays

Dr provides internal Rx or form

Botulinum toxin stock to patient sourced and paid by facility hospital Pharmacy

PBS use?

PBS supported

YES

Hospital pays

Dr provides internal Rx or form

PBS ineligible
VACCINE STORAGE AND COLD CHAIN MANAGEMENT (PD2017_014)

PURPOSE
This policy directive provides mandatory requirements for the storage and management of vaccines and aims to ensure consistent and effective vaccine storage and monitoring processes in all public health facilities. The policy also aims to ensure that all clients receive potent vaccines and that all vaccine cold chain breaches are identified and managed consistently, efficiently and effectively.

MANDATORY REQUIREMENTS
All facilities must ensure that:

- policies, procedures and protocols are in place for vaccine management in each facility according to the current editions of the National Vaccine Storage Guidelines Strive for 5 and The Australian Immunisation Handbook;
- all vaccines are stored in a purpose built vaccine refrigerator;
- all vaccine refrigerators are continually data logged and the data logging report is downloaded and reviewed at least weekly (refer to Section 3 Refrigerator Monitoring in Attachment 1 Vaccine Storage and Cold Chain Management: Procedures);
- all refrigerators have a back-to-base alarm;
- a base-line vaccine storage self-audit is conducted initially and annually thereafter (available on the Quality Audit Reporting System – QARS);
- plans are in place for responses to cold chain breaches and power failures in each facility, including reporting temperatures outside +2°C to +8°C range to the local public health unit (PHU) on 1300 066 055 within the same working day. Quarantine the vaccines until PHU advice is received;
- cold chain breaches resulting in vaccine wastage or recall and revaccination of patients must be reported in the Incident Information Management System (IIMS) to facilitate investigation, resolution and minimise the risk of future incidents;
- all vaccine refrigerator minimum/maximum temperatures are recorded twice daily on the NSW Health vaccine refrigerator monitoring chart, and;
- cold chain management resources (available on the NSW Health cold chain webpage) are utilised to facilitate staff education.

IMPLEMENTATION
Effective vaccine storage and management requires a coordinated approach by key personnel as follows:

Public facilities must:

- Ensure that vaccines are stored and managed according to the current edition of the National Vaccine Storage Guidelines – Strive for 5 and this policy directive.
- Ensure that all staff are aware of the requirements of this policy directive.

Health Protection NSW will:

- Provide ongoing vaccine storage and cold chain management support to public health units and facilities as required.
- Provide recall and revaccination advice following cold chain breaches as required.
- Ensure that updated vaccine storage and cold chain management advice is provided to local health districts and public health units.
Vaccine Storage and Cold Chain Management: Procedures.

1 BACKGROUND

1.1 About this policy

This policy provides specified procedures for the storage and monitoring requirements of vaccines that are either funded by NSW Health or purchased by facilities. Self-auditing requirements are also detailed in this policy which aims to:

- Ensure consistent and effective vaccine storage and monitoring processes in all public health facilities;
- Facilitate the administration of viable vaccines to vaccine recipients;
- Ensure vaccine cold chain breaches are identified and managed consistently, efficiently and effectively;
- Reduce vaccine wastage as a result of vaccine cold chain mis-management, and;
- Inform providers of requirements for ordering, storing and monitoring vaccines.

This policy should be read in conjunction with the current edition of the National Vaccine Storage Guidelines: Strive for 5 (referred to as ‘Strive for 5’) and the current edition of The Australian Immunisation Handbook.

1.2 Key definitions

Ambient temperature: temperature of the surrounding environment in which the vaccine refrigerator is operating.

Salvage plan: a plan of actions that ensures that vaccines will continue to be stored between +2°C to +8°C during power supply or refrigerator failures.

Cold chain: the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C.

Cold chain breach: exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, for example, when stock taking or restocking). A cold chain breach may also be referred to as an ‘adverse vaccine storage event’.

Cold chain monitors (CCMs): transport monitors that accompany vaccines during transit from the NSW Vaccine Centre to the immunisation provider. CCMs must be discarded after delivery and not used for routine temperature monitoring.

Data logger: a small electronic device that continuously measures temperatures and stores an electronic record of the refrigerator temperatures during a monitored period.

Public Health Unit (PHU): a team of health professionals based within a local health district who are responsible for a range of health protection issues, including immunisation. The PHU contact number is 1300 066 055.
**Purpose built vaccine refrigerators:** refrigerators designed and constructed specifically for vaccine storage.

**Vaccines:** complex biological products designed to induce a protective immune response effectively and safely.

**Vaccine management:** the storage and monitoring of vaccines, including stock rotation, effective management of cold chain breaches and nomination of a staff member responsible for cold chain management to ensure timely reporting to the local PHU when required.

### 2 VACCINE COLD CHAIN MANAGEMENT

- Health professionals have a legal and professional obligation to ensure their patients receive effective health products, for example, vaccines that have been stored appropriately and not adversely affected by heat, cold or light.
- Vaccines must be transported and stored within the recommended temperature range +2°C to +8°C at all times.
- Effective vaccine storage and cold chain management are essential as:
  - Freezing of vaccines can cause loss of potency which can never be restored.
  - Effective cold chain management ensures patients are vaccinated with potent vaccines to reduce their risk of disease. Patients vaccinated with ineffective vaccines may need to be recalled, counselled and revaccinated. In addition to the inconvenience of this, the total cost of a cold chain breach can be significant.

#### 2.1.1 Cold Chain Management Principles

- Store vaccines in a purpose-built vaccine/medication specific refrigerator (refer to section 3 Equipment).
- Nominate a staff member responsible for vaccine storage and cold chain management within their area, and a back-up staff member(s) in their absence. Refer to section 2.1.2 Governance.
- Ensure policies, procedures and protocols are in place for vaccine management in each facility (refer to the Vaccine Management Protocol in Appendix 1 of ‘Strive for 5’, 2nd edition for detailed information).
- Develop procedures for orientating new staff and staff with new roles who are responsible for cold chain management. Staff education records must be maintained for ongoing education as required. Refer to section 7 Education for detailed information.
- Ensure local procedures are in place and essential equipment is readily available for responses to cold chain breaches and power failures in each facility (refer to Management of Power Failure in Section 8 of ‘Strive for 5’, 2nd edition). A local procedure could include a salvage plan that provides a reference guide/chart for display on the front of the refrigerator that contains the contact details for the local public health unit (PHU) to seek advice following a cold chain breach. An example of a refrigerator protocol is provided at Attachment 4.
- Report temperatures outside the +2°C to +8°C range (excludes fluctuations up to +12°C, lasting no longer than 15 minutes) to the local PHU on 1300 066 055. The facility pharmacist should also be contacted as appropriate for advice on temperature sensitive medications that are stored in the refrigerator.

308(08/06/17)
20. PHARMACEUTICAL MATTERS

• Vaccines must not be discarded until PHU advice is received (refer to Cold Chain Breach Protocol in Appendix 3 of ‘Strive for 5’, 2nd edition).

• Follow the guidelines for using ice packs/gel packs and monitoring vaccines in coolers and cold boxes (refer to Coolers in Section 9 of ‘Strive for 5’, 2nd edition) as required during power outages.

• Refer to Caring for Vaccines During Immunisation Sessions in Section 7 of ‘Strive for 5’, 2nd edition if outreach and/or community clinics are conducted.

• Perform vaccine storage self-audits at least 12 monthly (refer to section 6 Vaccine Management and Storage Self-Audit).

2.1.2 Governance

In some health facilities vaccines may be stored in the central pharmacy, ward or clinic. In this situation, the following governance arrangements must be followed:

• the on-duty pharmacist or delegate is responsible for the cold chain management of vaccines that are stored in a central pharmacy, and;

• the Nursing Unit Manager (NUM)/Midwifery Unit Manager (MUM) or delegate is responsible for the cold chain management of vaccines that are removed from the central pharmacy and stored in the ward or clinic refrigerator until they are administered.

• Vaccines should be transferred from the pharmacy to the ward in a monitored cooler using a battery operated minimum/maximum thermometer. Refer to Coolers of ‘Strive for 5’ 2nd edition for detailed information. The person who transfers the vaccine (may be pharmacy or ward staff, as determined by local protocols) is responsible for ensuring the cooler is packed appropriately, the temperature of the cooler is recorded during transfer and at arrival to the ward. The person receiving the vaccines must record their receipt and that the cold chain was maintained during transfer on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) or on a locally developed vaccine register. The vaccines must be unpacked and stored immediately in the ward/clinic refrigerator.

• The nurse administering the vaccine is responsible for maintaining the cold chain from the time it has been removed from the refrigerator to administration.

3 EQUIPMENT

Regular maintenance of cold chain equipment should be conducted as specified in Key Recommendations for Effective Vaccine Storage Management in ‘Strive for 5’, 2nd edition and includes the following:

• Service the refrigerator (including a thermostat and calibration service) every 12 months and following any refrigerator malfunction;

• Recalibrate the data logger annually or as indicated by the manufacturer;

• Change the data logger battery at least every 12 months or as indicated by the manufacturer;

• Check the accuracy of the battery operated minimum/maximum thermometer at least annually or as indicated by the manufacturer (as appropriate);

• Change the battery operated minimum/maximum thermometer battery at least every 12 months or as indicated by the manufacturer (as appropriate).
20. PHARMACEUTICAL MATTERS

Purpose-built Refrigerators

Purpose-built refrigerators are the best-practice storage option as they are designed to store vaccines and temperature sensitive medication. They have a stable, uniform and controlled cabinet that maintains the temperature between +2°C to +8°C, however they must be monitored as specified in section 4 Refrigerator Monitoring. The following principles must be followed:

- Each refrigerator must have an audible alarm (preferably with a back to base/nurse call system) with preset parameters set outside +2°C to +8°C (to activate when temperature reaches less than +2°C and greater than +8°C and is maintained until the alarm is manually deactivated). A visual temperature display must accompany the auditory alarm.

- The refrigerator plug electricity connection must be clearly labelled “DO NOT turn off power or disconnect this refrigerator” so that it is not unplugged accidentally. Consideration should be given to hard-wiring the power board to prevent it from being accidentally disconnected.

- The refrigerator should be plugged into an uninterruptible power supply (UPS). Where a UPS is not available, an emergency generator should be used during interruptions to the power supply.

- Where a refrigerator door does not close easily, consider using a door closing device or leveraging the refrigerator to ensure the door closes freely and not left ajar after accessing the vaccines (front feet higher than back feet, check that this is acceptable with refrigerator manufacturer).

- The refrigerator must be placed with enough space between the wall and cabinet to ensure adequate air flow as specified by the refrigerator manufacturer (confirmed by asset/maintenance staff as appropriate).

- The refrigerator must be placed in a secure room where only appropriate staff have access. Alternatively, if a secure room is not available, the refrigerator door must be locked at all times with access only provided to the appropriate staff.

Bar refrigerators and domestic refrigerators must not be used for vaccine storage in NSW facilities.

- Data Loggers

To investigate temperature excursions, all refrigerators that store vaccines must have a data logger in place (portable or in-built) or back to base data logging. The data logger should be set to record temperatures at five minute intervals. Where a portable data logger is used, it should be secured to a shelf in the middle of the refrigerator to ensure consistent monitoring. Where a data logger has a probe, it should be placed inside a vaccine box to record the vaccine temperature rather than the ambient air. All facilities must have the appropriate equipment and software to download data logging/back to base monitoring reports.

Data logging reports must be downloaded and saved weekly and/or when a potential cold chain breach has been identified during the twice daily temperature checks to ensure viable vaccines are administered to patients. All staff should be trained on how to operate/manager the data logger and interpret its readings. Any actions taken in response to data logging should be documented and these records managed in accordance with the appropriate retention and disposal authorities.

Twice daily minimum/maximum temperatures must also be manually recorded on the NSW Health Vaccine Refrigerator Temperature Chart4 (NH700227) in addition to ongoing data logging/back to base monitoring as this process ensures a timely alert to any cold chain breach.

3 Refrigerator stickers and posters are available to download from the Australian Government website at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/IMM77-cnt

4 Order the NSW Health Vaccine Refrigerator Temperature Chart via the Stream Direct Catalogue as a POD print item (item number NH700227)
20. PHARMACEUTICAL MATTERS

- **Minimum/maximum thermometers**

A portable minimum/maximum digital thermometer must be simultaneously used to monitor the temperature of the refrigerator when it does not have a battery back-up for the in-built temperature monitoring system (or generator power back-up) or is not plugged into a UPS. Minimum/maximum thermometers are also required to monitor coolers that are used as alternate storage, for example during a power outage.

- **Cold Chain Monitors**

Cold chain monitors (CCMs) are used to detect heat and freeze breaches and accompany vaccines during transport from the NSW Vaccine Centre. When the vaccine order arrives from the NSW Vaccine Centre, the CCMs should be checked and recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH7000227) or on a locally developed vaccine register. CCMs must be discarded following receipt of the vaccine delivery and must not be stored in the refrigerator and/or used to monitor vaccines after delivery. All breaches following vaccine delivery must be reported immediately to the NSW Vaccine Centre on 1300 656 132. The vaccines must be quarantined in a functioning refrigerator until advice is received on the fate of the vaccines.

4 REFRIGERATOR MONITORING

- Manually record the refrigerator’s current, minimum and maximum temperatures twice daily (refer to Monitors in section 6 of ‘Strive for 5, 2nd edition’ on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227; refer to Attachment 3). These ‘current/minimum/maximum’ manual recordings are required regardless of continuous data logging or back to base alarm systems. This is to ensure vaccines have not been subjected to a cold chain breach prior to administration.

- Where a facility is not operational 24 hours/day for seven days/week, the refrigerator’s current/minimum/maximum refrigerator temperature must be checked on the first operational day (since the last recording) and twice daily thereafter. The data logging report should also be downloaded and checked before any vaccines are removed for administration.

- Reset the minimum/maximum thermometer after each reading, following any excursion outside +2°C to +8°C and on receipt of a new vaccine delivery. Ensure the refrigerator has returned to within +2°C to +8°C before resetting. If the refrigerator temperature reaches greater than 12°C for more than 15 minutes, refer to section 5 Management of Cold Chain Breaches.

- Record any events for example, refrigerator restocking following a vaccine delivery, or refrigerator servicing, on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227).

- Continuously data log the refrigerator. The data logging/back to base monitoring report must be downloaded and reviewed by the NUM/MUM/delegate weekly and following any identified cold chain breach (excludes fluctuations up to 12°C for less than 15 minutes).

- Each facility must have a local procedure for downloading and reviewing the data logging reports.

- All staff responsible for cold chain management must have access to and know how to download and review the data logging reports (stored centrally in an appropriately named folder for each refrigerator and date), including back to base monitoring reports as appropriate.

- A back-up hard copy of the data logging graphs should be stored centrally in a file by the NUM/MUM/delegate.

- For cold chain breach management, refer to Section 5 Management of Cold Chain Breaches.
5 MANAGEMENT OF COLD CHAIN BREACHES

5.1 Cold Chain Breach Protocol

A ‘cold chain breach’ has occurred if a purpose-built refrigerator’s temperature has been outside the recommended range of +2°C to +8°C. It excludes fluctuations up to +12°C, lasting no longer than 15 minutes, which may occur for example when stock taking or restocking a refrigerator. Such fluctuations must be recorded on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) to cross reference when reviewing the corresponding data logging report. All other cold chain breaches greater than +8°C that cannot be accounted for and any less than +2°C must be reported to the PHU for advice. Once a cold chain breach has been identified, the following procedures must be followed:

• Refrigerate and quarantine the potentially compromised vaccines (in a functioning refrigerator) between +2°C to +8°C and label ‘Do not use’.
• Inform the NUM/MUM/delegate immediately.
• Download and review the data logging report.
• Contact the local PHU on 1300 066 055 as soon as possible during business hours.
• Vaccines must not be discarded until advice has been provided by the local PHU on the fate of the vaccines.
• Report the type and number of vaccines wasted to the PHU as required.
• Contact the relevant manufacturer for advice on privately purchased vaccines (vaccines not sourced from the NSW Vaccine Centre) as the PHU is unable to provide advice on private stock.
• Contact the facility pharmacist for advice on temperature sensitive medications.

5.1.2 Patient Recall and Revaccination

Cold chain breaches that have been identified after patients have been vaccinated with potentially compromised vaccine(s) require detailed information to be forwarded by the ward/unit manager/delegate to the local PHU for advice on whether revaccination is required (refer to Attachment 1).

The PHU will assess each report on a case-by-case basis as not all cold chain breaches will result in patient recall and revaccination. A number of factors are considered by the PHU, including the type of vaccine and its thermostability, duration of breach and history of any previous breaches and the patient’s vaccination history. The PHU will consult with Health Protection NSW to decide on the need for revaccination.

6 VACCINE MANAGEMENT AND STORAGE SELF- AUDIT

Vaccine management and storage self-auditing is an essential component of routine quality assurance and risk management processes to ensure potent vaccines are administered. Facilities must ensure that:

• A base-line vaccine management self-audit is undertaken initially and at least annually thereafter (using the Quality Audit Reporting System-QARS). Audits may be required more frequently where there have been issues with equipment or cold chain breaches. All NUMs/MUMs/delegates must have access to QARS. The audit tool is also available on the NSW Health cold chain webpage.
• Facility managers retain a record of the results and discuss them as a standing agenda item on the relevant LHD locally agreed committee.
• The local public health unit (PHU) is contacted on 1300 066 055 for vaccine storage/management queries and/or issues identified during the audit.
• An Incident Information Management System (IIMS) report must be completed for cold chain breaches that result in patient recall/revaccination.

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7 EDUCATION

- All staff involved in vaccine transport, storage and administration must be trained in vaccine management to ensure the vaccines remain effective and potent.
- All cleaning and maintenance staff must be educated on the importance of vaccine storage and cold chain management.
- To facilitate staff education, cold chain management resources are available on the NSW Health website at: www.health.nsw.gov.au/immunisation and the vaccine online ordering system at: https://nsw.csldirect.com.au/
- The online Health Education and Training Institute (HETI) module ‘Vaccine Storage Cold Chain Management’ (available from mid-2017), must be undertaken by the following staff employed in NSW public facilities:
  - managers (in clinical areas where immunisations are administered)
  - staff members and their delegate(s) that have been nominated as responsible for vaccine storage and cold chain management;
  - pharmacy staff (where vaccines are stored in the pharmacy department);
  - clinical governance/quality audit staff that are involved vaccine storage and cold chain management audits and policy development, and;
  - staff that are involved in vaccine administration.

The HETI module will also be made available on the NSW Health cold chain webpage for staff employed in private facilities.

Refer to section 2.1.1 Cold Chain Management Principles for more information on the roles and requirements for cold chain management.

8 VACCINE ORDERING

- Review current stock to ensure order does not overload or exceed refrigerator capacity.
- Login to the web based online vaccine ordering system at www.nsw.csldirect.com.au using the facility login or coordinate vaccine ordering via the facility pharmacy department. Contact the local PHU on 1300 066 055 for queries regarding vaccine ordering procedures.
- Facilities must have a local procedure for detailing the login and password details for vaccine ordering. The details must be accessible only by staff responsible for ordering vaccines.

9 VACCINE DELIVERIES

- Each facility must have a written operating procedure for receiving vaccines from the NSW Vaccine Centre and where vaccines are transported from a central pharmacy to an alternate refrigerator in a ward/unit within the facility.
- The CCMs must be checked immediately upon delivery from the NSW Vaccine Centre to identify any cold chain breach that has occurred during transport.
The CCMS must be discarded following delivery and must not be stored in the refrigerator with the vaccines.

The vaccine delivery, including the CCM status, must be recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227).

All vaccines must be refrigerated immediately following delivery, placing the oldest stock with the shortest expiry date to the front of the purpose-built refrigerator.

Care should be taken so that that stock is not placed in such a way as to block or isolate a sensor that is located inside the refrigerator. Where this is a potential risk to block or isolate the sensor, add a label adjacent to the sensor to instruct staff not to place vaccines in front of it.

If a cold chain breach has been identified following a vaccine delivery from the NSW Vaccine Centre, the vaccines must be quarantined in a functioning refrigerator and the breach reported to the NSW Vaccine Centre on 1300 656 132 (refer to section 3 Equipment; Cold Chain Monitors).

To prevent overstocking, the maximum amount of vaccine stock must be determined (as specified by the refrigerator manufacturer and confirmed by pharmacy as appropriate) for each refrigerator and vaccine stock maintained accordingly.

Minimise refrigerator door opening to prevent the temperature rising above +8°C. The use of a vaccine location map on the front of the refrigerator may assist in quickly locating vaccines and reduce door opening to a minimum. The use of labelled baskets may also reduce clutter and assist in the ordering and restocking process.

Any temperature excursions (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking) must be reported to the NUM/MUM/delegate immediately and recorded on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227). The data logging report must be downloaded and reported to the local PHU on 1300 066 055. Refer to section 5 Management of Cold Chain Breaches.

10 LIST OF ATTACHMENTS

1. Recall and Revaccination Cold Chain Breach Report
2. PHU Cold Chain Breach Risk Assessment
3. NSW Health Vaccine Refrigerator Temperature Chart
4. Refrigerator Protocol

11 RELATED POLICIES AND LEGISLATION

PD2013_043 Medication Handling in NSW Public Facilities.

12 REFERENCES


ATTACHMENT 1: RECALL AND REVACCINATION REPORT

Cold Chain Breach Report
The form must be completed by the manager/delegate of the ward/unit/facility where the cold chain breach occurred and forwarded to the local PHU as requested

Hospital: ____________________________________________________

Facility/ward/clinic:____________________________________________

Minimum temperature reached: _____ °C

Maximum temperature reached:_____ °C

Duration of breach: ______________________________ minutes/hours/days (delete as appropriate)

Data log report attached? Yes___ No___

Reason for breach:

<table>
<thead>
<tr>
<th>Patient 2x2 ID</th>
<th>DOB Dd/mm/yyyy</th>
<th>Vaccine(s) Administered</th>
<th>Dose</th>
<th>Date Administered</th>
<th>Revaccination Advice PHU staff to complete</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

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## ATTACHMENT 2: PHU COLD CHAIN BREACH RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Facility: ___________________________</th>
<th>Ward/Clinic: ___________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of breach: / /</td>
<td></td>
</tr>
<tr>
<td>Fridge type: Vaccine specific ☐ Domestic ☐ Other (please specify) ________________</td>
<td></td>
</tr>
<tr>
<td>Fridge location: Ward/clinic ☐ Pharmacy department ☐ Other (please specify): __________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>Yes / No</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of last vaccine delivery (from NSW Vaccine Centre or vaccine transfer to ward/unit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does facility rotate vaccine stock following each delivery?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is this the first known breach for these vaccines?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason for breach known? If power outage and no data logging available, facility to contact electricity company and request information regarding duration of power outage</td>
<td>Reason:</td>
<td></td>
</tr>
<tr>
<td>Date of last fridge service?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has fridge temperature been stable prior to the breach?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min/max recordings available? Attach the NSW Health Vaccine Refrigerator Temperature Chart NH700227</td>
<td>Within range +2°C to +8°C? Yes ☐ No ☐</td>
<td></td>
</tr>
<tr>
<td>Is it possible that the min/max thermometer is faulty?</td>
<td>Date last battery change: / /</td>
<td></td>
</tr>
<tr>
<td>Data logging (DL) / back to base monitoring available? Attach data logging/report</td>
<td>Within range +2°C to +8°C? Yes ☐ No ☐</td>
<td></td>
</tr>
<tr>
<td>Is it possible there is a problem with the location of the data logger (if used instead of a back to base monitoring system)</td>
<td>Last calibration of DL:</td>
<td></td>
</tr>
<tr>
<td>Ambient room temperature during breach known? i.e. was it a very hot/cold day/night?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air conditioning in room on/off/not installed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is it possible that the breach is due to staff incorrectly recording the fridge temperature/not resetting the minimum/maximum thermometer?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were patients vaccinated with compromised vaccine? If yes, request a list of patients from the facility using the Recall and Revaccination Report (Attachment 1)</td>
<td>The facility must provide a list of patients to the PHU</td>
<td></td>
</tr>
</tbody>
</table>

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ORDER THE NSW HEALTH VACCINE REFRIGERATOR TEMPERATURE CHART VIA THE STREAM DIRECT CATALOGUE AS A POD PRINT ITEM (ITEM NUMBER NH700227)
ATTACHMENT 4: REFRIGERATOR PROTOCOL

Check Fridge Temperature Twice Daily
Aim for 5°C

Record the Current, Minimum & Maximum Temperature on Chart
Press ‘RESET’ after Temperature check completed

If inside range of +2°C to +8°C
No action required

If Fridge Temp range is <+2°C or >+8°C or the fridge has alarmed
Quarantine Vaccines/Medications
Label ‘DO NOT USE’

If temperature <+2°C or >+8°C and/or the fridge alarm is activated
Action MUST be taken immediately & documented on the
NSW Vaccine Refrigerator Temperature Chart
Refer to the cold chain breach steps on the chart

OTHER MEDICATIONS
- Notify facility Pharmacy Service provider
- Do NOT use meds until advice is received from Pharmacy

VACCINES
- Notify PHU on 1300 066 055
- Do NOT use vaccines until advice received from PHU

Additional Information
- Document all activity on the back of the NSW Vaccine Refrigerator Temperature Chart - Fortnightly, i.e. thermostat adjustment, restocking, power outage, data logger removal etc.
- Refer to the current edition of The Australian Immunisation Handbook and the National Vaccine Storage Guidelines – ‘Strive for 5’.
- NSW Health ‘Vaccine Refrigerator Temperature Chart – Fortnightly’ must be used on all fridges
- Vaccine Refrigerator Temperature Chart and cold chain management records must be managed according to the appropriate retention and disposal authorities

Vaccine Refrigerator Temperature Chart
NSW Vaccine Refrigerator Temperature Chart – Fortnightly: order from Toll Stream Direct, Order Number: NH700227

308(08/06/17)
UP-SCHEDULING OF OVER-THE-COUNTER CODEINE-CONTAINING MEDICINES  (IB2017_043)

PURPOSE
To inform staff in public health facilities of the up-scheduling of over-the-counter (OTC) low-dose codeine-containing medicines to Schedule 4 (prescription-only) of the NSW Poisons List from 1 February 2018.

KEY INFORMATION
Codeine-containing OTC medicines are to be up-scheduled from Schedule 2 or 3 to Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons, and consequently of the NSW Poisons List, on 1 February 2018.

The up-scheduling of OTC codeine-containing medicines applies to solid dose units (tablet or capsule) containing up to 12 mg codeine (equivalent to approximately 15 mg codeine phosphate) and liquid dose forms containing up to 0.25% codeine. These medicines (if also containing non-opiate therapeutic substance/s and with a recommended daily dose up to 100mg codeine, and in packs up to 5 days’ supply) are currently available without prescription for pain relief and for symptomatic treatment of coughs and colds. Of note, the scheduling of all other codeine-containing medicines remains unchanged (i.e. Schedule 8 or Schedule 4).

Implications for public hospitals:

- Hospital/Local Health District drug formularies should be reviewed to determine if lowdose codeine-containing medicines should be removed in light of the lack of evidence for efficacy greater than non-opioid analgesic medicines, and the risk of harm.

- Low dose codeine-containing medicines must no longer be included in Nurse Initiated Medicines (NIM) lists. However, Medication Standing Orders can be approved by the Drug and Therapeutics Committee (DTC) for specific medicines to allow Nurse/Midwife initiation of treatment if appropriate, noting that this requires an authorised prescriber to countersign the record of the administration within 24 hours.

- Electronic Medicines Management systems (eMM) must be reviewed to reflect changes to Nurse Initiated Medicines lists and hospital drug formularies.

- Availability of low-dose codeine-containing medicines in clinical areas (e.g. on ward imprest and any pre-packs kept in Emergency Departments) should be reviewed in light of removal from NIM lists and drug formulary changes. They should be retained only if considered to be clinically necessary as first-line pain treatment, in light of the evidence of lack of efficacy and risk of harms.

- Staff access to low-dose codeine-containing medicines must be vigilantly maintained in the Pharmacy and clinical areas to minimise the risk of misappropriation. This includes removal of all low-dose codeine-containing medicines from First Aid kits.

- Although Schedule 4 codeine-containing medicines are not currently in Appendix D of the Poisons and Therapeutic Goods Regulation (prescribed restricted substances), some facilities/LHDs have local policies requiring storage, recording and accountability for them, equivalent to S4D requirements. Such policies, where present, should also apply to low-dose codeine medicines if a facility decides to keep them or if patients bring their own into hospital.

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• Protocols for pain management on discharge should be reviewed to ensure they describe appropriate analgesic selection and the consideration of access to ongoing analgesia as required. There should be an opioid cessation plan for all patients discharged on oral opioids for acute pain such as after surgery and this should be communicated in writing to the patient and his/her general practitioner (GP).

• Patients should be informed of changes to the scheduling of low-dose codeine medicines if relevant, and referred for information to the consumer information on the TGA Codeine Hub https://www.tga.gov.au/codeine-info-hub or provided a copy of relevant leaflet/s.

• Patients who have been self-managing chronic pain with OTC codeine-containing medicines, or those with a substance use disorder involving codeine (e.g. those displaying signs or symptoms such as tolerance, dependence, withdrawal), may present to hospital Emergency Departments, outpatient services, pain clinics or addiction services. Requests for doses or prescriptions for opioid medicines, including codeinecontaining medicines, may increase. Facilities should have a documented consistent approach to dealing with such requests. Chronic or acute pain management protocols should be implemented and patient referral to pain clinics and addiction services considered as required. For further information refer to the ACI pain management website at www.aci.health.nsw.gov.au/chronic-pain.

BACKGROUND – Why are these medicines being up-scheduled?

1. Codeine (methyl morphine), an opioid drug commonly used for the relief of mild to moderate pain, is itself a weak analgesic which must be metabolised to its active metabolite, morphine, to have a therapeutic effect. There is large variability in individual responses to codeine – from poor metabolisers, who experience little therapeutic effect, to ultrarapid metabolisers, who have faster conversion of codeine to morphine, and therefore a greater risk of toxicity.

2. Current OTC codeine-containing medicines offer little or no additional pain relief when compared to paracetamol or ibuprofen alone. There is also limited good quality evidence of efficacy for the inclusion of codeine in cough and cold medicines as a cough suppressant, and significant health risks have been reported particularly in children younger than 6 years.

3. Although common adverse effects of codeine, including nausea, vomiting, constipation and drowsiness, are more likely with higher or repeated doses, medication overuse headaches, drowsiness and an increased risk of falls and motor vehicle accidents are reported even at recommended doses. Codeine should be used with caution in children, breastfeeding women and the elderly.

4. There is substantial evidence of harm, including tolerance, dependence, addiction, poisoning and, in high doses, even death, from the use, abuse and misuse of low-dose codeine-containing medicines. Opioid withdrawal symptoms upon cessation can perpetuate the cycle of misuse and dependency.

5. Adverse effects of the long term or excessive use of combination codeine medicines containing paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) have resulted in a rise in morbidity and mortality associated with liver damage, gastrointestinal perforations and respiratory depression. There are numerous case reports of serious adverse effects and deaths from combination codeine medicines, particularly related to paracetamol-induced hepatotoxicity and NSAID-induced gastrointestinal ulceration.

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A summary of the rationale and evidence behind the up-scheduling of low-dose codeine medicines can be found on the Therapeutic Goods Administration (TGA) website: Regulation Impact Statement: Codeine re-scheduling.

Further information on the health risks of low-dose codeine medicines is on the TGA website:
- George report: Review of the efficacy and safety of over-the-counter codeine containing analgesics for pain and codeine based antitussives
- Safety review: Codeine use in children and ultra-rapid metabolisers

MEDICINE INGREDIENT NAME CHANGES (IB2017_045)

PURPOSE
From April 2016 to April 2020, ingredient names for some medicines used in Australia will change to align with names used internationally. The purpose of this Information Bulletin is to inform NSW Health staff of the following:

1. activities that will be centrally co-ordinated, including changes to clinical systems
2. activities that will require implementation and management by Local Health Districts (LHD) and Specialty Health Networks (SN)
3. responsibilities of agencies and committees

KEY INFORMATION
A range of activities are required to manage the changes to medicine names in the NSW public health system. Activities that can be centrally co-ordinated have been identified, but some activities require both central and local coordination.

The table in section 1.6 below outlines activities that will be centrally co-ordinated and those that will need local implementation and management. The key team and/or agency responsible is listed.

LHDs and SNs need to ensure that their risk management plan addresses the high risk period when a clinical system switches from displaying the old drug name to the new drug name, especially if stock is held that displays the old drug name.

1.1 Background
The Therapeutic Goods Administration (TGA) regulates what ingredient name is used on medicine labels, in product information documents and Consumer Medicine Information leaflets. The TGA is managing communication with product sponsors, health professionals and consumers about the name changes. While the TGA does not regulate clinical systems, the changes to medicines names are adopted into NSW Health clinical systems as far as practicable.

A list of the affected ingredient names can be found on the TGA website at: https://www.tga.gov.au/updating-medicine-ingredient-names-list-affected-ingredients

The medicine ingredient name changes have been risk assessed by the TGA and categorised as major or minor. In some cases, both the old and new name will need to be displayed on the product label for an extended period, that is, dual naming will be used. For example, ‘adrenaline (epinephrine)’ replaces ‘adrenaline’.
1.2 Poisons Standard
The Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons SUSMP (see https://www.tga.gov.au/publication/poisons-standard-susmp) now references both new and old names for affected scheduled medicines. Both names are now ‘approved’ names, therefore prescriptions written in either name, and dispensing labels showing either name, are legally valid.

1.3 Australian Medicines Terminology
Australian Medicines Terminology (AMT) has been updated to the new name changes, including the dual labelling where required, allowing systems following AMT conventions to apply the name changes.

1.4 Safety Notice 001/16 - Changes to Medicine Ingredient Names
In May 2016, the Clinical Excellence Commission (CEC) issued Safety Notice 001/16 Changes to Medicine Ingredient Names - April 2016 to April 2020 (see http://www.health.nsw.gov.au/sabs/Documents/2016-sn-001.pdf). It advised health services and clinicians of the affected medicine ingredient name changes, and the actions required to minimise the risk of medication error due to these changes.

LHDs and SNs were directed to complete a local risk assessment and develop a local plan to identify and mitigate any potential medication errors due to the changes.

This bulletin incorporates requirements and activities detailed in the Safety Notice.

1.5 Governance and responsibilities
The NSW Medicine Ingredient Name Changes Working Group is a collaboration between Ministry of Health, eHealth NSW, the CEC, and LHD pharmacy service representatives. The working group has developed a state-wide co-ordination plan for managing the change process in NSW Health.

Chief Executive Officers in LHDs and SNs are responsible for ensuring that a local risk assessment and management plan has been developed and implemented that includes assigning long-term resources for deployment.

Drug and Therapeutic Committees (DTCs) in LHDs and SNs are responsible for:

- monitoring when product sponsors commence supply of products with name changes on product labels, implement stages of the risk assessment and management plans as it becomes relevant
- managing local documents and systems affected by the name changes including policies, clinical guidelines, procedures, pathways, patient leaflets, lists, equipment, lanyard cards and inventory management/procurement processes
- monitoring for signs of any potential patient safety risks associated with changes to medicine ingredient names of medicines used within their facility
- conducting an annual review of the risk assessment and management plan until the name change transition period is complete.

DTCs and Quality Committees, in conjunction with Chief Information Officers (CIO), are responsible for ensuring that locally managed IT systems are updated and local users are informed of these updates in a timely manner, which could be over several years.

Clinical groups and staff are responsible for informing patients about changes affecting their medicine at the time of supply.
## 1.6 Specific activities to manage changes

<table>
<thead>
<tr>
<th>Product lists</th>
<th>Co-ordination</th>
<th>Action</th>
<th>Responsible team/agency</th>
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</thead>
<tbody>
<tr>
<td>Hospital Pharmacy Product List (HPPL) for iPharmacy</td>
<td>Central</td>
<td>Provide name changes via routine bulk update process Test state-based iPharmacy dispensing labels</td>
<td>eHealth NSW HPPL team at Medications Support Service</td>
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<tr>
<td></td>
<td>Local</td>
<td>Test dispensing labels and reports in iPharmacy UAT environment Advise DTC when changes are scheduled to trigger local plan and change readiness</td>
<td>LHD/SN iPharmacy System Administrators</td>
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<tr>
<td></td>
<td>Local</td>
<td>For LHD/SNs not subscribing to HPPL: Update (and test) local iPharmacy product file</td>
<td>LHD/SN iPharmacy team</td>
</tr>
<tr>
<td>PharmNet Catalogue (PNC)</td>
<td>Central</td>
<td>Provide name changes for the standardised PharmNet Catalogue fields. Data to be made available via a Data Collection Worksheet (DCW)</td>
<td>eHealth NSW PNC team at Medications Support Service Note: Rural LHDs implementing Cerner Millennium will receive support from central eHealth NSW Medications Support team</td>
</tr>
<tr>
<td></td>
<td>Local</td>
<td>Update on each Cerner domain</td>
<td>LHD/SN Electronic Medicines Management Business as Usual teams</td>
</tr>
<tr>
<td>eviQ guidelines and procedures</td>
<td>Central</td>
<td>Identify and change affected antineoplastic medicine ingredient names Provide rationale for changes and publish on eviQ website</td>
<td>NSW Cancer Institute</td>
</tr>
<tr>
<td>Pharmaceutical contracts</td>
<td>Central</td>
<td>Update contracts with changed names Accept over label or packaging changes for contract items</td>
<td>HealthShare NSW, Business Procurement Services team</td>
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### Electronic prescribing and administration recording systems

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<th>System</th>
<th>Co-ordination</th>
<th>Action</th>
<th>Responsible team/agency</th>
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<tr>
<td>Cerner Millennium (PowerChart Order Catalogue, Medication Event Codes, PharmNet Inpatient Formulary)</td>
<td>Central</td>
<td>Provide editorial guidance where required to support name changes where there are system limitations Determine appropriate Event Codes</td>
<td>eMR Connect Program team</td>
</tr>
<tr>
<td></td>
<td>Local</td>
<td>Implement changes to PowerChart Implement changes to PharmNet Note: Changes are dependent on changes appearing in Multum</td>
<td>LHD Electronic Medicines Management Business as Usual teams Note: Rural LHDs implementing Cerner Millennium will receive support from central eHealth NSW Medications Support team</td>
</tr>
<tr>
<td>DXC MedChart®</td>
<td>Local</td>
<td>Identify and update changes to MedChart® Note: Changes are dependent on MIMS Knowledge Base, monthly drug updates and liaison with vendor</td>
<td>LHD/SN Electronic Medicines Management teams</td>
</tr>
<tr>
<td>Electronic Record for Intensive Care (eRIC)</td>
<td>Central</td>
<td>Provide name changes via routine change and release process</td>
<td>eHealth NSW eRIC Program team</td>
</tr>
<tr>
<td>Clinical or medication systems not centrally supported (e.g. oncology, haematology and endoscopy systems)</td>
<td>Local</td>
<td>As required Note: Vendors should be providing regular updates</td>
<td>LHD/SN DTCs and CIOs</td>
</tr>
<tr>
<td>Smart infusion pump dose-error reduction systems</td>
<td>Local</td>
<td>Ensure updates to software</td>
<td>LHD/SN DTCs</td>
</tr>
</tbody>
</table>

### Operational policies/protocols

<table>
<thead>
<tr>
<th>Document</th>
<th>Co-ordination</th>
<th>Action</th>
<th>Responsible team/agency</th>
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</thead>
<tbody>
<tr>
<td>NSW Health Policy Directives</td>
<td>Central</td>
<td>Identify and update affected PDs</td>
<td>Ministry of Health; CEC</td>
</tr>
<tr>
<td>CEC resources</td>
<td>Central</td>
<td>Identify and update affected resources</td>
<td>CEC</td>
</tr>
</tbody>
</table>

### Document | Co-ordination | Action | Responsible team/agency |
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</thead>
<tbody>
<tr>
<td>LHD/SN clinical policies, clinical guidelines, protocols, drug monographs, adverse drug reaction documentation</td>
<td>Local</td>
<td>Identify and update affected documents</td>
<td>LHD/SN DTCs and Quality Committees</td>
</tr>
</tbody>
</table>
Other operational materials:
- Imprest drug lists
- Shelf labels
- Drug formulary lists
- Medication lists for patients
- Ward/clinic medication pre-pack labels

Local
Identify and change affected medicine ingredient names
Note: For medications stored during the transition period, include old and new name on shelf labels. If a change in the storage sequence is required, implement strategies to ensure that medicines can be easily located

LHD/SN DTCs and Quality Committees

End-user readiness materials
Local
Provide easy access to the full list of changed medicine ingredient names
Educate clinician groups and staff affected by the name changes, including prescribers, pharmacists, nurses and staff working in nuclear medicine and diagnostic imaging
Inform patients at the time of medicine supply

LHD/SN DTCs and Quality Committees
Clinician groups and staff

1.7 Recommended strategies for implementing name changes in local clinical systems and databases

- Where feasible, make all the medicine name terminology changes in each clinical system at a single point in time. This approach simplifies education of clinician end users.
  Although name changes may occur in the clinical system, the product labels themselves may not be updated at the same time.

- Display medicine names in full with no abbreviation unless there are field length limitations within the system.

- For medicines that require dual labelling, the system should display the dual medicine name as outlined in the SUSMP, e.g. there is indefinite dual labelling for adrenaline and noradrenaline, and dual labelling required until 2023 for other dual-labelled medicines.

- For minor (spelling) changes, the new name should replace the old name, e.g. ‘meta-Cresol’ changes to ‘metacresol’, and ‘Bee’ changes to ‘honey bee’.

- For other significant changes the new name should replace the old name, e.g. ‘thyroxine sodium’ changes to ‘levothyroxine sodium’.

- For where an excipient ingredient name is shown, the new name should replace the old name.

- Inform clinicians and other staff of changes in advance of changes appearing in clinical systems and advise of any impacts. Notify again at the time the changes are implemented.

308(13/11/17)
SCHEDULE 8 CANNABIS MEDICINES AND UNREGISTERED SCHEDULE 8 MEDICINES  (IB2018_057)

PURPOSE

This Information Bulletin provides guidance on:

1. prescribing and dispensing registered and unregistered Schedule 8 cannabis medicines, and
2. prescribing and dispensing unregistered Schedule 8 medicines including compounded medicines, and
3. storage of refrigerated Schedule 8 and Schedule 4 Appendix D medicines in NSW public health facilities.

BACKGROUND INFORMATION

Definitions

For the purpose of this Information Bulletin:

Schedule 8 cannabis medicine means a therapeutic good containing cannabinoids found in the cannabis plant, prepared or packed for human therapeutic use, and included in Schedule 8 of the NSW Poisons List or Poisons Standard.

Cannabis medicines containing cannabidiol as at least 98% of the total cannabinoid content are Schedule 4 medicines, and are out of scope of this document.

Unregistered Schedule 8 medicine means an unregistered drug of addiction, or any therapeutic good that consists of a Schedule 8 substance and that is not registered on the Australian Register of Therapeutic Goods (ARTG), including both medicines registered in other countries and imported into Australia, and including compounded Schedule 8 medicines.

Compounded Schedule 8 medicine means any therapeutic good prepared in or for a hospital pharmacy that consists of a Schedule 8 substance, except:

a) a registered medicine reconstituted prior to dispensing;
b) a registered medicine prepared for administration in accordance with the approved Product Information; or
c) a registered medicine repacked without a change to the formulation (such as transferring the contents of an ampoule into a syringe).

Unregistered Medicines

Generally, medicines used in Australia must be registered on the Australian Register of Therapeutic Goods (ARTG), unless exempted from registration, or approved for supply as an unregistered good, by the Therapeutic Goods Administration (TGA). Unregistered medicines are not assessed for quality, safety or efficacy by the TGA.

To prescribe an unregistered medicine in Australia, the prescriber must obtain an approval to supply an unregistered good issued under the Commonwealth Therapeutic Goods Act 1989 by the TGA (Commonwealth Approval), under one of:

- Special Access Scheme, or
- Authorised Prescriber scheme, or
- Clinical Trial schemes.

Further, to prescribe an unregistered Schedule 8 medicine in NSW, the prescriber must hold an authority issued under the NSW Poisons and Therapeutic Goods Regulation 2008 by the Secretary, NSW Health (a NSW Health Authority).
Additionally, the use of any unregistered medicine (Schedule 8 or not) in a NSW public health facility must be approved by the Drug and Therapeutics Committee (DTC) of the hospital or Local Health District, whether the product is to be supplied by the hospital for individual patient use or as patient’s own stock, in accordance with PD2016_033 Approval Process of Medicines for Use in NSW Public Hospitals. A NSW Health Authority must be in place before the DTC can consider approval for the use of an unregistered Schedule 8 medicine in hospital.

**Cannabis Medicines**

Most cannabis medicines are unregistered, and the only cannabis medicine registered on the ARTG at the time of publication is *Sativex*® (nabiximols oromucosal spray).

Unregistered Schedule 8 cannabis medicines may be prescribed for human therapeutic use if the prescriber and product meet certain criteria. The cannabis must have been lawfully grown and manufactured in Australia or permitted to be imported by the Commonwealth, and must conform with the Commonwealth standard that specifies minimum quality requirements for medicinal cannabis products TGO 93 Standard for Medicinal Cannabis.

Administration and possession of a cannabis preparation which has not been lawfully prescribed or supplied remains an offence under the Drug Misuse and Trafficking Act 1985 (NSW).

Unlike registered medicines which typically have one or two active ingredients, the cannabis plant contains a complex of more than 400 compounds including flavonoids and terpenoids and approximately 70 cannabinoids other than tetrahydrocannabinol or cannabidiol. These cannabinoids have individual, interactive, and even entourage effects (effects of a compound that are only appreciable in the presence of other compounds) that are not fully understood and that contribute to the pharmacological effect of cannabis.

Although clinical trials and studies in animal models of some conditions have been conducted with individual cannabinoids (e.g. tetrahydrocannabinol or cannabidiol), as cannabis has so many constituents, the results of studies with individual cannabinoids cannot be extrapolated to cannabis plant material and plant extracts, and vice versa.⁴

Unlike registered medicines, the composition of unregistered cannabis preparations could vary substantially in content of tetrahydrocannabinol, cannabidiol or other cannabinoids.

Individual synthetically manufactured natural cannabinoids are approved medicines in the USA in the form of oral dronabinol and nabilone, but these are not registered medicines in Australia. Nabiximols is a complex of cannabinoids in a standard formulation approved in the UK and in Australia.

⁴ D'Souza DC, Ranganathan M. Medical marijuana, is the cart before the horse? JAMA 2015; Volume 313 (24); 2431-2

**PRESCRIBING AND DISPENSING SCHEDULE 8 CANNABIS MEDICINES**

Only a medical practitioner may be authorised to prescribe a registered or unregistered Schedule 8 cannabis medicine. Generally, to prescribe a Schedule 8 cannabis medicine a medical practitioner must obtain a NSW Health Authority. However there are exemptions in place for prescribing for a hospital inpatient. The requirement for a Commonwealth approval is not affected by these exemptions.

In an emergency, a medical practitioner may direct the administration of any Schedule 8 cannabis medicine to a hospital patient orally, by telephone, by e-mail or by facsimile. However, a medical practitioner may NOT direct the dispensing of an unregistered Schedule 8 cannabis medicine orally, by telephone, by e-mail or by facsimile.

308(10/12/18)
Initiating treatment

To initiate treatment with an unregistered Schedule 8 cannabis medicine for a hospital inpatient, a medical practitioner must obtain a NSW Health Authority prior to prescribing. Additionally, to prescribe an unregistered Schedule 8 cannabis medicine, a Commonwealth approval must also be obtained.

To initiate treatment with a registered Schedule 8 cannabis medicine for an inpatient, a medical practitioner must obtain a NSW Health Authority if the patient is to be treated with the medicine for more than 14 days as an inpatient. A Commonwealth approval is not required to prescribe a registered medicine. See TABLE 1.

A medical practitioner prescribing under a NSW Health Authority issued to him/her must endorse the prescription or the medication chart (or the electronic medication management system) with the reference number of the NSW Health Authority.

The Application Form for authority to prescribe is available on the NSW Health website.

Continuing treatment

Continuing treatment with a cannabis medicine which had been lawfully prescribed and dispensed before the patient’s admission to hospital, does not require a new NSW Health Authority, whether the cannabis medicine is registered or unregistered. In such circumstances, a medical practitioner in a hospital may prescribe, i.e. direct an order to administer the patient’s own medicine on a medication chart (or electronic medication management system), or issue a prescription for dispensing the medicine from the hospital pharmacy, without a NSW Health Authority. This exemption is in effect for the entire inpatient stay; there is no specific time limit.

If a medical practitioner prescribes an unregistered Schedule 8 cannabis medicine for dispensing in a hospital pharmacy, while the medical practitioner does not need to obtain a NSW Health Authority, he/she must obtain a Commonwealth Approval. See TABLE 1.

All requirements for writing Schedule 8 prescriptions apply – see in NSW Health PD2013_043 Medication Handling in NSW Public Health Facilities.

TABLE 1: NSW Health Authority and Commonwealth Approval requirements to prescribe and supply Schedule 8 cannabis medicines

<table>
<thead>
<tr>
<th></th>
<th>Initiating Prescribing &amp; Dispensing for Inpatient</th>
<th>Prescribing for Dispensing to Continue Treatment for Inpatient</th>
<th>Prescribing for Administration to Continue Treatment for Inpatient*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registered S8 Cannabis Medicine (Sativex)</strong></td>
<td>Obtain NSW Health Authority for more than 14 days of treatment</td>
<td>NSW Health Authority NOT required</td>
<td>NSW Health Authority NOT required</td>
</tr>
<tr>
<td></td>
<td>Commonwealth Approval NOT required</td>
<td>Commonwealth Approval NOT required</td>
<td>Commonwealth Approval NOT required</td>
</tr>
<tr>
<td><strong>Unregistered S8 Cannabis Medicine</strong></td>
<td>Obtain NSW Health Authority</td>
<td>NSW Health Authority NOT required</td>
<td>NSW Health Authority NOT required</td>
</tr>
<tr>
<td></td>
<td>Obtain Commonwealth Approval</td>
<td>Obtain Commonwealth Approval</td>
<td>NEW Commonwealth Approval NOT required (if existing approval is in place)</td>
</tr>
</tbody>
</table>

* for administration of patient’s own supply
Prescribing and dispensing for a clinical trial

The requirements for a NSW Health Authority and Commonwealth Approval to prescribe and dispense a registered or unregistered Schedule 8 cannabis medicine for a clinical trial are the same as for individual medical treatment. Similarly, only a medical practitioner can prescribe the cannabis medicine, and a prescription issued for dispensing must be endorsed with the NSW Health Authority reference number. Additionally, a record of this reference number must be made in the clinical trial records.

Any requirements or conditions of the Commonwealth Approval (CTN/CTX), Human Research Ethics Approval, or of the National Health and Medical Research Council (NHMRC) must be complied with.

Prescribing unregistered Schedule 8 cannabis medicines for children

Where the patient is a minor aged under 16 years or a person unable to give informed consent for use of an unregistered Schedule 8 medicine or Schedule 8 cannabis medicine, internal clinical governance advice should be sought. It is an offence under the *Children and Young Persons (Care and Protection) Act 1998* to administer a drug of addiction (Schedule 8 medicine) to a child for a period of more than 10 days in any 30 day period, unless appropriately authorised.

Hospital pharmacy dispensing of Schedule 8 cannabis medicines

A pharmacist may only dispense an unregistered Schedule 8 cannabis medicine on receipt of a prescription or a medication chart. Dispensing on an emergency telephone/email/fax order is not permitted.

When dispensing an unregistered Schedule 8 cannabis medicine initiated in hospital for an inpatient, the hospital prescriber must obtain a NSW Health Authority, and the authority number must be written on the prescription or the medication chart.

When dispensing a registered Schedule 8 cannabis medicine initiated in hospital for an inpatient, the hospital prescriber is not required to obtain a NSW Health Authority if treatment with the medicine is for a period not longer than 14 days. However, for more than 14 days treatment with the medicine, a NSW Health Authority is required, and the authority number issued must be written on the prescription or the medication chart. See TABLE 1.

All the usual requirements for a Schedule 8 medicine, such as adequate directions for use, handwritten quantity in words and figures and repeat intervals apply.

The supply of Schedule 8 medicines on discharge must accord with PD2011_015 *Care Coordination: Planning from Admission to Transfer of Care in NSW Public Hospitals*.

Schedule 8 cannabis medicines administration within a patient care area

In an emergency, a medical practitioner may direct the administration of any Schedule 8 cannabis medicine to a patient in the hospital, orally, by telephone, by electronic mail or by facsimile on a medication chart.

Where a pharmacist dispensed and labelled unregistered Schedule 8 cannabis medicine is brought into the hospital as patient’s own stock, having been commenced prior to hospital admission, hospitals must check that use of the product is appropriately authorised. Contact should be made with the pharmacy or prescriber named on the dispensing label in the first instance. A medical practitioner may direct an order for administration of the patient’s own stock of the Schedule 8 cannabis medicine to continue treatment on a medication chart (or electronic medication management system) without a NSW Authority (see TABLE 1).
Illegal cannabis plants and cannabis preparations

Some patients may be using illegal ‘black market’ cannabis preparations in expectation of symptom relief or hoping to modify the course of a disease. Possession of these prohibited drugs/plants is illegal under the Drug Misuse and Trafficking Act 1985 (NSW), even where patients are registered with the NSW Government Medical Cannabis Compassionate Use Scheme. See https://www.medicinalcannabis.nsw.gov.au/patient-access/medicinal-cannabis-compassionate-use-scheme

As such, NSW Health staff cannot store or administer these preparations in the hospital, nor administer them when providing care in the home setting. The preparations cannot be legally prescribed.

A history must be taken and disclosure of use encouraged. The risks of using these preparations of unknown composition and concentration of cannabinoids and other potentially dangerous substances, and the risk of drug interactions (some unpredictable or undocumented), must be discussed with the patient/carers.

It is recommended and good practice to document substance use in the patient’s clinical record. This should include information about advice given, any changes to therapy, and the decision of the patient. Ongoing open communication remains essential. Notwithstanding the above, patients should be made aware that continued use of any illegal cannabis preparation remains unlawful.

If a patient brings an illegal cannabis preparation onto hospital premises, the patient should be requested to have a carer remove the preparation from the hospital premises, or it should be dealt with as otherwise provided under a local protocol.

PREScribing AND dispensING AN UNREGISTERED SCHEDULE 8 MEDICINE (other than Cannabis medicines)

Only a medical practitioner may be authorised to prescribe an unregistered Schedule 8 medicine. Generally, to prescribe and dispense an unregistered Schedule 8 medicine a medical practitioner must obtain a NSW Health Authority and Commonwealth Approval, however there are exemptions in place for prescribing and dispensing for an inpatient in hospital.

A medical practitioner may NOT direct the supply/dispensing of an unregistered Schedule 8 medicine orally, by telephone, by electronic mail or by facsimile (as is allowed in an emergency for registered Schedule 8 medicines).

Initiating treatment

To initiate treatment of a hospital inpatient or outpatient with an unregistered Schedule 8 medicine, except a compounded Schedule 8 medicine, a medical practitioner must obtain a NSW Health Authority prior to prescribing.

Additionally, to prescribe an unregistered Schedule 8 medicine, a Commonwealth Approval must also be obtained, unless exempted from registration on the ARTG. See TABLE 2.

Exemptions from the requirement of a Commonwealth Approval include medicines compounded and dispensed in a hospital pharmacy, or for a hospital under a contract. The compounded medicines supplied under such a contract to treat patients of the hospital must be manufactured in Australia by a Commonwealth licensed manufacturer, to a specific hospital formulation where there are no listed or registered goods that are substantially similar to the medicine (see PD2015_007 Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services).
An Application Form for a NSW Health Authority is found on the NSW Health website.

A medical practitioner prescribing under a NSW Health Authority issued to him/her must write the authority number on the prescription or the medication chart.

**Continuing treatment**

Continuing treatment with an unregistered Schedule 8 medicine which had been lawfully prescribed and authorised before the patient’s admission to hospital does not require a new NSW Health Authority. In such circumstances, a medical practitioner in a hospital may write an order to administer the patient’s own supply on a medication chart (or eMeds system), or issue a prescription for dispensing the medicine from pharmacy, without a NSW Health Authority. This exemption is in effect for the entire inpatient stay; there is no specific time limit. See TABLE 2.

**TABLE 2: NSW Health Authority and Commonwealth Approval requirements to prescribe and supply unregistered Schedule 8 medicines (other than Cannabis medicines)**

<table>
<thead>
<tr>
<th>Medicine Type</th>
<th>Initiating Prescribing &amp; Dispensing</th>
<th>Prescribing for Dispensing to Continue Inpatient Treatment</th>
<th>Prescribing for Administration to Continue Inpatient Treatment*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unregistered S8 Medicine (other than a Compounded or Cannabis Medicine)</td>
<td>Obtain NSW Health Authority</td>
<td>NSW Health Authority NOT required</td>
<td>NSW Health Authority NOT required</td>
</tr>
<tr>
<td></td>
<td>Obtain Commonwealth Approval</td>
<td>Obtain Commonwealth Approval</td>
<td>NEW Commonwealth Approval NOT required (if existing approval is in place)</td>
</tr>
<tr>
<td>Compounded S8 Medicine (other than a Cannabis medicine)</td>
<td>NSW Health Authority NOT required</td>
<td>NSW Health Authority NOT required</td>
<td>NSW Health Authority NOT required</td>
</tr>
<tr>
<td></td>
<td>Commonwealth Approval NOT required if exempted</td>
<td>Commonwealth Approval NOT required if exempted</td>
<td>Commonwealth Approval NOT required if exempted</td>
</tr>
</tbody>
</table>

* for administration of patient’s own supply

**REFRIGERATED STORAGE OF SCHEDULE 8 AND SCHEDULE 4 APPENDIX D MEDICINES**

**Storage in hospital pharmacy**

Schedule 8 medicines stored in a hospital pharmacy must be kept in a safe (or vault) securely attached to the premises, and locked when not in immediate use - see Section 5.3.4 of NSW Health Policy Directive PD2013_043 *Medication Handling in NSW Public Health Facilities*, unless the medicine requires refrigeration.

If a Schedule 8 medicine requires refrigeration, it may be kept in a refrigerator, rather than a safe, that is in a room to which the public does not have access.

The refrigerator must be securely attached to the premises and locked when not in immediate use. Hospital engineering may be able to assist with fixing and fitting the refrigerator.

The usual requirements apply to access to a Schedule 8 medicine stored in a pharmacy, including:

- keeping the device (including a key) on the person of a pharmacist who is at the premises, or a separate safe that can be unlocked only by a pharmacist,
- disclosing a code or combination that is used to securely lock the refrigerator only to a pharmacist.
Unscheduled, Schedule 2, 3 or 4 therapeutic goods requiring refrigeration may be stored with Schedule 8 medicines, provided only a pharmacist has access to the refrigerator.

If other goods are required to be kept in the refrigerator, an exemption must be sought.

**Storage in a patient care area**

A **Schedule 8** medicine in a patient care area must be stored:

a) in a cabinet, safe or room; apart from all other medicines except other Schedule 8 and Schedule 4 Appendix D medicines; kept securely locked when not in immediate use; and to which the public does not have access, or

b) if requiring refrigeration, in a locked refrigerator securely attached to the ward, or in a refrigerator that is in a locked room; apart from all other medicines except other Schedule 8 and Schedule 4 Appendix D medicines; kept securely locked when not in immediate use; and to which the public does not have access.

If goods other than Schedule 4 Appendix D medicines are to be kept in the refrigerator, the Schedule 8 medicines must be kept separated from them, such as in a locked box attached to the refrigerator. Hospital engineering may be able to assist with fixing and fitting the refrigerator to the premises, or the locked box to the refrigerator.

The usual requirements apply to access to a Schedule 8 medicine stored in a patient care area, including:

- keeping the device (including a key) on the person of a nurse or midwife whenever it is in the ward, and is removed from the ward whenever there is no nurse or midwife in the ward, or in a separately locked safe to which only a nurse or midwife has access, and
- any code or combination that is required to unlock the locked cabinet, safe or room or refrigerator is not divulged to any unauthorised person.

An alternative to the usual Poisons and Therapeutic Goods Regulation 2008 requirements for **Schedule 4 Appendix D** medication storage in patient care areas (ward/clinic / unit) applies to the following medications:

- Darbepoetin
- Epoetins
- Erythropoietins
- Lorazepam injections.

The refrigerator containing these Schedule 4 Appendix D medications may be kept in a locked room containing any other medications. Access to this room must be restricted to staff authorised by the registered nurse / midwife in charge of the patient care area.

The medications must be accounted for under a local protocol approved by the Hospital / LHD Drug and Therapeutics Committee that ensures the detection and reporting of any loss or misappropriation.

Methods to mitigate and detect loss or misappropriation described in the protocol could include:

- Maintenance of a register to document the receipt, use and balance on hand of the medication
- Limit of supply to patient labelled medications (that is, no ward stock / imprest supply)
- Regular audit of iPharmacy dispensing reports of patient labelled supplies to the patient care area
- Regular audit and reconciliation of pharmacy inventory reports of imprest supplies to the patient care area against medication administration records.

308(10/12/18)
The requirement to report any loss or theft of an accountable medication (Schedule 4 Appendix D and Schedule 8 medications) remains (see section 6.16 of NSW Health Policy Directive PD2013_043 ‘Medication Handling in NSW Public Health Facilities’).

Alternatives to storage requirements under the Poisons and Therapeutic Goods Regulation 2008 may be granted for storage of other refrigerated accountable medications in hospital pharmacy or patient care areas on application to the NSW Ministry of Health.

Contact details for further information

Chief Pharmacist Unit, NSW Ministry of Health:
For enquiries on NSW Authority, or on prescribing, dispensing or storage of medicines
Email: MOH-PharmaceuticalServices@health.nsw.gov.au
Telephone: 02 9391 9944

NSW Cannabis Medicines Advisory Service:
Provides expert clinical guidance and support to NSW doctors and pharmacists
Email: HNELHD-CMAS@hnehealth.nsw.gov.au
Telephone: 02 4923 6200

Commonwealth Therapeutic Goods Administration:
For enquiries on Commonwealth Approval to access unregistered cannabis medicines
Website: https://www.tga.gov.au/access-medicinal-cannabis-products-1
Email: medicinal.cannabis@health.gov.au
Telephone: 02 6232 8866

Commonwealth Office of Drug Control:
For enquiries on the permission to import, cultivate, produce and manufacture cannabis
Website: https://www.odc.gov.au/medicinal-cannabis
Email: mcs@health.gov.au
Telephone: 02 6232 8433
OPIOID OVERDOSE RESPONSE AND TAKE HOME NALOXONE POLICY  
(PD2019_036)

PURPOSE
The Opioid Overdose Response and Take Home Naloxone (ORTHN) intervention is designed to increase access to naloxone for people who are likely to experience or witness an overdose, but who experience barriers (such as stigma, discrimination and economic disadvantage) to accessing naloxone over the counter or by prescription.

By addressing those barriers, the ORTHN intervention aims to prevent opioid overdose-related mortality and morbidity.

The ORTHN Policy and Procedures support NSW public health services and the Medically Supervised Injecting Centre (MSIC) to provide overdose response interventions, including the supply of naloxone, for clients at risk of experiencing or witnessing an opioid overdose.

A structured overdose response intervention can be delivered by an appropriately trained health worker (registered nurse, psychologist, social worker, counsellor, occupational therapist, alcohol and other drugs worker, health education officer, Aboriginal health worker, Aboriginal health practitioner, health service manager working in a Needle Syringe Program or the Connections Program, needle syringe program worker, needle syringe program coordinator, consumer worker, peer support worker, peer support coordinator, nurse practitioner with an addiction scope of practice, medical practitioner or pharmacist), employed in the MSIC or a public health facility in NSW. Where the legal instrument and Procedures are complied with, naloxone can be supplied to clients without a pharmacist or medical practitioner present.

This Policy Directive is relevant to the supply of naloxone to clients for later use. The Policy Directive does not apply to the supply of naloxone to clients in emergency department or inpatient settings. The Policy Directive does not apply to health workers directly administering naloxone to an overdosing client in a health service.

MANDATORY REQUIREMENTS
This Policy Directive (and associated Procedures) is for the management of clients by health workers of the MSIC and NSW public health services that target clients at risk of opioid overdose.

Eligible health workers at participating services must have successfully completed the ORTHN training and credentialing requirements set out in the ORTHN Procedures in order to supply naloxone using this model.

Credentialed health workers who are not otherwise authorised to supply Schedule 3 medications must comply with the Procedures when supplying naloxone.

Medical practitioners and nurse practitioners may follow these Procedures or may continue to follow existing models for prescribing and supply of scheduled medicines.

If pharmacists employed by Local Health Districts wish to supply naloxone, they must do so in compliance with these Procedures.

The Procedures provide the basis for Local Health District (LHD) Drug and Therapeutics Committees to adopt the ORTHN intervention. The MSIC must adopt and comply with the Procedures.

All facilities offering this intervention must implement appropriate governance structures, and identify and minimise the risks of adverse events as outlined under Implementation.

308(29/07/19)
20. PHARMACEUTICAL MATTERS

IMPLEMENTATION

Employees
- Only implement the ORTHN Procedures if appropriately trained and credentialed.
- Act in accordance with the Procedures.

Line Managers, Supervisors
- Ensure the ORTHN Procedures are followed by all relevant staff.
- Ensure only credentialed staff deliver the ORTHN intervention.

District/Service Managers, Directors
- Ensure governance structures are established and maintained.
- Nominated ‘Responsible Person’ performs key ORTHN implementation and compliance roles.
- Support employee implementation of the Procedures.
- Ensure compliance with the Procedures.

Medical and pharmacy employees
- Ensure support is provided to employees and ORTHN Procedures are followed.

NSW Ministry of Health
- Legally enable naloxone supply by credentialed health workers.
- Facilitate access to training and credentialing for public health services and the MSIC.

Opioid Overdose Response & Take Home Naloxone Policy: Procedures.

1 BACKGROUND

1.1 About this document
1.1.1 Purpose of the Procedures
These Procedures describe the conditions and process by which health workers can be trained, credentialed and authorised to supply take home naloxone medication as part of a structured overdose response intervention for the purpose of preventing opioid overdose-related mortality and morbidity. They also describe processes for governance, medication handling (including ordering, storing and supplying naloxone for take home use) and workforce credentialing by participating organisations.

These Procedures are relevant to the supply of naloxone to clients for later use. These Procedures do not apply to health workers directly administering naloxone and other emergency procedures in response to a suspected patient overdose in a health service setting.

1.1.2 Reducing opioid overdose mortality and morbidity
People who use illicit opioids have a mortality rate of 10-20 times greater than non-opioid users in the community. Pharmaceutical opioids also pose a considerable overdose risk, especially when used non-medically.

The National Drug Strategy 2017-2026 identifies increasing access to naloxone as an evidence-based strategy for preventing and responding to opioid overdoses.

The World Health Organization recommends that people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose.
1.1.3 Naloxone medication
Naloxone is a short-acting opioid antagonist registered in Australia for the reversal of opioid overdose. It is available in several formulations for injected (intravenous, intramuscular and subcutaneous) use, and for administration by intranasal spray. Naloxone is a relatively safe medication, with few precautions, contraindications or adverse events.

Naloxone is scheduled in Australia as a Schedule 3 medication – enabling over the counter supply by a pharmacist directly and with appropriate education to the customer. Some naloxone products are subsidised on the Pharmaceutical Benefit Scheme (PBS) if prescribed by a medical practitioner or nurse practitioner.

1.1.4 Making Take Home Naloxone accessible in NSW
Take Home Naloxone programs have been established in Australia and internationally to reduce mortality and morbidity for people who use opioids, are at risk of relapsing to opioid use or are likely to witness an opioid overdose. Take Home Naloxone programs provide overdose response interventions, including guidance for the supply of take home naloxone for administration by community members such as peers and carers in the event of an opioid overdose.

Uptake of Take Home Naloxone where supplied and subsidised via PBS prescription, or over the counter purchase in a community pharmacy, has been limited. Barriers include:

- over the counter cost is a barrier for highly disadvantaged groups;
- some people may be reluctant to ask a doctor or pharmacist about naloxone due to experiences of stigma relating to their or their family member’s opioid use; and/or
- people may prefer to undertake an education intervention with a service they already know and trust.

In NSW, South Eastern Sydney Local Health District (SESLHD) has been trialling innovative Take Home Naloxone delivery approaches since 2012, including procedures for the delivery of brief interventions for overdose prevention and supply of Take Home Naloxone to clients by a doctor on prescription or over the counter by a pharmacist.

In 2017 and 2018 an Overdose Response Take Home Naloxone (ORTHN) trial developed, piloted and evaluated an intervention delivered by trained and credentialed health workers in participating drug and alcohol and NSP services. Naloxone injection was supplied by credentialed workers directly to clients and training for its use, free of charge and without a medical practitioner or pharmacist involved in the intervention. The protocols piloted and evaluated by SESLHD and partner services (including the NSW Users and AIDS Association) under research trial conditions form the basis of these Procedures.

1.2 Health worker delivered ORTHN intervention
A legal instrument associated with these Procedures authorises appropriately trained and credentialed health workers to supply naloxone medication for the purpose of preventing opioid overdose-related mortality and morbidity.

The Procedures outline a structured opioid overdose response intervention. The Procedures must be complied with if naloxone is to be supplied by health workers not otherwise authorised to supply Schedule 3 medications (refer to definition of ‘Credentialled health worker’ below for the full list of worker designations that can supply naloxone under these Procedures).

If pharmacists employed in Local Health Districts wish to supply naloxone, they must undertake ORTHN training and credentialing and comply with these Procedures.

5 Lintzeris, Monds, Bravo et.al. (2019).
Nurse practitioners employed in the MSIC or public health services wishing to supply naloxone using the ORTHN intervention must undertake ORTHN training and credentialing. Medical practitioners may be guided by this client intervention but are exempted from the training and credentialing requirements. If medical practitioners and nurse practitioners seek to deliver overdose responses outside of these ORTHN Procedures, existing models for prescribing/supply of scheduled medicines are to be followed.

To be credentialed to deliver the ORTHN intervention, health workers must fulfill the requirements of the ORTHN Training and Credentialing Framework, including satisfactory completion of the ORTHN Health Worker Training Program, and competency assessment (See Section 4).

The ORTHN intervention defines the components of safe and quality care, and outlines education and credentialing so that an episode of care may be delivered entirely by a credentialed health worker in public health facilities and the Medically Supervised Injecting Centre (MSIC) in NSW, within a robust clinical framework.

Key features of ORTHN intervention include:

- Identification and assessment of the client against clear eligibility criteria.
- If client inclusion criteria are not met or there are concerns regarding the suitability of an individual client for Take Home Naloxone supply under the Procedures (e.g. due to client literacy, cognition or severe intoxication) the worker is required to revert to “usual care”, which may include providing urgent care, or referring the client to an appropriate service for further assessment and intervention.
- If the client’s care can be provided through the ORTHN intervention, the worker manages the episode of care using specified:
  - ORTHN Procedures, including documentation using the ORTHN Checklist and Record of Supply form (Appendix A); and
  - Consumer Information Sheets (Appendices C1 and C2).

### 1.3 Key definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client</strong></td>
<td>A person being considered for the ORTHN intervention. The person may be at risk of opioid overdose, or they may be a family member, carer or significant other who is likely to witness an opioid overdose.</td>
</tr>
<tr>
<td><strong>Credentialed health worker</strong></td>
<td>A health worker (registered nurse, psychologist, social worker, counsellor, occupational therapist, alcohol and other drugs worker, health education officer, Aboriginal health worker, Aboriginal health practitioner, health service manager working in a Needle Syringe Program or the Connections Program, needle syringe program worker, needle syringe program coordinator, consumer worker, peer support worker, peer support coordinator, nurse practitioner with an addiction scope of practice, medical practitioner or pharmacist) employed in a public health facility or the MSIC in NSW, who has satisfactorily completed the ORTHN Health Worker Training Program and been assessed as meeting the credentialing criteria as identified in the ORTHN Training and Credentialing Framework. Nurse practitioners wishing to supply naloxone outside of existing models for prescribing/supply of scheduled medicines must undertake ORTHN training and credentialing. Medical Practitioners are exempted from training and credentialing requirements.</td>
</tr>
<tr>
<td><strong>PHARMACEUTICAL MATTERS</strong></td>
<td>20.171</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>The definition of a Credentialed Health Worker includes health workers at SESLHD, SLHD, HNELHD, MLHD, WSLHD, St Vincent’s Health Network and the MSIC who successfully completed ORTHN training and credentialing as part of the ORTHN trial project that ran from 2016 to 2018.</td>
<td></td>
</tr>
<tr>
<td><strong>Overdose response and take home naloxone (ORTHN) intervention</strong></td>
<td>An intervention (that includes identification and assessment, client education and the supply of naloxone (as pre-filled syringes or intranasal preparations) that aims to prevent and respond to opioid-related overdoses.</td>
</tr>
<tr>
<td><strong>Opioid Overdose Response and Take Home Naloxone (ORTHN) Procedures</strong></td>
<td>These Procedures describe the delivery of overdose response interventions by credentialed health workers, including the identification and assessment of clients, the provision of client education, supply of Take Home Naloxone (as pre-filled syringes or intranasal preparations) to clients and relevant documentation.</td>
</tr>
</tbody>
</table>
| **Responsible Person** | A key role within an organisational governance framework responsible for ensuring that the participating site or service meets the requirements of the ORTHN Training and Credentialing Framework, and that medication is handled appropriately. Medication handling encompasses purchasing, storage, stock control, compliance with regulatory requirements and record-keeping.  

**In NSW Health services:**

The Responsible Person is usually a senior nurse or manager in a participating site or service.  

**In the MSIC:**

The Responsible Person is the manager/director responsible for ORTHN at the MSIC. |
| **Supply** | In the ORTHN intervention, ‘supply’ relates to provision of naloxone for clients to use at a later time.  

To provide to, or for a specific client, consistent with the definition of supply in Section 4 of the *Poisons and Therapeutic Goods Act 1966*. This includes medication selection, labelling, handover to client /carer, verbal counselling and provision of information sheets and/or Consumer Medicines Information.  

These Procedures do not refer to the ‘on-site’ administration of naloxone by health workers. |
2 PROCEDURES

2.1 What to do

The Procedures outline the delivery of the ORTHN Intervention by a credentialed health worker in an individual (one to one) clinical session. The ORTHN intervention takes approximately 10-20 minutes to deliver (subject to the setting, client and credentialed health worker characteristics), and has five core elements – client identification and assessment, client education, client consent, supply of ‘take home’ naloxone and documentation.

i. Client identification and assessment: Clients must be assessed for contraindications and eligibility for the intervention by the credentialed health worker. Specific eligibility criteria are described in Section 2.2.

ii. Client education: Client education is a mandatory component of the intervention, delivered by credentialed health worker, and is described in Section 2.3.

iii. Client Consent: Written consent by the client that they understand the risk factors for opioid overdose, how to identify an opioid overdose, and what to do in the event of a suspected opioid overdose, including the use of naloxone pre-filled syringe or nasal spray; and have been supplied with naloxone and relevant Consumer Information Sheet. Client consent is documented on the ORTHN Checklist and Record of Supply (Appendix A).

iv. Supply of ‘take home’ naloxone: Naloxone (as pre-filled syringes or intranasal preparations only) is supplied under the conditions of the ORTHN Procedures, and requires appropriate medication labelling.

v. Documentation: Credentialed health workers must complete documentation regarding the intervention. The ORTHN Checklist and Record of Supply includes the necessary documentation, written client consent and record of supply.

2.2 When to use ORTHN intervention

Clients attending participating services may be eligible for ORTHN intervention, and should be assessed by the credentialed health worker to confirm that the client meets eligibility criteria.

Client eligibility criteria for the intervention are:

- Clients at risk of opioid overdose as evidenced by current or recent (including prescribed) opioid use, or at risk of relapse to opioid use following a period of abstinence (e.g. withdrawal episode, rehabilitation program, hospital admission, incarceration); and/or

- Potential witnesses to an opioid overdose (for example family, friend or carer of someone at risk of opioid overdose); and

- Aged 16 years and over; and

- Able to give informed consent (i.e. not affected by severe intoxication, severe cognitive impairment, or severe active psychological or physical medical condition that impairs informed consent).

Contraindications for naloxone (hypersensitivity to naloxone) and precautions (pregnancy and breastfeeding) must also be assessed before determining client suitability for the ORTHN intervention.

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6 Hypersensitivity to naloxone is characterised as an anaphylactic reaction to naloxone and is extremely rare. Many people who use opioids may experience a withdrawal-like reaction following use of naloxone, but this is not hypersensitivity.
If eligibility criteria are not met or there are concerns regarding whether the ORTHN intervention is appropriate for an individual client (e.g. due to hypersensitivity to naloxone), it is recommended that the credentialed health worker seek additional assistance or advice (e.g. discuss with a colleague or supervisor who is experienced in delivering the ORTHN intervention), and document on the ORTHN Checklist and Record of Supply form. If the client is deemed to be not suitable for the ORTHN intervention, the credentialed health worker is required to revert to “usual care”, which may include referring the client to an appropriate worker (e.g. medical officer) or service for further assessment and intervention.

In treatment settings, ORTHN interventions should be considered as part of the care planning process, and included in the Global Care Plan or treatment plan. In non-treatment settings (e.g. NSP or the MSIC), ORTHN interventions may serve to increase interest in engaging in treatment, and appropriate referrals should be made in accordance with local practice.

2.3 How to deliver the ORTHN intervention

The key steps for the ORTHN intervention are summarised in the ORTHN Checklist and Record of Supply form, to be completed when each ORTHN intervention is delivered, for each client.

2.3.1 Introduce the intervention

The health worker providing the ORTHN intervention should describe the purpose of the intervention (‘to help people respond to suspected overdoses and prevent overdose death or harm’), that it usually takes between 10 and 20 minutes to complete, and involves the supply of ‘take home naloxone’ medication.

2.3.2 Assess what the client already knows

A key principle of brief interventions is to assess the person’s existing knowledge and attitudes, which allows more efficient tailoring of the educational intervention. To assess existing knowledge and attitudes use:

- an unstructured assessment (e.g. discussion using the ORTHN Consumer Information Sheet (Appendix C1 or C2) as a prompt); or
- a structured assessment (e.g. ORTHN Client Questionnaire Full (CQ-F) or Brief (CQ-B) (Appendix B1 or B2).

The CQ examines client understanding of high risk situations for opioid overdose, how to recognise an opioid overdose and what to do in response to a suspected opioid overdose. The CQ-F has approximately 20 questions, takes 5-10 minutes to complete, and is suited to longer interventions (e.g. 15-20 minutes). The CQ-B focusses on essential knowledge, can be completed in 2-3 minutes and is better suited to shorter interventions (e.g. less than 15 minutes).

Clients with literacy or cognitive challenges may need assistance in completing the questionnaire, or may be better suited to an unstructured assessment.

Note that it is not essential to retain a copy of the client’s ORTHN Client Questionnaire responses in clinical documentation.

2.3.3 Provide feedback, information and resources to client

Provide feedback
Examine client’s responses in the ORTHN Client Questionnaire, or to their understanding of overdose from the unstructured assessment. Provide positive feedback to correct responses, and address any incorrect responses with client. It is recommended that the Consumer Information Sheet (Appendix C1 or C2) be used when providing feedback.
Reinforce information on key messages regarding overdose prevention and response
Use the Consumer Information Sheet “Responding to an opioid overdose” (Appendix C1 or C2) to discuss the key education messages with the client, specifically:

- Identifying high risk situations for opioid overdose;
- How to recognise an opioid overdose; and
- What to do in response to a suspected overdose. These steps are highlighted in the Table 1 below.

Discuss with client the resources provided
Discuss the ORTHN Consumer Information Sheet and naloxone medication supplied. This may include information on how to assemble and use the naloxone pre-filled syringe and how to administer an intramuscular injection; or how to administer intranasal naloxone.

Discuss precautions for naloxone use with the client and check they understand them.

Illustrate using demonstration pack and/or instructional tools.

Table 1: Responding to a suspected opioid overdose: key messages to reinforce when providing the intervention to clients
(Note: these steps are specific to the ORTHN intervention. They differ from standard first aid procedures followed by people trained in CPR for other contexts such as a cardiovascular emergency)

<table>
<thead>
<tr>
<th>1. Danger</th>
<th>Check the environment that you and others are not in danger. Call for help from others if you are alone.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Call an ambulance</td>
<td>Dial 000 and follow the operator’s instructions. Tell them that you think this may be an overdose, and that you have access to naloxone.</td>
</tr>
</tbody>
</table>
| 4. Administer naloxone          | **Naloxone pre-filled injection (Prenoxad)**  
  
  Lie the person on their side in the recovery position. Assemble Prenoxad® pre-filled needle and syringe. Insert the needle into the person’s outer thigh or upper arm, through clothing if necessary, and inject the first dose (0.4ml), to the first black line. Withdraw the needle and syringe after the dose. Note the time given.  
  
  **Naloxone intranasal spray (Nyxoid)**  
  
  Lie the person on their back and check the nose is clear. Hold Nyxoid® device with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. Do not prime or test the device before you give the dose. Insert nozzle in one nostril. Press firmly on the plunger until it clicks to give the dose. |
| 5. Clear airways and perform rescue breathing if you know how | Lie person on their back, tilt head back, open mouth, and clear any obstruction. Exhale two times into the person’s mouth. |
6. **Put person in the recovery position & wait for ambulance to arrive.**

   If no improvement after 2 to 3 minutes: repeat naloxone dose/s.

   After further doses, perform rescue breathing if you know how, or else put person in recovery position and wait for ambulance to arrive.

   **Naloxone pre-filled injection**

   Give further intramuscular injections of 0.4ml Prenoxad Injection (to next black line) into the outer thigh or upper arm muscle every 2 to 3 minutes until the ambulance arrives or the person regains consciousness.

   **Naloxone intranasal spray**

   Give the second dose of Nyxoid, using the second Nyxoid device. Insert nozzle into the other nostril. Press firmly on the plunger until it clicks to give the second dose. Further doses may be given every 2 to 3 minutes if needed until ambulance arrives.

---

2.3.4 **Assess client competence with intervention**

The credentialed health worker delivering the intervention should be confident that the client understands the key aspects of an effective overdose response, and the rationale and instructions for naloxone use. The credentialed health worker is to complete the relevant section in the ORTHN Checklist and Record of Supply to indicate client competence.

2.3.5 **Seek client informed consent**

The client is asked to provide written informed consent on the ORTHN Checklist and Record of Supply form, documenting that they consent to receiving the intervention, and they understand when and how to use the naloxone product that they have been supplied with.

2.3.6 **Supply labelled naloxone and provide Consumer Information Sheet**

**ORTHN Checklist and Record of Supply**

Finalise and sign the ORTHN Checklist and Record of Supply, documenting the number and type of naloxone packs provided.

**Access stock and record stock movements**

Access naloxone stock (as pre-filled syringes or intranasal preparations only), and complete necessary record of supply. Each facility will maintain a record of naloxone supply, documenting each time medication is moved in or out of stock, with the credentialed health worker recording their name and date of supply and remaining stock balance.

LHD service credentialed health workers will access imprest stock.

**Packaging**

Naloxone must be supplied to the client in the manufacturer’s original packaging.

**Labelling**

Naloxone must be supplied with a completed dispensing label (Appendix D).

**Consumer Information Sheet**

When naloxone is supplied to the client, it should be provided with the Consumer Information Sheet for that product (Appendix C1 or Appendix C2).
2.3.7 Document the ORTHN Intervention

**If client has a medical record**
Where the client has a medical record (paper or electronic), the completed paperwork (ORTHN Checklist and Record of Supply) is to be filed (e.g. Medication Section of Client Medical Record), and an entry is to be made by the credentialed health worker into the client’s Clinical Notes regarding ORTHN intervention.

**If client does not have a medical record**
Where the client does not have a medical record – such as at a Needle Syringe Program or outreach setting, or if the client is a carer or family member likely to witness an overdose – the completed ORTHN Checklist and Record of Supply form should be filed in an ORTHN Intervention Folder, specific for each site, and retained in accordance with the relevant legislation or authority. The Responsible Person at the health facility must ensure these records are kept and audited.

**Naloxone record of stock**
The credentialed health worker should follow usual practice to record stock movements.

In services that do not supply other medicines, the worker should ensure completion of Naloxone stock control sheet (Appendix E).

2.4 Renewing clients’ naloxone supply
Naloxone medications have a limited shelf life, and if possible, attempts should be made to contact clients when their naloxone medication supply is approaching the expiry date and offer to renew their supply. The credentialed health worker should provide a ‘refresher’ repeat of the ORTHN intervention using this procedure when renewing naloxone supplies.

All the procedures described here are summarised in a Quick Guide to Delivering ORTHN Interventions for Credentialed Health Workers (Appendix F).

3 REGULATION AND GOVERNANCE FOR ORTHN

3.1 Legal and legislative framework
Under Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008 the Secretary of Health has authorised (for the purposes of the Act) credentialed health workers employed in a public health facility or the MSIC in NSW to supply Schedule 3 medications under clause 17 of the Regulation. The authorisation applies only to naloxone supplied under the intervention described in these Procedures.

3.2 Implementation pre-requisites
Key pre-requisites for the implementation of the ORTHN Procedures include:

**Governance**
- Each site is required to establish a local governance structure, and express support of care delegation and in delivering the ORTHN Intervention.
- In public health services, review and endorsement by the relevant Drug and Therapeutics Committee is required. Following endorsement, a senior nurse, pharmacist, medical practitioner or manager is required to perform key duties of the Responsible Person as described in Key Definitions of this document
- In the MSIC, review and local endorsement of these ORTHN Procedures is required.
ORTHN Health Worker Training Program and credentialing

- **Health worker training in the ORTHN Procedures**: Training will be delivered as a Ministry of Health-approved structured ORTHN Health Worker Training Program.

- **Credentialing of health workers**: Upon completion of training, each health worker will complete a post-training assessment of their knowledge, skills and competencies regarding the delivery of the ORTHN intervention. Successful completion of the assessment will result in credentialing of the health worker to supply naloxone within the ORTHN policy directive and these procedures. The Responsible Person in the service will ensure records of health workers who have successfully completed the health worker training and credentialing, are maintained and stored in an accessible location, and are able to be provided to NSW Health authorities on request.

3.3 Implementation of ORTHN Procedures

In implementing these Procedures, district/service managers and directors, and the designated Responsible Person, must ensure that:

- **A health worker operating under these Procedures is aware of their responsibility to**:
  Comply with the requirements of the ORTHN Procedures and ORTHN Training and Credentialing Framework as outlined in section 2.3 How to deliver the ORTHN intervention and 2.4 Renewing Clients’ Naloxone Supply.

- **Naloxone is supplied by the Pharmacy Department** to the service in accordance with PD2013_043 Medication Handling in NSW Public Health Facilities. LHD Pharmacies will provide naloxone to these services using imprest stock procedures. The Registered Nurse or Manager in charge of the unit is responsible for procurement & storage of imprest stock medications. Responsibility can be delegated to an appropriately authorised person where no Registered Nurse is employed in the service – such as may occur with an LHD-employed NSP manager under an HSM award (S 6.1, PD PD2013_043). In the MSIC, naloxone is supplied by the Pharmacy Department of a public hospital.

Nyxoid® is approved by the Therapeutic Goods Administration.

Prenoxad® solution for injection in a pre-filled syringe can be legally supplied in Australia. This product is not registered in Australia. It is supplied under section 19A of the *Therapeutic Goods Act 1989* to help address a shortage of registered naloxone pre-filled syringe products ([https://www.tga.gov.au/ws-s19a-index](https://www.tga.gov.au/ws-s19a-index)). Because of its section 19A status, Prenoxad® is labelled differently to medicines that are approved by the Therapeutic Goods Administration. Prenoxad® is also not listed by MIMS Australia as a result.

- **Naloxone storage and labelling meets requirements**: Naloxone is stored in locked cupboards with restricted access by credentialed health workers and the Responsible Person only. The manufacturer’s original packaging is used. Additional labelling requirements are described further in Section 2.3.6 of this document.

- **Relevant information is supplied**: including the ORTHN Consumer Information Sheet appropriate to the supplied naloxone product.

- **All records relating to the supply of medication are retained** in accordance with the relevant legislation or authority:
  - MSIC: *Health Records and Information Privacy Act 2002*. 

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4 TRAINING AND CREDENTIALING HEALTH WORKERS FOR ORTHN

4.1 Purpose of the ORTHN Training & Credentialing Framework

The ORTHN Training & Credentialing Framework (Appendix G) identifies the necessary prerequisites, training, competencies and assessment criteria required for a health worker to become credentialed to provide ORTHN interventions and supply naloxone under these Procedures. The Framework ensures that health workers have the appropriate knowledge, skills and competencies to deliver ORTHN interventions correctly.

Training will be delivered as a Ministry of Health-approved structured ORTHN Health Worker Training Program.

4.2 Who the training is for

Health workers who may be eligible to be credentialed include registered nurses, psychologists, social workers, counsellors, occupational therapists, alcohol and other drugs workers, health education officers, Aboriginal health workers, Aboriginal health practitioners, health service managers working in a needle syringe program or the Connections Program, needle syringe program workers, needle syringe program coordinators, consumer workers, peer support workers, peer support coordinators, nurse practitioners with an addiction scope of practice, medical practitioners and pharmacists employed in public health facilities or the MSIC in NSW.

Pharmacists and nurse practitioners employed in the MSIC or in public health services wishing to supply naloxone using the ORTHN intervention must undertake ORTHN training and credentialing. Medical practitioners are exempted from these training and credentialing requirements.

Nurse practitioners and medical practitioners may instead utilise existing models for prescribing/supply of scheduled medicines.

4.3 Core components of the training program

The core components of the training program include:

- Overview of overdose in opioid drug users: epidemiology, risk factors, overview of interventions aimed at reducing overdose;
- Overview of naloxone, including pharmacology, formulations;
- Overview of medication handling requirements and documentation;
- Outline of medico-legal requirements for delivering ORTHN interventions;
- Training on delivering brief interventions targeting overdose prevention and response including naloxone provision. This includes training on assessing client eligibility, contraindications and existing knowledge and attitudes; providing feedback, information and resources for responding to a suspected overdose; assessing client competence and seeking their consent; how to administer naloxone products; and the supply, labelling and documentation of naloxone medication;
- Overview of available resources for clients (client questionnaires, ORTHN Consumer Information Sheets) and workers (ORTHN Checklist and Record of Supply, Quick Guide to delivering ORTHN interventions); and
- ‘Troubleshooting’: responding to issues that arise.
4.4 Pre-requisites and assessment

The necessary pre-requisites, methods of assessment and competencies for a health worker to be credentialed to deliver the ORTHN intervention are shown in Table 2.

Table 2: Pre-requisites and assessment criteria for credentialing

<table>
<thead>
<tr>
<th>Pre-requisites</th>
<th>How assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Employed as a health worker in a participating alcohol and other drugs, NSP, community health or Justice Health &amp; Forensic Mental Health Network service</td>
<td>Employment within service in relevant role (role designation appears in the definition of ‘credentialed health worker’ in Key Definitions.</td>
</tr>
<tr>
<td>2. Experience providing health interventions with people who use opioids – including delivery of brief counselling and psycho-educational interventions</td>
<td>&gt;3 months experience in position providing such interventions (e.g. D&amp;A, NSP)</td>
</tr>
<tr>
<td>3. Current Certificate in basic life support/CPR</td>
<td>Evidence of satisfactory completion of an accredited basic life support/CPR course (e.g. Certificate in Basic Life Support (HETI Code 40101256) or Provide cardiopulmonary resuscitation (Australian course code HLTAID001).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assessment criteria</th>
<th>How assessed</th>
</tr>
</thead>
</table>
| 4. Appropriate knowledge, skills and competencies required to deliver ORTHN | a. Assessment of knowledge post-training workshop via multiple choice questionnaire  
|                     | b. Observation by training provider of delivery of ORTHN intervention (role play or direct client care) |
| 5. Agree to comply with ORTHN procedures                                      | Health worker signs that they understand and agree to comply with ORTHN procedures. |

4.5 Credentialing

Upon completion of training, each health worker will complete a post-training assessment of their knowledge, skills and competencies regarding the delivery of the ORTHN intervention. Successful completion of the assessment will result in credentialing of the health worker to supply naloxone within the ORTHN intervention and associated procedures. The Responsible Person in the service will ensure records of health workers who have successfully completed the ORTHN Health Worker Training Program and been credentialed are maintained and stored in an accessible location. In public health services, the competency advice should be stored alongside other qualifications the employee may hold. In the MSIC, the Responsible Person maintains records of training and credentialing of workers. Organisations must be able to provide evidence of workers’ credentialing if requested by NSW Health.
5 DOCUMENTATION
Relevant documents required for the implementation of this Procedure are included in the Appendices:

Appendix A       ORTHN Checklist and Record of Supply
Appendix B1      ORTHN Client Questionnaire Full (CQ-F)
Appendix B2      ORTHN Client Questionnaire Brief (CQ-B)
Appendix C1      Consumer Information Sheet: Responding to an opioid overdose – Prenoxad
Appendix C2      Consumer Information Sheet: Responding to an opioid overdose – Nyxoid
Appendix D       Sample pharmacy dispensing label
Appendix E       Sample drug stock control sheet / imprest
Appendix F       Quick Guide to delivering ORTHN interventions for credentialed workers
Appendix G       Training and Credentialing Framework for the NSW Implementation of Overdose response and Take Home Naloxone (ORTHN)

6 AUDIT
A self-audit of implementation of this Procedure will be conducted at each participating site within 12 months of implementation, and overseen by the Responsible Person.

7 REFERENCES


### APPENDIX A: ORTHN Checklist and Record of Supply

<table>
<thead>
<tr>
<th>Date</th>
<th>Index case ID (or MRN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Surname:</td>
<td>First Name:</td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

#### Health worker checklist

- **Confirm eligibility**
  - At risk of experiencing or witnessing opioid overdose
  - Aged 16 or over
  - Able to give informed consent (i.e. not affected by severe intoxication, severe cognitive impairment, or severe active psychological or physical medical condition that impairs informed consent)

*If eligibility criteria are not met, ORTHN intervention cannot be provided. Revert to usual care.*

#### Discuss contraindications and precautions

- **Contraindication:** Allergy/hypersensitivity to naloxone
- **Precautions:** Pregnant or breastfeeding

*If issues with contraindications or precautions are identified, describe issues and actions taken:*

| ……………………………………………………………………………………………………………… |

#### Intervention

- Purpose of naloxone and possible adverse events explained
- Education provided
- Consumer Information Sheet provided
- Client has demonstrated an understanding of:
  - The risks for opioid overdose
  - The signs of opioid overdose
  - Actions in the event of an overdose: (i) assess environment: ‘danger’; (ii) check for response; (iii) call ambulance; (vi) administer naloxone; (v) clear airways and perform rescue breathing; (vi) recovery position and stay with person until ambulance arrives; use more naloxone if no response.
  - What naloxone is, how and when to use it, including time to onset and duration of effects

*Assess risks and if concerned seek assistance from colleague. If the client considered not suitable for the ORTHN Intervention, revert to “usual care” and refer to an appropriate worker (e.g. medical officer) or service for further assessment and intervention.*

| ……………………………………………………………………………………………………………… |

#### Client checklist

- I agree to receive this intervention. I understand the risks of overdose, how to identify an overdose, and what to do in the event of an overdose, including the use of naloxone. I have been provided with Consumer Information Sheet and take home naloxone medication.

| ……………………………………………………………………………………………………………… |

| Client signature | Date: |
20. PHARMACEUTICAL MATTERS

<table>
<thead>
<tr>
<th>Medication (tick):</th>
<th>Dosage and Route:</th>
<th>Amount supplied:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenoxad pre-filled injection</td>
<td>Give 0.4ml of Prenoxad Injection (to first black line) into the outer thigh or upper arm muscle. If the person does not respond, repeat dose (to next black line) every 2 to 3 minutes as required.</td>
<td></td>
</tr>
<tr>
<td>Nyloid intranasal (2 devices in a pack, each containing 1 dose)</td>
<td>Insert Nyloid® device nozzle in nostril. Press firmly on the plunger until it clicks to give the dose. If the person does not respond after 2 to 3 minutes, give the second dose of Nyloid, using the second Nyloid device, in the other nostril.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health worker name:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

APPENDIX B1: ORTHN Client Questionnaire – Full (CQ-F)

1. Which of the following increase the risk of an opioid overdose? (tick all that apply)

| Using too much heroin or other opioids such as oxycodone, morphine, methadone, fentanyl | Change in tolerance (e.g. after prison/detox’)
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Using opioids alongside other substances</td>
<td>Using opioids on your own</td>
</tr>
<tr>
<td>Change in opioid drug purity (e.g. change in supply of heroin)</td>
<td>Switching from smoking/oral use to injecting</td>
</tr>
</tbody>
</table>

2. What are the signs of an opioid overdose (tick all that apply)

<table>
<thead>
<tr>
<th>Blood-shot eyes</th>
<th>Loss of consciousness / Can’t be roused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow/shallow breathing</td>
<td>Deep snoring</td>
</tr>
<tr>
<td>Turning blue</td>
<td>Pinned pupils</td>
</tr>
</tbody>
</table>

3. What should you do if you think a person may have overdosed on opioids (tick one per statement)

<table>
<thead>
<tr>
<th>Assess the surrounding area for danger</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check for a response</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call an ambulance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stay with the person until an ambulance arrives</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk the person around the room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inject saline (salt) solution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Give stimulants (e.g. black coffee etc.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shake the person</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shock the person with cold water</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Perform rescue breathing</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Place the person in the recovery position</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Cardiac compression</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Give naloxone</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Put the person in bed to sleep it off</td>
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</tbody>
</table>

4. Prior experience with naloxone
   a. Have you heard of naloxone before?
      ☐ YES ☐ NO ☐ UNSURE
   b. Have you ever used naloxone on someone else?
      ☐ YES ☐ NO ☐ UNSURE
   c. Have you ever had naloxone used on yourself?
      ☐ YES ☐ NO ☐ UNSURE
   d. Have you ever been trained to use take home naloxone before?
      ☐ YES ☐ NO ☐ UNSURE

5. What is naloxone used for? (tick all that apply)
   ☐ Reversal of any drug overdose
   ☐ Reversal of benzodiazepines overdose
   ☐ Reversal of opioid overdose (including heroin, methadone, oxycodone)
   ☐ Reversal of stimulant overdose (cocaine or methamphetamine)
   ☐ Reversal of alcohol overdose
   ☐ Don’t know

6. How long does naloxone take to start reversing an opioid overdose? (tick correct answer)
   ☐ 2-5 minutes
   ☐ 5-10 minutes
   ☐ 10-20 minutes
   ☐ 20-40 minutes
   ☐ Don’t know

7. How confident do you feel at using naloxone in the event of an overdose?
   | Very confident | Confident | Unsure | Not confident | Not at all confident |
   | ☐ | ☐ | ☐ | ☐ | ☐ |

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE
APPENDIX B2: ORTHN Client Questionnaire – Brief (CQ-B)

1. Which of the following increase the risk of an opioid overdose? (tick all that apply)
   - Using too much opioids such as heroin, oxycodone, morphine, methadone, fentanyl
   - Change in tolerance (e.g. after prison, detox)
   - Using opioids along with other substances
   - Switching from oral use to injecting opioids.
   - Change in drug purity (e.g. change in supply)

2. What are the signs of an opioid overdose (tick all that apply)
   - Slow/shallow breathing
   - Loss of consciousness / Can’t be roused
   - Turning blue
   - Deep snoring
   - Pinned pupils

3. What should you do if you think a person may have overdosed? (tick one per statement)

<table>
<thead>
<tr>
<th>Check for a response</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call an ambulance</td>
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<tr>
<td>Stay with the person until an ambulance arrives</td>
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<tr>
<td>Perform rescue breathing, if you know how</td>
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<tr>
<td>Place the person in the recovery position</td>
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<tr>
<td>Cardiac compression, if you know how</td>
<td></td>
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<tr>
<td>Give naloxone</td>
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</tr>
<tr>
<td>Put the person in bed to sleep it off</td>
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</tbody>
</table>

4. Have you heard of naloxone before?
   - YES
   - NO
   - UNSURE

5. How long does naloxone take to start reverse an opioid overdose? (tick one)
   - 2-5 minutes
   - 5-10 minutes
   - >10 minutes
   - Don’t know

6. How confident do you feel at giving a naloxone injection?
   - Confident
   - Unsure
   - Not confident

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE

308(29/07/19)
OPioid Overdose Response

Follow these steps if Prenoxad® naloxone injection is available

1. Danger: Make sure there is no danger to yourself or others. Call for help from other people.
2. Is this an overdose?
   - Unroursable: Person not responding to name, gentle shaking or shoulder squeeze.
   - Not breathing normally: shallow slow breathing or snoring
   - Pale or cold skin, blue lips.
   - Pinpoint ‘pinned’ pupils of eyes
3. Call Triple Zero (000) and follow instructions: “I think it’s an overdose”
4. Administer naloxone:
   i. Lie person on side.
   ii. Assemble Prenoxad®.
   iii. Insert needle into outer thigh or upper arm and inject 0.4ml (1st black line on syringe).
5. Airways and rescue breathing: If you know how, clear airways and provide ‘rescue breathing’.
6. Recovery:
   i. Stay with person until Ambulance arrives.
   ii. Put person in ‘recovery position’ if you know how
   iii. If no response after 2 to 3 minutes: inject another 0.4ml dose (to next black line).
      Repeat every 2 to 3 minutes until person recovers or Ambulance arrives.

See over for more information.

Preventing and responding to opioid overdose

When is the risk of opioid overdose increased?
- Using again after a break with reduced tolerance (e.g. after hospital or drug-free treatment, detox, prison).
- Mixing opioids with other sedating drugs - such as alcohol or benzos (e.g. diazepam, alprazolam).
- Using a greater amount (or purity) of opioid than usual.
- Injecting instead of other ways of using (e.g. swallowing, snorting, smoking).
- Having other health problems (e.g. a major infection, fever).
- Using by yourself - with no one able to call for help.

How to recognise an opioid overdose?
- Person is unconscious & does not respond to their name or physical stimulus (e.g. squeezing their shoulder).
- Person has blue lips, tongue and hands, cool pale skin.
- Person is breathing infrequently, snoring or not breathing at all.
- ‘Pinned’ (small) pupils.

How to respond to an opioid overdose?
1. Danger and call for help: Check the environment is safe - clear away any uncapped needles or other sharp objects. Call for help from other people if you are alone.
2. Is this an overdose? Look for pale cold skin, not breathing normally and unable to rouse the person by calling their name or squeezing their shoulder.
3. Call an Ambulance: call 000 and follow instructions. Let them know you think it may be an overdose. Police do NOT routinely attend.
4. **Administer Naloxone (Prenoxad®):** Inject one dose of naloxone into muscle in upper arm or outer thigh. Note time given. Repeat naloxone injections every 2 to 3 minutes until person recovers.
   a. Open plastic packaging by pulling the red tear strip on the side of the box
   b. Unscrew the clear plastic top from the syringe
   c. Remove needle from packaging (with sheath still on) and screw onto the syringe
   d. Remove needle sheath and inject the first dose of 0.4 ml by pushing the plunger to the first black line
   e. Take out the syringe with the needle attached and safely put it back into the case

5. **Airways and breathing:** If not breathing normally, clear airways & provide rescue breathing (if you know how):
   a. Roll the person onto their back
   b. Place one hand on forehead & place other hand under chin
   c. Tilt head backwards to open the airway
   d. Clear the airway of any blockages
   e. Pinch off nose & seal your mouth over theirs and give 2 quick breaths

6. **Recovery:**
   If person recovers, put them into recovery position:
   a. Roll person into position (see diagram)
   b. Tilt head backwards & turn mouth slightly downwards to allow drainage.
   c. Clear any obstructions from their mouth or throat
   d. Listen and look for normal breathing

   If person is not recovering, repeat naloxone injections every 2 to 3 minutes. Commence CPR if you know how. Continue until ambulance arrives.

   Stay until the ambulance comes: After using Prenoxad injection, keep the syringe in the box/disposal container and hand it to the ambulance crew so that they know it has been administered.

   Naloxone is used to reverse opioid overdose (e.g. heroin, morphine, oxycodone, methadone). It takes 2–5 minutes to start working and effects last about 30-90 minutes.

   For information on drug treatment call ADIS 24 hours a day, 7 days a week on free call 1800 250 015 from anywhere in Australia.
APPENDIX C2: Consumer Information Sheet: Nyxoid®

OPIOID OVERDOSE RESPONSE

Follow these steps if Nyxoid® intranasal naloxone spray is available

[Infographic]

1. Danger. Make sure there is no danger to yourself or others. Call for help from other people.
2. Is this an overdose?
   • Unrousable: Person not responding to name, gentle shaking or shoulder squeeze.
   • Not breathing normally: shallow slow breathing or snoring
   • Pale or cold skin, blue lips.
   • Pinpoint ‘pinned’ pupils of eyes
3. Call Triple Zero (000) and follow instructions: “I think it’s an overdose”
4. Administer naloxone
   i. Lie person on their back and check the nose is clear.
   ii. Do not prime or test device – it contains one dose only.
   iii. Insert nozzle in nostril.
   iv. Press until it clicks to give the dose.
5. Airways and rescue breathing: If you know how, clear airways and provide ‘rescue breathing’.
6. Recovery
   i. Stay with person until Ambulance arrives.
   ii. Put person in ‘recovery position’ if you know how
   iii. If no response after 2 to 3 minutes: Use 2nd Nyxoid device to give 2nd dose of Nyxoid in other nostril. If more naloxone is available, repeat every 2 to 3 minutes until person recovers or Ambulance arrives.

See over for more information.
Preventing and responding to opioid overdose

When is the risk of opioid overdose increased?

- Using again after a break with reduced tolerance (e.g. after hospital or drug-free treatment, detox, prison).
- Mixing opioids with other sedating drugs - such as alcohol or benzos (e.g. diazepam, alprazolam).
- Using a greater amount (or purity) of opioid than usual.
- Injecting instead of other ways of using (e.g. swallowing, snorting, smoking).
- Having other health problems (e.g. a major infection, fever).
- Using by yourself - with no one able to call for help.

How to recognise an opioid overdose?

- Person is unconscious & does not respond to their name or physical stimulus (e.g. squeezing their shoulder).
- Person has blue lips, tongue and hands, cool pale skin.
- Person is breathing infrequently, snoring or not breathing at all.
- ‘Pinned’ (small) pupils.

How to respond to an opioid overdose?

1. Danger and call for help: Check the environment is safe - clear away any uncapped needles or other sharp objects. Call for help from other people if you are alone.
2. Is this an overdose? Look for pale cold skin, not breathing normally and unable to rouse the person by calling their name or squeezing their shoulder.
3. Call an Ambulance: call 000 and follow instructions. Let them know you think it may be an overdose. Police do NOT routinely attend.
4. Administer Naloxone (Nyxoid®): Spray one dose (one spray) of Nyxoid in the person’s nostril. Do not prime or test the device before you give it. Note time given. If person doesn’t recover in 2 to 3 minutes use the second device to give a second dose in other nostril.
   i. Lie the person on their back, with their head tilted back.
   ii. Check the nose is clear.
   iii. Peel the backing off the blister pack to remove the Nyxoid device from its packaging.
   iv. Hold Nyxoid device with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.
   v. Insert nozzle in one nostril. Press firmly on the plunger until it clicks to give the dose.
5. Airways and breathing: If not breathing normally, clear airways & provide rescue breathing (if you know how):
   i. Roll the person onto their back
   ii. Place one hand on forehead & place other hand under chin
   iii. Tilt head backwards to open the airway
   iv. Clear the airway of any blockages
   v. Pinch off nose & seal your mouth over theirs and give 2 quick breaths
6. Recovery:
   If person recovers, put them into recovery position:
   i. Roll person into position (see diagram)
   ii. Tilt head backwards & turn mouth slightly downwards to allow drainage.
   iii. Clear any obstructions from their mouth or throat
   iv. Listen and look for normal breathing

If person is not recovering, repeat naloxone sprays every 2 to 3 minutes. Commence CPR if you know how. Continue until ambulance arrives.

Stay until the ambulance comes: After using Nyxoid intranasal naloxone spray, keep the devices and hand to the ambulance crew so that they know it has been administered.
Naloxone is used to reverse opioid overdose (e.g. heroin, morphine, oxycodone, methadone). It takes 2–5 minutes to start working and effects last about 30-90 minutes.

For information on drug treatment call ADIS 24 hours a day, 7 days a week on free call 1800 250 015 from anywhere in Australia.
APPENDIX D: Sample dispensing label

NALOXONE (Nyxoid) 1.8mg nasal spray 2 x 1 dose Qty: #
Supplied to a client of the Opioid Overdose Response & Take Home Naloxone intervention for use in any opioid overdose. Use as directed on Consumer Information Sheet.
Name: ________________________________________________
Date of supply: _________ Health worker: ___________________
Batch: XXX Expiry: day / month / year
Dubbo Drug & Alcohol Clinic
45 King St Dubbo NSW 2830, tel: XXXX XXXX
KEEP OUT OF REACH OF CHILDREN

NALOXONE 2mg/2mL injection (Prenoxad) Qty: #
Supplied to a client of the Opioid Overdose Response & Take Home Naloxone intervention for use in any opioid overdose. Use as directed on Consumer Information Sheet.
Name: ________________________________________________
Date of supply: _________ Health worker: ___________________
Batch: XXX Expiry: day / month / year
Dubbo Drug & Alcohol Clinic
45 King St Dubbo NSW 2830, tel: XXXX XXXX
KEEP OUT OF REACH OF CHILDREN
APPENDIX E: Sample drug stock control sheet / imprest

<table>
<thead>
<tr>
<th>Date of supply</th>
<th>Expiry date and batch number</th>
<th>Local reference number</th>
<th>Worker name &amp; signature</th>
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APPENDIX F:
A Quick guide to delivering ORTHN interventions for credentialed health workers

1. **Is the client eligible?** Clients at risk of overdosing on illicit or pharmaceutical opioids (those currently using, have recently used, or are at risk of returning to using opioids after taking a break), likely to witness an overdose, are aged 16+, and contraindications (hypersensitivity) and precautions (pregnant/breastfeeding) have been considered.

2. **Introduce ORTHN intervention to the client**, describe its purpose (‘to help people respond to and prevent deaths from overdose’), likely duration of intervention (10-20 minutes), and involves the supply of ‘take home naloxone’.

3. **Assess and address client’s understanding of overdose**: either unstructured (clinical assessment) or administer Client Questionnaire Full (CQ-F) or Brief (CQ-B) and provide feedback using the Consumer Information Sheet.

4. **Discuss with client the choice between prefilled syringe for intramuscular injection or intranasal naloxone. Demonstrate the contents and use of Prenoxad® (injected) and Nyxoid® (intranasal).**

5. **Health worker and client to complete the ORTHN Checklist and Record of Supply.**

6. **Health worker to supply naloxone to client** (client’s preferred formulation i.e. either nasal spray or pre-filled syringe if possible) in accordance with the Procedures, including labelling, and record in the Drug stock control sheet / imprest log book.

7. **File completed documents** in client medical record (where patient medical record exists) or where no individual client medical records are maintained (e.g. NSP, outreach), file in an ORTHN Intervention Folder at each participating site.
APPENDIX G: ORTHN Training and Credentialing Framework

OPIOID OVERDOSE RESPONSE & TAKE HOME NALOXONE TRAINING AND CREDENTIALING FRAMEWORK

Introduction
The purpose of the Overdose Response and Take Home Naloxone (ORTHN) Training and Credentialing Framework is to outline the broad requirements for an eligible health worker employed in the MSIC or a NSW public health facility to be selected, trained and credentialled to deliver ORTHN interventions, including the supply of take home naloxone.

Requisite Knowledge, Skills and Competencies
Within the Australian Qualifications Framework, learning outcomes are promoted as a means of describing the outcomes of a qualification and comparing qualification types. Learning outcomes encompass the three dimensions of:

- **Knowledge** – what students know or understand;
- **Skills** – what students can do or how they apply their knowledge and understanding; and
- **Competencies** – the context in which knowledge and skills can be applied. This dimension includes both specific and generic competencies.

The generic competencies are usually embedded within competency standards. They encompass the competencies that underpin every aspect of performance including the ability to communicate effectively, the capacity to problem-solve, and the professional and ethical attributes needed to exercise judgment and accept responsibility and accountability.

The health worker will be considered to have the generic competencies for the role if they meet the following criteria:

- The health worker is employed as a registered nurse, psychologist, social worker, counsellor, occupational therapist, alcohol and other drugs worker, health education officer, Aboriginal health worker, Aboriginal health practitioner, health service manager working in a needle syringe program or the Connections Program, needle syringe program worker, needle syringe program coordinator, consumer worker, peer support worker, peer support coordinator, medical practitioner, pharmacist, nurse practitioner (with an addiction scope of practice) in the MSIC; Justice Health & Forensic Mental Health Network; or a drug and alcohol service, Needle and Syringe Program or community health service delivered in the NSW public health system.
- The health worker must have >3 months experience providing clinical interventions to people who use opioids – including the delivery of brief counselling and psycho-educational interventions.
- The health worker must have a current certificate in Basic Life Support (HETI Code 40101256) or Provide cardiopulmonary resuscitation (Australian course code HLTAID001).
- The applicant must agree to comply with the Opioid Response and Take Home Naloxone Procedure.

Workers who do not meet the above criteria will not be accepted into the ORTHN Health Worker Training Program.

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ORTHN Health Worker Training Program

Method of Training
Training of selected health workers who have met the eligibility criteria will be conducted by a Ministry of Health-approved training provider.

Training of health workers to become credentialed health workers will be delivered via a three hour workshop or equivalent one to one, webinar or on-line delivery.

Learning Objectives
1. To understand opioid overdose epidemiology including risk factors and effective interventions.
2. To understand the rationale, effectiveness and safety of ORTHN interventions.
3. To be able to effectively deliver ORTHN interventions to target client populations.
4. To understand the medico-legal requirements for delivering ORTHN interventions.

Knowledge and Skills
On completion of the ORTHN Health Worker Training Program, a health worker should be able to demonstrate the following knowledge and skills:

Learning Objective One: To understand opioid overdose epidemiology including risk factors and effective interventions.
- Describe the trend of opioid overdose deaths.
- Describe the profile of opioid use.
- Describe the physiological effects on the body in an opioid overdose.
- List the contributing risk factors for opioid overdose.

Learning Objective Two: To understand the rationale, effectiveness and safety of ORTHN interventions.
- Identify evidence-based interventions that reduce opioid overdose deaths.
- Describe the characteristics of ORTHN programs.
- Describe the purpose of naloxone, its mechanism of action, routes of administration and its legal status.
- Describe the relative benefits of prefilled naloxone syringes and intranasal naloxone spray devices.
- Be able to appropriately respond to concerns regarding ORTHN interventions.

Learning Objective Three: To be able to effectively deliver ORTHN interventions to target client populations.
- Identify the eligibility criteria and contraindications for clients to participate in the program.
- Demonstrate an understanding of how to assess a client’s prior knowledge about overdose and naloxone.
- Demonstrate an understanding of psychological and emotional feelings clients may have in relation to prior overdoses.
- Describe what the ORTHN Brief Intervention is and how it is delivered.
- Describe the key components of delivering an ORTHN intervention to a client.
- Identify the correct documentation required to be completed when performing an ORTHN intervention.
- Identify the signs of an opioid overdose.
- Describe the correct response to a suspected opioid overdose.
- Demonstrate in a role-play or supervised scenario the process of delivering an ORTHN intervention to a client and provision of Consumer Information Sheet.
Demonstrate knowledge of the contents of a Prenoxad® pack and a Nyxoid® pack and how to administering both the injection and the intranasal products.

Learning Objective Four: To understand the medico-legal requirements for delivering ORTHN interventions.

- Demonstrate the correct procedure for supplying naloxone to a client and the documentation to be completed when supplying naloxone under the ORTHN intervention.
- Explain the legal status of Take Home Naloxone in NSW.
- Identify follow-up procedures for clients who have been issued take home naloxone.

Method of Assessment

Health workers who undertake the ORTHN Health Worker Training Program will be assessed by direct observation of participation in the workshop, completion of a multiple choice questionnaire, and by direct observation of an ORTHN Brief Intervention role play or supervised scenario.

Health workers who do not demonstrate the required knowledge and skills will not be eligible for credentialing.

Health workers must demonstrate the following elements when delivering an ORTHN intervention during the role play or supervised scenario:

1. Assessing the client’s suitability and eligibility, and introducing ORTHN to the client:
   a. Rationale for ORTHN intervention was described to the client; and
   b. Contraindications and precautions identified and explained to the client.
2. Assess the client’s knowledge of the risks and signs of an opioid overdose and educate the client on the risks and signs of an opioid overdose where necessary.
3. Assess the client’s attitudes towards overdose and provide support where necessary.
4. Explain the actions to take in the event of witnessing an overdose.
5. Explain to the client what naloxone is and how Prenoxad® and Nyxoid® kits are used in overdose reversal including how to administer each naloxone formulation, when to administer naloxone and the time to onset and duration of naloxone.
6. Demonstrate the correct process of obtaining client consent and ascertaining client competence.
7. Demonstrate the correct process of supplying Prenoxad®/Nyxoid®.
8. Demonstrate completion of the ORTHN documentation.

Credentialing

The purpose of credentialing is to verify qualifications, experience and professional standing for the purpose of forming a view about the health worker’s competence, performance and professional suitability to provide safe, high-quality health care services within specific organisational environments (Australian Council for Safety and Quality in Health Care, 2004).

In the context of ORTHN, the purpose of credentialing is limited to verifying a health worker’s qualifications, experience and competence to safely deliver ORTHN brief interventions in accordance with the ORTHN Procedure.

In order to be credentialed, the health worker must meet the eligibility criteria for, and successfully complete, the ORTHN Health Worker Training Program. On completion of the training program the training provider will complete an assessment of the health worker’s knowledge and delivery of an ORTHN brief intervention in accordance with ORTHN.
Procedures. If the health worker’s knowledge and skills are assessed as satisfactory based on the criteria, the training provider will indicate this on the assessment form and the health worker will be considered credentialed to begin delivering ORTHN brief interventions in accordance with the ORTHN Procedures. If a health worker fails to demonstrate satisfactory knowledge or skills in delivering an ORTHN Brief Intervention in accordance with the ORTHN Procedures they will be considered to have failed the training and will not be credentialed.

A record of the health worker’s certification is to be retained in the health worker’s personnel file or training file, as appropriate to the service. The Responsible Person at the health facility is to retain a record of health workers who have been credentialed and authorised to deliver the ORTHN brief intervention under the ORTHN Procedures. The training provider/s will maintain a database of trained and credentialed workers.