Policy Directive

Medication Handling

Summary This Policy Directive consolidates procedures and standards 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 Regulation 2008, NSW Health policies and NSW Health directives relevant to medication handling

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Distributed to Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Health Associations Unions, Tertiary Education Institutes

Audience All Clinical and Allied Health Staff

Secretary, NSW Health

This Policy Directive may be varied, withdrawn or replaced at any time.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

NSW Health

POLICY DIRECTIVE

Medication Handling

POLICY STATEMENT

NSW Health organisations must have appropriate processes in place to ensure the appropriate, safe, efficient and cost-effective use of medications in NSW public health facilities.

SUMMARY OF POLICY REQUIREMENTS

The Chief Executive is responsible for establishing a Drug and Therapeutics Committee for the governance of medication management.

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 Drug and Therapeutics Committee also has oversight of facility procedures for medication safety alerts, recalls, shortages and incident management.

Facility procedures for the procurement, storage, labelling, prescribing, dispensing, supplying, administering and recording of medications must be in accordance with *the Poisons and Therapeutic Goods Act 1966*, *Poisons and Therapeutic Goods Regulation 2008* and applicable NSW policies and guidelines.

Each facility must establish a High-Risk Medicines Program with a High-risk Medicines Register in accordance with NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045). Facility procedures must be developed for all high-risk medicines specified on this register.

Authorised prescriber requirements under the *Poisons and Therapeutic Goods Regulation 2008* to direct the administration of medication and issue prescriptions for pharmacist dispensing are in section 4 of the Policy procedures. The Regulation restricts the prescribing of specific medications to certain authorised prescribers and/or under the Authority of the NSW Health Secretary. Authorised prescribers may also supply medications for patient take home use from health facility stocks when the Pharmacy Service is not available.

Medications at the Pharmacy Service are under the governance of the director of pharmacy, or authorised pharmacist delegate where there is no director of pharmacy. At a facility where there is no employed/contracted pharmacist the medication supply service is managed by the director of nursing or medical superintendent authorised by the Chief Executive. Schedule 8 medications are to be stored in a safe or vault apart from all other medications and accounted for in a drug register.

Pharmaceuticals prepared for by, or on behalf of, a public health facility, must be managed in accordance with the Policy Directive *Pharmaceuticals – Preparation in NSW Public Health Facility Pharmacy Services* (PD2015_007).

Medications stored and used within a patient care area are under the governance of the registered nurse or midwife in charge. Specific storage requirements apply for Schedule 4 Appendix D and Schedule 8 medications as they are vulnerable to diversion. Schedule 8 medication transactions are to be recorded in a drug register.

Authorised staff administer and supply medications under facility procedures, such as:

- on a medication chart order, or
- on a verbal (face to face), telephone or video call, email or facsimile order, or
- under a Standing Order, or
- under a nurse-initiated medication protocol, or
- under a Schedule 4 medication clinical protocol.

Certain medications require a second person check in specified circumstances.

REVISION HISTORY

Version	Approved By	Amendment Notes
August - 2022 (PD2022_032)	Deputy Secretary, People, Culture and Governance	Full review of policy in PD2013_043 Medication Handling in NSW Public Health Facilities.
November 2013 PD2013_043	Deputy General	New policy to consolidate and update PD2007_077 Medication Handling in NSW Public Hospitals and Section 3 of PD2005_105 Medication Handling in Community-Based Health Services/Residential Facilities in NSW - Guidelines.

NSW GOVERNMENT

NSW Health

Medication Handling

CONTENTS

1 BACKGROUND

1.1 About this document

This Policy consolidates:

- the statutory requirements of the NSW *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2008*
- NSW Health policies relevant to medication handling
- recognised professional practice standards, such as those published by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Commonwealth Department of Health.

The Policy applies to all Public Health Organisation health facilities including hospitals, clinical services, outpatient clinics, community health centres, day centres, day procedure centres, community-based services, Hospital in the Home and outreach 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 public health facilities to develop detailed protocols and procedures specific to the local situation and circumstances, including where services are contracted to a non-government organisation.

Although the principles may be relevant, this Policy does not apply to HealthShare NSW patient transport service. Medication handling and administration within HealthShare NSW patient transport service is mandated in the separate Patient Transport Service Medication Management Policy endorsed by the HealthShare NSW Chief Executive.

Although the principles may be relevant, this Policy does not apply to medication handling and administration by paramedics and flight nurses employed by NSW Ambulance except for the following specific services provided by public hospital emergency departments:

- the provision of emergency supplies of morphine to NSW Ambulance paramedics (section 4.4.3)
- the provision of tenecteplase to NSW Ambulance paramedics under the Pre Hospital Thrombolysis Program (section 5.13.2).

Medication handling and administration within NSW Ambulance is mandated in the Medications Management Operating Procedure endorsed by the NSW Ambulance Chief Executive.

1.2 Key definitions

Accountable medication	All Schedule 8 medications and Schedule 4 Appendix D medications, as well as other Schedule 3 or 4 medication directed by the chief executive (or delegate) of the facility to be accounted for in a register.

Administration	The decision to give a medication, giving the medication (such as by mouth, topically or by injection) then documenting that the medication has been given.
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: • Medical practitioner • Nurse practitioner • Endorsed midwife • Podiatrist • Dentist • Midwife practitioner • Optometrist *Note*: For the purpose of this Policy, 'authorised prescriber' does not relate to a medical practitioner approved under the Commonwealth *Therapeutic Goods Act 1989* to prescribe a Special Access Scheme medication or to prescribe Pharmaceutical Benefits Scheme medications under the *National Health Act 1953*.
Closed-loop communication	A communication method used to minimise communication errors that involves confirming and verifying orders. In closed-loop communication the sender gives a message, the receiver repeats this back and the sender then confirms the message.
Dispensing	The labelling and supply of a medication, and recording of the supply, by a pharmacist for use by a particular patient on the order of an authorised prescriber. The order may be for patient take-home use of the medication or for administration to an inpatient or outpatient. In specific circumstances an authorised practitioner may be authorised for this activity (see section 5.9).
Dose administration aid	A sealed tamper-evident device that allows individual medication doses to be organised according to the prescribed dose schedule. Dose administration aids referred to in this Policy are those filled by the Pharmacy Service only.

Electronic medication management system, eMM system, eMeds system	The software and associated hardware used to create and document the entire medication procedure from the authorised prescriber's medication order, the pharmacist's review of the medication order and supply of medication, the recording of administration of the medication, and all the procedures in between. eMM systems are sometimes referred to as 'eMeds' within the electronic medication record (eMR).
Hospital in the Home	A clinical model that provides admitted acute/sub-acute care in the patient's home or the community as a substitute for in-hospital care. Instead of receiving care and hospital accommodation, patients receive hospital level care whilst being accommodated in their own home. Hospital in the Home services may include care in an ambulatory/clinic environment.
Imprest system	The method by which medications are supplied from the Pharmacy Service of a hospital to the health service or the wards, theatres, departments or clinics thereof, either in containers of the original manufacturer, or repacked containers in order to establish and maintain a stock of medications at a pre-determined level for use in such places.
Medication	Describes a drug, medicine, pharmaceutical preparation (including an extemporaneously compounded preparation), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing, device containing a medicine and a fluid for intravenous use. Includes Scheduled medication and unscheduled medication.
Medication order	A direction to administer a medication as a written order by an authorised prescriber on a Drug and Therapeutics Committee approved chart such as a National Standard Medication Chart or a speciality medication chart (including where approved as a State Form). An electronic order in the health facility's eMeds system and verbally (face to face) or by telephone, video call, email and facsimile.
Medication recall 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.

Medication review	A minimum standard of systematic appraisal of all aspects of patient medication management conducted or supervised by a qualified and suitably trained health practitioner (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.
Off-label use	The use of a medication other than that specified in the TGA-approved product information including when the medicine is prescribed or administered: • for an alternative indication • at a different dose • via an alternate route of administration, or for a patient of an age or gender outside the registered use.
Off-label use	The use of a medication other than that specified in the TGA-approved product information including when the medicine is prescribed or administered: • for an alternative indication • at a different dose • via an alternate route of administration, or • for a patient of an age or gender outside the registered use.
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, emergency department, operating theatre, specialised treatment unit (for example haemodialysis, oncology, radiology, dental), day surgery unit, community health centre, Hospital in the Home service, day centre, community-based service at the patient's home and Justice Health and Forensic Mental Health Network controlled health service.

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. For the purpose of this Policy includes the medication supply service (that is not part of a patient care area) at a facility where no 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.
Printed standard medication order set	A hard copy medication regimen comprised of printed medication names with medication orders on which the authorised prescriber may include additional particulars such as dosage calculations in handwriting. Used for inpatients and patients being treated in outpatients' clinics and includes and order that combines a medic To become a valid medication order the authorised prescriber must sign and date the medication order set in handwriting
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 defined as a 'restricted substance' in the Act and Regulation), or, *Schedule 8* 'Controlled Drug' (also defined as a 'drug of addiction' in the Act and Regulation).
Schedule 4 Appendix D medications	Schedule 4 medications listed in Appendix D to the *Poisons and Therapeutic Goods Regulation 2008* known to be liable to abuse or misuse, which require more secure storage in patient care areas. They include benzodiazepines (except those in Schedule 8), anabolic-androgenic steroids, ephedrine, erythropoietins, phentermine, phenobarbitone, pregabalin, quetiapine, tramadol and Schedule 4 barbiturates. See the Schedule 4 Appendix D list on the Ministry of Health website.

Schedule 4 Appendix B medications	Schedule 4 medications listed in Appendix B to the *Poisons and Therapeutic Goods Regulation 2008*, prescriptions (but not medication chart orders) for which must include intervals for repeats (if repeats are ordered), and after dispensing must be retained separate from all other prescriptions (except Schedule 8 prescriptions) at the Pharmacy Service. They include anabolic-androgenic steroids, injectable amylobarbitone and injectable pentobarbitone. See the Schedule 4 Appendix B list on the Ministry of Health website.
Schedule 8 cannabis medication	A therapeutic good containing cannabinoid/s found in the cannabis plant, prepared or packed for human therapeutic use, and included in Schedule 8 of the NSW Poisons List.
Special Access Scheme	Arrangements through the Therapeutic Goods Administration (TGA) which provide for the import and/or supply of a non-approved therapeutic good for individual patient use.
Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)	The Poisons Standard is the legal title for the Standard for the Uniform Scheduling of Medicines and Poisons. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into schedules and controls such as packaging and labelling. The NSW Poisons List adopts the Schedules of the SUSMP as in force at any time.
Unregistered medication	A medication or dosage form that is not currently approved for use in Australia and hence is not listed or registered on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG).

1.3 Legal and legislative framework

The Poisons and Therapeutic Goods Act 1966 (NSW) and the *Poisons and Therapeutic Goods Regulation 2008* (NSW) regulate the procurement, storage, labelling, prescribing, dispensing, supplying, administering and recording of both Scheduled and non-Scheduled medications in New South Wales at health facilities, and by health practitioners and pharmaceutical wholesalers. The *Poisons and Therapeutic Goods Regulation 2008* (NSW) is referred to as the 'Regulation' throughout this Policy.

This legislation is administered by Legal and Regulatory Services Branch of the NSW Ministry of Health.

2 GOVERNANCE

2.1 The Drug and Therapeutics Committee

All public health facilities in NSW must have a formally constituted, multidisciplinary Drug and Therapeutics Committee in place, or have access to a local health district or specialty health network drug and therapeutics committee.

The Committee must include representation from the facility's executive and the pharmacy, medical and nursing disciplines.

The Drug and Therapeutics Committee is responsible for governing the medication management systems, and ensuring the appropriate, safe, efficient and cost-effective use of medications in the health facility, local health district or speciality health network.

The Council of Australian Therapeutic Advisory Group (CATAG) *Guiding Principles for the Roles and Responsibilities of Drug and Therapeutics Committees in Australian Public Hospitals* provides guidance on the role, operation and evaluation of Drug and Therapeutics Committees.

Under facility procedures, 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. The Committee/s must also report quarterly to the facility's clinical quality committee (however named).

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.

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 formulary adherence, monitor medication use, and provide guidance to all health workers in the rational use of medications and the treatment guidelines that apply in the facility.

The Drug and Therapeutics Committee must include persons with relevant expertise in the safe, rational, high quality and cost-effective use of medications. Subcommittees with relevant expertise for specific projects or aspects of the quality use of medications, such as antimicrobial stewardship, medication safety, paediatrics, opioid stewardship, venous thromboembolism prophylaxis and eMeds 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) for each facility assigned to the Committee must include:

- the development and approval of medication protocols and facility procedures that support the quality, safe and cost-effective use of medications, including all aspects of medication management, aligned with relevant NSW Health policies

- assisting in the implementation of NSW Health policies concerning medications and medication management
- approval of medications for use in accordance with NSW Health Policy Directive *Approval Process of Medicines for Use in NSW Public Hospitals* (PD2016_033)
- oversight of any formulary restrictions
- oversight of compliance with NSQHS Medication Safety Standards
- oversight of eMeds systems in use
- monitoring of medication safety systems through review and analysis of medication data, for example, audits, self-assessments and analytics from eMeds systems
- collation and analysis of incident reports involving medications
- oversight of medication recall and product defect management procedures
- development and implementation of strategies for medication error prevention in accordance with NSW Health policies on incident management and patient safety
- design and approval of all specialty medication charts
- approval and review of standing orders for medication administration
- approval and review of the list of nurse-initiated medications and protocols for use
- oversight of non-medical prescribing
- oversight of risks of clinical trials to the organisation (other than the clinical considerations assessed by an ethics committee)
- communicating formulary decisions and any related safety requirements to relevant clinicians and medication-related governance committees
- oversight of the establishment and use of Fixed Interval Variable Dose (FIVD) order sets, especially in the facility's eMeds system, and ensure:
    - the construction of order sets containing fixed interval variable doses must enable the prescriber to meet their obligations to ensure orders are not open to misinterpretation, and enable the prescriber to specify the maximum individual dose, the maximum daily dose, the hourly frequency for administration, and the maximum number of doses or maximum duration of treatment
    - the prescriber is able to specify which clinical factors are to be used determine which dose is selected and administered at each dose interval. This detail may be contained in a clinical protocol
    - nursing staff must have skills and experience to assess such clinical factors and document the basis on which the dose has been chosen
    - documentation of effects and adverse effects from an administered dose be made to enable appropriate dose titration for the next dose
    - the prescriber is able to specify when an opioid dose would be withheld if adverse effects (especially respiratory depression) occur due to administration of a dose at the high end of the dose range.

2.2 High-risk medicines management

All facilities must establish a high-risk medicines program in accordance with NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045). All public health facilities must maintain, as part of the high-risk medicines program, a specific high-risk medicines register.

The register must include medicines used locally within the facility identified to be at 'high-risk' of misadventure. Facility protocols must be developed for all identified high-risk medicines specified on the register.

Standards are also included in NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) for specific high-risk medicines.

Supporting tools and information on safety and quality around high-risk medicine use are available on the Clinical Excellence Commission webpage.

2.3 Medication safety alerts, recalls, shortages and incident/problem reporting

2.3.1 NSW Health Safety Alert Broadcasting System

The NSW Health Policy Directive *Safety Alert Broadcast System* (PD2013_009) details the mechanism used to provide a systematic approach to the distribution of patient safety information to the NSW Health on the Safety Alert Broadcast System Register.

2.3.2 Medication recalls

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

Nationally the medication recall procedure is administered by the Commonwealth 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.

In NSW, the Clinical Excellence Commission leads the response to urgent system-level medication issues in accordance with NSW Health Policy Directive *Co-ordination of responses to urgent system-level medicine or medical device issues* (PD2019_019).

Medication recalls vary in the risk they pose to patient safety. All facilities must respond effectively and promptly to any medication recall notification.

Under facility procedures the medication recall coordinator is responsible for:

- coordinating the prompt removal of recalled medications (or implements other recall letter instructions) from use in all locations in the facility including for:
  - Hospital in the Home, community nursing and outreach program medications
  - medications brought into the facility by a patient, (including in a dose administration aid) residential aged care and flexible care units
- coordinating stock replacement strategies and/or replacement stock when required

- informing affected staff and facility executives about recalled medications
- during business hours, regularly monitoring the recall coordinator point of contact is current
- informing staff about medication alerts that require action other than the removal of the medication from use, such as those alerts broadcast as NSW Health Safety Alert Broadcast System Notifications.

Facility procedures must include the management of recalls after-hours. In circumstances where medications have been transferred to another health facility, that facility's medication recall coordinator must be notified for appropriate action.

The medication recall coordinator is responsible for notifying the Clinical Excellence Commission by email of any change to the email address assigned by the facility for the purpose of TGA medication recall notifications. To provide for periods of absence, management of the appointment of a person to deputise as medications recall coordinator in accordance with NSW Health Policy Directive *Coordination of Responses to Urgent System-Level Medicine or Medical Device Issues* (PD2019_019).

System for Australian Recall Actions

The System for Australian Recall Actions 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 TGA 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

Records relating to the recalled medications must be retained at the facility for ten years, and then stored as State Records in accordance with NSW Health Policy Directive *Health Care Records – Documentation and Management* (PD2012_029). Related records include policies for dealing with recall matters not related to individual issues, such as negotiation of jurisdiction and recalls procedure development.

2.3.3 Medication shortages

The Clinical Excellence Commission reviews and assesses critical shortages of medicines for NSW Health and where necessary establishes an inter-agency management team to formulate a plan that includes stock management as well as issuing a Shortage Communication or a Safety Notice.

Under NSW Health Policy Directive *Coordination of responses to urgent system-level medicine or medical device issues* (PD2019_019) in extreme instances of immediate, life-threatening risk or major system impact, coordination of the response may transition to the Chief Health Officer or Deputy Secretary, System Purchasing and Performance (depending on the nature of the incident).

The TGA monitors critical medicines shortages and initiatives for the Accessing medicines during a shortage. A Serious Scarcity Substitution Instrument may apply, which outlines

alternative products (for example, a different strength or dosage form of the same medicine) that could be substituted by a pharmacist.

The exercise of social and ethical responsibilities to ensure that purchasing for a constrained supply medication is managed sensitively with the whole of health system is under facility procedures.

2.3.4 Medication incident reporting

All incidents, including near-miss incidents, associated with medication use must be reported in the facility's incident management system in accordance with NSW Health policy on incident management.

Where a dispensing incident involves an individually patient-labelled medication obtained from the Pharmacy Service the detail of the incident must also be recorded in the patient's record in the Pharmacy Service dispensing system. Reporting an incident relating to the administration of a patient own medication in their home is under facility procedures.

Any suspected adverse drug reaction must be reported in accordance with facility procedures and to the TGA using the 'Blue card' adverse reaction reporting form 'Report of Suspected Adverse Reaction to Medicines or Vaccines' or the Australian Adverse Drug Reaction Reporting System.

Adverse events following immunisation must be reported to the local Public Health Unit. An Adverse Events Following Immunisation (AEFI) reporting form must also be completed.

2.3.5 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 recall coordinator. Such problems could include incorrect or illegible product labelling, discolouration, cloudiness, contamination or incorrect tablets/capsules or faulty packaging.

The facility's medication recall coordinator must report any suspected or known problem or defect with a medication promptly in the facility's incident management system and also to the Commonwealth TGA since this may indicate a fault in a manufacturer's procedures 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 Pharmacovigilance and Special Access Branch by telephone at 1800 020 653.

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.

3 PRESCRIBING

3.1 Authorised prescribers – general limitations to prescribing

Prescriptions may only be written for patients being treated by the service and relating to that episode of care. Prescribers must not write prescriptions for persons who are not patients of the service, for example, colleagues or family members. Prescribing is limited to formulary restrictions, including for individual or classes of prescribers.

The following staff are authorised to both issue a prescription for dispensing by a pharmacist and create a medication order for administration in accordance with:

- any endorsements, notations and conditions included with the person's registration on the Australian Health Practitioner Regulation Agency website
- any condition imposed on the person's employment at the facility
- Drug and Therapeutics Committee approved protocols and procedures
- formulary restrictions
- Drug and Therapeutics Committee approved limitations on non-medical prescribers, for example, limiting the prescribing of systemically active medications to admitting medical teams.

Medical Practitioner

Other than a Provisionally Registered Medical Practitioner (medical intern).

Provisionally Registered Medical Practitioner ('Medical Intern')

Only for the prescribing (medication chart orders and prescriptions) to a patient while at the facility, and under the supervision of a medical practitioner in accordance with the organisation's medical internship program.

Note: Medical students are **not** authorised to issue prescriptions or create medication chart orders for administration.

Nurse Practitioner

Within the approved scope of practice in accordance with NSW Health Policy Directive *NSW Health Nurse Practitioners* (PD2020_034).

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.

Midwife Practitioner

Within the approved scope of practice and in accordance with the medication list approved by the Secretary, NSW Health under section 17A of the *Poisons and Therapeutic Goods Act 1966*.

Endorsed Midwife

Holds an endorsement with the Nursing and Midwifery Board of Australia to obtain, possess, administer, prescribe or supply Scheduled medicines.

Dentist

Dental treatment only. While there is no restriction on a medication chart order for dental treatment, issuing a prescription for a Schedule 8 medication for an outpatient, or a patient on discharge from a hospital by a dentist is limited to a Schedule 8 medication included in the list of preparations that may be prescribed by participating dental practitioners for dental treatment only, set out in the Schedule of Pharmaceutical Benefits issued by the Commonwealth Department of Health.

Optometrist

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

Endorsement on the person's registration by the Podiatry Board of Australia to prescribe and supply specified medications in Schedule 2, Schedule 3, Schedule 4 and Schedule 8 (with endorsement as a podiatric surgeon) for podiatry treatment only.

Note: All podiatrists may use topical anaesthetics and Schedule 4 injectable local anaesthetics for parenteral use.

Hospital pharmacist initiation and administration of vaccines

The NSW *Poisons and Therapeutic Goods Regulation 2008* (clause 48A) authorises appropriately trained pharmacists to administer the specified vaccines to specific patient groups. More information is available on the NSW pharmacist vaccination program webpage.

A registered pharmacist employed at a public hospital who initiates and administers vaccines must comply with the following three components of clause 48A of the which prescribes rules for:

- completing an accredited vaccination training course
- conducting vaccinations under the NSW Pharmacist Vaccination Standards
- recording each vaccination.

The vaccinations must be conducted under a program approved by the public health facility's chief executive in accord with the NSW Pharmacist Vaccination Standards.

Note: Pharmacists are not authorised to write an order for the administration of a vaccine by another health practitioner (such as on a medication chart).

3.2 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 must ensure that endorsed standard prescribing terminology and abbreviations are used, consistent with the ACSQHC *Recommendations for Terminology, Abbreviations and Symbols used in Medicines Documentation* on prescriptions, medication chart orders, administration and dispensing records and other related documents.

Note: For eMeds systems this is in the eHealth NSW Design Standard *Terminology, Abbreviations and Symbols used in the Electronic Prescribing and Administration of Medicines* – see in NSW Policy Directive *Electronic Medication Management Systems Governance and Standards* (PD2019_050).

Additionally:

- medication names must not be abbreviated
- the route for administration must be specified
- prescriptions for pharmacist dispensing and medication orders must be written as the active ingredient/s of the medication. Except in specific circumstances when the ordering by the brand name is authorised by the Drug and Therapeutics Committee and in accordance with NSW Health policies (such as in combination products). Note: Under the Hydromorphone Standard in NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) prescribers must include the brand name of the hydromorphone preparation
- oral liquid medications must 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 5 mg/mL, dose *10 mg (= 2 mL)'*.

The TGA updated medicine ingredient names are now in force. A small number of medications require dual names, for example adrenaline (epinephrine).

3.3 Medication orders in patient care areas

3.3.1 Medication orders for administration

Only hard copy (paper-based) medication charts that have been approved by the Drug and Therapeutics Committee for a particular patient care area can be procured for use in that area.

The requirements in NSW Health Policy Directive *Electronic Medication Management System Governance and Standards* (PD2019_050) which must be met where an eMeds system is used to prescribe medications, record the administration and review or dispense medications in a NSW public health facility.

Where an eMeds system is not in use, the National Standard Medication Charts (NSMC) and associated guidelines published by the ACSQHC must be adopted in accordance with the NIMC Local Management Guidelines.

The NSMC includes the Paediatric National Inpatient Medication Chart (PNIMC) which allows for signatures of 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 as directed by the Drug and Therapeutics Committee.

There are also a range of State Form approved speciality medication charts (such as those developed by the Agency of Clinical Innovation) available through the state contracted supplier including:

- the NSW Adult Subcutaneous Insulin Chart
- the suite of NSW Pain Charts.

Where multiple eMeds systems or hybrid systems (paper based with electronic) are used, facility procedures must be in place that address the risk of duplicate orders or non-contemporaneous orders during the patient's admission and at transfer of care.

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

Printed standard medication order sets must be approved for use in the ward or clinic by the Drug and Therapeutics Committee, or a delegated standing interdisciplinary committee for:

- complex medication regimens for specialist inpatient and outpatient settings such as oncology, haematology, immunology, neurology and rheumatology
- advanced pain management medications in setting such as anaesthesia and palliative care
- naloxone, when ordered for use as an antidote to accompany orders for patient controlled analgesia using opioids
- medication on a medication chart endorsed as a State Form that aligns with the design and standards described in the ACSQHC NIMC User Guide (for example, for warfarin, insulin, venous thromboembolism prophylaxis).

The order set must be signed and dated in the authorised prescriber's handwriting to be a valid direction to administer and/or dispense the medication.

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

Prescribing terminology and abbreviations must be consistent with the ACSQHC *Recommendations for Terminology, Abbreviations and Symbols used in Medicines Documentation.*

A medication order on a hard copy (paper-based) medication chart must clearly specify:

- the medication's active ingredient/s and/or brand name (where approved for use at the facility and under NSW Health policies) with the strength, form and route of administration
- the indication for treatment. (*Note:* Indication must be listed/used when a medication is initiated by the prescriber. Where the medication is continued on admission and the

indication is unknown to the prescriber is to use “TBC” (To be Confirmed). The indication must be reviewed during the admission and at discharge and when indication/s for ongoing medications have been confirmed must be updated. eMeds order sets pre-populate the indication in the medication order and must be determined by the Drug and Therapeutics Committee

- 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 ongoing treatment)
- 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 ongoing treatment)
- the date the medication order is issued
- the prescriber’s name (printed) and handwritten signature, or electronic authorisation in an eMeds system, and contact telephone/pager number.
- where used to direct pharmacist dispensing the NSW Health authority number, where required under the Regulation (see section 3.7 for the specialist restricted Schedule 4 medications and section 3.8 for certain Schedule 8 medications).

Use of Fixed Interval Variable Dose (FIVD) eMeds medication orders is to be under eHealth NSW design standards with appropriate testing for use with oversight by the Drug and Therapeutics Committee.

Medication orders with a variable dosage range (for example, 5 to 10 mg) over a fixed interval for administration (for example every 6 hours) must be clear and unambiguous. This type of order is to be avoided for opioids unless specific clinical criteria are provided for nurses on selection of the dose and the times for administration. Nursing staff must have skills and experience to assess such clinical factors and document the basis on which the dose has been chosen.

Medication orders on hard-copy charts must be re-written if any changes are made. The reason for ceasing a medication order prior to when originally prescribed must be documented in the patient’s health care record, signed and dated by the prescriber with their name and contact telephone/pager number.

Hospital pharmacist medication chart entries

A hospital pharmacist may make a medication entry on a patient’s medication chart for subsequent checking and signing by an authorised prescriber. This applies to medication charts in paper form and in hospital eMeds systems.

The hospital pharmacist's entry in the medication chart is not a valid order to direct a nurse to administer the medication until it is signed by an authorised practitioner.

The hospital pharmacist must be authorised under facility procedures approved by the Drug and Therapeutics Committee. Facility procedures must include:

- the circumstances where the hospital pharmacist may make the medication entries, such as during eMeds system downtime or for rollback to eMeds use post downtime
- the procedure for forwarding the medication entries to an authorised prescriber for subsequent checking and signing.

3.3.2 Medication reconciliation

Medication reconciliation is the procedure of ensuring that patients receive all intended medications and that accurate, current and comprehensive medications information follows them at all transfers of care. Formalised medication reconciliation procedures have been shown to improve patient safety and the continuity of medication management.

In accordance with the NSQHS Standards, facilities must implement formal procedures for:

- obtaining information to compile a list of the patient's current medication regimen (including known allergies and previous adverse drug reactions)
- verifying the accuracy of the information obtained to achieve a best possible medication history (using at least two sources, for example, patient's general practitioner, community pharmacist, patient own medications)
- comparing the patient's current medication orders against their best possible medication history and the documented treatment plan and reconcile any discrepancies
- supplying a current medicines list and the reasons for any changes to the receiving clinician/s and patient.

The Clinical Excellence Commission Continuity of Medication Management program provides tools and resources to support facilities implement and improve medication reconciliation procedures.

The list of current medications must be used:

- to inform medication treatment
- for reference by prescribers preparing medication orders for a patient on admission.

3.3.3 Review of medication orders

Medication orders must be regularly reviewed in accordance with NSQHS Medication Safety Standard, relevant NSW Health policy requirements and Drug and Therapeutics Committee approved procedures.

Facility procedures must provide for the timely follow up by prescribers and pharmacists when medication orders have been highlighted for review. Procedures must address medication review prioritisation based on:

- patient clinical needs

- the presence of medication related problems.

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

3.3.4 Documentation of patient allergy and adverse drug reactions

Facilities must have procedures for documenting patient allergies and adverse drug reactions in the health care records including:

- documenting on admission information on known allergies and adverse drug reactions in the medication history, all forms on which medications are ordered, in the electronic health record and eMeds system
- documenting allergies and adverse drug reactions experienced by patients during an episode of care in the health care record and in the incident management system
- documenting medication allergies and adverse drug reactions in dispensing systems
- communicating allergy and adverse drug reaction information during clinical handover and transitions of care.

Procedures must include clinician roles and responsibilities for documentation of allergy and adverse drug reaction history.

Clear instructions must be provided to patients and/or their carer on how to report their allergy or adverse drug reaction to all future care providers.

Specifically, prescribers must:

- include the active ingredient/s name, the brand where the reaction is brand specific, description of reaction experienced and its severity, and date of when the reaction occurred (if known) when documenting allergies
- check both hard-copy and electronic health record (including sources such as the patient's My Health Record) for medication allergies and adverse drug reactions where hybrid systems are used
- ask patients/carers about their medication allergy and/or adverse drug reaction history at each admission
- not prescribe medications to which patients have previously experienced severe allergic reactions, even if having demonstrated tolerance leading up to that event. An exception to this is if the patient has undergone desensitisation/delabelling to that medication, or use is under specialist advice
- refer to the patient's medication allergy and/or adverse drug reaction history before, or at the point of, decision-making on every occasion when prescribing medications.

3.3.5 Verbal, telephone, video call, email and facsimile medication orders

Procedures for an authorised prescriber to provide verbal (face to face), telephone, video call, email and facsimile orders are in section 6.3.

Following the order the prescriber must attend the patient for review as soon as he or she considers appropriate in the circumstances of the case.

Note: Under the Regulation, 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 and Forensic Mental Health Network if confirmation of the order for administration is given in accordance with the requirements in the approved facility procedures.

3.4 Issuing prescriptions for pharmacist dispensing

3.4.1 Forms of prescriptions

Prescriptions for pharmacist dispensing may be issued by an authorised prescriber either:

1. Handwritten by the prescriber (see section 3.4.2 and section 3.4.3), or
2. Issued in electronic form (only, with no printed paper-based prescription) by the prescriber using the eMeds system approved for use by the public health facility Chief Executive. The data elements for the prescription are in Standard 16 of NSW Health Policy Directive *Electronic Medication Management System Governance and Standards* (PD2019_050), or
3. Created and printed in paper using an electronic system compliant with the NSW Ministry of Health TG184 Criteria for Issuing Printed Computer-Generated Prescriptions. The Cerner Millennium eMeds 'Prescription Output Version 2' (POV 2) meets the printed (paper) prescriptions requirements and is a legally valid form of prescription, or
4. Created and printed in paper on the discharge summary document (however named) in accordance with facility procedures. The prescription must be dispensed at the Pharmacy Service of the public health facility where the prescription is issued.

The authorised prescriber must document the issuance of a prescription in the patient's health care record in accord with facility procedures.

An authorised prescriber's medication chart order may also be used to direct a pharmacist to dispense:

- discharge or leave medication for patient take home use
- medication for individual patient use at the public health facility (inpatient or outpatient).

Active ingredient prescribing is now in force for medications prescribed under the Pharmaceutical Benefits Scheme (PBS). It means that prescriptions dispensed under the PBS must include the active ingredient of the medication other than in specified circumstances.

3.4.2 Handwritten prescriptions for medications other than Schedule 8 medications

A handwritten prescription for a medication (other than a Schedule 8 medication – see section 3.4.3 below) must include:

a) the date the prescription is issued
b) the patient's name
c) the patient's address (as applicable to outpatient/discharge dispensing)
d) the patient's date of birth (in force from 1 November 2022)
e) the medication's active ingredient/s and/or, brand name (as applicable), form and strength
f) the quantity of the medication to be supplied. Take home supplies of regular use medications must not exceed 7 days' supply to patients when they are discharged from hospital in accord with facility procedures
g) adequate directions for use, including the dose, route for administration and frequency of administration
h) the number of repeat supplies, if any
i) the authorised prescriber's handwritten signature
j) the name, address and telephone number of the facility
k) 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
l) for Schedule 4 Appendix B medications (such as anabolic-androgenic steroids), an interval for repeat dispensing
m) the endorsement required for the Schedule 4 medications with restricted prescribing rights listed in section 3.7.

The particulars must be in the prescriber's clear and legible handwriting.

A 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, date of birth, address and/or patient care area and medical record number (if applicable)
- Under facility procedure the prescriber is to confirm 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.

The authorised prescriber must document the issuance of a prescription in the patient's health care record in accord with facility procedures.

3.4.3 Handwritten 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 paper-based Schedule 4 medication prescription above in section 3.4.2 at a)-k) 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 repeats are prescribed)
- must not include any other medication (Note: Different strengths of the same medication, for example buprenorphine sublingual film/tablets, are allowed)
- in the case of a type A drug of addiction prescribing, must include the NSW Health authority reference number issued to the prescriber (see section 3.8), either;
    - as an individual reference number issued to the prescriber on a patient-by-patient basis in the form 'AU*XXXXXXX*", or
    - as a reference number in the form '*S28CXXXXXX*' issued to a specialist medical practitioner for prescribing in accordance with the associated NSW Ministry of Health approved criteria, or
    - as a reference number in the form '*CNSXXXXXX*' issued to a specialist medical practitioner for prescribing in accordance with the associated NSW Ministry of Health approved criteria.

The authorised prescriber must document the issuance of a prescription in the patient's health care record in accord with facility procedures.

3.4.4 Discharge summary

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

The discharge summary must:

- identify changes to the medication regimen during the patient's stay and outline the reason/s for the changes
- include an ongoing plan for medication management including the duration of treatment, any ongoing monitoring requirements and any dose adjustment requirements.

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) in a timely manner (ideally on discharge).

3.4.5 Emergency verbal, telephone, video call, email and facsimile prescriptions

In an emergency, an authorised prescriber may either verbally (face to face), by telephone, video call, email or facsimile direct a pharmacist to dispense a prescription for any medication. Medication orders via Short Message Service (SMS) or texting are not permitted and are not legally valid. Relevant details as listed in section 3.4.3 for Schedule 8 medication and section 3.4.2 for other medication must be included in the order to the pharmacist.

The authorised prescriber must make a record of the verbal, telephone, video call, email or facsimile direction to the pharmacist to dispense a prescription. Under the Regulation, the authorised prescriber must:

- immediately issue a prescription
- endorse the prescription with words that indicate the prescription has been issued in confirmation of a verbal (face to face), telephone, video call, email or facsimile direction to the pharmacist
- send the prescription without delay and within 24 hours to the pharmacist to whom the direction was given.

3.4.6 Security of prescription stationery and eMeds passwords

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

Pre-printed prescription stationery may include under facility procedures:

- unique, consecutive numbering of each form
- the words ‘not valid for Schedule 8 drugs’ (or the like) pre-printed or stamped on the form, if applicable to the patient care area.

Under facility procedures strategies to support security of prescription stationery must be implemented including:

- distribution through a centralised service such as the facility’s Pharmacy Service
- the return of unwanted prescription stationery to the Pharmacy Service for destruction.

Forged and fraudulently altered prescriptions and lost or stolen prescription stationery from the facility must be reported in the facility incident management system and to the NSW Ministry of Health Pharmaceutical Regulatory Unit.

The pharmacist must report a forged or fraudulently altered prescription presented to pharmacy to the local police. The pharmacist must document the Event Number issued by the police in accordance with facility procedures.

Facilities must have Drug and Therapeutics Committee approved procedures to maintain the security of user identity and passwords for eMeds systems to prevent unauthorised access to medication ordering.

3.5 Medications for 'off-label use' and unregistered medications

Prescribers considering use of a specific medicine (formulary or individual patient use) in an off-label manner, or the use of an unregistered medication, must follow a systematic procedure to assist with their assessment on whether such use is justified.

NSW Health Policy Directive *Approval Process of Medicines for Use in NSW Public Health Facilities* (PD2016_033) establishes a standard procedure for the approval of medicines and their use.

3.6 Medications for clinical trials

A clinical trial involving a medication administered to or on humans must be approved by a 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 TGA.

Drug and Therapeutics Committees must be notified of any clinical trials involving medications occurring in the health service organisation and must also have oversight of risks of clinical trials to the organisation (other than the clinical considerations assessed by an ethics committee).

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 *Ethical and Scientific Review of Human Research in NSW Public Health Organisations* (PD2010_055), 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 Authorisation to Commence Human Research in NSW Public Health Organisations* (PD2010_056).

3.7 Restrictions on issuing prescriptions for certain Schedule 4 medications

Due to potential hazards with their use, the prescribing of certain Schedule 4 medications is restricted under the Regulation to authorised prescribers in accordance with the corresponding qualifications and/or conditions.

However, in an emergency, under Clause 37 of the Regulation, a pharmacist may obtain a telephone, video call, email or facsimile order from the prescriber (see section 3.4.4).

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.*

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 order by an authorised prescriber at the hospital for the term of the patient's inpatient stay.

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 NSW Ministry of Health Pharmaceutical Regulatory Unit.

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation',* or alternatively, with the individual authority reference number (*RA.....*) that has been issued to a particular prescriber by the NSW Ministry of Health.

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 order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'*.

C. clomifene, cyclofenil

Prescribing is restricted to a specialist who is either:

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

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 order by an authorised prescriber at the hospital for the term of the patient's inpatient stay.

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'*, or alternatively, with the individual authority reference number (*CL.....*) that has been issued to a particular prescriber by the NSW Ministry of Health Pharmaceutical Regulatory Unit.

D. follitropin beta, luteinising hormone, urofollitrophin

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

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'*.

E. dinoprost

Prescribing is restricted to either:

- A specialist who is either a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists or a Fellow of the Royal College of Obstetricians and Gynaecologists, or
- A 'GP Obstetrician', defined as a medical practitioner who is not a specialist obstetrician or gynaecologist but who has completed the Diploma of the Royal Australian and New Zealand College of Obstetricians after January 1992, or who has completed the Diploma of the Royal Australian and New Zealand College of Obstetricians prior to 1 January 1992 and has attended a course approved by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists or Royal Australasian College of General Practitioners on the use of prostaglandins in obstetrics.

The prescribing must be in accordance with the NSW Health guideline on *Prevention, Detection, Escalation and Management of Postpartum Haemorrhage*.

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'*, or alternatively, with the individual authority reference number (*PGT.....*) that has been issued to a particular prescriber by the NSW Ministry of Health Pharmaceutical Regulatory Unit.

F. dinoprostone (in any form)

Prescribing is restricted to either:

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

adverse reactions and which has been approved and signed by the Director of Obstetrics and Gynaecology.

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'*, or alternatively, with the individual authority reference number (*PGT.....*) that has been issued to a particular prescriber by the NSW Ministry of Health Pharmaceutical Regulatory Unit.

G. hydroxychloroquine

Prescribing is restricted to either:

- A medical practitioner practicing in a public hospital to treat patients of the hospital, or
- A medical practitioner registered in the specialty of either;
    - dermatology
    - intensive care medicine
    - paediatrics and child health
    - emergency medicine
    - physician, or
- A medical practitioner practicing in general practice for the purpose of continuing treatment initiated by a medical practitioner registered in such a specialty, or
- A dentist registered in the specialty of oral medicine, or

The prescription or medication order used for pharmacist dispensing must be endorsed by the prescriber with words to the effect '*Issued under clause 37 of the Poisons and Therapeutics Goods Regulation'.*

H. ivermectin

Prescribing is restricted to either:

- A medical practitioner registered in the specialty, or field of specialty practice, of either;
    - dermatology
    - gastroenterology and hepatology
    - paediatric gastroenterology and hepatology
    - infectious diseases
    - paediatric infectious diseases, or
- A medical practitioner or nurse practitioner using ivermectin as part of a clinical trial approved by, or notified to, the Secretary of the Commonwealth Department of Health under the *Therapeutic Goods Act 1989*, or
- A medical practitioner or nurse practitioner practising in a public hospital to treat patients of the hospital, or

- A medical practitioner or nurse practitioner prescribing or supplying topical preparations of ivermectin.

3.8 Requirements for certain Schedule 8 medication prescriptions

An authority to issue a prescription for Schedule 8 medications issued under the specific requirements at section 28 of the *Poisons and Therapeutic Goods Act 1966* (a "NSW Health Authority') is distinct from an authority issued by Medicare Australia for the prescribing of Pharmaceutical Benefits Scheme listed medications.

When prescribing a Schedule 8 medication, it is the responsibility of the prescriber to ensure they have obtained the appropriate Schedule 8 medication NSW Health Authority, administered by the NSW Ministry of Health Pharmaceutical Regulatory Unit.

The specific circumstances for requiring a NSW Health Authority are:

A. For a Type A drug of addiction (being dexamfetamine, lisdexamfetamine, methylphenidate or an extemporaneously compounded Schedule 8 medication), including for a clinical trial, either by:

   - An authorised prescriber issued with a NSW Health Authority reference number on a patient by patient basis in the form '*AUXXXXXXX*', or
   - a specialist medical practitioner who has been issued an approval under the Regulation that includes a reference number in the form '*S28CXXXXXX*', for prescribing in accordance with the associated NSW Ministry of Health approved criteria, or
   - a specialist medical practitioner who has been issued an approval under the Regulation that includes a reference number in the form '*CNSXXXXXX*', for prescribing in accordance with the associated NSW Ministry of Health approved criteria.

   The authorised prescriber must include the NSW Health Authority reference number on the prescription.

B. For any person who, in the opinion of the authorised prescriber, is a drug dependent person, as defined in the *Poisons and Therapeutic Goods Act 1966* as a person who has acquired, as a result of repeated administration of either a Schedule 8 medication or a prohibited drug (for example heroin, methylamphetamine, ecstasy), an overpowering desire for the continued administration of the substance.

C. To a person for continuous treatment for a period exceeding two months of;

   - a Schedule 8 medication packaged and labelled for injection, inhalation, spray, or for application to mucous membranes, other than if a Schedule 8 cannabis medicine
   - alprazolam
   - buprenorphine other than as transdermal patches
   - flunitrazepam

- hydromorphone
- methadone.

Note: If the patient is, in the opinion of the authorised prescriber, is a drug dependent person, as defined in the *Poisons and Therapeutic Goods Act 1966,* a NSW Health Authority must be obtained prior to prescribing any of the above medications.

D. A Schedule 8 preparation extemporaneously compounded for a particular patient for use outside of a public health facility, including for a clinical trial. The authorised prescriber must include the NSW Health Authority reference number on the prescription.

E. An unregistered Schedule 8 medication for a clinical trial.

Exemption for prescribing to a hospital inpatient

An exemption to obtaining a NSW Health Authority in the circumstances at A. to C. above applies for the prescribing to an inpatient for a period of up to 14 days following admission.

Following this 14 day period the hospital authorised prescriber may continue to prescribe in accord with the NSW Health Authority issued to a community based authorised prescriber prior to the patient's admission, or obtain a NSW Health Authority from the NSW Ministry of Health if there is no such NSW Health Authority (meaning the medication was initiated in hospital).

Schedule 8 discharge medications for inpatients on release from the facility must be prescribed in accordance with a NSW Health Authority issued to the hospital authorised prescriber required in the specified circumstances A. to E. above.

Prescribing for children

A general exemption order has been issued by the Secretary, Department of Communities and Justice under the *Children and Young Persons (Care and Protection) Act* 1998 (NSW) published on the Department of Communities and Justice website.

Under the *Children and Young Persons (Care and Protection) Act 1998* (NSW), a person must not carry out a special medical treatment on a child, including any medical treatment that involves the administration of a drug of addiction within the meaning of the *Poisons and Therapeutic Goods Act 1966* (NSW) (a Schedule 8 medication) over a period or periods totalling more than 10 days in any period of 30 days.

Under this general exemption order, a medical practitioner may treat a child:

- with any drug of addiction for the medical treatment of cancer, or
- with dexamfetamine, lisdexamfetamine or methylphenidate for the medical treatment of Attention Deficit Hyperactivity Disorder (ADHD), or
- with dexamfetamine or methylphenidate for the medical treatment of narcolepsy.

For any other special medical treatment of a child a medical practitioner must apply for an exemption under the Act for consideration on a case-by-case basis.

4 THE PHARMACY SERVICE

4.1 Responsibility

The director of Pharmacy Service, or the pharmacist delegated by the Chief Executive where there is no director of pharmacy, is responsible for the storage of all medications at the facility other than those that have been supplied to a patient care area.

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

Where no pharmacist is employed or contracted at the facility the responsibility of the storage and distribution of medications from the facility's medication supply service is assigned to the authorised officer at the facility, defined as:

- the director of nursing of the facility (however named), or
- the medical superintendent of the facility (however named)

appointed by the facility's chief executive.

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.

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

4.2 Medication procurement

4.2.1 Medication purchasing

NSW public health facilities are eligible to obtain medications from a licensed pharmaceutical wholesaler as a public institution under the NSW *Poisons and Therapeutic Goods Act 1966.*

Orders for medications may be placed with the pharmaceutical wholesaler in writing, or electronically (telephone, electronic document interface, email or facsimile).

All hospitals must have procedures in place to ensure contract compliance as part of their purchasing process.

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

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

NSW Health Policy Directive *Goods and Services Procurement Policy* (PD2019_028) provides further guidance regarding purchasing procedures. Medication safety and equity of access must be considered in purchasing decisions.

Procurement of NSW contract and non-contract medications

Facilities are required to purchase medications in accordance with the supply contracts arranged by the NSW State Contracts Control Board. If a contracted medication is not available, the supplier is obligated to substitute with an equivalent ARTG product where available. Items for which there is no contracted equivalent may be purchased as required.

Procurement concentrates on the strategic process of product or service sourcing, for example researching, negotiation and planning. Purchasing process focuses on how products and services are acquired and ordered, such as raising purchase orders and arranging payment.

HealthShare NSW negotiates and manages the state pharmaceutical contract that is a Whole-of-Health contract for the supply of pharmaceuticals for all health facilities. All state contracts have a continuous best price clause and therefore suppliers are required to report any local offer for a contracted item below the contract price to the pharmaceutical procurement team at HealthShare NSW.

Facilities can undertake all procurement related activities up to $250,000 within the framework of the procurement policy at a local level. For procurements over $250,000, Facilities are to seek assistance from HealthShare NSW or the Ministry of Health. HealthShare NSW local contracts team coordinates and manages all local contracts.

Medicines Access Programs

Medicines Access Programs are offered by pharmaceutical companies (sponsors) to facilitate deferred cost, cost-free or subsidised access to medicines for hospital patients before the implementation of relevant funding arrangements.

Medicines Access Programs include, but are not limited to, the following:

- Compassionate Use Programs
- Expanded Access Programs
- Product Familiarisation Programs (also known as patient familiarisation programs – PFPs)
- Cost-Share Programs.

See CATAG Guiding Principles for the Governance of Medicines Access Programs in Australian Hospitals.

4.2.2 Medication purchasing from a community pharmacy

Under facility procedures, in circumstances where a medication required for a particular patient is not in stock at a facility, and not available through the patient's primary health practitioner, an arrangement for supply from a community pharmacy may be made. Medication supplied under a sponsor facilitated Medicine Access Program may be included.

In addition, 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 and any licensing of wholesale supply required under the legislation. NSW Health Policy Directive *Pharmaceuticals - Preparation in NSW Public Health Facility*

Pharmacy Services (PD2015_007) outlines the conditions and requirements for procuring non-ARTG listed products from a community pharmacy.

4.2.3 The Life Saving Drugs Registers (antidotes and antivenoms)

The Life Saving Drugs Registers for NSW and ACT public hospitals provide indicative stock holding information of life saving drugs, including antivenoms and antidotes, in hospitals, their location within the hospital and hospital contact details to enable access to stock in urgent situations.

4.2.4 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 senior nursing and/or medical staff.

After-hours deliveries of Schedule 8 medication(s) must be handled in accordance with the procedure in section 4.2.5 below.

4.2.5 Receipting for the delivery of Schedule 8 medications

Under the Regulation, 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.

Under the Regulation, when the Schedule 8 medication sealed parcel is received at the Pharmacy Service, a delegated pharmacist, or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted must:

- check the contents against the original purchase order
- sign and date a receipt confirming the supply of the Schedule 8 medication(s)
- 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.

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 (safe or vault).

Facility procedures must include the provision for the after-hours delivery of a sealed parcel containing a Schedule 8 medication being stored unopened in an appropriate patient care area Schedule 8 medication storage unit (for example the Emergency Department) pending the return to duty of a pharmacist, or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted.

The corresponding Schedule 8 drug register entry in the patient care area must be on a separate page to all other medications, and recorded as, for example '*one unopened sealed package*' with the consignment/invoice number where available, pending transfer to the Pharmacy Service.

4.3 Medication storage in the Pharmacy Service

4.3.1 Medication security and access – general provisions

The Pharmacy Service is an area requiring high security. Refer to the NSW Health *Protecting People and Property Manual* for advice concerning the management of security in the Pharmacy Service.

Access to the Pharmacy Service must be restricted to staff authorised by the director of pharmacy, or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted. Procedures for authorising and auditing access to the Pharmacy Service by keys or other means must also be implemented. Only a pharmacist may be authorised to access the Schedule 8 medication safe or vault at the Pharmacy Service.

4.3.2 After-hours access to the Pharmacy Service

Access to the Pharmacy Service must be in accordance with Drug and Therapeutics Committee approved procedures and restricted to delegated senior nursing and/or medical staff. After-hours to the Pharmacy Service where a pharmacist is employed/contracted must not include access to the Schedule 8 medication safe or vault.

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 must be held under maximum security with the facility's security service.

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

4.3.3 General medication storage requirements

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

Storage temperatures must be consistent with the range specified on the manufacturers' labels (typically not above 25°C for 'general' storage, and 2-8°C for refrigerated storage) and monitored accordingly.

In the event of temperature storage conditions falling outside those specified by the manufacturer, the director of pharmacy must evaluate the event and take appropriate action. Facilities must have procedures for cold chain management in place.

Vaccines must be stored in accordance with the Commonwealth *National Vaccine Storage Guidelines 'Strive for 5* and NSW Health Policy Directive *Vaccine Storage and Cold Chain Management* (PD2020_028). This policy provides mandatory requirements for the storage

and management of vaccines in all public health facilities to ensure vaccine potency and that all vaccine cold chain breaches are identified and managed effectively.

A system of stock rotation, monitoring of expiry dates, quarantining and disposal of expired and unwanted medications must be in place under facility procedures approved by the director of pharmacy.

Where additional access controls are deemed appropriate, under facility procedures specific non-Schedule 8 medications:

- may be stored separately in locked cupboards with restricted access by authorised staff members, and/or
- may be accounted for in a register.

Medications that could be considered for increased access controls include Schedule 4 benzodiazepines, propofol, methoxyflurane, tramadol, codeine phosphate hemihydrate combination products or pseudoephedrine containing products.

4.3.4 Storage of Schedule 8 medications

Under the Regulation all Schedule 8 medications in the Pharmacy Service or medication supply service at a facility where there is no employed/contracted pharmacist must be stored in a separate safe or vault apart from all other medications or goods other than cash or documents.

Note: An exception applies to a Schedule 8 medication requiring refrigerated storage (see below). A 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 Regulation, ‘Storage in Pharmacies’. The safe/vault must be kept locked when not in immediate use.

Requirements for the management of key (metal keys, electronic keys, electronic swipe card access and key pad codes) security in the Pharmacy Service and key control is in NSW Health *Protecting People and Property Manual*. Where fingerprint security is in use, facility procedures must include security requirements.

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

Where a code, combination or electronic access is required to unlock the safe/vault, this must only be known to authorised pharmacists, or the authorised officer of the medication supply service at a facility where no 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 must be stored in a Schedule 8 medication safe/vault until collected or delivered.

4.3.5 Schedule 8 medication requiring refrigerated storage

As an exception to storage in a safe or vault, the refrigerator containing a Schedule 8 medication be in a room or enclosure (such as a cupboard or other receptacle) to which the public does not have access, and:

- the refrigerator must be securely attached to the premises and kept locked when not in immediate use
- the locked refrigerator may contain other medications, but not food or other goods
- the refrigerator may be accessed only by a pharmacist
- any key or other device, or any code or combination required to access or unlock the refrigerator, room, cupboard or other receptacle must be kept, and be accessible only by, a pharmacist.

4.4 Medication supplies

4.4.1 Authorised recipients of Pharmacy Service medications

The Pharmacy Service at a public health organisation is authorised to supply medications:

- to patient care areas and other Pharmacy Services in the public health organisation's own public hospitals, public health facilities, health services and health support services, as stock and imprest medications or as patient-labelled medication, including medications for Hospital in the Home, community nursing and outreach services
- to another public health organisation under the Special Licence for wholesale supply, being to the director of pharmacy or authorised officer at a facility where no pharmacist is employed/contracted (Note: Schedule 8 medications are excluded)
- as patient-labelled medication to inpatients on discharge and non-admitted patients/outpatients attending a public health facility or receiving community nursing or outreach services. For immunoglobulins see under NSW Health Guideline *Establishing a Subcutaneous Immunoglobin Hospital Program* (GL2020_024) for eligible patients for patient-labelled medications
- in an emergency, morphine ampoules to a NSW Ambulance paramedic (see section 4.4.3)
- under a routine procedure or program approved by the NSW Ministry of Health or the Drug and Therapeutics Committee, for example nicotine replacement therapy, in a public health response and for disaster management
- for the urgent treatment of a specific non-health facility patient upon receipt of a prescription where approved by the director of pharmacy, or Chief Executive, Medical Administrator/nominee in accord with NSW Health Policy Directive *Pharmaceutical and Safety Net Arrangements for Outpatients and Patients on Discharge* (PD2022_017)
- for a clinical trial drug dispensed for an individual patient of a public health facility or at a private health facility under a service level agreement and facility procedures for participation in the trial.

4.4.2 Patient payment for medications

There is no charge for medication supplied to an inpatient during their hospital stay or on discharge, or for an outpatient treated during the outpatient encounter.

The provision, payment, and quantities of medications supplied to eligible outpatients for take home use, including Section 100 Highly Specialised Drugs (S100 HSD) under the *National Health Act 1953* is detailed in NSW Health Policy Directive *Pharmaceutical and Safety Net Arrangements for Outpatients and Patients on Discharge* (PD2022_017).

4.4.3 Emergency supplies of morphine ampoules to NSW Ambulance paramedics

The director of pharmacy must have oversight of procedures for emergency supplies of morphine ampoules to NSW Ambulance paramedics. In emergency circumstances, a pharmacist may supply a NSW Ambulance paramedic with a reasonable quantity of morphine sulfate pentahydrate 10 mg/mL, 1 mL ampoules from the Pharmacy Service stock.

The 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.

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.

4.4.4 Pharmaceuticals preparation

Pharmaceuticals prepared on or behalf of a NSW public health facility must be prepared in accordance with NSW Health Policy Directive *Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services* (PD2015_007).

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.

There are a range of professional standards that may apply including those from the Pharmacy Board of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia and the Therapeutic Goods Administration (TGA).

Barcode scanning during dispensing

All pharmacy services must have barcode verification incorporated into dispensing procedures to reduce the rate of product selection errors. Barcode verification must be used for all medications which have a barcode on the packaging. Barcoding verification must be incorporated into the dispensary workflow such that it acts as to confirm the correct product selection when the dispensing label is applied. The only exclusion is the dispensing of medication packs that do not include an appropriate barcode, for example:

- When dispensed for a clinical trial, or

- Obtained under the Special Access Scheme or Authorised Prescriber Scheme (and not on the ARTG), or
- A compounded or reconstituted medication, either outsourced to an external manufacturer or prepared locally.

All pharmacy staff involved in the dispensing procedure including pharmacists, pharmacy technicians and pharmacy interns, must be provided with education and training on how to use barcode scanning to confirm the correct product selection.

The Clinical Excellence Commission has an Information for Staff education package to assist pharmacy services implement of barcode scanning.

4.4.5 Sensitisation due to occupational exposure

All staff are to 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 under facility procedures.

NSW Work, Health and Safety legislation requires that all workplace risks, including those associated with the handling of pharmacological agents, be identified, assessed and controlled. NSW Health Policy Directive *Work Health and Safety: Better Practice Procedures* (PD2018_013) provides guidance on implementing the *Work Health and Safety Act 2011* and *Work Health and Safety Regulation 2017.*

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 such as masks, gloves, gowns and respirators
- applying facility procedures specific to the situation to minimise exposure
- taking prompt action where symptoms of allergy or sensitisation occur
- regularly reviewing effectiveness of facility procedures.

4.4.6 Schedule 8 medication deliveries by a facility staff member

Under facility procedures, imprest and stock Schedule 8 medications ordered by the registered nurse/midwife in charge of a patient care area may be delivered to the patient care area by a facility staff member, under the direction of a pharmacist, or by the authorised officer of the medication supply service at a facility where no 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/s ordered from the Pharmacy Service when ordered 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 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.

4.4.7 Schedule 8 medication delivery by a courier

When imprest and stock 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.

Under the Regulation, 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. Under facility procedure, the courier must then arrange for this 'proof of delivery' receipt to be forwarded to the Pharmacy Service that supplied the medication.

Under the Regulation, 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 in accordance with facility procedures. A copy of this receipt must also be retained at the patient care area.

4.5 Dispensing patient-labelled medications

4.5.1 Orders for dispensing patient-labelled medications

Patient-labelled medications for inpatient or clinic administration

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

- From the authorised prescriber's clear and legible medication order either forwarded to the Pharmacy Service as a photocopy, by facsimile or as a scanned copy in an email, or
- On an authorised prescriber's electronic order in the eMeds system, or
- On a paper-based prescription issued by an authorised prescriber, with the relevant details listed in section 3.4.3 for Schedule 8 medications and in section 3.4.2 for Schedule 4 medications and other non-Schedule 8 medications, or

- From a verbal (face to face), video call, telephone, email or facsimile order of an authorised prescriber (see section 4.5.3).

Under facility procedures, medications dispensed for an individual patient are to be reviewed by a pharmacist 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 either:

- A prescription issued by an authorised prescriber, with the relevant details listed in section 3.4.3 for Schedule 8 medications and in section 3.4.2 for Schedule 4 medications and other non-Schedule 8 medications. See section 3.4.5 for verbal (face to face), telephone, video call, email or facsimile order of an authorised prescriber provisions, or
- The discharge medication order section of a paper-based medication chart either sighted then photocopied by the pharmacist, or forwarded to the Pharmacy Service by facsimile, email or another approved electronic form. *Note* that for Schedule 8 discharge medication orders, the authorised prescriber must also issue a paper-based prescription as the original is required as detailed in section 3.4.3, or
- Where approved at the facility, the discharge summary document (however named) printed and signed by the authorised prescriber. For Schedule 8 discharge medication the authorised prescriber must also issue a paper-based prescription as detailed in section 3.4.3), or
- An electronic discharge prescription using the eMeds system approved for use by the public health facility Chief Executive.

Under facility procedures, the pharmacist dispensing medication(s) for an individual patient must review the medication order or prescription in the context of the patient's full medication regimen and clinical status (where available) prior to the medication(s) being provided to the patient (or patient's carer).

Outpatient Dispensing

Prescriptions for dispensing Schedule 4 medications and Schedule 8 medications for outpatients to take home must be in the paper form detailed in section 3.4.2 and section 3.4.3 respectively or in the eMeds system under facility procedures.

All pseudoephedrine preparations may only be dispensed for patient take home use on a prescription in the format detailed in section 3.4.2, that is treated as a Schedule 4 medication.

4.5.2 Schedule 8 prescriptions – additional requirements

A pharmacist must not dispense a prescription for a Schedule 8 medication if the authorised prescriber's authority to prescribe such a medication has been withdrawn under the *Poisons and Therapeutic Goods Regulation 2008*.

The current list of withdrawn Schedule 8 drug authorities under the Regulation is on the Ministry of Health website. Withdrawn authorities are also published in the NSW Government Gazette as they occur.

A paper-based prescription for a Schedule 8 medication must not include any other medication. Orders for dispensing discharge medications on the patient's medication chart are excluded from this requirement.

The Regulation requires that a pharmacist must not dispense a paper-based prescription for a Schedule 8 medication unless he/she:

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

4.5.3 Emergency verbal, telephone, video call, email or facsimile prescriptions

In an emergency, a pharmacist may dispense a prescription for any medication on the verbal (face to face), telephone, video call, email or facsimile order of an authorised prescriber (see section 3.4.5).

A pharmacist can only dispense an unregistered Schedule 8 medication, including an unregistered Schedule 8 cannabis product, on receipt of a prescription or medication order. Dispensing on an emergency telephone, video call, email or facsimile order is not permitted under the Regulation.

For all other Schedule 4 or Schedule 8 medication orders, the prescriber must send the prescription without delay (and within 24 hours) to the pharmacist to whom the direction was given. If this prescription is not received with 7 days, this fact must be reported by the pharmacist involved to the NSW Ministry of Health Pharmaceutical Regulatory Unit.

4.5.4 Prescription forgeries

Detected prescription forgeries for any medication must be reported by the director of pharmacy or delegated senior pharmacist to NSW Police and obtain the NSW Police issued Event Number. Prescription forgeries are to be reported to the NSW Ministry of Health Pharmaceutical Regulatory Unit where related to the theft of prescription pads from the facility.

4.5.5 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 re-packing medications.

Therapeutic Goods Order No.95 'Child-Resistant Packaging Requirements for Medicines' (TGO 95) specifies those medications that must be supplied in child resistant packaging, the

standards that must be met and the situations and conditions under which they are exempt from these requirements.

TGO 95 also provides exemptions to the use of child resistant packaging, including 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
- medications intended to be administered by injection
- 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.

Medications identified by TGO 95 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.

Pharmacy information systems – format of the warning flag and statement for child resistant packaging

Child resistant closure warning flags and statements 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 procedure. The warning flag or statement does not need to be printed on the main dispensing label used for the labelling of patient medications, or 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. 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 in the dispensing system. Where the warning flag appears it will be presented as the text ‘KIDCAP’

Warning statement text in the dispensing system. Where the warning statement appears it will be presented as the text '*Child resistant packaging required*' with *'This medicine MUST be supplied in child resistant packaging except if it is to be administered in a hospital or nursing home'.*

Medications within scope of the Hospital Pharmacy Product List (HPPL) that require child resistant packaging as per TGO95 will have the KIDCAP warning flag assigned in the iPharmacy application for HPPL affiliated sites. A comprehensive list of these medications is captured in the *Hospital Pharmacy Product List Warning Codes* document and can be found via the eHealth NSW Service Delivery SharePoint page. Users must check this page for the current list as updates are made regularly.

Facilities that do not subscribe to HPPL must have procedures in place to identify medications requiring child resistant packaging.

Settings where child resistant packaging must be used

All medications identified by TGO 95 as requiring child resistant packaging, and are not exempted, must be supplied in child resistant packaging. This includes the supply by both a pharmacist and an authorised prescriber.

Medications for use within the hospital and outside of the hospital that require child resistant packaging include:

- outpatient medications dispensed/supplied for take-home use
- discharge medications
- medications dispensed for day or weekend leave
- pre-packs of medication in patient care areas 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 *'This medicine MUST be supplied in child resistant packaging except if it is to be administered in a hospital or nursing home'*.

Under facility procedures, a pharmacist can exercise discretion, in consultation with the authorised prescriber as appropriate, and not dispense the medication in child resistant packaging when the pharmacist and/or the authorised prescriber is of the opinion that the patient would suffer undue hardship through difficulty in opening the container. This must be documented in the pharmacy dispensing system.

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.

4.5.6 Labelling of dispensed medications

Dispensed medications must be labelled in accordance with Appendix A to the Regulation, with:

- the patient's name

- the medication's active ingredient/s, brand name (where applicable), form, strength and the quantity supplied
- adequate directions for use including, where ordered, the instructions specified by the prescriber (*Note*: Under facility procedures, may be excluded for inpatients where administration is by staff)
- the Pharmacy Service's dispensing reference number
- the date of dispensing (unless that date is also in the dispensing reference number)
- the name and address of the hospital
- the words KEEP OUT OF REACH OF CHILDREN in red on a white background
- 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
- if the substance is supplied in the circumstances referred to in section 4.5.3 on a verbal, telephone (face to face), video call, email or facsimile order, the words '**EMERGENCY SUPPLY'**
- 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 ARTG product or a standard Australian Formulary does not exist, 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.

4.5.7 Mandatory ancillary labels and warning statements

Specified sedating medications

The container of the specified sedating medications listed in Appendix K to the Poisons Standard must bear a label with 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*'.

Specified stimulant medications (in Appendix A of the Regulation)

The medications are:		
amphetamine	chlorphentermine	dexamfetamine
ephedrine	diethylpropion	lisdexamfetamine
methylphenidate	phentermine	propylhexedrine

The 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 a label with 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.

Quinine

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

4.5.8 Unregistered medications for clinical trials

A clinical trial drug which is not registered or listed on the ARTG must be labelled, stored, prescribed, administered and recorded either:

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

4.5.9 Records of dispensing

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

- entering the details in the electronic dispensing system (such as 'iPharmacy'), or
- writing the details in a prescription book, or
- retaining the prescription, or a copy of the prescription or medication 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:

- the date on which the prescription or order was issued
- the patient's name, and address and/or patient care area
- the patient's date of birth when required under the Regulation

- the medication's active ingredient/s, brand name (where applicable, as supplied), strength, form and the quantity supplied
- adequate directions for use including, where ordered, the instructions specified by the prescriber
- where prescribed, the number of repeat supplies of the medication
- where repeats are ordered for Schedule 8 or Schedule 4 Appendix B medications the interval at which the medication may be repeat supplied
- the name and designation of the authorised prescriber, and the name, address and telephone number of the facility
- the unique reference dispensing number issued at the Pharmacy Service
- the date on which the medication was dispensed
- the name of the pharmacist who dispensed the medication.

Where a medication is dispensed as an 'EMERGENCY SUPPLY' on a telephone, video call, email, or facsimiled order from an authorised prescriber in accordance with section 4.5.3, the pharmacist must report to the NSW Ministry of Health Pharmaceutical Regulatory Unit the circumstance of a prescription that is not received within seven (7) days.

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

All dispensing records, as well as the (original) dispensed paper-based 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.

Where the name and designation of the authorised prescriber of the medication order is recorded in an eMeds system and is linked with the record of dispensing through a unique identifying number, these prescriber details may be omitted from the dispensing record. The link must remain in place for the required period for retaining records (see section 5.11).

4.6 Imprest and stock supplies to patient care areas

4.6.1 Requisitions for medications

Medications may be supplied from the Pharmacy Service either:

- With reference to the approved imprest list for the patient care area including the list generated by an automated dispensing cabinet system, or
- On the clear and legible requisition of the registered nurse/midwife in charge of the patient care area where the medication is to be used, either as the original hand written (hard copy) order, by facsimile, by email or electronic order such as generated by an automated dispensing cabinet, or
- From a clear and legible medication order by an authorised prescriber, either sighted then photocopied by the pharmacist (or the authorised director of the medication

supply service at a facility where no pharmacist is employed/contracted) or alternatively forwarded to the Pharmacy Service by facsimile, email or eMeds order.

The range of medications and respective stock levels on an imprest list must be set by agreement between the nurse/midwife or appropriately authorised person 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 medications to patient care areas.

4.6.2 Re-packaging and labelling of imprest and stock medications

Medications supplied from the Pharmacy Service to patient care areas must 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 pharmacist. Re-packaging of medications must be carried out by, or under the supervision and checked by, a 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 2.1 to 2.6 of the Poisons Standard.

Medications requiring child resistant packaging must be re-packed as such when provided to the Emergency Department and other settings where the medication may later be supplied to a patient for take-home use (see section 4.5.5).

Labelling of re-packed medications must include, as a minimum, the following details:

- the medication's active ingredient/s, brand name (where applicable), form, strength and the quantity supplied
- the name and address of the facility
- 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
- any applicable additional information included on the manufacturer's original pack
- 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
- if applicable under facility procedures, that the preparation is a Schedule 8 or Schedule 4 Appendix D medication.

4.7 Pharmacy Service Schedule 8 medication accountability

4.7.1 Entries in the Schedule 8 drug register

The director of pharmacy or delegate is responsible for ensuring that a record is kept of all Schedule 8 medication transactions in a drug register. Unless in an approved electronic form under NSW Health *Framework for Use of an Electronic Drug Register Requiring Signal*

Signature, the drug register must be the State Forms bound book with consecutively numbered pages. A separate page must be used for each form and each strength of the Schedule 8 medication. Brands of the same strength and form (for example, Methadone Syrup and Methadone Oral Solution) may be recorded on separate pages under facility procedures.

Only a pharmacist, or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted, may make an entry in the Schedule 8 drug register.

The record in the drug register must be made on the day the transaction occurred and must include in handwriting or in an approved electronic form:

- the date of the transaction
- 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 medical record 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 physical balance on hand after the transaction. An 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, reported and investigated in accordance with the procedure detailed in section 4.9
- 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
- for imprest supplies, the name of the requisitioning registered nurse/midwife in charge, or the name of the authorised prescriber for patient-labelled medications
- the full and legible name and signature of the pharmacist, or the authorised officer of the medication supply service at a facility where no pharmacist is employed/contracted, making the entry
- where the Schedule 8 medication is destroyed, in accordance with the additional requirements detailed in section 4.8.2.

Under the Regulation, a pharmacist, or the authorised officer of the medication supply service at a facility where no 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, or 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.

4.7.2 Schedule 8 medication balance checks

Under the Regulation, a count of the balance of all Schedule 8 medications held in the Pharmacy Service, or medication supply service at a facility where there is no employed/contracted pharmacist, must be made during March and September each year as a minimum, and at other times under facility procedures, including:

- opened containers of liquids must be decanted and measured by a 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 count of all Schedule 8 medication stocks
- any detected loss (deficit) must be reported to the NSW Ministry of Health Pharmaceutical Regulatory Unit, as described in section 4.9.

A delegated pharmacist or authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist 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.

4.8 Disposal/destruction of medications

4.8.1 Disposal of medications – general requirements

The Pharmacy Service or medication supply service at a facility where there is no employed/contracted pharmacist must have procedures to dispose of all expired, unusable unwanted medications, including cytotoxic medications, in accordance with NSW Health Policy Directive *Clinical and Related Waste Management for Health Services* (PD2020_049).

Expired, unusable or unwanted medication must not be collected for the purpose of donation for humanitarian relief, in accordance with the *Australian Guidelines for Drug Donations to Developing Countries*.

4.8.2 Destruction of expired, unusable or unwanted Schedule 8 medications

Under Drug and Therapeutics Committee approved procedures, the following staff may destroy expired, unusable, or unwanted Schedule 8 medications at the Pharmacy Service:

- the director of pharmacy of the Pharmacy Service or a pharmacist authorised by the director of pharmacy, or
- at a facility where there is no employed/contracted pharmacist, the authorised officer of the medication supply service.

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

- a pharmacist, or

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

The record of destruction in the Schedule 8 drug register must include:

- 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.

A NSW Ministry of Health inspector appointed under section 42 of the *Poisons and Therapeutic Goods Act 1966* or a NSW police officer may also destroy Schedule 8 medications at a Pharmacy Service or medication supply service at a facility where there is no employed contracted pharmacist. A witness to the destruction is not required.

Schedule 8 medications must be destroyed in such a way:

- that a medication is made unidentifiable (that is, not disposed of intact in the original labelled packaging)
- that a medication is made unusable and unrecoverable (by having them absorbed on to absorbent material such as cat litter or commercial medication disposal product that renders the medication unrecoverable)
- that is not likely to cause damage to the environment and not likely to pose a risk to any person.

Recommended procedures for the destruction of Schedule 8 medications are detailed in section 4.8.3.

4.8.3 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.

Where appropriate, the person destroying the medication must 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 must be 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 to render Schedule 8 medications unusable and unrecoverable are:

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 procedure.
3. Pour the resulting slurry onto absorbent material such as cat litter granules or shredded paper or commercial absorption system and dispose of in a pharmaceutical waste bin.

Liquids

1. Pour the liquid onto absorbent material such as cat litter granules or shredded paper.
2. Dispose of in a pharmaceutical waste bin.

Powders, granules and botanical material

1. Grind the material if necessary, then 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 pharmaceutical waste bin.

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

Injectable medications

Glass ampoules/small vials;

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

Plastic ampoules, plastic IV infusion bags and large vials;

1. Pour the contents onto absorbent material such as cat litter granules or shredded paper.
2. Dispose of in a pharmaceutical waste bin.

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 or pharmaceutical waste bin.

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. See the NSW Therapeutic Advisory Group advisory on Fentanyl Oromucosal Formulations.

4.9 Reporting the loss, theft or deficit of accountable medications

Accountable medications are Schedule 8 medications, Schedule 4 Appendix D medications and other medications also accounted for in a register under facility procedures.

A pharmacist who detects the loss, theft or deficit of an accountable medication must immediately report this fact to the director of pharmacy. The pharmacist or authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist who detected the 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, or authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist, must complete and submit a report in accordance with the facility's incident management system under the requirements of NSW Health Policy Directive *Incident Management* (PD2020_047).

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 4.8.2 for Schedule 8 medications and section 4.8.1 for other accountable medications.

The director of pharmacy, or the authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist, must notify the NSW Ministry of Health Pharmaceutical Regulatory Unit of the loss, theft or deficit of the Schedule 8 medication immediately using the on-line notification form (and retain a copy of this notification). An exception is provided for the loss of liquid by spillage and the loss in broken or damaged bottles and ampoules that the director of pharmacy does not consider suspicious.

This immediate notification to the NSW Ministry of Health must 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 must be submitted to the NSW Ministry of Health using the on-line notification form.

The director of pharmacy or authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist 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 health practitioner, under facility procedure, ensure the matter is reported to the particular health practitioner's national registration board as well as to the NSW Ministry of Health Pharmaceutical Regulatory 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 also must be reported to the NSW Ministry of Health Pharmaceutical Regulatory Unit. Failure to report may result in harm to a patient or to the member of staff, particularly where a possibility exists that this staff member has substance use problems and/or is health impaired.

4.10 Reporting a lost, destroyed or tampered Schedule 8 drug register

A pharmacist who detects that a drug register (including electronic 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 or authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist must immediately:

- notify the NSW Ministry of Health Pharmaceutical Regulatory Unit in writing of the known detail of the circumstances of the loss, destruction or tampering
- enter the balance on hand of the Schedule 8 medications involved in a drug register
- under facility procedures and in accordance with NSW Health Policy Directive *Incident Management* (PD2020_047), complete and submit a report.

4.11 Retention periods for records, prescriptions and drug registers

The following retention periods apply to records relating to dispensing and supply of medications by the Pharmacy Service, as State Records in accordance with NSW Health Policy Directive *Health Care Records – Documentation and Management* (PD2012_069) under General Retention and Disposal Authority 17 (GDA 17):

- **2 years** for;
  - prescriptions (except 'Section 100' Highly Specialised Drugs prescriptions which are for 7 years)

- records of medication orders, requisitions, receipts/records of deliveries, inventory control records, manufacturing records and purchase orders

- **7 years** for;
  - drug registers
  - records relating to the supply of 'Section 100' Highly Specialised Drugs 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, whether the medication is held at the Pharmacy Service or in a patient care area
- **10 years** for;
  - records relating to reports of loss or theft of Schedule 8 and Schedule 4 Appendix D medications
  - Schedule 8 drug registers
- **15 years** for clinical trial medication supplies **or** until the patient attains 25 years of age, whichever is longer.

5 PATIENT CARE AREAS

5.1 Responsibility and oversight

The Drug and Therapeutics Committee must have oversight of medications used in patient care areas. The registered nurse/midwife in charge of a patient care area is responsible for the procurement from the Pharmacy Service or medication supply service at a facility where there is no employed/contracted pharmacist, and the storage of all medications.

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, Needle and Syringe Program units).

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 that minimises medication error due to a mix-up between preparations
- a routine procedure of stock rotation and monitoring of expiry dates under facility procedures, with unwanted, unusable, or expired medications disposed of in accordance with section 5.15.1 and also section 5.15.2 for Schedule 8 medications
- temperature storage consistent with the specifications on the manufacturer's pack.

The range of medications and respective stock levels on an imprest list must be set by agreement between the nurse/midwife, or appropriately authorised person (described above), 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.

NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) also includes requirements regarding imprest and stock high-risk medicines.

5.2 Medication procurement by patient care areas

5.2.1 General provisions

Patient care areas may obtain medications either from:

a) The Pharmacy Service or medication supply service at a facility where there is no employed/contracted, either as imprest stock or labelled for an individual patient in accordance with a medication order or prescription issued by an authorised prescriber. Individually dispensed medications must only be used for the patient for whom the medication was dispensed, or

b) Directly from a pharmaceutical wholesaler (commonly referred to as 'Vendor Managed Inventory'), in accordance with facility procedures.

The Drug and Therapeutics Committee is responsible for formulary management at the facility's patient care areas in accordance with NSW Health Policy Directive *Approval Process of Medicines for Use in NSW Public Hospitals* (PD2016_033). This policy establishes a standard procedure for the approval of medications and their use.

Medications may be ordered from the Pharmacy Service/medication supply service by the registered/nurse midwife, appropriately authorised person in charge of the patient care area or by an authorised prescriber. Orders must be an (original) written order, facsimile or email.

Medications must not be transferred to, or received from, private health facilities other than under specific licence such as during a pandemic response.

5.2.2 Receipting Schedule 8 medication deliveries

In accordance with facility procedures, Schedule 8 medication in a sealed package may be delivered to a registered nurse/midwife of the patient care area either:

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

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

Under the Regulation, the registered nurse/midwife who receives the Schedule 8 medication on behalf of the patient care area must provide to the Pharmacy Service/medication supply service or pharmaceutical wholesaler (as applicable) 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. An exception is for a Schedule 8 discharge medication for on-supply to the patient under facility procedures.

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 receipt in the patient care area drug register and lock the medication in the Schedule 8 drug storage unit with a witness. Under facility procedures, a pharmacist or pharmacy technician may witness the entry of receipt in the patient care area drug register.

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

- by checking that tamper-evident seals are intact
- conducting audits with checks against the signed and dated receipts of supplies to, and transfers from the patient care area (see section 5.14.4)
- that the ordering, supply, delivery and receipting of Schedule 8 medications are not undertaken by the same staff, that is, there is clear separation of staff/persons involved in the procedure.

5.2.3 Transferring Schedule 8 medications between patient care areas

Transfer of Schedule 8 medications between facilities must only occur where there is no Pharmacy Service at the facility requesting the Schedule 8 medication. The requisitioning and supply must be by the registered nurse/midwife in charge at the facility.

Facility procedures must detail the circumstances 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/medication supply service is not available.

When transferring Schedule 8 medication to 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 receiving the Schedule 8 medication
- two registered nurse/midwives, one of whom must be a senior registered nurse/midwife such as an After Hours Nurse Manager, must be involved in the transfer. The two registered nurse/midwives must maintain custody of the Schedule 8 medication throughout the transfer.

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.

5.2.4 Pharmacy Service packs and re-packs

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

An exception is provided for medications required urgently in medical emergencies or 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.

5.2.5 Use of patient own medication including complementary medication

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 stock 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. However, regular use patient own medication is to be used for Hospital in the Home and community nursing services.

Under Drug and Therapeutic Committee approved procedures, in specialised residential services patients may be deemed responsible for their own medication administration and for administration to infants/children in their care, for example Karitane Child and Family Health Services and Tresillian Family Care Centres. Procedures must ensure safe medication storage. Schedule 8 medications must be stored and accounted for in accordance with sections 5.4.2, 5.4.4 and 5.14.1.

Under facility procedures, ongoing use of patient own medications, dispensed and labelled by a pharmacist where applicable, may be permitted for the following medications/therapies:

- implantable pump therapy
- insulin pump therapy
- disposable insulin pen
- specialised formulations for individual patients (such as paediatric patients)
- adrenaline (epinephrine) autoinjectors (see additional requirements below)
- clinical trial medications
- medication obtained under the Special Access Scheme
- medication supplied under a sponsor facilitated Medicine Access Program
- non formulary medications (for example specific eye drops or inhalers)
- complementary medications
- unregistered Schedule 8 cannabis medicines (additional requirements below).

All patients must have their complete medication regimen reviewed on admission to establish the appropriate regimen to continue during the admission. The use of a patient own medication in a patient care area must be specifically notated on the medication order as appropriate for use. A hospital pharmacist must verify the medication is suitable for use.

Storage of the patient's own medications for self-administration must be in accordance with section 5.4.3 and not remain with the patient, with the exception of adrenaline (epinephrine) autoinjectors or under facility procedures for other medications. An exception is also provided for patients attending a non-inpatient setting (see in section 6.10.1) where a staff member is assisting the patient in self-administration.

When not returned to the patient on discharge for whatever reason, the patient's own medications must be disposed of in accordance with section 5.15, and must not be retained as stock for administration to other patients.

The CATAG *Guiding Principles for the Use of Complementary and Alternative Medicines in Hospitals* provides guidance to facilities in the development of facility procedures for the management and use of complementary and alternative medications alongside conventional medical or surgical treatments.

Adrenaline (epinephrine) autoinjector

Patients and/or carers who are assessed as capable to self-administer may retain their adrenaline (epinephrine) autoinjector (for example EpiPen®) on their person/at the bedside in accordance with facility procedures.

The adrenaline (epinephrine) autoinjector must be stored out of other patient access. In circumstances where adrenaline (epinephrine) is required for an anaphylactic reaction, staff (who have the required skills and knowledge) may administer adrenaline (epinephrine) using the 'patient own' autoinjector.

In circumstances of anaphylaxis/suspected anaphylaxis, the facility Clinical Emergency Response System must be activated in accordance with facility procedures whenever adrenaline (epinephrine) is used.

Facility procedures must include:

- the requirement for a pharmacist to check the adrenaline (epinephrine) autoinjector is fit for use
- storage requirements: adrenaline (epinephrine) autoinjector must be stored out of other patient access
- staff education required to correctly use the autoinjector
- arrangements for replacing the patient's own used adrenaline (epinephrine) autoinjector.

Disposable insulin injector pens

Patients who normally administer their insulin using a disposable insulin injector pen may continue to do so under supervision in accordance with facility procedures. Insulin injector pens must be stored out of other patient access.

To reduce the risk of administering the wrong dose, patients prescribed high concentration insulin, must self-administer their insulin under supervision. Safety Alert Broadcast SN:007/19 High Concentration Insulin Products - Updated includes information on managing high concentration insulin products. Also refer to NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045).

Facility procedures must include:

- requirement for a pharmacist to check the insulin injector pen is fit for use
- storage requirements
- guidance on conducting a patient assessment to ascertain their suitability to self-administer insulin using an insulin injector pen.

Suspected illicit substances including illegal cannabis plant and cannabis preparations

A substance suspected to be illicit which is brought to the health facility by the patient must be removed by the patient's family member or carer or destroyed with the patient or carer's consent under facility procedures. As the content of the substance (such as in powder, liquid, tablet, capsule or plant form) is unknown it must not be managed as a Schedule 8 medication.

Where consent is not granted by the patient or carer for the facility to destroy the substance the matter must be escalated to a medical officer suitably qualified to assess the patient's continuing risk of self-harm (where relevant) and decision-making capacity. It may be appropriate to consider treating the patient under the provisions of the *NSW Mental Health Act 2007* and/or the *NSW Guardianship Act 1987* – see also SN:008/18 on Return of Patient's Own Medicines.

Facility procedures must include circumstances where the matter is to be escalated to the NSW Police, such as when:

- the patient has what seem to be trafficable quantities in their possession, or
- if harm has, or could have, resulted from use of the substance and the supplier can be identified.

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 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 must include information about advice given, any changes to therapy, and the decision of the patient. Ongoing open communication remains essential.

Notwithstanding the above, patients must be made aware that continued use of any illegal cannabis preparation remains unlawful.

5.3 Methadone and buprenorphine for Opioid Treatment Program patients

The NSW Health *NSW Clinical Guidelines: Treatment of Opioid Dependence* (GL2018_019) provides guidance for opioid treatment in NSW.

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 must be supplied to patient care areas from the Pharmacy Service as separate daily doses either as pre-packed and labelled (stock) doses or as individual patient labelled doses.

However, facility procedures may provide for specific high use patient care areas, such as drug detoxification units, to obtain the manufacturer's 200 mL pack size, or a smaller (for example 50 mL) re-packed supply from the Pharmacy Service.

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

Long acting injectable buprenorphine formulations must be administered by health care professionals who are trained and competent in depot injection administration. Long acting injectable buprenorphine formulations must not be dispensed or supplied directly to the patient or the patient's carer.

Patient's own ('take-away') supplies of Opioid Treatment Program medications must 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 and agreed accordingly.

Use of an electronic administration and recording device

An electronic medication administration device (such *as* iDose®) may be used to accurately extract methadone oral solution/syrup from a bottle and record each dose administered in an electronic medication administration record – see in NSW Health Information Bulletin *Use of the iDose™ System by Registered Nurses* (IB2020_049).

Registered Nurses may transfer methadone between bottles of the same brand and batch number with use of the device if they are trained and competent to safely do so under facility procedures.

Any residual methadone oral solution/syrup remaining in a partly used stock bottle at the end of each day's dosing must be transferred to another partly used stock bottle of the same brand and batch number. In circumstances where the residual amount cannot be transferred

into another partly used bottle (of the same brand and batch number), both bottles are to be returned to the safe and the balance recorded.

Handling and recording of medications when electronic 'downtime' prevents the use of the electronic device is under facility procedures.

5.4 Medication Storage in patient care areas

5.4.1 General storage requirements

Medications in patient care areas must be secured out of access to staff not authorised to administer to patients.

Secure storage of public health facility supplied medications in the patient's home for Hospital in the Home and community nursing/outreach services is under facility procedures.

Facility procedures for medications requiring refrigeration in patient care areas may include temperature sensor monitoring and alarm when the required temperature range (normally 2-8°C) is breached. Appropriate action following events when the storage temperature deviates from the manufacturer's nominated temperature range must be taken, further to the assessment of the risk by the director of pharmacy that the quality, safety and/or efficacy of the medication(s) has been compromised.

Vaccines must be stored in accordance with NSW Health Policy Directive *Vaccine Storage and Cold Chain Management* (PD2020_028). This policy includes mandatory requirements for the, monitoring and management of vaccines including procedures for managing cold chain breaches.

5.4.2 Storage of Schedule 8 medications

Stock levels of Schedule 8 medications must 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 patient own Schedule 8 medication(s) and Schedule 8 medication(s) labelled for supply to a patient on discharge. Schedule 8 medicines requiring refrigeration, for example some cannabis medicines, may be stored in a refrigerator rather than the Schedule 8 medication storage unit (see section 5.4.4).

Under the Regulation, all Schedule 8 medications must be stored apart from all other medications, except when stored with Schedule 4 Appendix D medications or propofol, 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 is to be a five lever lock, or have a locking mechanism which provides at least equivalent security. Consideration is to 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 are to be upgraded with the installation of metal safes.

Access to the Schedule 8 medication storage unit must be with the witness who signs the record of the transaction (procurement, supply or administration) in the drug register.

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. Where fingerprint security is in use, facility procedures must include security requirements.

The registered nurse/midwife in charge of the patient care area must hold the Schedule 8 medication storage unit key/s during his/her work shift or keep the key/s secured under facility procedure. The key is to be provided to the registered nurse/midwife or authorised prescriber requiring access to the Schedule 8 medication storage unit. 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.

Provision must 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 the case of a Schedule 8 medication storage unit within an operating theatre, under facility procedures a delegated registered nurse/midwife in charge or an authorised prescriber (such as an anaesthetist) is to hold the key on behalf of the registered nurse/midwife in charge.

In accordance with facility procedures, when a patient care area is closed for any purpose, any keys to that area's Schedule 8 medication storage units must be either:

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

A code, combination or swipe card access 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 facility procedures. Regular changing of the code or combination is required, also in accordance with facility procedures.

Requirements for the management of keys (metal keys, electronic keys, electronic swipe card access and key pad codes), is detailed in NSW Health *Protecting People and Property Manual* on key control. A spare key to a patient care area Schedule 8 medication storage unit or an override key for electronic locks (the downtime key) must be retained in a safe or key safe at the facility's Nursing and/or Midwifery Administration.

Schedule 8 medications must not be transferred to medication trolleys for administration during a medication round, except in accordance with facility procedures. 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 must be securely locked to prevent unauthorised access. Under facility procedures, when a patient care area is closed for an extended period of time, the Schedule 8 medication packs must be sealed with tamper evident tape or in tamper evident packs, and transferred into another appropriate

patient care area Schedule 8 medication storage unit or to the Pharmacy Service/medication supply service.

NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) includes additional high-risk medicine storage requirements. The Hydromorphone Standard includes requirements for hydromorphone storage including separating hydromorphone from morphine, not storing hydromorphone in clinical areas where use is infrequent and restrictions on routinely storing high-concentration formulations of injectable formulations.

5.4.3 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 with propofol, or
- When stored in the Schedule 8 medication storage unit, or
- When stored on an emergency trolley or cupboard, anaesthetic trolley, or operating theatre trolley. In these cases, Schedule 4 Appendix D medications must be kept at minimal levels and the trolley kept in a locked room when the patient care area is closed, with access only by authorised persons, or
- For refrigerated Schedule 4 Appendix D medications, in accordance with the requirements in section 5.4.4.

Facility procedures to enhance security and accountability of Schedule 4 Appendix D medications on an emergency trolley or cupboard must be implemented.

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 may include the ‘Schedule 8 drug cabinet within a Schedule 4 Appendix D drug cupboard’ model.

A code, combination or swipe card access required to unlock the Schedule 4 Appendix D medication storage unit must only be provided to a staff member authorised by the registered nurse/midwife in charge of the patient care area to access the medication. Code and combination lock access provisions must be changed regularly.

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).

Under the Regulation, 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 5.4.4. This will restrict access to the key to a registered nurse/midwife or an authorised prescriber.

Under facility procedures, 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.

5.4.4 Schedule 8 and Schedule 4 Appendix D medications requiring refrigeration

Schedule 8 medications

Schedule 8 medications requiring refrigerated storage, for example some cannabis medicines, may be stored as follows:

- in a locked refrigerator securely attached to the ward, or in a refrigerator that is in a locked room which is accessible only to persons authorised to access Schedule 8 medications
- apart from all other medications except Schedule 4 Appendix D and other Schedule 8 medications.

If goods other than Schedule 4 Appendix D medications are to be kept in the refrigerator, the Schedule 8 medications 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 and the locked box to the refrigerator.

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

- keeping the locking device (such as a key) on the person of a registered nurse or midwife in the patient care area, or in a separately locked safe to which only a registered nurse/midwife has access when the patient care area is closed
- ensuring any code or combination that is required to unlock the room or refrigerator is not divulged to any unauthorised person.

Schedule 4 Appendix D medications

The refrigerator containing the following Schedule 4 Appendix D medications may be kept in a locked room containing any other medications:

- epoetins and erythropoietins including darbepoetin
- lorazepam injections.

Access to this room must be restricted to staff authorised by the registered nurse/midwife in charge of the patient care area.

This is an alternative to the usual requirements for Schedule 4 Appendix D medication storage in a patient care area. However, the requirements for reporting loss, theft or deficit of accountable medications apply.

The medications must be accounted for under facility procedures that ensures the detection and reporting of any loss.

5.4.5 Unscheduled, Schedule 2, 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, in a locked room or a locked cabinet securely attached to the wall or floor of the premises, with the following exceptions:

- on a medication trolley used for medication rounds, which must be kept in a locked room when not in use
- on an anaesthetic trolley or operating theatre trolley which is kept in a locked room when not in use
- minimal quantities of medications held on an emergency trolley
- in a secure cabinet (such as a bedside cabinet), including that used for patient self-administration in an approved program (such as disposable insulin injector pens), 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. Facility procedures must 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
- patient own adrenaline (epinephrine) autoinjector in accordance with section 5.2.5.

The key, code, combination or swipe card access 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, and for patients approved for self-administration. Cleaners must not access medication storage areas unless supervised by one of the above clinicians. 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

The Drug and Therapeutics Committee must consider the risk of misappropriation of medications with a risk of misuse in addition to Schedule 4 Appendix D medications.

To mitigate the risk facility procedures can require that specific non-appendix D Schedule 4 medications be stored in separate (discrete) medication storage areas with similarly separate key, code, combination or swipe card access to all other medications. Examples of medications that may be considered for separate storage include propofol, methoxyflurane and the Schedule 4 codeine phosphate hemihydrate combination products.

Non-Appendix D Schedule 4 medications may also be accounted for in a register at the patient care area in accordance with facility procedures as described in section 5.15 and then must also be managed as accountable medications, with any loss, theft or deficit reported to the NSW Ministry of Health Pharmaceutical Regulatory Unit.

5.4.6 Storage of medications in automated dispensing cabinets

The Drug and Therapeutics Committee may approve the use of (electronic) automated dispensing cabinets at particular patient care areas. Drug and Therapeutics Committee approval is also required for the size and type of the automated dispensing cabinets used in each patient care area. An electronic dual signature drug register integrated with the automated dispensing cabinet storing Schedule 8 medications must accord with the

requirements in NSW Health *Framework for Use of an Electronic Drug Register Requiring Dual Signatures*.

Facility procedures must address:

- training required to access the automated dispensing cabinet for all staff members
- staff access to the cabinet including detailed procedures for assigning user access credentials for electronic access
- verifying the requirement for ongoing access
- requirements for storing patient own medications in the cabinet
- transferring medications including Schedule 8 medications to/from automated dispensing cabinet (if required)
- auditing the access to accountable medications
- downtime events including:
  - contact details for assistance both during hours and after-hours times
  - procedures for unlocking the cabinet
  - procedures for circumstances when the cabinet is unable to be unlocked
  - procedures for accounting for medications taken from the cabinet when it is unlocked (non-accountable and Schedule 8)
  - post-downtime procedures to ensure that the cabinet is relocked.

The following requirements must also be addressed:

1. The automated dispensing cabinet(s) must be securely attached to the wall or floor in a manner approved by the facility's security service, with the key, code or combination to any associated locking device under the governance of the nurse/midwife in charge and any spare key retained in a safe or key safe at the facility's Nursing and/or Midwifery Administration. Note: An exception to non-attachment to the wall or floor is when the automated dispensing cabinet is kept in a locked room accessible only by staff authorised by the nurse/midwife in charge, but only when Schedule 4 Appendix D and/or Schedule 8 medications are excluded.
2. Assessment for use of an alarm monitoring system approved by both the facility's Drug and Therapeutics Committee and security service to detect and alert any tampering or unauthorised movement of the automated dispensing cabinet(s).
3. Assessment to include cctv monitoring of the automated dispensing cabinets.
4. 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.
5. The automated dispensing cabinet system is to be evaluated *ISMP Guidelines for the Safe Use of Automated Dispensing Cabinets* to confirm the safe and quality use of the system.

6. Medications stored in the automated dispensing cabinet in the packs received from the Pharmacy Service.
7. Under facility procedures, Pharmacy Service staff members may be permitted access to the cabinets for the purpose of stocking medications, other than Schedule 8 medications.
8. 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.
9. 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.
10. 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.
11. All access events by staff members must be recorded and retained in the automated dispensing cabinet system for the purpose of audits.

5.5 Principles for the safe storage of accountable medications

Schedule 8 medications and Schedule 4 Appendix D medications are defined collectively as 'accountable medications'. Under facility procedures, other medications that are also accounted for in a register at the patient care area as described in section 5.15 are accountable medications for the purpose of this section.

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

- under the Regulation, accountable medications being stored in accordance with a) section 5.4.2 for Schedule 8 medications, b) section 5.4.3 for Schedule 4 Appendix D medications, and c) section 5.4.4 for non Schedule 4 Appendix D medications when accounted for in a register in accordance with section 5.15. Note that non-Schedule 4 Appendix D (other than propofol) and Schedule 8 medications must not be stored with Schedule 4 Appendix D or Schedule 8 medications even when recorded in a register
- 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 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 in NSW Health Policy Directive *High-risk Medicines Management* (PD2020_045) 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 MS Contin and OxyContin
  - 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 must not be routinely stocked, but must 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. NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) includes a Hydromorphone Standard that details requirements for hydromorphone storage
  - 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 and the associated risk of a selection error
  - 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 a second person check can be performed with both people sighting the original medication order at the time of the selection of the medication 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/enteral liquid medications
  - checking for clutter, and reviewing signage
  - adding a workbench underneath medication storage units to reduce spillage and breakage
  - eliminating the location of waste bins from under medication storage units to reduce potential losses
- labelling of shelves and medications with;
  - the inclusion of suggested order (imprest level) 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. The National Tall Man Lettering List was developed to help reduce the risk of medication selection errors for medications with look-a-like, sound-a-like medication names. . A Tall Man Lettering resource for staff is on the Clinical Excellence Commission webpage.

Medication safety, as well as routine storage/access requirements, must be considered during the development or redevelopment of clinical areas.

Considerations in the redesign must 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 lockable refrigerators to enable refrigerated accountable medication to be appropriately stored
- considering the appropriateness of the use of automated dispensing 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.

5.6 Procedural units/operating theatres – additional considerations

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

Systems must include:

- the regular review of requests for non imprest list medications by the registered nurse/midwife in charge of the unit with the pharmacist and attending authorised prescribers, for the purpose of additional medications being included on the imprest list
- assessment and verification by a pharmacist of the suitability for use of additional imprest medications before being placed into stock
- separated storage of imprest and non-imprest medications
- Under facility procedures, unused patient-labelled medications being returned to the Pharmacy Service

- a registered nurse/midwife checking all stock on receipt to identify any variation from the current medication packs, pack sizes or brand names
- facility procedures to notify staff when new medications, or variations to existing medications, are introduced
- facility procedures to regularly review medication storage units (including size and design) and shelf labelling to confirm suitability.

5.7 Radiopharmaceuticals – additional considerations

Nuclear medicine facilities are required to have a Radiation Management Licence and Radiation Management plan for the safe use of radiopharmaceuticals.

Good Radiopharmacy Practice is covered in the Australian Radiation Protection and Nuclear Safety Agency 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 2013* 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.

Standards for the security of radioactive substances is in the NSW Health *Protecting People and Property Manual*.

5.8 After-hours 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 must 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 pharmacist. Schedule 8 and Schedule 4 Appendix D medications must be stored apart from all other medications. The medications in NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045), which includes methotrexate tablets, must not be included in the after-hours medication store.

The medication store must be located in a convenient, supervised area and must be locked when not in immediate use. Consideration must be given to the layout of the store to reduce the risk of medication selection errors.

Under facility procedures, the store must only be accessed after hours and only by senior nursing or midwifery staff, for example the after-hours nurse/midwife manager/delegate, or medical staff. Procedures must include the maintenance of a register to track the date and time each staff member accesses the store and procedures for reviewing medication orders to ensure medication selection is correct. Schedule 8 drug register transactions must be made with a witness.

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

- the date and time the store is accessed
- 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 and designation of the staff member removing the medication.

5.9 Supply for patient at home use by an authorised prescriber

It is always safer for medications for patients to take home to be dispensed from the Pharmacy Service. To accommodate situations when patients are discharged after-hours and the Pharmacy Service is unavailable, the patient care areas must have access to a store of medications that are packed and labelled suitable for discharge, such as in the after-hours medication store.

Where there is no after-hours medication store, or the required medication is not in the store, the authorised prescriber may access medications in a patient care area (such as the Emergency Department) under facility procedures. The medication store must include Drug and Therapeutics Committee approved stock of essential medications for supply by an authorised prescriber, or by an authorised registered nurse/midwife in a remote area facility in the circumstances provided for in section 5.13.1. The use of this store will minimise the need to access the Pharmacy Service after hours.

The store is for use in the following circumstances:

- non-admitted patients requiring immediate treatment upon leaving the facility
- circumstances when a patient presents to the facility seeking a previously prescribed essential medication for which his/her supply has been unexpectedly exhausted
- inpatients discharged after-hours when the Pharmacy Service is unavailable
- palliative care in the home setting when crisis packs are required after hours.

The facility must have a Drug and Therapeutics Committee approved procedure for documenting supply from this store. The procedure must include the maintenance of a register to track the date and time each staff member accesses the store and procedures for reviewing medication orders to ensure medication selection is correct.

The Drug and Therapeutics Committee must have procedures in place that significantly limit in what circumstances an authorised prescriber may dispense Schedule 8 and Schedule 4 Appendix D medications as there is a significant risk of persons having these medications supplied by multiple prescribers. In such circumstances pre-packaged and labelled doses are preferable. Schedule 8 medication recording in the patient care area drug register must be in accordance with section 5.14.1.

The medications dispensed by an authorised prescriber for a patient to take home must be recorded in full in the patient's medication record. Under facility procedures, health facilities may require an additional record for stock control purposes.

The authorised prescriber must label the medication with:

- the date of supply

- the patient's name
- the name, strength, form and quantity of the medication supplied
- adequate directions for use
- the words KEEP OUT OF REACH OF CHILDREN in red on a white background
- the name, address and telephone number of the hospital
- 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
- if applicable, the ancillary label with the associated warning statement required for the particular medication (see section 4.5.7).

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 is recommended for this purpose.

The medications specified in section 4.5.5 are to be supplied in child resistant packaging, although the authorised prescriber can exercise discretion and not supply the medication in child resistant packaging of the opinion that the patient would suffer undue hardship through difficulty in opening the container.

Repacked medication in blister sheets must be supplied in a carton or zip-lock bag.

5.10 Medication kits for home visits and patient transport services

5.10.1 Community nursing, Hospital in the Home and outreach services

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

The list of medications and the quantities stored in this medication kit must be approved by the Drug and Therapeutics Committee. The Pharmacy Service must oversee the medication storage and temperature requirements.

Maintenance of the stock levels in the medication kit is the responsibility of the registered nurse/midwife in charge of the patient care area or service. 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, the car must be locked and the kit kept out of sight.

The staff member (registered nurse/midwife or authorised prescriber) 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 as advised by the Pharmacy Service.

The kit must not 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 storage unit(s). Facilities must make and 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.

Under facility procedures, medications administered from the kit may either be nurse-initiated medications, on a medication order by an authorised prescriber, as a telephone, video call, email or facsimile order to the staff member or under a Standing Order. The administration must be recorded on the medication order (as applicable) as if the medication was administered in a patient care area.

Unwanted medications may be taken by the patient or patient's carer to a community pharmacy for disposal. Where this is not practical, the public health facility staff member may deliver the medications to the community pharmacy or return these to the public health facility for disposal under local procedures.

NSW Health *Protecting People and Property Manual* section Working in the Community details standards for staff in patients' homes, within community health centres and public venues such as schools or community halls and in mobile units.

5.10.2 Patient transport services

When patients are transported between facilities or a home address by a public health organisation patient transport service, arrangements may be made for the patient to self-administer patient-labelled medications during transit. The medications must be securely packed, for example, in a sealed plastic bag. The bag must be labelled with the patient details. During transportation the medication can be placed with the patient's luggage. This must be communicated in handover to the receiving facility or at the patient's home (as applicable).

Otherwise a nurse is to administer any required medications on a medication chart order as if the patient was at a public health facility.

A nurse may also carry a kit of medications that may be required for emergency use during transport, however, only a registered nurse or midwife may carry a stock supply of a Schedule 8 medication. The administration of the medication is to be:

- On a telephone or email order from an authorised prescriber, or
- Under a standing order, or
- Under nurse-initiated medication protocols (excludes Schedule 4 and Schedule 8 medication).

Note: HealthShare NSW nurses have been authorised under the *Poisons and Therapeutic Goods Regulation 2008* to administer a small range of medications for emergency use under protocols in the HealthShare NSW *Patient Transport Service Medication Management Policy*.

5.11 Disaster packs supplies

Medications included in disaster medical equipment kits are determined in accordance with the NSW Health Guideline *Major Incident Medical Services Supporting Plan* (GL2018_017).

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.

5.12 Discharge medications and return of patient own medications

Under facility procedures a registered nurse/midwife, enrolled nurse, authorised prescriber or pharmacist may provide the following medications to a patient, or the patient's carer, on discharge:

- discharge medication dispensed and labelled by the Pharmacy Service, or labelled and recorded by an authorised prescriber
- the patient own medications surrendered by the patient to the patient care area on admission.

5.12.1 Supply of discharge medications

All discharge supplies must be recorded in the patient's health care record as having been provided to the patient (or the patient's carer).

Schedule 4 Appendix D and Schedule 8 medications must be stored separate to all other medications pending supply to the patient in accordance with section 6.3.2 and section 6.3.3. An exception is for discharge medications supplied in a sealed, tamper evident container labelled with the contents and patient details which may be stored in the Schedule 4 Appendix D medication cabinet or Schedule 8 medication safe or cabinet. Schedule 8 medications kept in the patient care area must be recorded in the drug register with a witness.

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 *Care Coordination: Planning from Admission to Transfer of Care in NSW Public Hospitals* (PD2011_015) and the provided in the *Guiding principles to achieve continuity in medication management*.

Systems must include the following:

- planning for a patient's discharge, temporary leave, or transport to another point of care, including the arrangement for medication supply 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 pharmacist taking into account the individual needs of the patient, for example those with visual impairment or manual dexterity impairment, who 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 facility procedures) initiated for the patient at the time of admission. This includes checking patient 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) at the time of discharge
- written information being provided to patients on how to take their medication at home, and of any changes to their medication regimen since admission. This may also include Consumer Medicine Information and/or facility published information pertaining to the treatment.

5.12.2 Return of patient own medications

Medications surrendered by the patient on admission must be placed in a labelled and sealed transparent bag. The patient identification sticker/label must not be applied directly to the patient's own medications as this may be misconstrued to be a dispensing label and/or may obstruct important information.

Under facility procedures all patient own medications and medications for discharge (meaning Schedule 4 Appendix D, Schedule 8 and all other medications) may be kept together and stored out of public access pending being provided to the patient for at home use. Access to the storage unit must only be by staff authorised by the nurse/midwife in charge of the ward/clinic.

Under facility procedures, patient own medications are to be retained in the patient care area and disposed of with the patient or carer's consent, where a medication or substance:

- Cannot be identified/verified, or
- Is in a dose administration aid, or
- Is unlabelled, or
- Does not have a dispensing label affixed or is labelled for another person, or
- Has been ceased since admission, or
- The amount of medication brought in is excessive.

In addition, for patients who have been admitted with deliberate self-poisoning, the attending medical officer must determine whether it is appropriate for the patient own medications brought into the hospital to be returned to the patient on discharge.

Where consent is not granted by the patient or carer for the facility to retain patient own medication, the matter must be escalated to a medical officer suitably qualified to assess the patient's continuing risk of self-harm (where relevant) and decision-making capacity. Decision-making capacity can be impaired by mental illness and other conditions such as

dementia and delirium. It may be appropriate to consider treating the patient under the provisions of the *NSW Mental Health Act 2007* and/or the *NSW Guardianship Act 1987* – see also Safety Notice SN008/18 Return of Patient's Own Medicines.

Any medications returned on discharge must be recorded in the patient's health care record as having been returned to the patient or carer.

5.13 Additional supplies by registered nurses

5.13.1 Emergency after hours supply by registered nurses in rural and remote areas

Registered nurses are authorised by an instrument issued under the Regulation to supply emergency Schedule 2, 3 or 4 medications (Schedule 8 medications are excluded) to outpatients (including the emergency department) attending a rural or remote Local Health District 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 the facility to supply the medication to the patient
- an authorised prescriber has authorised the supply (dispensing) of the medication to the patient for emergency use remotely (outside of the health facility) by electronic order in the facility's eMeds system, or by telephone, video call, facsimile, or email
- the patient is in immediate need of the medication and neither a community pharmacy nor hospital Pharmacy Service is available in close proximity
- 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 authorised prescriber and the quantity of medication supplied to the patient in the patient's health care record
- where possible, the authorised prescriber's telephone order is confirmed by a second person
- the medication is supplied in its unopened pack
- a label containing the information in section 5.9
- 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 volume in mL for the nurse to enter on the medication label
- where applicable, the labelled medication is checked by the second person who confirmed the authorised prescriber's telephone order.

5.13.2 Supply of tenecteplase to NSW Ambulance Paramedics

A registered nurse in charge (or his/her delegate) of the Emergency Department of a public hospital that receives a patient following prehospital administration of thrombolytic therapy, is permitted to supply a NSW Ambulance paramedic with one vial of tenecteplase 50 mg from Emergency Department stock to restock the Ambulance medication kit in accordance with the NSW Health Information Bulletin on *Tenecteplase Replacement in Public Hospitals for Ambulance Paramedics* (IB2013_063).

5.14 Patient care area Schedule 8 drug register

5.14.1 Records in the Schedule 8 drug register

The registered nurse/midwife in charge of the patient care area is responsible for ensuring that a record is kept of all transactions in a drug register relating the Schedule 8 medications stored in the Schedule 8 medication drug safe/cabinet.

Unless otherwise approved in electronic form under NSW Health *Framework for Use of an Electronic Drug Register Requiring Dual Signatures*, the drug register must be the State Forms bound book with consecutively numbered pages (unless otherwise approved under facility procedures).

A separate page must be used for each form and each strength of the Schedule 8 medication active ingredient. Where brands of the same strength and form need to be differentiated (for example, methadone liquid formulations) they may be on separate pages under facility procedures.

A separate page may be used for each individual patient use medication also under facility procedures. Patient own medication and discharge medication in a tamper-evident bag labelled with the contents may be recorded on a separate page.

The record in the drug register must include in handwriting or in an approved electronic form:

- the date and time of the transaction
- 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 administered to a patient, supplied to a patient (for example as discharge medication or returned patient own medication) or supplied to an authorised prescriber (such as an anaesthetist) for a procedure, the patient's name, the name of the prescriber, and the amount administered or supplied as;
    - for liquids, in millilitres (mL), or
    - for solid dosage forms, as discrete units, for example *1* or *0.5* with tablets (if the medication is suitable to be given as a part tablet), or
    - for ampoules, as discrete units, (for example *1* or *0.5*) OR as the dose (for example 10 mg or 5 mg) in accordance with Drug and Therapeutics Committee approved procedures

- the amount discarded, where only a portion of the medication (tablet or injection) is administered. Note: The exception is for a medication supplied to an authorised prescriber (such as an anaesthetist) for a procedure (see section 6.9.1).
- where known, the irretrievable and discarded amount in the delivery device, such as in the dead space of an oral/enteral syringe (for example, 0.2 mL, depending on the particular syringe)
- for a medication which is expired, unusable or unwanted, the amount destroyed by a pharmacist or the authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist (see section 5.16.2).
- the balance remaining in the drug register after the transaction. Any deficit must be recorded and reported in accordance with section 5.17
- the full and legible name and signature of the person making the entry, either receiving, administering, discarding, destroying, or carrying out a balance check
- the full and legible name and signature of the witness to the transaction.

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 marginal note or footnote explaining the error (signed and dated by both staff members), also marked with an asterisk.

Implementing the New Ward Register of Drugs of Addiction (November 2015) is available on the NSW Health webpage.

Notes

For oral liquids, reconciliation of the balance on hand must occur after the last available dose is removed from the bottle. Overage (excess) is accounted for by adjusting the balance upwards with an additional entry on the next line of the drug register page.

Other than for reconciliation after the last available dose is removed, liquids must not be decanted for measuring by anyone other than a pharmacist, or delegate approved by the nurse/midwife in charge of the patient care area. Exceptions are for methadone liquid dosing devices, see section 5.3.

Where the Schedule 8 medication is being administered to a patient temporarily transferred from another patient care area, this must 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.

Unused doses such as those refused by the patient or ampoules drawn up but not used (for example in resuscitation units) must be entered back into the drug register by the administering person with the same witness, with a footnote explaining the circumstance. The reason for the non-use must also be documented in the patient's health care record (as applicable in the circumstance). Under facility procedures, the medication is to be secured in

a sealed, clear container and labelled with the medication name and amount and kept in the Schedule 8 drug safe/cabinet. Destruction must be by a pharmacist, or the authorised officer of the medication supply service at a facility where there is no employed/contracted pharmacist (see section 5.16.2).

For spillage or breakage of a Schedule 8 medication witnessed by at least two staff members, as it actually happens, the two staff members must immediately discard the medication (see in section 6.9). The circumstances of the spillage or breakage must be entered in the drug register with a witness as a footnote (or under facility procedures in an electronic drug register) and reported to the nurse/midwife in charge of the patient care area (see section 5.17.1).

5.14.2 Witness to Schedule 8 medication transactions

The witness to a Schedule 8 medication transaction must be a person who is fully familiar with Schedule 8 medication handling and recording procedures. This may include a registered nurse or registered midwife, an authorised prescriber, a 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 or anaesthetic technician.

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.

Facility procedures must include risk mitigation strategies for circumstances where the witness cannot be present throughout the procedure. For example, throughout the administration of an infusion containing a Schedule 8 medication and second person checks in the circumstances specified in section 6.8.

5.14.3 Balance checks in the Schedule 8 drug register

The registered nurse/midwife in charge of the patient care area must ensure that the balance of Schedule 8 medications recorded in the drug register is checked against the physical balance in the Schedule 8 medication storage unit(s) at least once every 24 hours. However, an exception is provided if the patient care area is closed when the balance check is due and the drug safe key (where used) is secured under facility procedures (see section 5.4.2).

In accordance with facility procedures, in high usage patient care areas a Schedule 8 medication balance check is be done every shift change, such as two to three times daily depending on the setting.

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 balance check must be carried out by a registered nurse/midwife with a witness 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. A visual estimate of liquid medications is to be conducted.

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 section 5.17.

5.14.4 Schedule 8 drug register audits

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

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

Audits must be performed by two staff members authorised under facility procedures to perform the task, one of which must be independent of the patient care area's nursing/midwifery staff.

Facility audit procedures must include:

- checks of entries recording stock received against the patient care area and Pharmacy Service records
- checks and verification of signatures for the purpose of detecting forgeries
- verification of the drug register contents page against the corresponding drug register pages
- verification of the 'carried forward' balances
- verification that the routine 24-hour balance checks (or more frequently in accordance with facility procedures) have been conducted
- verification 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 5.17
- a review of the frequency of broken ampoules and discarded portions of ampoules and tablets
- a review of the presence of altered, obliterated and cancelled entries
- a selection of patient medication chart checks against the respective Schedule 8 drug register entries.

5.15 Additional accountable medication recording in a register

In order to minimise the risk of misappropriation or misuse, under the Drug and Therapeutics Committee approved procedures, the facility Chief Executive 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 have a risk of misappropriation such as in operating theatres and recovery wards.

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

Typical medications that may be recorded in a register are:

- Schedule 4 Appendix D medications such as benzodiazepines, particularly midazolam
- non-Appendix D Schedule 4 medications such as;
  - propofol
  - methoxyflurane
  - the Schedule 4 codeine phosphate hemihydrate combination products.

Note: Additional medications, other than a Schedule 4 Appendix D medication or propofol, recorded in a register must not be stored with Schedule 8 and/or Schedule 4 Appendix D medications.

5.16 Disposal of expired, unwanted or unusable medications

5.16.1 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.

Each patient care area must have Drug and Therapeutics Committee approved procedures for the disposal of unwanted medications, which also must be in accordance with NSW Health Policy Directive *Clinical and Related Waste Management for Health Services* (PD2020_049).

The specific requirements for the destruction of Schedule 8 medications are detailed in section 5.16.2. For other medications, facility procedures will direct either the disposal at the patient care area, or return to the Pharmacy Service for disposal.

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.

5.16.2 Destruction of expired, unusable or unwanted Schedule 8 medications

Expired, unusable, or unwanted Schedule 8 medications must:

- remain recorded in the Schedule 8 drug register with the usable medication of the same type, except for patient 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 pharmacist or the authorised officer of the medication supply service at a facility where no 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 procedure for securing and identifying these medications from the usable 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 person destroying the medication and with the registered nurse/midwife witness also signing the drug register, in accordance with the detail listed in section 5.14.1.

The recommended procedures for destroying the various forms of Schedule 8 medications are detailed at section 4.8.3.

5.17 Managing and reporting the loss, theft or deficit of accountable medications

Managing and reporting the loss, theft or deficit of the following medications is in the table in section 5.17.1 below for:

- Schedule 8 medications
- Schedule 4 Appendix D medications
- Non-Appendix D Schedule 4 medications accounted for in a register

Reporting is not required for:

- An intact but expired, unusable or unwanted medication when;
  - for an accountable Schedule 4 medication, disposed of in accordance with section 5.16.1
  - a Schedule 8 medication destroyed in accordance with section 5.16.2
- the unwanted portion of a tablet or ampoule discarded when a dose is prepared
- where known, the irretrievable amount in the delivery device such as in the dead space of an oral/enteral syringe (for example, 0.2 mL depending on the particular syringe) that is accounted for in the drug register as discard.

Under facility procedures, in all other cases the person who detects the loss, theft, or deficit of an accountable medication must immediately:

- for an accountable Schedule 4 medication in a register, immediately record the physical balance on hand in the register

- for a Schedule 8 medication, record the physical balance on hand in the drug register with a witness) with a note highlighting the deficit from the arithmetical balance.

5.17.1 Reporting the loss, theft or deficit of accountable medications.

Situation	Report to the nurse/midwife in charge	Report in facility incident management system	Report to director of nursing (see Note A below) and director of pharmacy	Report to the NSW Ministry of Health (see Note B below)
Loss of an accountable medication (including unwitnessed spilt medications or broken ampoules).	Required, by nurse/midwife who detected the loss.	Required	Required, by nurse/midwife in charge immediately (and within 24 hours).	Required, by the director of pharmacy or the director of nursing immediately (and within 24 hours). The director of pharmacy must be copied into the notification made by the director of nursing and vice versa.
Suspected theft of an accountable medication.	Required, by nurse/midwife who detected the loss.	Required	Required, by nurse/midwife in charge immediately (and within 24 hours).	Required, by the director of pharmacy or the director of nursing immediately (and within 24 hours). The director of pharmacy must be copied into the notification made by the director of nursing and vice versa.
Deficit detected at the change of a liquid medication bottle (eg 205 mL stock on hand and 210 mL balance in the drug register).	Required, by nurse/midwife who detected the deficit.	Required	Required, by nurse/midwife in charge immediately (and within 24 hours).	Not required unless deemed necessary by the director of pharmacy and/or director of nursing.
Spilt medications and broken ampoules witnessed by at least two staff members when it actually happens (see **Note C** below).	Required, by nurse/midwife who observed the spillage, or breakage.	Required	Required, by the nurse/midwife in charge immediately (and within 24 hours).	Not required, except when the loss gives rise to any suspicion of the theft of the medication.

Note A: Under facility procedures, the director of nursing must:

- ensure 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, ensure the matter is reported to the particular health practitioner's national registration board as well as to the NSW Ministry of Health Pharmaceutical Regulatory Unit.

Where there is no apparent loss of an accountable medication, a staff member with knowledge of possible or admitted misappropriation of medication must submit a report to the director of nursing for further appropriate action. Failure to do this may result in harm to a patient or the staff member of concern, particularly where a possibility exists that this staff member has substance use problems and/or is health impaired.

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

Note B: For the loss, theft or deficit of medication that must be reported to the Ministry of Health (in Table 1) the director of pharmacy or the director of nursing must immediately notify the NSW Ministry of Health Pharmaceutical Regulatory Unit using the on-line notification form and retain a copy of this notification.

The immediate notification to the NSW Ministry of Health Pharmaceutical Regulatory Unit must 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 must be submitted to the NSW Ministry of Health again using the on-line notification form.

Note C: For spillage or breakage of Schedule 8 medication witnessed by at least two staff members, as it *actually happens*, the two staff members must immediately discard the medication. The circumstances of the spillage or breakage must be entered in the drug register with a witness as a footnote (or under facility procedures in an electronic drug register) and reported to the Director of Nursing and Director of Pharmacy (see section 5.14.1).

5.18 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, or with an electronic drug register has lost data, 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 *Incident Management* (PD2020_047)
- notify the director of pharmacy and the director of nursing (however named).

The director of pharmacy must then immediately (and within 24 hours) notify the NSW Ministry of Health Pharmaceutical Regulatory 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 with a witness.

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

5.19 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 Health Policy Directive *Health Care Records - Documentation and Management* (PD2012_069) and *Government Retention and Disposal Authority 17* (GDA 17):

- **2 years** for;
  - for medication requisitions and purchase orders
  - receipts and records of medication deliveries
  - inventory control records
- **7 years** for;
  - for medication charts
  - Schedule 8 drug registers
- **10 years** for;
  - records relating to reports of the loss or theft of Schedule 8 or Schedule 4 Appendix D medications
  - records of the loss or theft of Schedule 8 drug registers
- **15 years** for records relating to clinical trial drugs **or** until the patient attains 25 years of age, whichever is longer.

6 ADMINISTERING MEDICATION

6.1 Staff administering 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.

This section addresses medication administration from a medication order described in section 6.2.

Competency to administer medications is included in the qualifications of medical practitioners, dentists, nurse practitioners, midwife practitioners, registered nurses, registered midwives, enrolled nurses and, under scope of practice, podiatrists and optometrists.

However, this is 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 health care workers may administer medications under the Regulation and in accordance with facility procedures. Procedures for medication administration must address the following:

- the Schedule of the medications
- the route of administration
- whether the medication is imprest or requisition stock, or labelled for a particular patient including if in a dose administration aid
- the health care worker's role at the facility
- any training and accreditation requirements
- risks associated with the administration of the medication.

Examples of health care workers which may be authorised under facility procedures, which include allied health practitioners, are:

- pharmacists
- oral health therapists
- physiotherapists
- orthoptists
- radiographers (for contrast)
- radiation therapists (for contrast)
- podiatrists, for topical anaesthetics and Schedule 4 local anaesthetics for parenteral use (Note: Podiatrists with a registration endorsement to prescribe and supply medications on the National Board list may also administer these medications at health facilities)
- respiratory physiologists
- nuclear medicine technologists (for radiopharmaceuticals, contrast)
- certified anaesthetic technicians
- cardiopulmonary technicians certified as clinical perfusionists
- health care staff for non-inpatients at a day centre, community setting (such as community mental health) or domiciliary setting (such as the patient's own home) for the purpose of assisting the patient to self-administer the medication that has been dispensed and labelled for the patient
- care workers at Local Health District residential care and flexible care services.

Facilities must ensure all persons authorised to administer medications 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. Where applicable, procedures must address medication administration by trainees or students.

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 clinical support required must also be considered relevant to each clinical situation and according to best professional practice guidelines.

Trainees and students undertaking medication administration

A student placement agreement must be in place for a student to administer medications within the facility. Trainees or students in any category must adhere to facility procedures when administering medication and recording the administration. A trainee or student must be directly supervised by the appropriate authorised person when administering any medication.

6.2 Orders for medication administration

An authorised prescriber's order for the administration of unscheduled, Schedule 2, Schedule 3, Schedule 4, and Schedule 8 medications to a patient may be in the form of:

- a written order on an individual patient's medication chart or anaesthetic record
- an electronic order in the eMeds system
- a Standing Order
- a verbal (face to face), telephone, video call, email or facsimile order

Medication orders via Short Message Service (SMS) or texting are not permitted and are not legally valid.

The person administering the medication must record the administration in the appropriate section of the patient's medication record. Where applicable, the staff member witnessing the administration must countersign the administration record.

6.3 Administering from a verbal, telephone, video call, email or facsimile order

6.3.1 Verbal (face to face) medication orders

Verbal (face to face) orders must not be used with the exception of:

- emergency situations where providing a written or eMeds order would compromise the speed of delivery/administration of the emergency medication
- during circumstances where the prescriber is undertaking a procedure on a patient and is unable to create a written order for that patient.

The person receiving a verbal order must be an authorised person to administer the particular medication in the patient care area. The prescriber must verify with the person receiving the order that all medication records have been checked, and that the patient does not have an allergy or has not experienced a significant adverse drug reaction to the medication before giving the order.

Due to the risk of misinterpretation, all verbal (face to face) orders must be verified with the prescriber prior to administration. A 'closed-loop' communication technique must be used to verify the:

- patient identity (including the patient's name, date of birth and medical record number)
- medication, form and strength
- route for administration
- dose (with numbers in figures and words (for example, *50mg: fifty milligrams, five zero milligrams*)
- patient's allergy and adverse drug reaction status.

Verbal (face to face) orders must be documented in the patient's health care record.

Under the Regulation, the prescriber must confirm all doses administered on a verbal (face to face) order as soon as possible either by:

- Counter-signing the record of administration (in electronic form where recorded in an eMeds system), or
- Sending written confirmation of the order via email or facsimile for inclusion, as applicable, on the patient's hard copy (paper) medication chart or scanned in the patient's electronic health care record.

If verbal (face to face) orders are not confirmed by the prescriber within 7 days, the facility is required to report this in writing to the NSW Ministry of Health Pharmaceutical Regulatory Unit so that Ministry officers can monitor compliance.

6.3.2 Telephone and video call orders

Telephone or video call orders must only be provided in circumstances when the prescriber is unable to write directly into a medication chart or provide an eMeds system order. The person receiving a telephone or video call order must be an authorised person to administer the particular medication in that patient care area. The prescriber must verify with the person receiving the order that the patient does not have an allergy or has not experienced a significant adverse drug reaction before giving the order. Due to the risk of misinterpretation, all telephone or video call orders must be verified with the prescriber prior to administration.

A 'closed-loop' communication technique must be used to verify the:

- patient identity (including the patients name, date of birth and medical record number)
- medication, form and strength
- route for administration
- dose (with numbers in figures and words (for example, 50mg is stated as *'fifty milligrams, five zero milligrams'*)
- patient's allergy and adverse drug reaction status.

Under facility procedures, the prescriber is to repeat the telephone or video call order to a second person authorised to administer the particular medication in that patient care area (where available). The order is to be verified by the second person with the prescriber prior to

administration. However, facility procedures to mitigate risks associated with telephone or video call orders must be in place where the staff member taking the order does not have a person present, such as for Hospital in the Home and community nursing/outreach services.

When a person administers a medication from a telephone order, the administration must be recorded on the medication chart in the 'Telephone Orders' section or in the eMeds system under facility procedures.

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 must also be made in patient's health care record, including the reason given for ceasing the order.

The prescriber must confirm within 24 hours all doses administered on a telephone or video call order either by:

- Counter-signing the record of administration (in electronic form where recorded in an eMeds system under facility procedures), and attending to review the patient as soon as appropriate, or
- Sending written confirmation of the order via email or facsimile for inclusion, as applicable, on the patient's hard copy medication chart or scanned in the patient's electronic health care record.

If telephoned or video call 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 the NSW Ministry of Health Pharmaceutical Regulatory Unit so that Ministry officers can monitor compliance.

6.3.3 Email and facsimile orders

Email and facsimile orders must only be provided in circumstances when the prescriber is unable to write directly into a medication chart or provide an electronic order. The person receiving such an order must be an authorised person to administer the particular medication in that patient care area. The prescriber must verify with the person receiving the order that the patient does not have an allergy or has not experienced a significant adverse drug reaction before giving the order.

When a person administers a medication from an email or facsimile order, this order must, as applicable, be attached to the patient's hard-copy medication chart or scanned in the patient's electronic health care record. This order is used to administer the medication until the order is updated with the other medication orders on the patient's medication chart or electronic medication order by an authorised prescriber. Under the Regulation email or facsimile orders must not be used for ongoing medication administration.

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

6.4 Standing orders and administration/supply under a protocol

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 (with the exception of a standing order for dose adjustments only which require a medication order prior to commencement).

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

The Drug and Therapeutics Committee must:

- maintain oversight of all standing orders
- approve all standing orders
- have a program for re-approving and re-endorsing all standing orders under the locally determined time period for review (such as every one to two years).

All standing orders must be:

- consistent, as applicable, with the respective medication's approved Product Information, evidence-based clinical practice guidelines (including for off-label use) and other relevant NSW Health policies and directives
- endorsed, signed and dated by an appropriate senior medical officer.

A standing order must contain sufficient detail for the information of staff administering the medication (or supplying for administration where applicable) including:

- indications and contraindications for use (including possible interaction with other medications)
- the medication's form, strength, dose, route of administration and frequency of administration.

In addition, standing orders include:

- any specific training, qualifications, skills or competencies required to prescribe or administer the medication
- any restriction on the categories of staff who may administer or supply the medication
- the clinical areas where the standing order can be used.

The NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) must be referred to when developing a standing order for a high-risk medicine.

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.

6.4.1 Standing orders for emergency treatment

An authorised prescriber approved under the standing order must confirm the administration by countersigning the record of the administration relevant to the order within 24 hours.

6.4.2 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 intravenous unfractionated heparin, insulin or infusions of inotropes. A medication order is required prior to commencement.

Dose adjustments must be recorded in the patient's medication record. Under facility procedures, an approved prescriber must document every 24 hours on the medication record that the order is to continue.

NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) includes the Anticoagulants Standard which includes requirements for intravenous unfractionated heparin protocols.

6.4.3 Individual prescriber standing orders

An individual prescriber's standing order authorisation provides for administration of medication to their patients only. Examples may include medications and fluids administered peri-operatively or for analgesia during labour at the specific request of an individual prescriber. The individual prescriber or approved delegate must countersign the record of administration relevant to the order in the patient's medication record within 24 hours.

6.4.4 Standing orders for routine procedures and programs

In the absence of an authorised prescriber, medication administration or supply for patient take-home use for 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 6.1 'Who May Administer Medication'). Examples include:

- agents administered by anaesthetic technicians
- agents administered by clinical perfusionists
- contrast administered by radiographers or radiation therapists
- radiopharmaceuticals and contrast administered by nuclear medicine technologists
- registered nurses for a public health emergency response in accordance with NSW Health Policy Directive *Statewide Standing Orders for the Supply and Administration of Medication for Public Health Response* (PD2016_035).
- registered nurses in emergency departments under NSW Health Policy Directive *Emergency Department, Nurse Delegated Emergency Care, Medication Standing Orders* (PD2015_024).

Facility procedures must determine whether the particular procedure or program requires that an authorised prescriber approved under the standing order must confirm the administration/supply by countersigning the record of the administration/supply

Note: A standing order for a Schedule 4 or Schedule 8 medication must be confirmed by an authorised prescriber by countersigning the record of the administration/supply relevant to the order within 24 hours.

6.4.5 Administration/supply under a protocol

Statewide protocols have been implemented for health facility staff administration and/or supply of medication for patient at home use. An authorised prescriber's counter signature subsequent to the administration or supply is not required. Protocols have been implemented for:

- vaccine administration by accredited registered nurse/midwife vaccinators for the purpose of a vaccination program under NSW Health Policy Directive *Authorised Nurse Immunisers and Authorised Midwife Immunisers* (PD2022_016)
- sexual health treatments under NSW Health Policy Directive *RN Supply and Administration of STI Therapies in Publicly Funded Sexual Health Services* (PD2020_024)
- naloxone (Schedule 3) under NSW Health Policy Directive *Take Home Naloxone* (PD2020_027)
- pharmacist initiation and administration of vaccines under the NSW Pharmacist Vaccination Standards, under a program approved by the Chief Executive.

6.5 Nurse/midwife initiated medication

Nurse/midwife initiated medications are those medications for minor symptom relief and short term use that may be administered without an authorised prescriber's order. Schedule 4 and Schedule 8 medications must not be a nurse/midwife initiated medication.

Written protocols must be developed for nurse/midwife initiated medications. The Drug and Therapeutics Committee must:

- maintain oversight of all nurse/midwife initiated medications
- approve all nurse/midwife initiated medication protocols
- have in place a program for re-approving and re-endorsing all nurse/midwife initiated medication protocols under the locally determined time period for review (such as every one to two years).

Nurse/midwife initiated medication protocols must include:

- the medication name, strength, dose, route and frequency of administration
- the maximum number of nurse/midwife initiated doses that can be administered. Generally protocols must include requirement that only one dose is administered, with the exception being protocols that address emergency circumstances where additional doses may be required
- indications and contraindications
- any restrictions on administering to specific patients, for example children up to 16 years of age
- any restrictions on categories of nursing/midwifery staff who can administer, for example only registered nurses or midwives. (*Note*: Enrolled nurses may administer locally approved nurse initiated medications under the supervision of a registered

nurse/midwife. The supervising registered nurse must confirm verbally with the enrolled nurse prior to the administration that the medication is appropriate and safe for the patient)

- the time frame for protocol review and re-endorsement (a minimum of every two years).

Prior to administering a nurse/midwife initiated medication, the nurse/midwife must ascertain that:

- the patient does not have a known allergy and/or adverse drug reaction to the medication
- no other formulations of the same medication are concurrently being prescribed or administered.

A record of the administration must be made in the patient's medication record, such as the 'nurse initiated medications' section of a chart in the National Standard Medication Chart suite. The medication must be reviewed and ordered by an authorised prescriber if required for ongoing treatment.

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.

6.6 Principles for safe medication administration

NSW Health policy adopts safe and accurate medication administration in the 5 Rights ('the 5 R's') of:

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

For every medication administered the staff member must:

- refer directly to the medication order which must be clear, legible and not open to misinterpretation
- check the patient's allergy or adverse drug reactions status
- read the product label and verify 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'
- prepare the medication including checking the medication name, strength, form, route of administration and expiry date against the medication order

- check the dose, form and route of administration of the medication and the time for administration
- confirm the patient's identity prior to administration
- re-check, at the point of administration to the patient, the patient's identification, known allergies, adverse drug reactions and any additional second person check requirements (see section 6.8)
- document the administration on the medication administration record
- monitor the effects of the medication.

In addition:

- the staff member administering a medication must contact the pharmacist, prescriber (or authorised delegate) for clarification prior to administering the dose if:
  - they consider a medication order is unclear or ambiguous, or
  - they are concerned that the order may be incorrect or inappropriate for the particular medical condition or patient
- if the patient and/or carer states that the medication or dose is incorrect, the staff member must check any documentation in the patient's health care record to ascertain if there has been an intentional change in the patient's medication or dose. If the staff member is unable to ascertain that the change in medication or dose is intentional, they must contact the prescriber prior to administering the dose
- the same person must select, prepare, administer and record the administration
- doses must be prepared for one patient at a time, and prepared for immediate administration. Prepared medications must not be 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. Exceptions include nurses preparing parental injections or oral medications for future self-administration by the patient (or where assisted by a carer), such as under the Caring@Home project. In addition, Justice Health and Forensic Mental Health Network has medication procedures with delayed and advanced administration provisions including during patient transit
- all Schedule 8 oral medications must be witnessed as having been administered to/consumed by the patient. All other medications requiring a second person check must be witnessed as having been administered to/consumed by the patient (*Note:* Exceptions are for patients self-administering medications at the health facility or home care setting)
- unwanted portions of tablets must be discarded in accordance with facility procedures at the time the dose is prepared. For Schedule 8 medications, the procedures detailed at section 6.9 must be followed
- medications must be administered, or prepared for administration, directly from the container supplied by the Pharmacy Service
- medication storage areas and medication trolleys must not be left unlocked unless in immediate use

- administration documentation must be made on a National Standard Medication Charts in accordance with the implementation and user-guides, on another Drug and Therapeutic Committee approved medication chart or in the eMeds system
- staff members must access further information on medications if required by contacting the prescriber, pharmacist and referring to facility procedures and protocols or resources provided in the Clinical Information Access Portal (CIAP).

User-applied labelling of injectable medications, fluids and lines

Injectable medications, fluids and lines must be labelled in accordance with the ACSQHC's National Standard for User-applied Labelling of Injectable Medicines Fluids and Lines (Labelling Standard).

The Labelling Standard ensures accurate communication of injectable, medications, fluids and lines information through standardised user-applied labelling. Labelling Standard labels must not be customised. Facilities must ensure that the required labels are available for use in clinical areas.

The Labelling Standard sets out the requirements for labelling of:

- containers of injectable medications and fluids that can no longer be identified by their original packaging
- conduits (for example, intravenous administration lines, intravenous catheters, epidural lines) used to deliver injectable medications
- fluids and non-injectable fluids (oral, enteral, buccal, rectal and inhalation medications) that can no longer be identified by their original packaging.

Topical lotion, cream or ointment in multi-dose tubes/pots/containers (excluding hand hygiene products)

- Open multi-dose lotion or cream or ointment in tubes/pots/containers must only be used for an individual patient's use in accordance with NSW Health *Infection Prevention and Control Policy* (PD2017_013)
- Standardised connectors for liquids and gases
- Where available, products compliant with International Organization for Standardization ISO 80369 Small-Bore Connector Standards must be used.

Administration of liquid medications using enteral or oral route – additional requirements

Luer lock syringes (used for parenteral injections) must not be used for oral or enteral medication administration. Oral/enteral dispensers (also called oral/enteral syringes) or graduated medication cups must be used to prepare, measure and administer all liquid doses intended for oral or enteral use.

The enteral dispensers and the devices ('straws' and 'stoppers') to assist measurement and withdrawal of medication doses from liquid containers, must be ISO *Small-Bore Connectors Standard* (ISO 80369-3) compliant. ISO 80369-3 *Enteral Feeding* Standard specifies the dimensions and requirements for small-bore connections on enteral medical devices and

accessories. Enteral dispensers and devices to assist administration purchased from NSW Health Enteral Nutrition and Support Services Feeding Contract (Contract 955) are ISO 80369-3 compliant and will meet the necessary safety requirements.

Oral/enteral dispensers:

- must be used when liquid doses are not readily measured by available calibrations using an oral medication measure or cup
- must be disposable, meaning for single patient use then discarded. If several liquid medication doses are to be given to one patient at the same time of day, they must each be separately prepared and administered
- must be over-wrapped, individually or in small quantities, to facilitate clean handling
- must be readily available in clinical areas where liquid medication doses for routes other than injection are prepared
- must be stored separately from parenteral syringes and storage areas clearly identified.

Medications administered via the enteral route must be administered in accordance with facility procedures and the medication's Product Information. Consideration must be given to:

- whether the tip of the enteral tube is lying in the stomach, duodenum or jejunum
- whether an alternative non-solid presentation (for example, syrup) is required
- the compatibility, solubility, stability of medication
- the appropriateness of crushing any tablet or opening any capsule.

For patients who are unable to swallow tablets whole, clinicians must refer to the 'Don't Rush to Crush Handbook' (available via CIAP) and/or a pharmacist for advice. The Handbook provides advice on whether tablets can be crushed or broken, and administration recommendations for patients with swallowing difficulties or with enteral feeding tubes.

Liquids for buccal, inhalation, intranasal or rectal administration

Liquids for buccal, inhalation, intranasal, or rectal administration must be purchased in ready to use units wherever possible.

Preparing liquid medications for buccal, inhalation, intranasal or rectal administration in clinical areas is considered a high-risk procedure. Due to the risk of accidental intravenous administration, luer lock syringes used for parenteral medication administration must not be used to prepare and administer buccal, inhalation, intranasal or rectal medications except in circumstances where withdrawal of doses from vials requires the use of a needle and luer compatible syringe.

In circumstances where ready to use units are not available for buccal, inhalation, intranasal or rectal administration:

- prepare the dose at the bedside to reduce the risk of inadvertent parenteral injection
- label the dispenser with the intended route of administration
- conduct a second person check (see section 6.8).

If a multi-dose container of liquid for inhalation is used, a non-luer dispenser must be used to withdraw doses and expel them into labelled inhalation reservoirs.

Cytotoxic and other hazardous medications

Cytotoxic medications must be prepared, administered and disposed of by appropriately accredited staff members. Cytotoxic and other hazardous medications must be handled in accordance with any cautionary advisory labelling. The NSW Government guide on Cytotoxic Drugs and Related Waste - Risk Management provides advice on minimising the risk to health associated with handling cytotoxic drugs and related waste within health care establishments and community settings.

Additional medication handling requirements included in Safety Alert Broadcasts

The NSW Health Safety Alert Broadcast System may specify specific medication handling requirements above those mentioned in this Policy identified through serious medication incidents. These specific requirements must be followed in addition to the requirements set out in this Policy.

Clinical handover

Clinical handover must address ongoing medication issues and identify actions and monitoring that need to occur in accordance with NSW Health *Clinical Handover* (PD2019_020).

6.7 Administration by injection – additional requirements

Facilities must develop procedures for the administration of medications by injection. Facility procedures must include:

- second person check requirements in accordance with section 6.8
- any infection control or workplace safety requirements.

Clinicians must also refer to Australian Injectable Drugs Handbook in CIAP for information regarding preparing and administering medications by injection. Information in the handbook must be used in conjunction with facility procedures.

Administration of epidural anaesthesia or analgesia

Epidural administration must be governed by facility procedures. Nursing and midwifery staff that 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.

Single use injections

When only a portion of a dose is required for a patient, the unused balance must be discarded, with the exception of circumstances where incremental dosing is used, in accordance with facility procedures. Requirements for discarding of part doses of Schedule 8 injections are included in section 6.9.

Multi-dose injections

In accordance with NSW Health policy on Infection Prevention and Control, injections must not be shared between patients ('multi-dosed'), except for multi-dose vials where there is no other alternative available on the Australian pharmaceutical market.

Additions to intravenous fluid container

When available, pre-mix infusion of high-risk medications are to be used in preference to those additions to intravenous fluids prepared in clinical areas. Additions of medications or electrolytes to an intravenous fluid container must be made under controlled environmental conditions where possible, or else prepared immediately prior to administration using aseptic technique.

In particular, high-risk medicine potassium chloride ampoules must not be available as ward/imprest stock. Commercially prepared pre-mix potassium chloride solutions must be used. NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) includes a Potassium (Intravenous) Standard that outlines the minimum actions required to mitigate risks associated with intravenous potassium, including requirements for commercially prepared pre-mixed solutions and requirements for storing potassium ampoules only in critical care areas or operating suites where higher doses of potassium are considered necessary.

Mandatory requirements for potassium chloride pre-mixed infusion solutions include:

- clear differentiation from other intravenous fluids, for example, through use of colour coded over-pouches and labelling
- orders for intravenous potassium salts must be expressed in millimoles (mmol). In addition, weight such as grams (g) or milligrams (mg) may be included.
- small volume intravenous solutions (minibags) must not have an additive port or, if prepared in-house, the additive port must be capped.

6.8 Second person checks prior to administration

6.8.1 Second person checks – general requirements

Independent second person checks are an important medication safety strategy. An independent second person check requires two people to separately check each component of selecting, preparing and administering a medication.

To be effective, a second person check must be conducted independently by the second person to reduce the risk of bias that occurs when the person preparing and checking the medication is likely to see what they expect to see, even if an error has occurred. Two people are unlikely to make the same mistake if they work independently. If they work together or influence the checking procedure by suggesting what the checker must find, both could follow the same path to error. When performed correctly, independent second person checks have been found to detect 95% of errors (ISMP, 2013).

This Policy does not mandate a second person check when the medication is administered by an authorised prescriber or when self-administered by the patient, except when under NSW Health policy or facility procedures. Patient self-administration of high concentration

insulin under supervision is in section 5.2.5 in accord with Safety Alert Broadcast SN:007/19 High Concentration Insulin Products - Updated.

Exceptions are also for the administration of Schedule 8 medications in home care settings, including for patient's self-administering of facility supplied medications – see medications in a facility home care setting).

When conducting an independent second person check, each person must independently follow the procedure steps below:

Procedure steps		
1	Product selection	confirm the selection of the correct medication and fluid against the medication and/or fluid order.
2	Preparation	confirm that the dose is appropriate and the calculations are correct confirm that the dose is being administered using the correct route and at the correct time when in use, check that the rate limiting device, for example, infusion pump, is correctly set.
3	Administration	confirm the identity of the patient prior to administration (at the bedside or with the patient present) and in accordance with facility procedures
4	Documentation	document the administration, preferably in the same record, in accordance with facility procedures.

A video demonstrating how to conduct an independent second person check is available at My Health Learning within the Safe Use of High-Risk Medicines module.

For Schedule 8 medications, a second person check is required under the Schedule 8 medication witness requirements outlined in section 5.14.2. The purpose of the Schedule 8 witness procedure is to account for the Schedule 8 medication. The purpose of a second person check prior to administration is to reduce risks associated with medication administration.

Facility procedures must include procedures to confirm the suitability of staff members to act as a second person checking the preparation and administration of the medications specific to the patient care area. NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045) includes second person check requirements for high-risk medications.

The Drug and Therapeutic Committee must determine what additional medications and circumstances, in addition to those outlined in the tables below, require a second person check. Tables 1, 3, 4, 5, 6 and 7 outline second person check requirements and required risk mitigation strategies. The Table 2 outlines Schedule 8 medication witness, and additional second person check requirements.

6.8.2 Table 1. Inpatient settings (except Hospital in the Home) excluding Schedule 8 medications

Inpatient Circumstance / condition	Second person check requirements	Notes
Medications administered by injection to patients aged 16 years and over.	Independent second person check required in all circumstances. In emergency situations, for example cardiac arrest, the principles of an independent second person check must be followed for verbal (face to face) orders..	
Medications administered to children aged up to 16 years.	Independent second person check required for all doses administered by injection (including in emergency situations). Independent second person check required for all doses requiring a drug calculation (including in emergency situations).	The Drug and Therapeutics Committee must approve the list of medications (if any), and conditions in which they can be administered, based on a risk assessment, without a second person check, for example topically applied lotions and creams.
Contrast administered by a radiographer via all routes, including under a standing order	Independent second person check required in all circumstances. Includes at outpatient clinics.	The second person check can be conducted by an authorised prescriber, registered nurse, enrolled nurse or medical radiation practitioner.
Radiopharmaceuticals for diagnostic or therapeutic purposes administered by a nuclear medicine radiation technologist or a nuclear medicine scientist	Independent second person check required in all circumstances. Includes at outpatient clinics.	The second person check can be conducted by an authorised prescriber, registered nurse, enrolled nurse or medical radiation practitioner.
Inhalation, intranasal, buccal or rectal administration for patients aged 16 years and over.	Independent second person check required if dose is not in a ready to use form.	

6.8.3 Table 2. Inpatient Schedule 8 medication procedure requirements

Procedure Stage	Schedule 8 witness requirements	Additional second person check requirements
Product selection	Observe the removal and replacement of medication from the Schedule 8 medication storage unit.	Independent second person check required. Two persons (person administering and witness) must independently: Confirm the selection of the correct medication and/or fluid (including strength and form). Confirm dosage form.
Documentation	Make a record in the Schedule 8 drug register.	
Preparation	Observe preparation of the medication. Observe the discarding and rendering unusable any unused portion of the medication.	Confirm that the dose is appropriate and the calculations are correct. Confirm that the dose is being administered using the correct route and at the correct time. When in use, check that the rate limiting device, for example, infusion pump, is correctly set.
Documentation	Document the discard in the Schedule 8 drug register.	
Transfer	Observe transfer of the medication to the patient.	
Administration	Observe administration or commencement of the medication to the patient.	Confirm the identity of the patient prior to administration (at the bedside or with the patient present) and in accordance with facility procedures.
Documentation		Document the administration, preferably in the same record, in accordance with facility procedures.

6.8.4 Table 3. Inpatient settings (Except Hospital in the Home) – Schedule 8 medications

Circumstance	Second Person Check Requirement	Documentation requirements	Additional risk mitigation requirements
Inpatient administration of Schedule 8 medications for all routes (including children aged up to 16 years).	Independent second person check required prior to administration of every dose.	All dose administrations must be signed for on the medication order by two authorised persons.	Facility procedures include circumstances where the second person is not at the bedside, such as in an isolation room.
Administration of an intravenous or subcutaneous infusion containing a Schedule 8 medication via an infusion device (including children aged up to 16 years).	Independent second person check required on commencing the infusion. Two authorised persons must check all dose adjustments including checking: • against the medication order • that the infusion pump rate has been correctly set.	All dose adjustments must be documented and signed for on the medication order. All medication discard (including zero discard) must be documented in the patient's health care record and signed by two authorised persons.	Drug and Therapeutics Committees must approve any circumstances where, based on a risk assessment, a second person check is not required for dose adjustments. For example, the Drug and Therapeutics Committee may determine that a single nurse check is sufficient for dose adjustments if infusion device dose error reduction software is in use.
Injectable incremental dosing of Schedule 8 medications using a syringe. Note: The use of incremental dosing is not encouraged due to risks of medication error and drug diversion.	Independent second person check is required.	Document the time of the incremental dose administration. Incremental dose administrations must be signed by two authorised persons on the medication order. Medication discard (including zero discard) must be witnessed and signed by two authorised persons (see section 5.14.2).	See below *Injectable incremental dosing of Schedule 8 medications protocol requirements*.* The registered nurse/registered midwife administering the Schedule 8 medication must maintain possession of the syringe. Syringes containing Schedule 8 medications must not be left unsecured (at the bedside or elsewhere). Syringes must be labelled with a user-applied label and in accordance with the Labelling Standard.

**** Injectable incremental dosing of Schedule 8 medications procedure requirements***

In clinical areas where it is determined that incremental dosing of an injectable Schedule 8 medications via a syringe is required, facility procedures and ensure inclusion of the following:

- incremental Schedule 8 medication dosing via a syringe must be limited to post-anaesthetic care units and emergency departments

- specific staff training, qualifications, skills or competencies to administer Schedule 8 medication incremental doses
- the requirement for an independent second person check. Details of those circumstances (if any) where only a single registered nurse or registered midwife is on duty or available in the department to administer an incremental dose when delay in accessing a second person to check the dose would be detrimental to patient care
- the list of medications, doses and minimum time interval for incremental dosing
- the time period after which syringes must be discarded, for example, discarding residue in the syringe after 30 minutes
- patient criteria for incremental administration including additional considerations for high-risk patient groups such as paediatric, pregnant and elderly patients
- patient assessment requirements prior to incremental dose administration and monitoring to ensure a timely response to adverse events or side-effects
- procedures for managing adverse events or side-effects
- instructions for documentation.

6.8.5 Table 4. Hospital in the Home with one nurse/midwife

Hospital in the Home circumstance / condition	Check requirements	Documentation requirements (with witness requirements)	Additional risk mitigation strategies
All doses administered by injection.	Check by the (single) nurse preparing and administering the injection (see above single nurse check requirements).		Medications must be dispensed by a pharmacist and labelled for an individual patient. If medication is taken from imprest supply, an independent second person check of all components that can be checked, such as the medication name, formulation and dose must be conducted before stock leaves the facility. Palliative care crisis packs: In the circumstance where a crisis pack is required it must be dispensed by a pharmacist and labelled for an individual patient, or When required for a patient after-hours, crisis packs must be dispensed in accordance with section 5.9.
Administration of a subcutaneous fixed rate infusion containing a Schedule 8 medication to a palliative care patient in a home care setting.	Check by (single) nurse preparing and administering the infusion (see above).	All medication discard (including zero discard) must be documented according to facility procedures and signed by the nurse (see section 5.14.2).	
Administration of non-injectable Schedule 8 medications in home care setting.	Check by (single) nurse preparing and administering the medication (see above).	All medication discards must be documented according to facility procedures and signed by the nurse (see section 6.9).	

Generally medications must be dispensed by a pharmacist and labelled for an individual patient to reduce the risk of medication selection error.

When a single nurse is preparing and administering medications they must:

- check the identity of the patient

- check the patient's allergy and adverse drug reaction status
- check the selection of the correct medication and fluid
- check that the dose is appropriate and the calculations are correct
- check that the dose is being administered using the correct route and at the correct time
- when in use, check that the rate limiting device, for example, infusion pump, is correctly set
- sign for the administration against the medication order.

6.8.6 Table 5: Palliative care in the home setting with one nurse/midwife

Palliative care home care setting	Check requirements	Documentation requirements	Risk mitigation
Administration of a subcutaneous fixed rate infusion containing a Schedule 8 medication to a palliative care patient in a home care setting.	Check by a (single) nurse administering infusion.	All medication discards (including zero discard) must be documented in accordance with facility procedures (see section 6.9).	Medications must be dispensed by a pharmacist and labelled for an individual patient. If medication is taken from imprest supply, an independent second person check of all components that can be checked, such as the medication name, formulation and dose must be conducted before leaving the facility. Palliative care crisis packs: In circumstances where a crisis pack is required it must be dispensed by a pharmacist and be labelled for an individual patient, or When required for a patient after-hours, crisis packs must be dispensed in accordance with section 5.9).
Administration of non-injectable Schedule 8 medications in home care setting.	Check by nurse administering medication.	All medication discards must be documented in accordance with facility procedures (see section 6.9).	
All doses administered by injection.	Check by nurse administering medication.		

When a single nurse is preparing and administering medications they must:

- check the selection of the correct medication and fluid
- check that the dose is appropriate and the calculations are correct
- when in use, check that the rate limiting device, for example, infusion pump, is correctly set
- check the identity of the patient prior to administration
- sign the record of administration against the medication order
- check the patient's allergy and adverse drug reaction status.

6.8.7 Table 6. Community Home Care with one nurse/midwife

Community setting circumstances	Check requirements	Documentation requirements (with witness requirements)	Risk mitigation requirements (all circumstances)
Administration of a subcutaneous fixed rate infusion containing a Schedule 8 medication to a palliative care patient in a home care setting.	Check by (single) nurse administering infusion (see above).	All medication discard (including zero discard) must be documented according to facility protocol and procedure (see section 6.9).	Medications must be dispensed by a pharmacist and labelled for an individual patient. If medication is taken from imprest supply, an independent second person check of all components that can be checked, such as the medication name, formulation and dose must be conducted before leaving the facility. Palliative care crisis packs In circumstances where a crisis pack is required it must be dispensed by a pharmacist and be labelled for an individual patient. When required for patients after-hours, crisis packs must be dispensed in accordance with section 5.9).
Administration of non-injectable Schedule 8 medications in home care setting	Check by (single) nurse administering medication (see above)	All medication discards must be documented according to facility procedures (see section 6.9)	
All doses administered by injection	Check by (single) nurse administering injection		
All doses administered to children aged up to 16 years	Check by (single) nurse administering medication	For Schedule 8 medication: All discard (including zero discard) must be witnessed and signed by nurse (see section 6.9)	

When a single nurse is preparing and administering medications they must:

- check the selection of the correct medication and fluid
- check that the dose is appropriate and the calculations are correct
- check that the dose is being administered using the correct route and at the correct time
- when in use, check that the rate limiting device, for example, infusion pump, is correctly set
- check the identity of the patient prior to administration
- sign the medication order

  check the patient's allergy and adverse drug reaction status.

6.8.8 Table 7. Other clinical settings operated with only one nurse/midwife (remote health facilities, community health centres)

Clinical settings where there is only one nurse or midwife	Check requirements	Documentation requirements (with witness requirements)	Risk mitigation
Administration of Schedule 8 medications (including children aged up to 16 years)	Check by (single) nurse or midwife administering medication. Schedule 8 medication transactions must be witnessed in accordance with facility protocol and procedures (see section 5.14.2)	All medication discards must be documented in accordance with facility procedures (see section 6.9)	Medications must be dispensed by a pharmacist and labelled for an individual patient. If medication is taken from imprest supply, an independent second person check of all components that can be checked, such as the medication name, formulation and dose must be conducted.
All doses administered by injection (including children aged up to 16 years)	Check by (single) nurse or midwife administering medication		

When a single nurse or midwife is preparing and administering medications they must:

- Check the selection of the correct medication and fluid
- Check that the dose is appropriate and the calculations are correct
- When in use, check that the rate limiting device, for example, infusion pump, is correctly set
- Check the identity of the patient prior to administration
- Sign the record of administration against the medication order
- Check the patient's allergy and adverse drug reaction status.

6.9 Schedule 8 medication discards

6.9.1 General principles

Procedures involving Schedule 8 medications with a witness must in accordance with section 5.14.2, other than those conducted by an authorised prescriber, such as an anaesthetist.

Note that an authorised prescriber must expel a partly used injectable Schedule 8 medication into a sharps container and only discard empty vials, ampoules and syringes/infusions in the sharps container. The amount discarded must be recorded in the patient's health care record or anaesthetic record, as applicable.

For patients who die in hospital or home care setting, infusions of Schedule 8 medications must be left attached to the body, where required, in accordance with NSW Health Policy Directive *Coroner's Cases and the Coroners Act 2009* (PD2010_054).

6.9.2 Home care setting

Where applicable, facility procedures must address requirements for discarding partly used Schedule 8 medications in a home care setting including discarding patient own Schedule 8 medications.

Procedures must include:

- Requirement for the discard to be documented and signed by the nurse
- Procedures for discarding oral medications and ampoules
- Requirements for discarding used Schedule 8 transdermal patches, including requirement to fold transdermal patch in half so that the medication is trapped within the adhesive surface, wrap and dispose in the garbage, out of reach of children.

6.9.3 Patient care areas

Tablets or ampoules

Where only a portion of a Schedule 8 tablet is required for administration, any unused tablet portions must be discarded in the sharps container in the presence of the witness to the administration.

Where only a portion of a Schedule 8 ampoule is required for administration unused portions of an injectable medication must be drawn up into a syringe and the contents expelled into a sharps container in the presence of the witness to the administration. Ampoules containing Schedule 8 medications must not be discarded with any medication remaining in the ampoule.

The discarded amount must be recorded in the drug register with the record of the administration.

Oral liquid medications

The irretrievable amount in a delivery device such as in the dead space in an oral/enteral dispenser (for example, 0.2 mL, depending on the type of syringe used) must be discarded in the sharps container in the presence of the witness to the administration. The discarded amount must be recorded in the drug register with the record of the administration.

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 manner that renders the drug unusable and unrecoverable in accordance with facility procedures.

The quantity of the discarded portion must be recorded on the relevant medication order, signed and dated by the registered nurse/midwife and countersigned and dated by a witness to the procedure. It is not necessary to record the discard from partially used infusions into

the Schedule 8 drug register. Medication orders and/or charts used for documenting infusions containing Schedule 8 medications must include an area for documenting the discard including the date, time, total drug discarded and signatures of registered nurse/midwife discarding the drug and 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.

Transdermal patches

Used transdermal patches must be removed from the patient in the presence of a witness, even if a new patch is not to be applied.

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 on the medication order or in the patient's health care record (as applicable), signed and dated by the registered nurse/midwife and countersigned and dated by the witness to the procedure. eMeds systems must provide an area to document Schedule 8 transdermal patch removal.

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 5.17.

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 comes into contact with the skin or other body surface, immediately wash off thoroughly with soap and water.

Care must be taken to ensure that a Schedule 8 transdermal patch is not misplaced in the patient's clothes/bed linen or dropped onto the floor.

Additional information regarding opioid skin patch safety is in NSW Health Policy Directive *High-risk Medicines Management Policy* (PD2020_045) and in the NSW Therapeutic Advisory Group document Opioid skin patches are high-risk medicines.

Oromucosal medications

Partially used oromucosal medications (for example fentanyl lozenges and disintegrating tablets) must be disposed of by a registered nurse/midwife in the presence of a witness into a sharps container.

The discarding must 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.

6.10 Patient self-administration of medications

Generally patient self-administration of medications is not permitted at public health facilities. However, the Drug and Therapeutics Committee must approve all specific circumstances and procedures where the patient may self-administer medication either independently or with the

assistance of a non-nurse carer – see in section 5.2.5. In specific circumstances, medications may include those dispensed for the patient in a dose administration aid (see section 6.12).

Under local procedures, facilities providing residential services such as Karitane and Tresillian parents and/or carers may self-administer, or administer medication to the child in their care. Inmates at Correctional Centres may self-administer medications under the Justice Health and Forensic Medicine Network Medication Procedures.

Consideration must be given 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 adrenaline (epinephrine), medications for Parkinson's disease and medications for diabetes including insulin). See section 6.11.

Medication orders for medication self-administration must contain an explicit instruction by the prescriber that the medication is for self-administration.

Medications for patient self-administration must be stored in accordance with the requirements in section 5.4.

6.10.1 Patient training and education programs

The Drug and Therapeutics Committee must implement a formal patient education program for patients 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 must 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 6.12), 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.

6.10.2 Non-inpatient day centres

Staff may assist a patient to self-administer patient own medications in a non-inpatient day centre in accordance with facility procedures.

6.11 Time critical medications

Time critical medications are those where early or delayed administration by more than 30 minutes may cause harm to the patient or result in suboptimal therapeutic effect.

Drug and Therapeutics Committees must identify a facility specific list of time critical medications. Written protocols must be developed for medications on this list. Protocols must include:

- the time critical window in which the medication must be given, for example;
  - insulin which must be administered within a specified period of time before, after, or with meals
  - conventional levodopa formulations for Parkinson's disease must be administered within the specified time as normally taken by the patient

- instructions for managing administration of the time critical medication while the patient is admitted in hospital (administration times must be kept as close as possible to the patient's normal dosing times)
- instructions for managing time periods when the patient is nil by mouth
- requirements for patient self-administration of the medication.

6.12 Dose administration aids

Dose administration aids must not be used for the routine administration of medications, other than as an option to residential care or flexible care residents under the *Commonwealth Aged Care Act 1997* at a public hospital or Multi-Purpose Service, or at Correctional Centres. Under facility procedures, dose administration aids **may** also be used in patient care areas to train or assess a patient's ability to self-medicate (see section 6.10).

Additionally, patients may present to day centres with medications packed in a dose administration aid by a community pharmacist.

Dose administration aids may comprise blister packs, plastic 'packettes' (sachets) or 'dosette boxes'. Dose administration aids packed and labelled by a pharmacy service are preferred and safer than patient/carer filled dosette boxes. 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 medication packs that have been dispensed and labelled by a pharmacist.

The packing and labelling, with the inclusion of the required warning and precautionary labels, must be in accordance with *Pharmacy Board of Australia Guidelines on Dose Administration Aids and Staged Supply of Dispensed Medicines*.

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
- recording the administration of dose administration aid packed medication on the patient's medication chart
- confirming the dose administration aid meets the child resistant packaging requirements in section 4.5.5
- the need for a moisture-proof container for some medications, and the protection of individual doses from contamination
- minimising the risk of spillage and the potential mix-up of medication, especially for a person with visual impairment or poor manual dexterity
- use with patient self-administration of 'time critical' medications (see section 6.11).

7 REFERENCES

7.1 Related documents:

- Agency of Clinical Innovation
  - NSW Adult Subcutaneous Insulin Chart
  - Suite of NSW Pain Charts
- ACSQHC
  - Electronic Medication Management Systems: A Guide to Safe Implementation
  - National Safety and Quality Health Service (NSQHS) Standards
  - National Standard Medication Charts
  - Recommendations for Terminology, Abbreviations and Symbols used in Medicines Documentation
  - National Guidelines for On-Screen Display of Medicines Information
  - National Inpatient Medication Chart User Guide
  - National Standard for User-Applied Labelling of Injectable Medicines Fluids and Lines
  - National Tall Man Lettering List
- Australian Government Department of Health
  - Australian Guidelines for Drug Donations to Developing Countries
  - National Vaccine Storage Guidelines 'Strive for 5'
- Council of Australian Therapeutic Advisory Groups
  - Achieving Effective Medicines Governance: Guiding Principles for the Roles and Responsibilities of Drug and Therapeutics Committees in Australian Public Hospitals
  - Guiding Principles for the Use of Complementary and Alternative Medicines in Hospitals
- eviQ
- National Health and Medical Research Council
  - National Statement on Ethical Conduct in Research Involving Humans
- NSW Government Guide
  - Cytotoxic Drugs and Related Waste – Risk Management
- NSW Health Information Bulletins, Guidelines and Policy Directives:
  - Adult and Paediatric Hospital in the Home Guideline
  - Approval Process of Medicines for use in NSW Public Hospitals

- Care Coordination: Planning from Admission to Transfer of Care in NSW Public Hospitals
- Clinical and Related Waste Management for Health Services
- Clinical Handover
- Coordination of Responses to Urgent System-Level Medicine or Medical Device Issues
- Coroners Cases and the Coroners Act 2009
- Documentation and Management of Health Care Records
- Electronic Medication Management System Governance and Standards
- Goods and Services Procurement
- Health Care Records – Documentation and Management
- High-Risk Medicines Management
- Incident Management
- Infection Prevention and Control Policy
- Major Incident Medical Services Supporting Plan
- Maternity – Prevention, Early Recognition & Management of Postpartum Haemorrhage (PPH)
- NSW Clinical Guidelines – Treatment of Opioid Dependence
- Pharmaceutical and Safety Net Arrangements for Outpatients and Patients on Discharge
- Patient Safety and Quality Program
- Pharmaceuticals – Preparation in NSW Public Health Facility Pharmacy Services
- Protecting People and Property: NSW Health Policy and Standards for Security Risk Management in NSW Health Agencies
- RN Supply and Administration of STI Therapies in Publicly Funded Sexual Health Services
- Rural Adult Emergency Clinical Guidelines
- Rural Paediatric Emergency Clinical Guidelines
- Safety Alert Broadcast System Notifications
- Tenecteplase Replacement in Public Hospitals for Ambulance Paramedics
- Vaccine Storage and Cold Chain Management
- Work Health and Safety Better Practice Procedures

- Society of Hospital Pharmacists of Australia
  - Standards of Practice for Clinical Pharmacy Services