	Western Health 🔍		
Medication Prescription, Supply, Storage and Administration			
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1. Overview

This document outlines the procedures for prescription, supply, storage and administration of unscheduled (non-restricted), Schedule 2, 3, 4 and 8 medicines. It incorporates the storage and administration requirements of certain Schedule 4 medicines identified as having abuse potential and classified as Schedule 11 medicines.

Western Health supports the right of all staff to be certain and comfortable in all practices relating to medications.

If a clinician is unsure, uncomfortable or concerned about prescribing, dispensing or administering a medication it is their responsibility to seek clarification and support immediately, and to resolve the issue in a timely fashion. It is the duty of other clinicians to respectfully respond to these enquiries.

2. Applicability

This procedure applies to all Western Health sites and is relevant to nursing, midwifery, medical, pharmacy and podiatry staff.

It does not apply to NorthWestern Mental Health (NWMH) units located on WH sites, which follow NWMH and Melbourne Health policies and procedures.

Hazeldean's pharmacy service is provided by a contracted community pharmacy service provider and separate arrangements apply for supply of medication (see *Section* <u>8.6</u>).

3. Responsibility

The Director of Pharmacy and Directors of Nursing and Midwifery are responsible for implementing this procedure.

The Director of Pharmacy, Divisional Directors, Operations Managers, Nurse/Midwife Unit Managers and Heads of Units are responsible for ensuring that staff members in their areas are aware of and comply with the procedure.

There are no exclusions to these responsibilities.

4. Authority

There are no exceptions to this procedure due to legislative requirements.

5. Associated Documentation

In support of this procedure, the following policies, procedures and forms apply:

P-EP3	Credentialing and Defining the Scope of Clinical Practice	
P-GC6	Medication Use and Management	
OP-CM5	Patient Clinical Records Documentation	
OP-EP3	Credentialing and Defining the Scope of Practice for Senior Medical Practitioners	
OP-EP3	Nursing and Midwifery Scope of Clinical Practice and Credentialing	
OP-GC3	Adult Enteral Feeding	
OP-GC3	Adult Nasogastric Tube (NGT) Insertion and Management	
OP-GC3	Percutaneous Endoscopic Gastrostomy (PEG) Insertion and Management	
OP-GC6	Adult Venous Thromboembolism (VTE) Prevention	
OP-GC5	Standard and Transmission Based Precautions	
OP-GC6	Adverse Drug Reaction Recording and Reporting	
OP-GC6	Delivery of Medication from Pharmacy to Clinical Areas by Non-pharmacist Staff	
OP-GC6	Hazardous Medications – Cytotoxics	
OP-GC6	Insulin Infusion (Intravenous) in Adults	
OP-GC6	Insulin Prescription, Supply, Storage and Administration	
OP-GC6	Intermittent Opioid Analgesia in Adults for Acute Pain and Associated Observations (Inpatients Only)	
OP-GC6	Medical Management of Drug Dependent Persons and Prescription of Long Term Opioid Medication	
OP-GC6	Medication Refrigeration	

OP-GC6	Nurse and Midwife Initiated Medications
OP-GC6	Pharmacy Services and Referral to Clinical Pharmacist
OP-GC6	Pyxis® MedStation System
OP-GC7	Clinical Incident Investigation and Governance
OP-GC8	Consent, Prescribing and Administration of Blood and Blood Products
OP-RS5	Key and Lock Management
OP-RS5	Security Access Management
Allied Health DG-CC2	Advanced Practice Physiotherapy in the Emergency Department
Children's Services DP-GC3	Neonatal and Paediatric Oro/Nasogastric Tube Insertion and Management
Children's' Services DP-GC6 PACU DP-GC6 PACU DP-GC6 Podiatry DP-EP3	Use of Western Health Neomed Medication Resource Post Anaesthetic Care Unit (PACU) Opioid Administration for Adults Post Anaesthetic Care Unit (PACU) Opioid Administration for Paediatric Patients Advanced Practice Podiatry: Endorsement for Scheduled Medicines
AD61	ED & after hours IRCMAC
Forms	Category A, B and C Special Access Scheme (SAS)
Form	Individual Patient Usage (IPU)

6. Credentialing Requirements

The Clinical Nurse/Midwife Educators, Nurse/Midwife Unit Managers, the Medical Education Unit and Pharmacy managers will ensure that appropriate staff members have the credentialing requirements and orientation necessary to perform the clinical practices outlined in this procedure.

Credentialing requirements exist for Registered Nurses, Registered Midwives, Medical Officers and Podiatrists. Refer to <u>P-EP3 Credentialing and Defining the Scope of Clinical Practice</u>, <u>OP-EP3 Credentialing and Defining the Scope of Practice for Senior Medical Practitioners</u>, <u>OP-EP3 Nursing and Midwifery Scope of Clinical Practice and Credentialing</u>. <u>Podiatry DP-EP3 Advanced Practice Podiatry: Endorsement for Scheduled Medicines</u> and individual position descriptions for detail.

All nursing and midwifery staff must ensure that they develop and maintain a working knowledge of medication administration, WH procedures, and undergo relevant training and education as required by their Nurse/Midwife Unit Manager and Clinical Nurse/Midwife Educators.

7. Definitions and Abbreviations

For purposes of this procedure, unless otherwise stated, the following definitions/abbreviations shall apply:		
ACE Team	Advice, Coordination and Expertise Team (formerly Immediate Response Service)	
ADR	Adverse Drug Reaction	
Advanced Practice Physiotherapist	An Advanced Practice Physiotherapist is a physiotherapist who has undergone advanced practice credentialing within Western Health, and has been approved to practice by the Western Health Allied Health and Care Coordination Credentialing and Professional Advisory Committee	
AHA	After Hours Administrator	
APINCH	Mnemonic for a defined list of high risk medications. See <u>Section 8.3</u> .	
Authorised Person/Personnel	RN, ENmed, RM, MO, dentist or pharmacist	
CAM	Complementary and Alternative Medicine	
DAA	Dose Administration Aid	
Designated Pharmacist	Pharmacist allocated to a ward or clinical area to provide clinical pharmacy services (see OP-GC6 Pharmacy Services and Referral to Clinical Pharmacist)	
(E)DONM	(Executive) Director of Nursing and Midwifery	
DTC	Drug and Therapeutics Committee	
DVA	Department of Veterans Affairs	
ED	Emergency Department	
EMR	Electronic Medical Record	

ENmed	 Enrolled Nurse qualified in medication administration and whose registration has an absence of conditions related to the medication administration. (<u>NOTE</u>: An Enrolled Nurse who is not qualified in medication administration has the notation '<i>Does not hold Board-approved qualifications in administration of medicines</i>' attached to their registration.) The medication administration by an Enrolled Nurse with medication endorsement must be in accordance with their specific level of medication qualification. The three levels of medication qualifications are: ME 1 Oral and topical. 	
	 ME 2 Oral, topical, subcutaneous and intramuscular. 	
	• ME 3 Oral, topical, subcutaneous, intramuscular and intravenous.	
FH	Footscray Hospital	
GP	General Practitioner	
НІТН	Hospital in the Home	
HREC	Human Research Ethics Committee	
IBAC	Independent Broad-based Anti-corruption Commission	
ICCA	Intellispace Critical Care & Anaesthesia system (used in ICU only)	
ICU	Intensive Care Unit	
INR	International Normalised Ratio	
IPU	Individual Patient Usage	
IRCMAC	Interim Residential Care Medication Administration Chart	
MAR	Medication Administration Record on approved electronic prescribing program	
MAW	Medication Administration Wizard on approved electronic prescribing program	
Medication	Preferred term for scheduled medicines when prescribed, supplied or administered to a patient.	
Medicine	Term used in the Poisons Standard July 2020 to describe any poison for therapeutic use.	
МО	Medical Officer	
NBS	Newborn Services	
NG	Naso-gastric	
NIMC	National Inpatient Medication Chart	
NJ	Naso-jejunal	
Nurse Immuniser	Registered nurse who is registered in Division 1 of the Nursing and Midwifery Board of Australia register who provides evidence to the employer of currency of competence and ongoing professional development in immunisation.	
Nurse Practitioner	Registered nurse whose registration has been endorsed by the Registered Nursing and Midwifery Board of Australia to use the title Nurse Practitioner in relation to a defined scope of practice. Nurse Practitioners at WH have the same ability to prescribe medications as a senior registrar and their scope of practice is overseen by the Nursing & Midwifery Credentialing and Scope of Practice Committee.	
NWMH	NorthWestern Mental Health	
'Off-label' Use	Applies when the medication is used other than specified in the TGA approved product information, including when prescribed or administered:	
	 For another indication, at a different dose or via an alternative route. 	
	• For a patient of an age or sex outside the registered use. <u>NOTE</u> : this definition excludes using a modified formulation of a TGA-registered medicine (e.g. extemporaneous or compounded preparations, such as preparation of special creams or a liquid suspension by crushing tablets). This is considered unlicensed use.	
PACU	Post Anaesthetic Care Unit	
PBS	Pharmaceutical Benefits Scheme	
PCA	Patient Controlled Analgesia	
PCEA	Patient Controlled Epidural Analgesia	

PEG	Percutaneous Endoscopic Gastrostomy
Pharmacy	Pharmacy refers to Western Health Pharmacy Departments, except if otherwise stated.
PPID	Positive Patient Identification
Prescriber	Medical officer, nurse practitioner, dentist or podiatrist with endorsement to prescribe scheduled medicines.
PRN	Pro re nata (when required)
Pyxis [®] device	A computerised medication storage device that securely automates control, management and distribution of medications.
RACF	Residential Aged Care Facility
RM	Registered Midwife
RN	Registered Nurse or Nurse Practitioner
Schedule 2 Medicine	Substance listed under Schedule 2 of Poisons Standard; Pharmacy Medicine.
Schedule 3 Medicine	Substance listed under Schedule 3 of Poisons Standard; Pharmacist Only Medicine.
Schedule 4 Medicine	Substance listed under Schedule 4 of Poisons Standard; Prescription Only Medicine. Formerly called Restricted Substance.
Schedule 8 Medicine (S8)	Substance listed under Schedule 8 of Poisons Standard; Controlled Drug. Formerly known as Drug of Addiction.
Schedule 11 Medicine (S11)	Sub-group of Schedule 4 medicines that are subject to abuse. Includes: bromazepam, chloral hydrate, clobazam, clonazepam, diazepam, lorazepam, methoxyflurane, midazolam, nitrazepam, oxazepam, temazepam, paracetamol/codeine phosphate 30mg, and tramadol.
SDH	Sunbury Day Hospital
SH	Sunshine Hospital
Special Access Scheme (SAS)	A scheme approved by the Commonwealth of Australia to access medications not registered by the TGA.
Specialist Clinic	Clinic providing non-admitted patient activity
TGA	Therapeutic Goods Administration
TPN	Total Parenteral Nutrition
UM	Unit Manager
VTE	Venous Thromboembolism
WH	Western Health

8. Procedure Detail

8.1 WH Drug Formulary

The WH Drug Formulary is accessible to all staff via the intranet. Refer to P-GC6 Medication Use and Management.

8.2 Medicines Information

Medicines Information resources are available through the Clinicians Channel link in Cerner EMR or via the <u>Library intranet</u> <u>site</u>, e.g:

- Australian Medicines Handbook.
- Australian Injectable Drugs Handbook.
- Royal Children's Hospital Paediatric Injectable Guidelines.
- MIMS Online (includes Don't Rush to Crush).
- Therapeutic Guidelines (eTG Complete).
- Renal Drug Database.
- DRUGDEX (Micromedex).

If unable to locate the necessary information in the clinical area or intranet:

- During Pharmacy opening hours:
 - o Contact your designated pharmacist (or contracted community pharmacy for Hazeldean).
 - \circ If no designated pharmacist contact Medicines Information (extension 56770).
- Outside Pharmacy opening hours:
 - $\circ \quad \ \ \text{Contact the covering MO.}$

• The covering MO may request the AHA to contact the on-call pharmacist.

See OP-GC6 Pharmacy Services and Referral to Clinical Pharmacist for further information.

8.3 High Risk Medications (APINCH)

High risk (<u>APINCH</u>) medications have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly.

APINCH medications (Table 1) have specific work practices, management systems and storage requirements to promote safer use, reduce opportunity for error and minimise the risk of patient harm.

Table 1: APINCH medications

Α	Anti-infective agents	
Ρ	Potassium and electrolytes	
Ι	Insulin	
N	Narcotics and other sedatives	
	Neuromuscular blocking agents	
С	Chemotherapeutic agents	
Н	Heparin and other anticoagulants	

Clinicians should be familiar with the APINCH medications and special considerations in their area.

8.4 Medication Related Incidents

8.4.1 Incident Reports

The appropriate MO must be notified immediately of any incident that involves prescribing, supplying or administering a medication e.g. wrong medication, dose, route, time or patient; medication not administered.

Medication related incidents must be entered into RiskMan within 24 hours and followed up as detailed in <u>OP-GC7 Clinical</u> <u>Incident Investigation and Governance</u>, including feedback to patients/carers.

8.4.2 Adverse Drug Reaction (ADR) Reports

Medical, nursing and pharmacy staff have joint responsibility for determining the allergy/ADR status of the patient and for ensuring that this is documented on the medication chart/MAR and medical history.

Refer to OP-GC6 Adverse Drug Reaction Recording and Reporting.

8.4.3 Schedule 8 and Schedule 11 Medicine Discrepancy Incident Reports

The process in <u>Appendix 2</u> must be followed no matter how minor the S8 or S11 medicine discrepancy.

A discrepancy must be reported as an incident and investigated when the stock cannot be accounted for or when it involves misappropriation, including but not limited to:

- Missing stock.
- Ampoule/vial breakages where the contents cannot be fully accounted for.
- Any loss of any doses, including those dropped in sharps bins, down sinks, under fridges, dropped on floor or unable to be located.

Report in RiskMan as a 'Non clinical Non OHS incident' with an incident type 'Hazard – Emergency/Lost/Missing/Theft Medicines'. Document the incident number in the register entry.

Oral Liquid Schedule 8 and Schedule 11 Medications (also see Section 8.8.5).

Always measure the volume when removing the last of the contents of the container.

<u>Note</u>: Any variance in mL and % in the register entry and ensure that the balance is corrected **before** opening a new bottle. *Do not carry an incorrect balance over to a new bottle*. If the variance exceeds **9.0%** (i.e. is 9.1% or greater), complete a RiskMan incident report as above and commence a preliminary discrepancy investigation as per <u>Appendix 2</u>.

An exception exists for JKWC Newborn Services only, where RiskMan incident reporting and discrepancy investigation are required for a variance above 40.0%.

8.5 PRESCRIPTION

8.5.1 Standard Requirements

A record of all medications ordered and administered must be maintained in the patient's medical history.

The following staff members are permitted to order medications on an electronic MAR/medication chart or WH PBS prescription form:

• Prescribers.

The following staff members are permitted to order medications on an electronic MAR/medication chart:

- Nurses or midwives ordering nurse-initiated or midwife-initiated medicines, in accordance with <u>OP-GC6 Nurse and</u> <u>Midwife Initiated Medications.</u>
- Nurse immunisers ordering vaccines or Schedule 4 medicines for treatment of anaphylaxis, in accordance with Secretary Approval – Nurse Immunisers.
- Appropriately credentialed Emergency Department Advanced Practice Physiotherapists initiating a single dose of paracetamol and/or ibuprofen for administration.

All aforementioned staff must adhere to their relevant formulary restrictions or to the conditions of an IPU approval and prescribe or order within their scope of practice.

Minimum patient identifiers

Are required for each section of any prescription or MAR/medication chart:

Family name	Given name
UR number	Date of birth

Must be either:

- Provided on the MAR where applicable; or
- Provided by an automated patient identification label; or
- Handwritten by the prescriber.

Where a label is used, the prescriber must also print the patient's name in the designated section below.

In the case of an unknown patient, document:

Resuscitation UR number Gender

Add full patient identifiers to the MAR/medication chart and any additional charts once known.

Table 2: Other important details required

Detail	Inpatient medication orders	PBS prescriptions (discharge, outpatients)	Other prescriptions (leave medication, HITH)	Notes
ADR/Allergy status	Y	Y	Y	Review with every medication order
Date	Y	Y	Y	
Generic medication name	Y	Y	Y	Australian approved
Dose	Y	Y	Y	
Strength	Ν	Y	N	
Frequency (including maximum frequency for PRN medication)	Y*	Y	Y	*Including times for regular administration orders
Route	Y	Y	Y	
Dose form	Y*	Y	Y*	*If not clear from route

Quantity/duration	Ν	Y	Y	Must be specified in words and figures for S8 medicines
No. of repeats (normally permitted for outpatients only. See <i>Section</i> <u>8.5.6</u> and <u>8.5.7</u> .)	Ν	Y*	N	*Prescriptions for S8 medicines must state 'no repeats' in words, except where repeats are authorised
Prescriber name, signature & contact details	Y	Y	Y	Contact details must appear at least once on each chart or form
Prescriber number & address of practice	Ν	Y	Y	
Treating unit	Ν	Y	Y	
Patient's address	Ν	Y	Y*	*Or leave destination
Patient's Medicare and concession, DVA, safety net no.	Ν	Y*	N	*If applicable

Clarity of prescribing

Handwritten prescriptions must be printed legibly in black or blue ink (not pencil, fountain pen or felt tip pen).

Brand names may be used in addition to generic names to help distinguish between different formulations, in particular: • Oral opioids, e.g. Oxycontin[®], Oxynorm[®], MS Contin[®], Kapanol[®], etc.

- Inhalers containing a combination of medications, e.g. Symbicort[®], Trelegy Ellipta[®], Ultibro Breezhaler[®], etc.
- Vaccines, e,g, Boostrix[®], Infanrix[®]-IPV, Prevenar[®]-13 etc.

Where there may be ambiguity about a dose, specify in both words and figures.

Only use approved abbreviations and symbols and clear dosage units.

Refer to OP-CM5 Patient Clinical Records Documentation procedure for acceptable abbreviations.

Table 3: Examples of high risk abbreviations

Full name	Acceptable	Not acceptable
Units or international units	units	U, IU
Micrograms	microg	mcg, µg
Subcutaneous	subcut	sc, s/c
Sublingual	subling	sl, s/l

Specific requirements for certain medications

Retinoids, prostaglandins, thalidomide, lenalidomide and ovulatory stimulants may only be prescribed by an MO who holds a warrant or MO acting in accordance with the directions of a warrant holder. Endorse the warrant number and name of warrant holder on the prescription.

Medications that are not listed on the WH formulary require <u>Individual Patient Usage (IPU)</u> approval. Refer to <u>P-GC6 Medication Use and Management</u>.

Medications that are only available through the <u>Special Access Scheme (SAS)</u> require an additional form to be completed and sent to Pharmacy when prescribing. Refer to <u>Section 8.5.4</u> or contact the Clinical Trials pharmacist.

Certain medications are subject to specific prescribing, storage, administration and monitoring requirements, e.g. chemotherapy, clozapine, heparin, insulin, methadone, mifepristone, narrow therapeutic index medications.

In some cases, a permit may be required to prescribe S8 medicines. See <u>OP-GC6 Medical Management of Drug Dependent Persons and Prescription of Long Term Opioid Medication</u>.

All use of medicinal cannabis must follow WH requirements for S8 medicines. In addition, continuation of a patient's own medically prescribed cannabis while under the care of WH requires Head of Unit approval, followed by IPU approval, and the patient to provide the product for their own use from their usual approved supplying pharmacy.

Refer to the relevant procedure/guideline or contact Pharmacy for further information.

8.5.2 Inpatient Medication Charts and Orders

Medications for inpatients must be prescribed using an appropriate approved electronic prescribing program, or, where

applicable, on an appropriate approved WH medication order form (Table 4), which follows the NIMC template and principles.

Table 4: Approved paper medication order forms				
Code	Name	Code	Name	
AD271.2	Adult (>16 yr) Medication Chart	AD271.3	Paediatric Medication Chart	
AD275	Chemotherapy Drug Chart	MR167NR	Hazeldean Medication Chart	
AD285	Intravenous & Subcutaneous Fluids Order Form	AD157.8	Neonatal Unit Fluid Balance & Treatment Orders	
AD284.2	Unfractionated Heparin (UFH) Intravenous Infusion Chart	AD278	Analgesic Infusion Orders	
AD263.2	Anaesthesia Record	AD138	Regional Obstetric Analgesia Document (ROAD)	
AD272	Long Stay Medication Chart			

Table 4: Approved paper medication order forms

Where in use, medication charts and any additional charts should be stored in the designated space adjacent to the patient's bed or room or in a central location to ensure timely access.

General Prescribing Requirements

Wherever paper medication charts are in use, the <u>NIMC User Guide</u> prescribing requirements must be followed. WH requires prescribers to:

- Order each medication separately e.g. paracetamol/paracetamol & codeine is not acceptable.
- Where doses vary according to route, order each route separately e.g. prochlorperazine 12.5/5mg IM/Oral is not acceptable.
- Document the cessation date for finite courses (e.g. antibiotics, prednisolone).
- Bring any 'Once Only' orders to the attention of an RN/RM who must initial to indicate that they have received the
 order.
- For adults, complete the VTE prophylaxis section on one NIMC according to <u>OP-GC6 Adult Venous</u> <u>Thromboembolism (VTE) Prevention</u>.

A limited number of medications may be initiated by an RN/RM/ENmed according to <u>OP-GC6 Nurse and Midwife Initiated</u> <u>Medications</u>.

Parenteral Infusions

Infusions are prescribed on Cerner EMR or ICCA where these systems are in use, including:

- Parenteral medication infusions and fluids;
- TPN;
- Analgesia infusions including PCAs, PCEAs and non-obstetric epidurals;
- Subcutaneous syringe drivers;
- Continuous insulin infusions;
- Heparin infusions;

Exclusions:

- Chemotherapy infusions, blood and blood products, anaesthesia and obstetric epidurals are ordered on the relevant paper charts (see Table 4 and Table 5).
- Continuous infusions and fluids in NBS are ordered on the Neonatal Unit Fluid Balance & Treatment Orders.

Table 5: Infusions ordered on paper medication charts

Category	Where to order	Examples
Blood products	Blood/Blood Product Consent and Prescription Form (see <i>OP-GC8 Consent, Prescribing and</i> <i>Administration of Blood and Blood Products</i>)	Red cells, platelets, plasma, albumin, Prothrombinex [®] -VF, Biostate [®] Berinert [®]
Epidurals in obstetrics, anaesthetic orders	Regional Obstetric Analgesia Document (ROAD, AD138) in obstetrics; AD263.2 Anaesthesia Record (paper)	
Chemotherapy	Chemotherapy Drug Chart (AD275)	

Variable dose orders

The prescriber must select on the MAR or print the dose and time to be administered.

Where therapeutic drug monitoring is required, ensure that the time the blood sample is to be/was taken is clearly documented.

Warfarin

Prescribe warfarin using the orderset in the EMR or as directed in ICCA.

The indication must be selected, as well as the brand of warfarin required.

Also see Altering and ceasing medication orders, below.

Coumadin[®] is the preferred brand at WH. Marevan[®] will only be supplied to continue existing therapy.

Where paper medication charts are in use, order in the warfarin section of the NIMC and circle the brand name, i.e. Coumadin[®] or Marevan[®]. Print the target INR, INR results, dose to be given and initial each ordered dose in the relevant sections.

Insulin

Order subcutaneous insulin **by brand name** on the MAR using insulin ordersets or ICCA, or on the Insulin Orders page of the NIMC (where the EMR is not in use). See <u>OP-GC6 Insulin Prescription, Supply, Storage and Administration</u>. Also see **Altering and ceasing medication orders**, below.

Intravenous insulin infusions are restricted to certain clinical areas. See OP-GC6 Insulin Infusion (Intravenous) in Adults.

Transdermal patches

Order transdermal patches on the MAR using ordersets or ICCA, or clearly on the NIMC (where the EMR is not in use). Every patch that remains in situ for more than 24 hours must be checked and documented by nursing staff once a shift.

See <u>Appendix 3</u> for further information.

Altering and ceasing medication orders

Medication orders must not be altered, especially to change dose, frequency or route of administration.

On the MAR, the prescriber should choose Cancel/DC or Cancel/Reorder.

An exception applies in Cerner EMR for warfarin and regular insulin orders where doses may be variable. Under those circumstances, the prescriber can select Modify to alter the dose and/or duration.

NOTE: 'Suspend' should only be selected when patients are on leave or other extenuating circumstances exist e.g. temporarily nil by mouth.

On a paper medication chart, the prescriber must cease and rewrite the order on a separate line if any changes are required:

- Draw a single clear diagonal line through the order, leaving the previous order legible.
- Draw a single line through the relevant administration section.
- Annotate reason e.g. 'cease', sign, print name, and date over the administration section.

Errors made on prescriptions must be crossed through and initialled, not obliterated.

When changing a medication order, document the reason for the change in the patient's medical history.

8.5.3 'Off-label' Use of Medications

Off-label use should only be considered when all other options, including medications approved by the TGA, are unavailable, in short supply, not tolerated or unsuitable for the patient. The decision should take into account the quality of evidence available for the intended use. The prescriber is responsible for ensuring all the necessary requirements are completed including involving the patient in the decision and obtaining consent.

Where use of a medication off-label is considered 'non-routine' or 'research or investigational use', i.e. use of a medication is unusual, experimental, has a high risk of adverse patient outcome or a medication of last resort, the prescriber should be of sufficient seniority and have the recognised expertise to make the decision to prescribe that medication. The clinician should also consider discussing their choice with the Chief Medical Officer before prescribing.

See <u>Definitions</u> and <u>Appendix 4</u> for further details on approval, consent and monitoring requirements.

See <u>Appendix 5</u> for examples of information sources to support decisions about appropriate off-label use.

8.5.4 Non-TGA Approved Medications

Non-TGA approved medications (outside of Clinical Trials) can be accessed via the <u>Special Access Scheme (SAS)</u> or Authorised Prescribers.

Approval from the DTC via <u>WH Drug Formulary</u> listing or an IPU is required.

When prescribing a non-TGA approved medication the prescriber must:

- Ensure that the patient/person responsible understands that the medication is non-TGA approved.
- Explain the indication, complications and possible adverse effects.
- Discuss the alternative medications.
- Obtain and document informed consent from the patient/person responsible.
- Complete the SAS Category A, B or C form or apply for Authorised Prescriber status.
 <u>NOTE</u>: SAS forms are not generally required for compounded medications supplied by a TGA licensed facility; however all other steps above still apply.
- If applicable, complete the form 'Consent to treatment and indemnity for use of product derived from biological tissues including human blood or plasma'.

Where use of non-TGA approved medication is unusual, experimental, has a high risk of adverse patient outcome or is a medication of last resort, the prescriber should be of sufficient seniority and have the recognised expertise to make the decision to prescribe that medication. The prescriber should also give consideration to discussing their choice with the Chief Medical Officer before prescribing the medication.

8.5.5 Complementary and Alternative Medicines (CAMs)

CAMs include vitamin and mineral supplements, herbal medicines, nutritional supplements, traditional medicines such as Ayurvedic medicines and Traditional Chinese Medicine, homeopathic medicines and aromatherapy oils.

The quality of information about benefits and risks of CAMs is variable. Interactions with other medicines, conditions and procedures can be unpredictable.

There are significant concerns regarding product information, quality control, potential adverse effects and interactions with many preparations.

WH has a duty of care to ensure that any medications (including CAMs) supplied to or used within the health service are safe, whether patient/carer administered or not; therefore patient disclosure regarding the use of CAMs should be encouraged.

The prescriber must:

- Decide whether to approve or advise against use of each CAM.
- Review appropriate references to consider possible risks, potential for interactions with other medications and suitability with current treatment or surgery.

If needed, contact Medicines Information (see Section 8.2).

Where approved, the order on the MAR/medication chart must include active ingredient(s), brand name, dose and frequency.

Should a patient wish to use a CAM against the prescriber's advice, the prescriber must document in the patient's clinical record:

- The specific concerns that led to the decision being made that continuing treatment is not in the best medical interest of the patient, e.g. potential for interactions, adverse effects or other risks.
- Details of the discussion with the patient/person responsible, including exact advice that was given regarding the continued use of the CAM and the name of the person responsible if there are concerns regarding a patient's cognition.
- That the patient/person responsible, in the opinion of the prescriber, understands the risks and is willing to take full responsibility for the outcome.
- Any changes to the treatment plan that have been necessary due to the continued use of the CAM.

The patient or their person responsible must supply any CAM to be continued during WH treatment unless initiated by a WH prescriber, in which case approval from the DTC via <u>WH Drug Formulary</u> listing or an IPU is required.

Refer to P-GC6 Medication Use and Management.

8.5.6 Discharge and Leave Prescriptions (Inpatients)

Prescribers must complete a WH PBS prescription (see Section 8.5.8).

See <u>Section 8.5.1</u> for standard prescription requirements.

In addition prescribers should:

- Refer to the current MAR/medication chart(s) and Pharmacy Admission Note (if available).
- Include all medications that the patient is to continue on discharge/leave, including over the counter and CAMs, to
 ensure that the patient can receive a comprehensive medication list.
 <u>NOTE</u>: Repeats will not be issued on discharge prescriptions, except where specific medications require PBS
 telephone authority.
- Endorse leave prescriptions with the dates and times that the patient will be away from the ward. <u>NOTE</u>: Leave medication is not claimable under PBS.
- When possible, prepare prescriptions at least 24 hours before discharge/leave.
- Follow the appropriate clinical area's process for notifying Pharmacy/designated pharmacist.

For discharges to RACFs see Section 8.6.2.

8.5.7 Specialist Clinics, Same Day and Emergency Department Patients

Prescribers must complete a WH PBS prescription form (see Section 8.5.8).

See Section 8.5.1 for standard prescription requirements.

In addition prescribers should:

- Refer to the current MAR/medication chart(s) and Pharmacy Admission Note (if available).
- Only prescribe medication directly related to the presentation, appointment, procedure or consultation.

Repeats are available to specialist clinic patients when:

- The medication is only available from a hospital pharmacy; or
- It is more appropriate than the patient seeing their usual doctor for continuing treatment.

Repeats are not permitted on prescriptions written for ED or same day patients on discharge.

For clinical trial medications, endorse the study protocol number or Human Research Ethics Committee (HREC) number.

For ED discharges to RACFs see Section 8.6.3.

8.5.8 PBS Hospital Prescription Stationery

WH PBS Hospital prescription stationery (PBS prescription form pads and PBS prescription paper for computer generated prescriptions) must never be left unattended in an area open to the public/patients.

PBS prescription stationery is issued to specific clinical areas.

Empty prescription pads must be returned to Pharmacy in order for replacement stock to be issued.

The ward/area must notify Pharmacy in advance for replacement PBS prescription stationery, when supplies are low.

Each area's manager is responsible for ensuring that PBS prescription stationery is:

- Stored in a locked cupboard/drawer or locked away with access only by authorised personnel* when not in use. *In wards, this must be in a medication room under camera surveillance.
- Made available to prescribers when needed.
- Returned and secured when no longer required.
- Not supplied to other areas or clinics.
- Only used in printers with a lockable printer drawer for PBS prescription paper.

Wards, Day Areas and EDs

When not in use, prescription stationery must be locked away.

Specialist Clinics

The area administering the clinic will ensure that prescription stationery is:

- Made available to prescribers on arrival at the consulting room(s).
- Immediately locked away at the end of the clinic.

8.6 SUPPLY: Distribution and Dispensing

This does not apply to Hazeldean where medication is supplied by a contracted community pharmacy.

8.6.1 Clinical Areas

Each clinical area has an imprest supply of commonly used scheduled and unscheduled medications.

Alterations to the imprest list need approval from the area's manager and a senior pharmacist or Deputy Director of Pharmacy.

Alterations to the imprest list of S11 and/or S8 medicines require Director of Pharmacy approval.

In larger clinical areas the imprest is maintained and replenished to agreed levels by a pharmacy technician, working to a regular schedule under supervision.

In other areas nursing/midwifery staff maintain and replenish the imprest as required by forwarding a written request to Pharmacy.

In inpatient areas nursing/midwifery staff are responsible for placing imprest medication into each patient's medication drawer or bedside locker as required.

Where a basic clinical pharmacy service is provided to a clinical area, nursing/midwifery staff and the designated pharmacist are jointly responsible for ensuring adequate quantities of medications are available. The designated pharmacist and UM must review the imprest list quarterly or more frequently if either party identifies a need.

Table 6: Supply of medication during Pharmacy opening hours

Supply arrangements	Action if an item is not available during Pharmacy opening hours
Imprest area replenished by pharmacy staff	Fax completed <u>Medication Request Form</u> to Pharmacy
Imprest area replenished by nursing staff	RN/RM to request supply from Pharmacy using requisition book
Non-imprest medication	Complete a Medication Request on the EMR or fax completed <u>Medication Request</u> <u>Form</u> and valid medication order to Pharmacy.

Also see OP-GC6 Delivery of Medication from Pharmacy to Clinical Areas by Non-pharmacist Staff.

Collecting S8/S11 medicines from Pharmacy

If it is necessary for S8/S11 medicine(s) to be collected from Pharmacy, an RN/RM must:

- Check that each S8/S11 medicine supplied matches the details on the printed requisition, including medication name, strength, form and quantity.
- Check that the clinical area on the requisition is the correct area to which the S8/S11 medicine is to be delivered.
- Sign the 'received by' section on the printed requisition page and print their name.
- Transport the S8/S11 medicine (in an opaque bag) and a copy of the signed requisition directly to the clinical area.
- Immediately store the S8/S11 medicine(s) in the appropriate S8 safe or S11 storage facility and, with a second authorised person, make an entry in the corresponding register in the area's S8 or S11 register, including the requisition number. See **Transaction records in Schedule 8 and Schedule 11 medicine registers** (page 27). Store the copy of the requisition in the plastic document pouch with the register.

<u>NOTE</u>: Documentation stored by the area/ward relating to the supply or transfer of S8 and S11 medications must be filed by the area's manager and retained for three years.

Supply of medication outside Pharmacy opening hours

It is not permitted to write N or N/A on a medication chart.

Make every attempt to source the medication at the time the order is required (see <u>Appendix 1</u>):

- Check whether the patient has their own labelled supply, in date and in its original container.
- Check the <u>global imprest list</u>.
- If it is available in an after hours cupboard, contact that site's AHA for access.
- If it is available on a ward on another campus, contact your site's AHA to arrange transfer.

If medication is to be borrowed from another area, see Interward/Intercampus medication borrowing after hours below, except S8/S11 medicines. See Transfer of Schedule 8 and Schedule 11 Medicines where applicable.

If the medication is not available from any of the above sources, contact the covering prescriber. If the prescriber advises that the medication is required before Pharmacy opens, contact the AHA, who will contact the on-call pharmacist if necessary.

Interward/Intercampus medication borrowing after hours

To borrow a medication from another clinical area (after hours only):

- Provide the name and UR number of the patient requiring the medication to an RN/RM in the area from where the medication is to be borrowed. This can be done in person (same campus) or by telephone (different campus).
- Fill out the providing area's Interward / Intercampus transfer book, ensuring that the names of both staff members involved in the transaction are clearly documented.

Once a month, a Pharmacy staff member will review the transactions for the purposes of replenishing stock and charging to the receiving clinical area, if appropriate, and document that the reconciliation has been completed in the 'Pharmacy Only' column.

Transfer of Schedule 8 and Schedule 11 medicines

S8 and S11 medicines supplied by Pharmacy must not be transferred across campuses.

Transfer of S8 and S11 medicines between clinical areas may only occur after hours.

Only an authorised person may transport an S8 or S11 medicine between clinical areas.

To transfer S8 or S11 medicines between clinical areas on the same campus:

- Present the medication order to an RN/RM in the area from where the medication is to be borrowed.
- Fill out the providing area's red transfer book. The original white page must follow the medication to the receiving ward, where it must be signed under 'received by' and stored in the plastic document pouch with the register.
- Two authorised personnel, one from the area providing and one from the area receiving the medication and one of
 whom must be an RN/RM, must record the transfer out of the providing area's S8 or S11 register, including the red
 transfer book number and page number.
- The authorised person who signed the providing area's register and another authorised person, one of whom must be an RN/RM, must record the transfer into the receiving ward's register, including the red transfer book number and page number.
- Record administration to the patient (see <u>Section 8.8.5</u>).

NOTE: Documentation stored by the area/ward relating to the supply or transfer of S8 and S11 medications must be filed by the area's manager and retained for three years.

Return of Medication

When a patient is discharged or medication is discontinued, the RN/RM/ENmed should promptly return:

- Patient's own medication to the patient (see <u>Section 8.6.2</u>).
- Imprest medications to the imprest shelves.

<u>Note</u>: If medication has been stored in a patient room/care area where transmission based precautions are in place, wipe medication container with hospital approved disinfectant wipes e.g. Clinell® before returning to imprest. The following medications must not be returned:

- Open bottles of tablets/capsules/granules/liquid medication
- Blister packs that have compromised foil backing

• Medication with packaging surfaces not suitable for wiping with a disinfectant wipe

Refer to OP-GC5 Standard and Transmission Based Precautions.

- Where a Pyxis[®] device is utilised, unused S8 and S11 medicines to the 'return bin' and all other scheduled medicines to the appropriate drawer/pocket.
- Non-imprest medication to the Pharmacy Returns box/area in the medication room, unless specific storage requirements apply, e.g. refrigeration, S8/S11, in which case alert Pharmacy staff.

For transfer of medication with patients, see <u>Section 8.7.5</u>. Pharmacy staff will return non-imprest medications to Pharmacy in a timely manner.

8.6.2 Discharge and Leave Medication (Inpatients)

See Section 8.6.3 for same day patients.

In order to facilitate timely supply of discharge/leave medication, ward staff should:

- Communicate regularly with the designated pharmacist regarding potential discharges/leave.
- Ensure prescriptions are printed/written at least 24 hours prior to discharge.
- Annotate the prescription with:
 - Patient's discharge or leave destination (e.g. home, aged care facility, respite).
 - Expected discharge or leave date and time.
 - When a patient is going on leave, the time period that the patient is expected to be away from the ward, e.g. Friday 1800 hours to Sunday 1000 hours.
- Advise the designated pharmacist when a prescription has been prepared; OR
- Where there is no basic clinical pharmacy service, fax the prescription to the dispensary.

A pharmacist will:

- Review and reconcile the prescription with the current inpatient medication and Pharmacy Admission Note (if available).
- Resolve any issues with the prescriber.
- Consult with the patient/carer regarding medications required.
- Annotate the prescription with supply details and any changes to pre-admission medications.
- Forward the prescription to the dispensary for processing.

Table 7: Cut off times for receipt of reconciled prescriptions in the dispensary

Type of prescription	SH, FH, Williamstown			
	Weekdays	Weekends/Public Holidays*		
Discharge	1600 for same day dispensing 1530 at Williamstown	1100 for same day dispensing		
Leave	24 hours prior to planned leave [#]	Urgent requests only		

*Williamstown pharmacy department is closed on weekends/public holidays.

[#]Discuss prescriptions for urgent leave with the designated or dispensary pharmacist; however they must be received at least one hour prior to the patient commencing leave and no later than 1600 hours Monday to Friday (1530 hours at Williamstown).

Dose Administration Aids (DAA)

If a pharmacist believes a DAA is required, they will liaise with a carer and/or community pharmacy.

If a DAA is recommended by another health professional, they should discuss with the pharmacist to determine if appropriate.

New DAAs for discharge require 24 hours' notice to arrange with a suitable community pharmacy.

Discharge/leave process with clinical pharmacy service

The pharmacist will:

- Provide a labelled bag containing, as required:
 - o Dispensed medication.
 - o Pharmacy generated medication list.
 - Consumer medication information.
 - Invoice (on discharge only).
- Return to the ward clerk to forward to Health Information for priority scanning and automatic transmission to the GP via the Gateway (no staples; ward clerk to attach patient identification label):
 - o Pharmacy generated medication summary for the patient's GP.
 - Where a WH PBS prescription form is used, the red triplicate copy (marked 'medical record copy').
- Complete the checklist on the Pharmacy Discharge Note in the EMR.
- Where possible, during usual operating hours:
 - Offer to counsel the patient or carer regarding each medication and explain any changes in medications, dosage or directions.

- o Return patient's own medications to the patient or carer, as appropriate.
- o Obtain consent to discard expired, unnecessary or inappropriately packaged medications and document.
- o Request the patient/carer to sign for receipt of the supplied medications.
- Explain, where applicable:
 - That an invoice has been provided and the available methods of payment.
 - The need to see the local doctor/specialist for further supplies of medication.
 - The importance of maintaining an up to date medication list.

Discharge/leave process when there is no clinical pharmacy service available

Discharge or leave medications will be sent to the ward where an RN/RM/ENmed/MO will:

- Give the medication to the patient/carer and provide counselling regarding each medication, explaining any changes in medications, dosage or directions.
- Where applicable, explain that an invoice is enclosed and available methods of payment.
- Return the patient's own medication to the patient/carer.

NOTE: RN/RM/ENmeds must NOT dispense discharge medications from imprest or individual inpatient supplies.

NOTE: None of the Pharmacy processes described on pages 15-16 apply if the prescription is not received by WH pharmacy staff.

Refused discharge/leave medication

If a patient refuses supplied discharge or leave medications:

- Notify the treating unit.
- Return unwanted medications returned to Pharmacy as soon as practicable.

Once medications have left the hospital, they cannot be returned to Pharmacy for reuse.

Return from leave

On return from a period of leave, the pharmacist should remove any unused medication the patient has brought back to hospital.

If the patient is thought not to have consumed the medications as prescribed, notify the treating unit and discuss with the patient.

Left medication

If a patient's own medication or discharge medication is left at the hospital and the patient or carer cannot return to collect it, it may, if necessary, be suitably and securely packed and then sent to the patient, with the patient's prior consent and at the clinical area's expense, via registered mail or taxi.

S8 and S11 medicines cannot be sent by post. Contact Pharmacy for more information.

After Hours Discharge and Leave Medication

RN/RM/ENmeds may only give discharge/leave medications dispensed and labelled by Pharmacy to a patient or carer.

RN/RM/ENmeds must NOT dispense discharge medications from imprest or individual inpatient supplies (non-imprest).

For **unplanned** after hours discharges a prescriber may write a WH PBS prescription for the patient to have dispensed by a community pharmacy.

The prescriber or nurse caring for the patient should:

- Give **both** copies of the EMR prescription OR the **top two copies** of the WH PBS paper prescription form to the patient.
- Photocopy the top copy before giving to the patient and fax to the patient's GP.

If it is not possible for the patient to obtain medication from a community pharmacy **AND** the medication is urgently required, a prescriber may dispense medication for a patient after hours, as follows:

- Prepare a hospital prescription, either generated from the EMR or on a WH PBS Prescription form.
- Dispense medication only from prepacked stock in the ED After Hours Cupboard.
- Record details of dispensed medication in the medical history and the After Hours Cupboard Dispensing Register

with signature and date.

- Legibly complete the blank fields on the pharmacy generated dispensing label, including the patient name, prescriber name and date. In some cases the dose requires clarification e.g. one/two tablets. Indicate the intended dose with a strike through the inapplicable quantity e.g. one/two. "
- Counsel the patient regarding use of the medication.
- Endorse the prescription with 'Dispensed by Medical Officer/Nurse Practitioner'.

For discharges, the prescriber or nurse caring for the patient should fax a copy of the prescription to the GP before filing in the medical record.

If a patient must go on unplanned leave, consider whether the duration of the leave period can allow the patient to receive their regular medication in hospital as prescribed.

Discharges to RACFs (except from ED)

During normal Pharmacy opening hours, the processes on pages 15-16 will be followed.

Also, the pharmacist will:

- Liaise with the servicing pharmacy to check what medications are required to be dispensed.
- Dispense only those medications requested.

Pharmacy will dispense the prescription and generate an Interim Residential Care Medication Administration Chart (IRCMAC) where required, according to Pharmacy's standard operating procedure for RACF Discharges. The IRCMAC can be used to administer medication for up to 7 days and the GP is to review the patient within this time to write up an ongoing RACF chart.

The dispensed medications, IRCMAC and a photocopy of the WH PBS prescription form, relevant consumer medication information, invoice and the patient's own medication (if applicable) will be placed in a bag with a patient name label attached.

The pharmacist will, where appropriate:

- Counsel the patient/carer on any changes to their medications.
- Explain that the community pharmacy has requested certain medications to be dispensed.
- Explain, where applicable, that an invoice is provided and available methods of payment.
- Request the patient/carer to sign for receipt of the supplied medications.

If this is not possible the prescription form is to be signed by the nurse in charge.

The medications, IRCMAC and a photocopy of the WH PBS prescription form must be transported with the patient.

At the time of discharge, the nurse caring for the patient or the nurse in charge must communicate to the RACF the doses that have been administered that day, prior to discharge. It would be prudent to also document the administered doses onto the IRCMAC.

Outside normal Pharmacy opening hours, see After Hours Discharge and Leave Medication (page 16).

8.6.3 Specialist Clinics, Same Day and Emergency Department patients

Table 8: Dispensing WH Prescriptions

Type of prescription	Where can patients have their WH prescription dispensed?			
	Weekdays	Weekends/Public Holidays*		
Specialist Clinics Outpatients Pharmacy (SH/FH) Community pharmacy* Community pharmacy		Community pharmacy*		
ED	Outpatients Pharmacy (SH/FH) Community pharmacy*			
Day Oncology (S 1E)	SH Level 1 Satellite Pharmacy [#] Outpatients pharmacy (SH/FH)	N/A		
Same day patients	Outpatients Pharmacy (SH/FH) Community pharmacy*	Community pharmacy*		
Jnless medications prescribed can only be supplied via a public hospital pharmacy department.				

[#]Ideally. In some circumstances, e.g. oral chemotherapy clinic prescriptions, medication may need to be dispensed by Outpatients Pharmacy (SH/FH).

In some instances, specialist clinic consultants may liaise with the SDH senior pharmacist for a prescription to be dispensed at the SH pharmacy and delivered to SDH for a patient to collect.

Generally, prescriptions written on a prescriber's personalised prescription form cannot be dispensed by the WH pharmacies and should be dispensed by a community pharmacy.

Emergency Department Discharges to RACFs

A prescriber must:

 Complete a WH PBS prescription, according to <u>Section 8.5.6</u>, including all new or changed medication as a minimum.

The prescription may be:

- Dispensed by Pharmacy during normal opening hours; or
- o Transported with the patient to be dispensed by the servicing community pharmacy; or
- Dispensed by the prescriber according to <u>After Hours Discharge and Leave Medication</u> (page 16, after hours only).

AND

- Prepare a DMR e-form AD61 ED & after hours IRCMAC:
 - Each medication order must include:
 - Date;
 - Medication;
 - Route;
 - Dose;
 - Administration times;
 - Prescriber's signature and name.
 - Complete the Medications Ceased in Hospital section.
 - List any other relevant information in the Comments section.

Note: Ensure that all medications on the IRCMAC are included on the WH PBS prescription.

Where medications have been ceased since admission to hospital, it is advisable to:

- Obtain a faxed copy of the patient's RACF chart.
- Clearly strike through the ceased medication order.
- Sign and date the cessation.
- Return the amended copy of the chart with the IRCMAC to the RACF.

The prescriber must hand **both** copies of the EMR prescription OR the **top two copies** of the WH PBS prescription form and the printed ED & after hours IRCMAC to the nurse caring for the patient, to be transferred to the RACF with the patient.

For patients returning to an RACF under the Aged Care Liaison Service for IV antibiotic administration against an IRCMAC, a prescriber should complete a WH PBS prescription for any oral antibiotic therapy required to follow the course of IV antibiotics, if appropriate. Send the prescription to the RACF with the patient.

The nurse caring for the patient or the nurse in charge in ED is responsible for ensuring it will be possible for the prescription to be dispensed by the local servicing pharmacy in a timely manner before the patient is discharged. This may involve liaising with the RACF nurse in charge to make appropriate arrangements.

If medication supply cannot be organised from the RACF's servicing pharmacy in a timely fashion, the nurse should contact the WH pharmacy department for assistance. After hours, this may require the discharge to be postponed until pharmacy is open, or, for urgent discharges, escalation to the on-call pharmacist via the AHA.

At the time of discharge, the nurse caring for the patient or the nurse in charge must communicate to the RACF the doses that have been administered that day prior to discharge.

8.7 STORAGE

Medications are stored in clinical areas and each pharmacy department.

Each area's manager must ensure that:

- Medications are stored securely in accordance with legislative requirements.
- Only <u>authorised personnel</u> and pharmacy support staff have access (see <u>Section 8.7.1</u>).

The area's manager and pharmacy staff must ensure that storage conditions are adequate to maintain the quality of the products and assist in the safe use of medications, e.g. by:

- Keeping storage areas temperature-regulated and monitored, clean and tidy.
- Following manufacturers' storage instructions (e.g. temperature, protect from light).
- Arranging medications in product groups and alphabetically (generic) aligned to printed barcodes.
- Separating look-alike medications.
- Ensuring relevant high risk medication and safety initiatives (e.g. Tallman lettering) are in place.
- Replenishing medications appropriately including removing damaged/deteriorated/unwanted items.
- Rotating medications (shortest dated at the front) and identifying short-dated medications.
- Pharmacy removing and disposing of stock prior to expiry.

Appropriate security and storage also applies to medications being transported between areas.

Contact Pharmacy for information on particular requirements for transporting medication between sites.

8.7.1 Schedule 2, 3 and 4 Medicines

All schedule 2, 3 and 4 medicines must be stored in a locked storage facility that:

- Complies with legislation pertaining to schedule 4 medicines & all other relevant legislation.
- Must not be used to store other items (includes refrigerators).

Access must be restricted to authorised personnel and pharmacy support staff.

Managers are responsible for ensuring that access is only provided to these authorised staff members, whether by key, swipe card, authorised Pyxis[®] access or other.

Where medication rooms are multipurpose and require access by unauthorised staff members (e.g. ward clerks, ENs without medication endorsement, environmental services staff) the following must be stored in a locked storage device within the room:

- All scheduled medicines.
- Patients' own medications.
- Pharmacy returns.
- Discharge medications.

If unauthorised staff members require access to an area containing scheduled medicines they must be supervised by authorised personnel.

Where a Pyxis[®] device is utilised, scheduled medications will only be stored in the Pyxis[®] device. Only remove a dose of medication immediately before it is due to be given.

Do not store injections and refrigerated medications in bedside lockers/medication drawers. See <u>OP-GC6 Medication Refrigeration</u>.

The only exception is insulin which, once opened, is for single patient use only. See *OP-GC6 Insulin Prescription, Supply, Storage and Administration.*

8.7.2 Schedule 8 and 11 Medicines

S8 medicines must be locked in an S8 medicine safe or Pyxis[®] device.

S11 medicines must be locked within an S11 storage cabinet, refrigerator (if necessary, e.g. lorazepam injection), Pyxis®

device, or anaesthetic / resuscitation trolley (e.g. IV benzodiazepines). If a trolley is used, it must be locked and secured with a tamper evident seal when not in use.

S8 safes, S11 storage cabinets/refrigerators, Pyxis[®] devices and resuscitation trolleys must comply with legislative and WH requirements, e.g.:

- Only used to store S8 and S11 medicines respectively and not items other than medication, e.g. patient valuables, money, keys.
- One key per S8 medicine safe or S11 storage facility, kept on the person of the RN/RM in charge or other delegated RN/RM.
- Keys to the S8 medicine safe, S11 storage facility and REM bodyguard pumps must be kept together on one designated lanyard, separate to other keys for a clinical area.
- Access restricted to <u>authorised personnel (see Section 8.7.3)</u>.
 Pharmacy technicians may also have access to S11 storage facilities.

All S8 safes are under camera surveillance.

Resuscitation trolleys that include S11 medicines are stored are under camera surveillance in areas that are not accessible to the public.

If a clinical area will be closed for >24 hours (excluding weekends/public holidays), the S8 and S11 medicines will be returned to Pharmacy and re-issued upon opening of that area.

8.7.3 Keys and Swipecards Providing Access to Medication Storage Facilities

Any keys providing access to scheduled medications (e.g. imprest cupboards, medication drawers, bedside lockers) must be managed according to the <u>OP-RS5 Key and Lock Management</u> procedure.

Keys must be:

- Issued at the beginning of each shift and returned at the end of each shift.
- Stored in a key cabinet when not in use.

Any key for a key cabinet must be:

- Held with the S8 and S11 keys.
- Stored as per the S8/S11 keys if an area is vacated overnight.

Access to S8 safes and S11 storage cabinets by dual swipe is only granted to authorised persons within their scope of practice.

Where an area that contains an S8 medicine safe or S11 storage facility is vacated overnight, the S8 and/or S11 key shall be stored in a suitable secure safe (meeting the same standards as a safe used to store S8 medicines) in the designated 24-hour ward on the same campus.

Operating room S8 medicine safe and S11 storage facility keys will be locked in a secure location when not in use and access will be controlled by the RN in charge:

- In normal working hours, S8 medicine safe and S11 storage facility keys must be signed out by the RN in charge of the shift and the anaesthetic nurse responsible for the keys in each operating room.
- Out of hours the central S8 medicine safe and S11 storage facility keys must be held by the RN in charge or PACU nurse.
- Anaesthetic or resuscitation trolleys must be locked when not in use and the key held with the S8 medicine safe key.

Lost or misplaced keys/swipecards

The loss of a key or swipecard providing access to scheduled medicines must be reported immediately to at least one of:

Divisional Director	After Hours Administrator		
Director of Nursing	Executive Director of Nursing & Midwifery		
and			
Pharmacist in charge or on call pharmacist			

A decision will be made as to whether the locks and keys must be changed.

The loss of an S8 or S11 key/swipecard must **also** be reported immediately to Security, who will complete a Security Incident Report as a 'Non clinical Non OHS incident' on RiskMan.

If the S8 safe or S11 storage facility is unlocked, secure medications until the key/swipecard is recovered and balances are checked.

If the key is not located or personally returned by the person who removed it within one hour, the lock must be changed.

If the swipecard is not located within one hour, it must be suspended by Security (see <u>OP-RS5 Security Access</u> <u>Management</u>).

If the S8 safe or S11 storage facility is key locked, medications can be obtained from another clinical area or pharmacy until the lock can be changed.

8.7.4 Patients' Own Medications

Encourage patients to bring all their medications into hospital with them.

Patients are not permitted to self-medicate during their admission, except where required under specific procedures or a self-medication program with appropriate nursing supervision.

When a patient is admitted to ED or directly to a ward, the admitting RN/RM/ENmed must:

- Check if the patient has brought in their own medications.
- Record all medications in the Emergency observation chart or the medical history.
- Document the name, strength and exact quantity of any S8 or S11 medications.
- Place medications into a patient's own medication green storage bag (available from FMIS) and attach an automated patient identification label.
- Lock medication in the patient's bedside locker/medication drawer/dedicated area in medication room.

A patient's own S8 or S11 medicines, including any in a DAA, must be:

- Stored in the ward's S8 medicine safe or S11 storage facility respectively.
- Documented and clearly identified as patient's own in the S8 or S11 register.

The balance must be checked at the end of each shift by a member of staff from each shift.

Where a basic clinical pharmacy service is available (see <u>OP-GC6 Pharmacy Services and Referral to Clinical Pharmacist</u>), do not send the patient's own medications home until assessed by the designated pharmacist.

Once reviewed and documented by the pharmacist, send patient's own medication home with a carer/relative with the patient's consent where possible.

Where a basic clinical pharmacy service is not available, the RN/RM/ENmed caring for the patient must return patient's own medications to the patient/carer after the admitting MO has reviewed and documented the relevant details.

8.7.5 Transfer of Medications with Patients

When a patient is to be transferred to another ward or campus, the RN/RM/ENmed caring for the patient is to ensure that they:

- Place patient's own medications in a 'patient's own medication' green storage bag (from FMIS).
 <u>NOTE</u>: Any patient's own S8 or S11 medicines must be placed in a separate green bag along with the original (white) page from the red transfer book, which must include all details (name, strength, form and quantity) and be signed by the same two authorised personnel who record the transfer out of the S8 or S11 register (see <u>Section</u> <u>8.8.5</u>).
- Place medications dispensed by Pharmacy for the individual patient (including injections) in a red 'inpatient only' bag (from FMIS).
- Place imprest medications that are not available on the receiving ward in a red 'inpatient only' bag.
- Do not place medications intended for use within a hospital in the same bag as the patient's own medications.
- Document the details on the nursing transfer notes.

The RN/RM/ENmed on the receiving ward must:

- Review the nursing transfer notes.
- Check particularly for medications requiring special storage, e.g. S8, S11, refrigerated items.
- Check which medications have arrived with the patient and that the quantity transferred is sufficient, particularly for overnight and weekend requirements.

If the quantity is insufficient, arrange for further supply so that the patient does not miss any doses. See <u>Section</u> <u>8.6.1</u>.

If medication is not transferred across campuses with a patient and later has to be transported by taxi, the clinical area that did not follow the above procedure will be required to cover the associated cost.

8.8 ADMINISTRATION

8.8.1 Standard Requirements

Medications must only be administered to a patient in accordance with an original, valid, legal and signed order from a prescriber, except:

- When a verbal or telephone order may be given by the prescriber who is attending the patient (see <u>Section 8.8.2</u>).
 OR
- In the case of nurse and midwife initiated medications (see <u>OP-GC6 Nurse and Midwife Initiated Medications</u>).
 OR
- For the administration of vaccines and Schedule 4 medicines used for the management of anaphylaxis when ordered and administered by nurse immunisers (see <u>Secretary Approval – Nurse Immunisers</u>).
 OR
- In the case of an Advanced Practice Physiotherapist, a single dose of paracetamol and/or ibuprofen in ED within their scope of practice (see <u>Allied Health DG-CC2 Advanced Practice Physiotherapy in the Emergency Department</u>).

Only authorised and suitably credentialed personnel may administer medications to patients.

The person(s) administering the medication must:

 Review any allergies/ADRs and obtain verbal Positive Patient Identification (PPID) before commencing the medication round.

Where the patient can't respond verbally, read aloud the patient's name, date of birth and UR number from the patient's identification band.

Refer to OP-GC6 Adverse Drug Reaction Recording and Reporting, if necessary.

- Where the medication is ordered on Cerner EMR, follow all steps in the appropriate EMR Quick Reference Guide:
 - Medication Administration Wizard (MAW);
 OR
 - Medications Medication Administration Wizard (MAW) with Second Nurse Witness, where two authorised personnel are required (see <u>Section 8.8.4</u>).

<u>NOTE</u>: The MAW process must be followed in all circumstances, except where a scanner is not available for use or where the patient is in a contact precautions room and requires isolation. If one of these exceptions applies, follow the EMR Quick Reference Guide: <u>Medications – Administering a Medication</u>.

- Where the medication is ordered on ICCA, follow all appropriate steps in this procedure and the ICCA Orders Nursing User Guide.
- Where paper medication charts are in use, carefully check the patient's name, UR number, date of birth and the complete written order following the 5 Rights of medication administration (right patient, right medication, right route, right dose, right time). Clarify any illegible orders or orders considered inappropriate with the prescriber.
- Prepare medication immediately before administering.
- Observe the patient to ensure that oral medication has been consumed.
- When all medications are administered, ensure that the MAW/MAR/NIMC is signed per the applicable process.

Vaccines

All vaccines administered to all patients at WH must be prescribed and documented on the MAR/MAW/NIMC.

All vaccines administered to neonatal and paediatric patients at WH must also be documented in the 'My Health, Learning and Development Book (Green Book)'.

Nurse Immunisers may document a vaccine order for the purposes of administration on the MAR/MAW/NIMC

PRN orders

When a PRN order has a dose range the person(s) administering must:

- Check the maximum PRN dose in 24 hours and the timing of any previous dose (either PRN or regular).
- Observe the patient to ensure that oral medication has been consumed.
- Record the specific dose given on the MAW/MAR/NIMC.
- Record the time and signature of the person administering the dose.

Medication not administered

On the MAW/MAR, enter the appropriate reason for not administering in the mandatory comment box.

On the NIMC, record the appropriate 'reason for not administering' code.

Circle the code to ensure that it will not be misread as initials.

It is not acceptable to write (N) or N/A on the NIMC.

Make every attempt to source the medication at the time the order is required (see Section 8.6.1 and Appendix 1).

Document the reason for not administering in the patient's history.

Where a medication is not administered or is withheld by non-medical staff, notify the treating unit as soon as possible.

Where a medication is refused by a patient, notify the treating unit as soon as possible.

8.8.2 Verbal and Telephone Orders

A verbal order may be given by a prescriber in an emergency situation.

A telephone order may be given in the occasional instance where a prescriber can't order a medication on the EMR (including remotely).

Only an RN or RM can receive a verbal/telephone order.

The RN/RM must document in the orders section of the EMR or in the telephone orders section on the NIMC:

- Date and time of verbal/telephone order (automatically filled on the EMR).
- Generic name of medication.
- Route of administration (only use accepted abbreviations, see <u>Section 8.5.1</u>).
- Dose and frequency.
- Name of prescriber giving the verbal/telephone order.
- Electronic signature on the EMR or initials of the RN/RM taking the verbal/telephone order.

A second RN/RM/ENmed* must:

- Repeat the order and other relevant information to the prescriber.
- Check that the electronic/written order is correct.
- Add their initials into the order comments section on the EMR or on the NIMC.
 - *Or Welfare Worker in the Drug and Alcohol Detoxification and Dual Diagnosis Residential Rehab Units only.

Verbal/telephone orders must be signed and dated by the issuing prescriber within 24 hours, other than in exceptional circumstances such as being off-site and unable to access the EMR remotely, in which case they must confirm the order when they next attend the hospital.

If any clarification is needed in order to safely dispense the medication, the prescriber must speak to the pharmacist directly.

No chemotherapeutic agents will be dispensed or administered from a verbal order.

8.8.3 Oral Liquid and Crushed Medications

Oral administration

ENFit® syringes are:

- To be used to administer oral liquid medicines requiring precise dosing.
- For single use only.

ENFit® bottle adapters are available to aid withdrawal of medication from a bottle, as follows:

- Attach the ENFit[®] syringe to the ENFit[®] adapter.
- Invert the bottle then withdraw the required amount.
- Expel all excess fluid into the bottle.
- Ensure there is no medication in the tip of the syringe to prevent connector becoming clogged with medication or feeds.

The only oral liquids that are exempt from ENFit[®] syringes use and will be administered using medicine cups are: lactulose syrup, antacid mixtures e.g. aluminium hydroxide compound mixture (Gastrogel[®]) and lidocaine (lignocaine) oral gel.

PEG, NG and Jejunal Tubes

Refer to <u>OP-GC3 Adult Enteral Feeding</u>, <u>OP-GC3 Adult Nasogastric Tube (NGT) Insertion and Management</u>, <u>OP-GC3</u> <u>Percutaneous Endoscopic Gastrostomy (PEG) Insertion and Management</u> and <u>Children's Services DP-GC3 Neonatal and</u> <u>Paediatric Oro/Nasogastric Tube Insertion and Management</u> for more detail.

Tubes without ENFit® Enteral Connectors

ENFit® syringes are to be used to administer oral liquid or crushed/dissolved medications via a PEG or NG tube (see above). Use a Transitional Adaptor (e.g. <u>LK01 from Medicina[™]</u>) to connect the ENFit[®] syringe to the NG or PEG tube if necessary.

Crushing / Dispersing Medication

The 'Don't Rush to Crush' Handbook (The Society of Hospital Pharmacists of Australia (SHPA)) is the preferred text for information regarding suitable methods of crushing and/or dispersing solid dose forms.

'Don't Rush to Crush' is a recommended text for all patient areas and is also available via <u>MIMS Online</u>. Altering a dose form may render its use unlicensed (see <u>Section 8.5.3</u>).

To crush a tablet, use a mortar and pestle, as follows:

- Use patty pans to reduce cross-contamination and the amount of medicine lost to the mortar (see figure below for correct technique). Patty pans should be used on all occasions even if the mortar and pestle are dedicated to one patient, with the exception of ICU.
- After each use, wipe the mortar and pestle with Clinell[®] wipes (or similar disinfectant wipes) and leave to air dry. The mortar must be dry prior to placing a new patty pan in place.

NOTE: For ICU practice, refer to nurse in charge.

Mortars and pestles are to be kept in treatment rooms:

Using patty pans in a mortar and pestle to crush medications for administration



8.8.4 Checking and Administration Process for Two Authorised Personnel

The administration of the following must be checked by two <u>authorised personnel</u> within their scope of practice, one of whom must be an RN or RM:

Type of medication	Extra requirements
S8 and S11 medicines	See Section <u>8.8.5</u> for transaction records.
Insulin	See <u>OP-GC6 Insulin Prescription, Supply, Storage and Administration</u> .
Warfarin	See Section <u>8.5.2</u> for prescribing requirements.
Mifepristone and misoprostol	See <u>Women's Services DG-GC6 Prescription and Administration of Mifepristone and</u> <u>Misoprostol for Women Experiencing Miscarriage, Termination and FDIU</u> .
Cytotoxic medications	Document independent double check of calculated dose. See <u>OP-GC6 Hazardous</u> <u>Medications – Cytotoxics</u> .
Intrathecal medications	Care must be taken to ensure that intrathecal medications are NEVER given by the wrong route. See OP-GC6 Hazardous Medications – Cytotoxics.
All parenteral medications	<u>NOTE</u> : IV infusions (except vesicant neoplastics) must be administered via an infusion pump or 'smart pump' by selecting the appropriate clinical profile and drug entry option fro the drug library.
	Vesicant anti-neoplastics should be administered by free-flow using gravity to mitigate extravasation risk.
	Use single dose vials, ampoules or prefilled syringes whenever available; multidose vials should not be used, except where for exclusive use of an individual patient, e.g. insulin, or where specifically endorsed by the Head of Infectious Diseases Unit (where the endorsement will be noted alongside the relevant WH Drug Formulary entry).
	Only administer IV bolus doses of opioids in accordance with <u>OP-GC6 Intermittent Opioid</u> <u>Analgesia in Adults for Acute Pain and Associated Observations (Inpatients Only), PACU</u> <u>DP-GC6 Post Anaesthetic Care Unit (PACU) Opioid Administration for Adults or PACU DF</u> <u>GC6 Post Anaesthetic Care Unit (PACU) Opioid Administration for Paediatric Patients</u> or in accordance with the appropriate NeoMed profile for neonates (see <u>Children's' Services</u>
All medication given to paediatric and neonatal patients	DP-GC6 Use of Western Health Neomed Medication Resource). Document independent double check of calculated dose. Both persons must electronically sign the MAW/MAR or initial the administration section o the NIMC, as applicable.

Other medications may be administered by one authorised person.

Exceptions where administration of the above may be by one RN are:

- PACU, in accordance with PACU DP-GC6 Post Anaesthetic Care Unit (PACU) Opioid Administration for Adults or PACU DP-GC6 Post Anaesthetic Care Unit (PACU) Opioid Administration for Paediatric Patients.
- HITH.
- ACE Team, where an RN is working alone at an external RACF or on in-reach.
- Drug and Alcohol Detoxification and Dual Diagnosis Residential Rehab Units where one RN is rostered per shift.

In Drug Health Services Outpatients setting one Nurse Practitioner or one MO may administer long-acting buprenorphine injection without requiring a witness.

The two authorised personnel cannot comprise two graduate nurses or a graduate nurse and an ENmed.

A student nurse/midwife must be directly supervised by an RN or RM, either a WH staff member or an approved clinical teacher provided by the university. Both the student nurse/midwife and the supervising RN/RM must enter their credentials on the MAW/MAR or initial and sign the medication chart for each medication given.

One medication should be administered to one patient at a time.

Two authorised personnel, within their scope of practice, one of whom must be an RN or RM, must:

- Follow the administration process in <u>Section 8.8.1.</u>
- Separately perform any calculations required and check each answer corresponds exactly.

One authorised person prepares and administers the medication.

The second authorised person assists and witnesses.

Preparing and checking the preparation of a medication involves:

- Reading the container label for contents and expiry date.
- Adding the correct type and volume of diluent, if required.
- Mixing thoroughly and gently according to manufacturer's directions, if required, and observing for discolouration, precipitation, foreign bodies.
- Following national recommendations for safe preparation of medicines, including applying the appropriate labelling for injectable medicines, fluids and lines (per <u>National Standard</u>).
- For infusions, checking placement of the line by tracking it from the bag to the patient.

One authorised person signs for the administration against the medication order and documents the time, if required.

Where required, e.g. warfarin, the second authorised person electronically witnesses the administration on the MAW/MAR or countersigns the paper medication chart to confirm an independent double check.

Where an S8 or S11 medication is administered, the same two authorised personnel who administer the medication to the patient must record the transaction in the register (see <u>Section 8.8.5</u>). The complete process must be followed before administering medication to the next patient. It is not appropriate to remove strips of S8 or S11 medications from the medication room and administer to multiple patients before returning to the medication room.

Where a Pyxis[®] device is used, transactions will be recorded electronically by both staff members involved, except if a power blackout occurs where manual recording is required. See <u>OP-GC6 Pyxis[®] MedStation System</u>.

8.8.5 Schedule 8 and Schedule 11 Medicine Transactions, Records, Liquid Balances and Disposal

Maintenance of Schedule 8 and Schedule 11 medicine registers

All clinical areas must maintain appropriate registers to record all transactions involving any S8 and S11 medicines they hold.

Pre-printed, adhesive labels featuring the specific medicine details for each clinical area's S8 and S11 imprest medicines must be used to assist with medicine legislation compliance; reduce the risk of transcription errors; and reduce the time required to transcribe medicine details.

For each new page of the S8 or S11 register, a member of nursing or midwifery staff must:

- Attach the specific pre-printed label for the clinical area to the register.
- Ensure that it is attached correctly and does not cover any existing records.
- Stamp the label on both sides using the seal stamp.
- Complete the balance check according to the process on page 29.

Ward clerks order labels at the request of the UM via FMIS (two week turnaround time required). Spare labels are to be stored in the medication room.

To change label content:

- UM completes a Request for Imprest Change Form and forwards to the clinical area's Deputy Director of Pharmacy or Pharmacist in Charge (Williamstown).
- Deputy Director or Pharmacist In Charge requests approval from the Director of Pharmacy.
- If approved, Deputy Director or Pharmacist In Charge emails the printers with the label template change, updates the imprest list on dispensary software, then instructs the UM when new labels can be ordered.
- After ordering, the proof for the new labels is sent to the Deputy Director or Pharmacist In Charge for confirmation.
- When new labels arrive, UM organises removal of obsolete labels and forwards to Pharmacy for destruction.

For non-imprest medications or if pre-printed labels are temporarily unavailable, handwrite the name, strength and form of each medicine at the top of the next unused column of the appropriate register using blue or black ink.

Do not disturb authorised personnel during the process of entering transaction records or carrying out balance checks.

Registers and red transfer books should only be in the possession of pharmacy technicians, pharmacists, RN/RMs and MOs and should not be removed from clinical areas unless returning to Pharmacy.

Once a new register is issued out, retain the old completed register on the ward until the next balance check. Once this has been completed, return the old register as soon as possible to Pharmacy, where it will be stored in a secure location for three years.

Dispensary Managers at Sunshine and Footscray Hospitals, and the Pharmacist in Charge at Williamstown Hospital are responsible for following up on a monthly basis the location of registers that have been issued out to clinical areas and not returned.

If registers have not been returned from high S8/S11 turnover areas within 3 months or low S8/S11 turnover wards within 6 months, the issue should be escalated to the relevant Divisional Director or DONM, via the Director of Pharmacy.

If a register remains unaccounted for, the issue should then be escalated to the Executive Director of Operations.

Transaction records in Schedule 8 and Schedule 11 medicine registers

For all transactions involving an S8 or S11 medicine, two <u>authorised personnel</u>, one of whom must be an RN or RM, must record the details required in the appropriate register.

It is mandatory for the two authorised personnel to count, check and sign for the transaction at the time that the safe is open. It is unacceptable to seek a second signature in the register at a later date/time.

The two authorised personnel cannot comprise two graduate nurses or a graduate nurse and an ENmed.

An ENmed may only witness S8 and S11 medicine transactions for routes they are endorsed to administer.

Exceptions to this only occur in:

- Drug and Alcohol Detoxification and Dual Diagnosis Residential Rehab Units where this is done by one RN.
- Drug Health Services Outpatients, where one Nurse Practitioner or one MO may record the removal from the safe and the administration of long-acting buprenorphine injection without requiring a witness.
- Pharmacy departments, where this is done by two pharmacy staff members.
- Operating rooms, where the two authorised personnel are an RN/RM and either an RN/RM/ENmed or an
 anaesthetic consultant or trainee:
 - The anaesthetic RN will print the patient's name and UR number and sign the register on removing the requested medicines from the S8 safe and/or S11 storage cabinet.
 - If the person providing the second check is unable to leave the patient's bedside, they should witness the removal of the medicine(s) from the safe at the time the safe is open, and then sign the register as soon as practicable.

Legibly print each S8 and S11 medicine transaction on a separate line in the S8 or S11 medicine register.

For each transaction record:

- Medication name, form, strength and quantity.
- Patient's name and UR number, where applicable.
- Signature and printed name (block letters) of two authorised personnel.

Where the transaction is administration of a medication, the same two authorised personnel who record the transaction must administer the S8 or S11 medicine to the patient (see <u>Section 8.8.4</u>).

Document the record of administration immediately prior to administering the medication.

Where a Pyxis[®] device is utilised, the details will be electronically recorded by both staff involved in the transaction, except if a power blackout occurs where manual recording is required. See <u>OP-GC6 Pyxis[®] MedStation System</u>.

If incorrect information is written in the register, draw a single line through the entry (so that it remains legible), date, initial by both authorised persons and re-enter on the next line.

Use of whiteout or other obliteration or removal of the transaction is prohibited.

Oral Liquid Schedule 8 and Schedule 11 Medications

It is not necessary to measure the balance each time it is checked.

It is sufficient to estimate the volume by observation and note the entry as estimated.

Do not use any form of adhesive tape in a strip form to identify the remaining volume in a bottle.

The volume must always be measured when removing the last of the contents of the container.

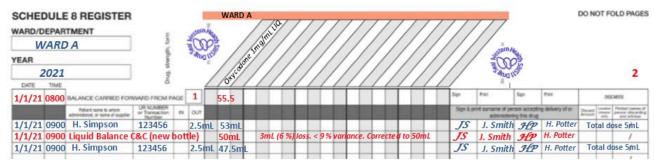
Document any variance in mL and % in the register entry and ensure that the balance is corrected **before** opening a new bottle.

Do not carry an incorrect balance over to a new bottle.

If the variance exceeds **9.0%** (i.e. is 9.1% or greater), complete a RiskMan incident report (see <u>Section 8.4.3</u>) and commence a preliminary discrepancy investigation as per <u>Appendix 2</u>.

An exception exists for JKWC Newborn Services only, where RiskMan incident reporting and discrepancy investigation are required for a variance above 40.0%.

Example of Liquid Schedule 8 register entry:



Portions of Unit Doses (S8 or S11)

Where only a portion of a unit dose (e.g. half a tablet) is needed to administer a dose, record the details of the portion being administered to the patient in the S8 or S11 medicine register. There are two options for the remaining portion of the medicine:

Option 1: Discard

The remaining **portion of an S11 medicine or S8 tablet/lozenge** may be immediately disposed of by two <u>authorised</u> <u>personnel</u>, at least one of whom must be an RN or RM, and recorded in the comments section of the register. E.g. oxycodone dose ½ x 5mg tablet: 2.5mg administered and 2.5mg discarded into sharps container. Both persons must initial the entry.

See Disposal of Schedule 8 and Schedule 11 Medicines, below.

Option 2: Retain for use

Alternatively the remaining portion can be stored in the original blister packaging for future use.

E.g. oxazepam dose 7.5mg BD:

- ½ x 15mg tablet administered in the morning and ½ x 15mg tablet placed carefully back in the original package.
- The remaining ½ x 15mg tablet is retained and included in the total stock balance until administered in the evening.

If the portion of a unit dose is not likely to be used promptly (i.e. within 1-2 days), it should be discarded per Option 1.

Disposal of Schedule 8 and Schedule 11 Medicines

Opened sterile dose units or medications that have come into direct patient contact, e.g. regurgitated tablets or used patches, should be immediately discarded as described below.

S8 or S11 medicines that are no longer required are to be destroyed by two <u>authorised personnel</u> on the ward **or** returned to Pharmacy as per Table 9. If unsure, contact Pharmacy.

The two authorised personnel cannot comprise:

- Two ENmeds;
- Two graduate nurses;
- A graduate nurse and an ENmed.

In the Drug and Alcohol Detoxification and Dual Diagnosis Residential Rehab Units, disposal is undertaken by two RNs at handover.

The persons disposing of the S8 or S11 medicine are legally responsible for recording in the register:

- Name, strength, form and quantity of medicine destroyed and bag number, if applicable.
- Method and place of destruction.
- Printed names and signatures of the two authorised personnel.

Where a Pyxis[®] device is utilised, this information will be electronically recorded by both persons involved in the disposal of the S8 or S11 medicine, except if a power blackout occurs where manual recording is required.

If an infusion was prepared on another ward or from stock in a Pyxis[®] device or contains multiple S8 and/or S11 medications (e.g. in a syringe driver), make a new entry in the register indicating that part or all of the infusion has been discarded:

- Date, time, patient name and UR number.
- Medication name and strength (e.g. 100mg/100mL morphine infusion).
- Quantity and method of discard (e.g. 50mg given, 50mg discarded in sharps container).
- Printed names and signatures of two authorised personnel.

Discard the waste into a sharps container (do not leave in a syringe or IV bag).

Store unused unit doses of **S8 medicines (other than portions of tablets or lozenges)** designated for destruction with a pharmacist in purpose-produced plastic bags (available from FMIS).

Securely seal and label the bag with:

- The date and time that the medicine was designated for destruction.
- The medicine name, form, strength and quantity.
- The names of two authorised personnel.

It is the responsibility of the Nurse In Charge to inform a pharmacist of the requirement to witness destruction of a medicine and ensure that this is undertaken.

Ensure that the quantity to be returned or destroyed is included in the register stock balance until the time that the medicines are removed from the S8 safe or S11 storage facility for return or destruction.

Any S8 or S11 medicine disposal that does not meet the requirements above must be reported as a Medicine Discrepancy Incident per *Section 8.4.3* and <u>Appendix 2</u>.

Table 9 Discarding S8 and S11 Medications

	Two authorised personnel on ward	RN/RM and pharmacist on ward	Return to Pharmacy
S11 unit dose (including unused portion of a dose, dose refused, dropped, removed in error, or measured liquid in oral dispenser)	Y		
S8 unit dose (including dose refused, dropped, removed in error, measured liquid in oral dispenser) except a portion of a tablet or lozenge		Y	
Portion of S8 tablet or lozenge that is not required for administration to a patient	Y		
Remnants of S8 or S11 dose in open ampoule	Y		
An S8 or S11 vial that has had medication removed from it	Y		
An S8 or S11 vial without any medication removed (even if pierced or tamperproof cap removed)			Y
An infusion that is no longer required	Y		
A patient's own medication (patient deceased or has given consent to destroy)		Y	
Expired medication		Y	
Any other S8 or S11 medicines			Y

Register and Balance Checks

Register and physical balances of all medicines stored in an S8 medicine safe and/or S11 storage facility within a clinical area must be counted and checked at the change of each shift.

The balance check must be recorded in <u>red</u> pen in the relevant register and signed by two RN/RM/ENmeds, including one person from each shift, one of whom must be an RN or RM. Each person must sign and print their name (block letters).

Any outer packaging must be opened and medication inspected on receipt and at every balance check.

If a clinical area is not open continuously, check balances on opening and closing as well as any change of shift, following the same process.

When carrying forward balances from page to page in a S8 or S11 medicine register or from a completed S8/S11 medicine register to a new book, two authorised personnel, one of whom must be an RN or RM, must check and verify balances, including physical balances. This documentation should be made in <u>red</u> pen:

- Both staff members must sign and print their name to verify balances are correct.
- Transfer balances to next available page and complete 'From page.....' on the new page.
- Document register book numbers in new and old registers, so that it is clear which register precedes the current
 register for that clinical area.

The exceptions to this occur in:

- Drug and Alcohol Detoxification and Dual Diagnosis Rehabilitation Units where this is done by one RN.
- Pharmacy departments where this is done by two pharmacy staff members.

Where a Pyxis[®] device is utilised, an S8 and S11 medicine register and balance check will be electronically recorded by both staff completing the check. Only two authorised personnel, one of whom must be an RN or RM, can undertake a balance check.

S8 and S11 Stock and Balances in Operating Suites

Transactions must be recorded as above.

Two <u>authorised personnel</u>, one of whom must be an RN or RM, must restock operating room or procedure room S8 medicine safes, S11 storage cabinets and anaesthetic trolleys from the central S8 medicine safe and S11 storage cabinet.

The same two authorised personnel must:

- Record transfer of stock in the central S8/S11 medicine register at the time the central S8 medicine safe/S11 storage facility is open.
- Count, check and sign transferred stock into the relevant S8 or S11 medicine register.

All S8 and S11 medicines stored in an operating room, procedure room or anaesthetic trolley will be counted and checked against the S8 and S11 medicine registers by two authorised personnel at the beginning of each session and at the end of each day.

Where a Pyxis[®] device is utilised in an operating room, two authorised personnel, one of whom must be an RN/RM, are responsible for checking S11 and S8 medicines into the Pyxis[®] device.

9. Document History

Number of previous revisions: 12

Previous issue dates: March 2001, April 2003, May 2004, May 2005, December 2006, October 2008, October 2011, March 2014, August 2016, May 2017, March 2018 and October 2018

Minor amendment: May 2021 and April 2022

Documents superseded and/or combined:OP-PS1.2.23Medicated Transdermal Patches - Safe ManagementOP-PS1.2.6Medication Prescription, Supply, Storage and Administration

10. References

Drugs, Poisons and Controlled Substances Act 1981 (Vic) and associated Regulations including the Drugs, Poisons and Controlled Substances Regulations 2017 (Vic)

STANDARD FOR THE UNIFORM SCHEDULING OF MEDICINES AND POISONS, No. 30, July 2020

National Health Act 1953 and National Health (Pharmaceutical Benefits) Regulations 2017

Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990

Therapeutic Goods (Victoria) Act 2010

CATAG Guiding Principles for the quality use of off-label medicines, November 2013

11. Sponsor

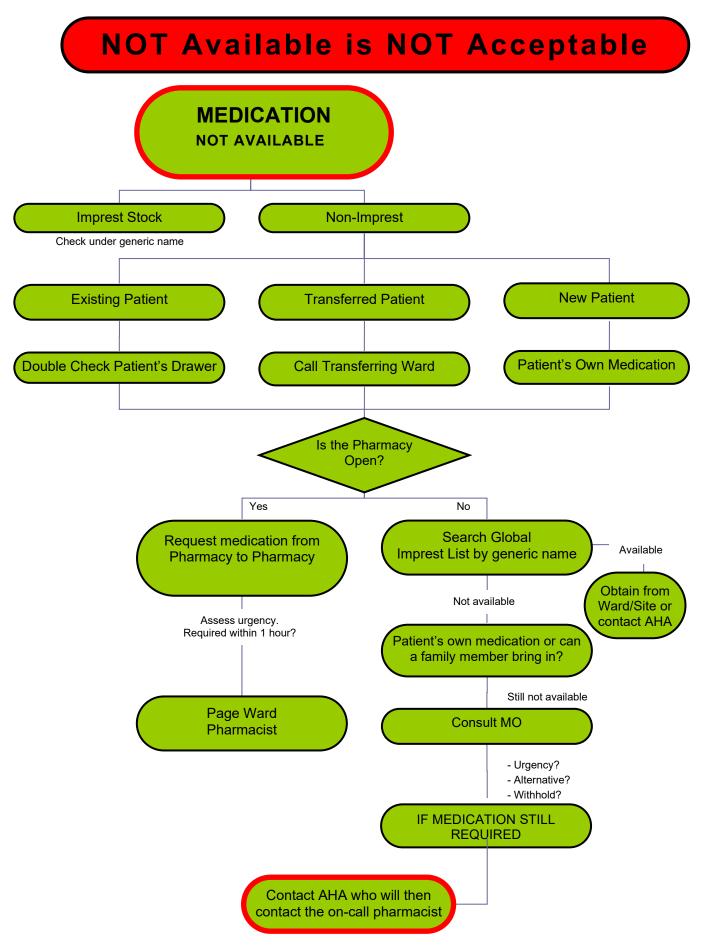
Director of Pharmacy

12. Authorisation Authority

Chief Medical Officer

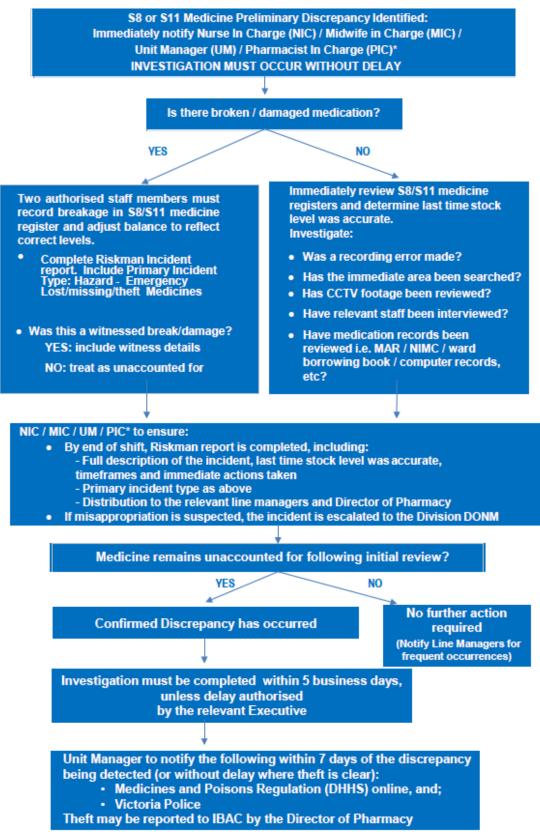
Appendix 1:

Actions to be Undertaken if a Medication is Not Available for Administration





Appendix 2: Medicine Discrepancy Investigation Flowchart



* For Pharmacy Department Discrepancies

<u>Click here</u> to report to Medicines and Poisons Regulation online and select the form 'Make a notification of lost scheduled substance (for organisations to complete)'.



Prescriber

Nurse

Pharmacist

Medicated Transdermal Patches Safety



Transdermal patches are a useful alternative to oral medications.

See the 'Western Transdermal Medication Patch Identification Chart' on the Medication Safety intranet page for examples.

Medication errors with patches, especially opioids, have been associated with serious adverse events including deaths.

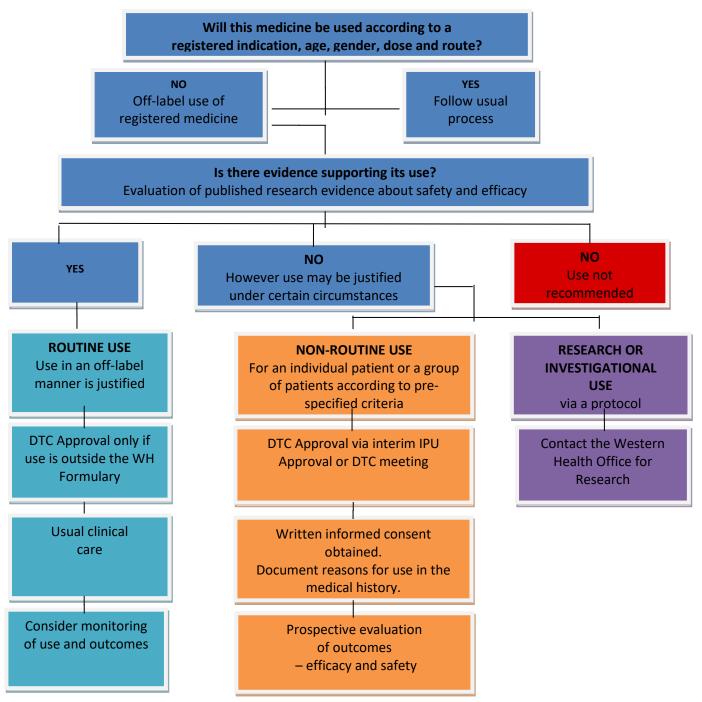
 On Admission: ASK about transdermal patches as part of a medication history LOOK for patches in situ during examination DOCUMENT medication, dose, indication, predicted duration, date, time of application 	 When Changing Dose: ALWAYS cease existing order and rechart NEW dose NEVER modify an existing order ALWAYS prescribe the TOTAL dose in a single order, never 2 separate doses. 	On Discharge: DOCUMENT in the discharge summary: patches commenced, changed or ceased during the inpatient stay Indication Intended duration	
On Admission: CHECK if a patient has a patch in situ DOCUMENT when and where it was applied and when it is due to be removed or changed MRI MRI/Radiology staff - CHECK and temporarily remove patch(es) prior to MRI and reapply the patch after MRI Some patches contain aluminium, which may cause burns during these procedures.	Administration Practice Points: ALWAYS check all previous patches are removed ALWAYS wear gloves during application, removal and disposal NEVER cut a patch to adjust the dose APPLY to clean, dry, hairless skin and DOCUMENT administration NEVER apply heat onto or near to a patch. Heat increases drug absorption TEMPORARILY remove patch(es) prior to Elective Defibrillation and reapply same patch (as per practice point on MRI) NEVER apply occlusive dressings over a patch ROTATE application sites CHECK patch in situ on each shift and DOCUMENT DISCARD by folding adhesive side in half and placing in sharps container DOCUMENT disposal of Schedule 8 patches as per WH procedure 		
 On Admission: ASK about transdermal patches as part of a medication history DOCUMENT when it was applied and when it is due to be removed or changed 	Durine Admission: CHECK if there has been a dose change and supply as needed CHECK MAR to see if appropriate patch application checks have been ordered	Discharze: ENSURE patient or carer understands how to use the patch PROVIDE instructions for use, safe disposal and storage 	

Prepared by: QUM Pharmacist, Pharmacy Department. Version 4. 16/09/2019



Appendix 4. Off-label Use of Medications: Categories and Requirements (Part 1)

Assessing appropriateness of off-label medication use and process for approval, consent and monitoring:



For further information access the CATAG `Guiding Principles for the quality use of off-label medicines' via the link: <u>http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final.pdf</u>

Source: Adapted from CATAG Guiding Principles for the quality use of off-label medicines, November 2013



Appendix 4 continued: Off-label Use of Medications: Categories and Requirements (Part 2)

Category of off-label use	Definition	Approval required	Involve the patient/ person responsible in shared decision-making and obtaining consent	Monitor outcomes, effectiveness and adverse events.
Routine use	Where there is 'high' quality evidence supporting the safe, efficacious and cost-effective use of the medicine off-label and an overall favourable harm : benefit ratio for the intended clinical use and population, e.g. rituximab for rheumatoid arthritis (adults)	DTC approval only if use is outside the WH Formulary	Follow the usual clinical care process, with provision of information and discussion. This should occur as part of usual clinical care and does not require additional measures. In some cases, it may be appropriate to explain the reason for prescribing the medicine off-label and what this means. This will be a matter of clinical judgement, especially if there is something known about the patient that would indicate that they would attach some significance to this aspect. In this case, documentation of this discussion and consent in the medical record may be appropriate (in some cases, obtaining written informed consent may be judicious).	Prospective evaluation of clinical outcomes and/or use may be required in specific circumstances, e.g. evaluation of the longer term safety of a newly marketed medicine or monitoring of adverse events (e.g. for high-risk medicines or high-risk populations).
Non-routine use	 For an individual patient: there is 'low' or 'very low' quality evidence, but potential benefits appear greater than potential harms, based on available evidence, where pre-specified criteria are met, e.g. serious or rare condition and no alternative treatments are available, or have been exhausted, e.g. rituximab for chronic, refractory immune thrombocytopenic pupura (adults) For a certain patient group: there is 'low' to 'moderate' quality evidence, but potential benefits appear greater than potential harms and there is reasonable justification for use in the certain group of patients, defined by pre-specified criteria (e.g. disease type, age, standard treatments been tried and failed) and they receive treatment according to an agreed protocol. A condition of such use should involve systematic reporting of effectiveness and safety outcomes so that an evidence base can be developed. Reviewing appropriateness of continued therapy at regular intervals (for the individual and group of patients) should occur, e.g. rituximab in adults with systemic lupus erythematosus, with moderate-severe active disease, where pre-specified standard immunosuppressive therapy has failed. 	Approval via interim IPU or DTC meeting	 Written informed consent should be obtained, with documentation of the reasons for use in the medical records. As there is usually more uncertainty about the benefits and harms with the use of the medicine, a detailed discussion about these aspects with the patient and/or person responsible, as well as the benefits/harms of available alternatives is required. For a certain patient group or according to pre-specified criteria: Approval of use is conditional on further monitoring and assessment of effectiveness and safety. If these conditions are not met or if new information indicates an unfavourable harm: benefit profile, then the approval may be reviewed and there is potential for discontinuation of the medicine. Information collected about the use of this medicine may be shared with others in order to add to knowledge about this medicine. Detailed discussion about these aspects with the patient and/or person responsible and consent to potentially sharing information with others is required. 	Prospective evaluation of clinical outcomes (safety and effectiveness) should occur in all cases routinely. Monitoring of use should also occur in all cases to ensure it is consistent with DTC approved criteria (including ensuring that requirements for written informed consent are met).

Research or investigational use	If there is 'low' or 'very low' quality of evidence, with uncertain benefits and harms that are unknown or that may be significant, but where there is potential for clinical benefit then this is classified as investigational or experimental to be considered to be used via a research protocol and reviewed and approved by an HREC, e.g. rituximab in adults with systemic lupus erythematosus with moderate-severe active disease refractory to standard immunosuppressive therapy	Research and Ethics Committee	It is necessary to explain to the patient that ethically to prescribe this medicine it is necessary to use it in a research manner. Requirements include: provision of written patient information; written informed consent, as part of an approved research protocol; and reporting of outcomes (with appropriate regard to privacy).	As per research protocol
Not recommended	If there is a 'low' or 'very low' level of evidence with uncertain benefits or harms, or the available evidence indicates that the overall harm: benefit ratio is (or would be) unfavourable for the intended clinical use or population, e.g. rituximab in adults with multiple sclerosis (available evidence indicates no benefit in this condition).	Not applicable	Not applicable	Not applicable



Appendix 5: Examples of Information Sources to Support Decisions About Appropriate Off-Label Use of Medications

- 1. Decisions of competent regulatory bodies from other countries:
 - US Food and Drug Administration (FDA) (<u>http://www.fda.gov/</u>).
 - European Medicines Agency European public assessment reports –(<u>http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar_search.jsp</u>).
 - NZ Medsafe (<u>http://www.medsafe.govt.nz</u>).
- 2. Secondary or summarised sources of high quality research evidence:
 - Cochrane database of systematic reviews.
 - UK National Institute for Health and Care Evidence (NICE) Evidence Summaries. (<u>http://www.nice.org.uk/mpc/evidencesummaries/unlicensedofflabelmedicines/home.jsp</u>).
 - The US Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov).
 - The Canadian Agency for Drugs and Technologies in Health (CADTH) (www.cadth.ca).
 - UpToDate (http://www.uptodate.com/home/product).
- 3. Evidence-based therapeutic guidelines and other medicines information sources
 - National Health and Medical Research Council.
 - Therapeutic Guidelines Ltd.
 - Australian Medicines Handbook (AMH) / AMH Children's Companion.
 - British National Formulary / British National Formulary for Children.
 - eviQ (https://eviq.org.au).
 - Specialty Societies practice guidelines, for example, Palliative Care Guidelines.
 - NSW TAG therapeutic review documents and position statements (<u>http://www.ciap.health.nsw.gov.au/nswtag/reviews/lit-reviews.html</u>).

<u>Note</u>: Secondary sources of summarised evidence, guidelines or other medicines information sources may have limitations. They are generally variable in quality and currency or not available in a timely manner to provide useful guidance for newly marketed medicines, where many off-label uses are frequently initiated in hospitals. They may also not provide useful information on comparative effectiveness, safety or cost-effectiveness. Therefore rigorous review of primary research evidence is often needed to enable well informed decisions.

Source: Appendix 4 of CATAG Rethinking medicines decision-making in Australian hospitals. Guiding principles for the quality use of off-label medicines, 2013.