VicTAG

VICTORIAN THERAPEUTICS ADVISORY GROUP

Victorian Framework for **Medicines with Potential for Harm or Unsafe Use**

Health service guide for the management of Schedule 9, Schedule 8 and Schedule 4D medicines

2025

Guidance document is for clinicians across health services involved with the management of Schedule 9, Schedule 8, Schedule 4D medicines.

The Victorian Therapeutic Advisory Group (VicTAG) funded the development of this Framework. VicTAG's purpose is "to promote quality use of medicines by sharing unbiased, evidence-based information about medication therapy and to support the goals of, and facilitate the National Medicines Policy of access, quality and safety in the use of medicines in Victorian hospitals"[1]

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Authors and acknowledgements

VicTAG Medicines with Potential for Harm and Unsafe Use Advisory Group

Thank you to members of the Medicines with Potential for Harm and Unsafe Use Advisory Group (hereinafter referred to as the Advisory Group) for developing the content of this Framework:

- Cynthia Donarelli (Project Lead), Senior Pharmacist - Quality and Medication Safety, Northern Health
- Aleksandra Florian, Director of Pharmacy, Central Gippsland Health
- Geoff Haar, Clinical Risk Manager Medication Safety, Senior Pharmacist Quality Use of Medicines, Eastern Health
- Lisa Yan, Clinical Pharmacist, Grampians Health
- Lisa Ciabotti, Professional Officer, VicTAG
- Karrie Long, Chief Nursing and Midwifery Officer, Safer Care Victoria
- Jacqueline Chan, Senior Compliance Officer, Medicines and Poisons Regulation, Victoria
- Julina Tran, Lead Pharmacist (Workforce), Western Health
- Margaret Carroll, Electronic Drug Registers Pharmacist (HS8), Austin Health
- Mark Sheppard, Assistant Deputy Director of Pharmacy – Medication Safety & Stewardship Services, Monash Health
- Mazdak Zamani, Associate Program Director Pharmacy – Quality of Medicines, Eastern Health
- Marissa Izzard, Mediation Safety Pharmacist, Barwon Health
- Naomi Lim, Professional Officer, Pharmaceutical Defence Limited (PDL), Victoria
- Nicole O'Shea, Medication Safety Pharmacist, Grampians Health
- Sara Linton, Medication Safety Pharmacist, Melbourne Health
- Stephanie Russo, Safer Care Victoria Nursing Representative
- Youseph Dib, Senior Pharmacist – QUM, Peter McCallum Cancer Centre

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- Sylvia White, Clinical Pharmacy, St John of God Subiaco Hospital
- Hayley Griffin, Acting Assistant Deputy Director of Pharmacy – Team Leader – Medication Safety and Adverse Drug Reactions, Monash Health
- Gary West, Senior Professional Officer, Pharmaceutical Defence Limited (PDL), Victoria
- Tim Bownas, Medicines and Poisons (industry) Team Leader, Regulatory Compliance and Operations, Victoria

Abbreviations and Definitions

Term	Definition
Automated Dispensing Cabinet (ADC)	Are a decentralised electronic medication management system aimed at improving medication storage and distribution[2]. ADC may also be referred to as Automated Dispensing Systems (ADS), Automated Dispensing Machines (ADM) or Automated Medication Cabinets (AMCs).
Authorised person	Are persons as defined and specified in Section 13 of Drugs, Poisons and Controlled Substances (DPCS) Act 1981 (Vic) and Regulation 7(1) of the

	DPCS Regulations 2017 (Vic), to obtain and possess a Schedule 9, Schedule 8, Schedule 4 medicine relating to their scope of practice. Authorised persons include (but not limited to) medical practitioner, veterinary practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist, authorised podiatrist, registered nurse, pharmacist.
Biometric authentication	When an organisation or agency takes an electronic copy of your biometric information which may include features of your face, fingerprints, palm, iris and this data is used to authenticate your identity[3.]
Clinical Area Managers	Include Nurse/Midwifery unit manager, Director of Pharmacy (or delegate), Pharmacist- In- Charge or Director of Nursing (or delegate)
Destruction/Destroy	The process of rendering a medicine non-recoverable and non-identifiable. Drugs of dependence must be rendered non-recoverable and non-identifiable prior to being disposed of in a pharmaceutical waste bin[4,5,6]. For example, crushed, expelled onto absorbent material or placed in a purpose made drug disposal kit containing a chemical neutralising agent.[6] Victorian legislation requires all pharmaceutical waste to ultimately be destroyed by incineration[4].
Disposal/Dispose/ Discard	The process of placing a container, primary pack, medicine or substance into an appropriate pharmaceutical bin. Victorian legislation requires Drugs of Dependence to be destroyed prior to being disposed of in a pharmaceutical bin[4].
Diversion	The unlawful transfer of pharmaceuticals from legal sources and intended uses to the illicit marketplace or individual misuse[7].
Drug of Dependence	Are medicines that are listed in Schedule 11 of the DPCS Act 1981 (Vic)[8] known to be subject to misuse and trafficking. Medicines include: ● All Schedule 8 medicines ● Medicines in Schedule 2, 3 and 4 that have a higher risk of diversion. The Victorian Department of Health recommends that diazepam and similar Schedule 4 medicines be referred to as Schedule 4 Drugs of Dependence, rather than Schedule 11 medicines[9].
Medicine	Defined as *including prescription, over-the-counter and complementary medicines*[10].
Medicines subject to misuse (MSM)	Are medicines that are Schedule 2, 3, and 4 that carry a higher risk of harm, including potential misuse, abuse, addiction, overdose and illicit use, which *are not* listed in Schedule 11 of the DPCS Act 1981 (Vic). For the purposes of this framework, these substances will be referred to as Medicines Subject to Misuse (MSM). Any substance that is closely related to, is a derivative of, or is a synthetic analogue of such a substance would also carry similar risks, and should be treated the same way. These medicines may require additional controls similar or equal to that for Schedule 4 Drugs of Dependence. Refer to Table 1 for the medicine list.
Monitored medicine	Are prescription medicines that present the greatest risk of harm to the Victorian community and are monitored through SafeScript[11].
Monitored medicine database	A real-time monitored medicine electronic platform, such as SafeScript, that provides information to prescribers, nurse practitioners and

	pharmacists (dispensers) about a patient's history and use of monitored medicines[12].
Schedule 4 Drugs of Dependence (S4D)	Are Schedule 4 medicines that have a higher risk of diversion and have more stringent controls applied for destruction of these substances to minimise risks. Along with other medicines at higher risk of diversion, S4Ds are part of Schedule 11 of the DPCS Act 1981 (Vic) *See definition for Drugs of Dependence*
Schedule 11	Medicines listed in the Schedule 11 section of the DPCS Act 1981 (Vic) See definition for *Schedule 4 Drugs of Dependence*
Schedule 8 Medicine (S8)	Medicines are listed in Schedule 8 Controlled Drugs of The Poisons Standard (SUSMP) and have strict legislative controls[13]. Refer to Table 1 for a list of medicines.
Schedule 9 Medicine (S9)	Medicines listed in Schedule 9 Prohibited Substances of The Poisons Standard (SUSMP) and have strict legislative controls[13]. These medicines may be abused or misused, where possession, supply and use should be prohibited by law except when required for medical or scientific research. Refer to Table 1 for a list of medicines.
Scope of practice	Defined as a time-sensitive, dynamic aspect of practice that indicates those professional activities that an authorised person, intern pharmacist or pharmacy technician is educated, competent and authorised to perform, and for which they are accountable[14]
Witness	A process whereby another person (e.g. registered nurse, pharmacist), observes the medicines being transacted and independently reconciles the particulars of the transaction in the presence of the person making the transaction.
Storage facility	A cabinet, receptible, cupboard, refrigerator or room and can include electronic storage and recording equipment as defined in the *DPCS Regulations 2017 (Vic).*
The *Act*	Refers to the Drugs, Poisons and Controlled Substances Act 1981 (Vic)[8].
The Poisons Standard (SUSMP)	Promote uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. May also be cited as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
The *Regulations*	Refers to the Drugs, Poisons and Controlled Regulations 2017 (Vic)[4].
Transactions	To prepare, use, transfer within and between premises, administer, dispose or destroy of a Schedule 4, Schedule 8, Schedule 9 medicine.
Unknown/ Illicit Substances	Prohibited from possession, manufacture, sale or supply under an authorisation, including illegal and unknown drugs which have the potential for numerous harms for patients and consumers.

Background

The archived document "*Recommendations on the security and custody of Schedule 8 and Schedule 4 drugs within hospitals"* (formerly Melbourne Teaching Hospital's Drug Usage Group (MTHDUG))[1] published in 2003, provided recommendations regarding the management of Schedule 8 and Schedule 4 medicines within hospitals. Since its publication in 2003, changes to Victorian legislation and practice guidelines have come into effect. Technology has advanced and automated products and systems for handling medicines have been introduced into the Australian market. Victorian health services have requested an update to the archived document.

Purpose

The Victorian Framework for Medicines with the Potential for Harm or Unsafe Use (The Framework) aims to facilitate the management of these medicines that adheres to the minimum legislative requirements and is in accordance with best practice.

The Framework includes guidance on:

- Requirements for the storage and security, including for medicines that require refrigeration and utilisation of automated dispensing cabinets
- Guidance on recording of transactions, including electronic solutions
- Requirements for transport
- Processes for destruction and disposal
- Requirements for real time prescription monitoring
- Measuring liquids and acceptable volume discrepancies
- Auditing and managing incidents, including reporting to Victoria Police and Medicines and Poisons Regulation Victoria
- Management of patients own and discharge medicines

Intended audience

The Framework is intended for use in Victorian health services where it applies to all clinical staff involved in medicines with the potential for harm or unsafe use. Pharmacy staff are considered instrumental in the implementation of the Framework. Governance is ultimately the responsibility of the Health Service Permit (HSP) holder (commonly the Director of Pharmacy), or a clinical area manager where there are limited or no pharmacy service).

The content within the Framework may also apply to a range of other health settings in the private sector and non-hospital environments (e.g. residential aged care facilities, supported residential services) and should be applied with consideration to the unique requirements of the intended setting.

Introduction

The Framework provides Victorian health services with guidance for the management of medicines listed as Schedule 9 (S9), Schedule 8 (S8) and Schedule 4 Drugs of Dependence (S4D) in The Poisons Standard (SUSMP). The Framework considers the legal, environmental and practical requirements to ensure compliance with Victorian legislation, Australian Standards and National Safety and Quality Health Service Standards and best practice guidelines. The framework does not cover for all circumstances and local practices; therefore, consideration of local context is required when applying this guidance.

The HSP holder is primarily responsible for the possession, storage, use, record of transactions of scheduled medicines and compliance with other requirements. The manner in which compliance is achieved is detailed within the conditions of the HSP and in the online form specific to that permit holder when obtaining, reviewing or amending the HSP for that health service. Whilst these requirements will be similar to those contained in the Victorian regulations, the most recently completed Medicine Poisons Regulation online form might contain requirements that **are more specific or additional** to regulatory requirements.

Scope of a pharmacy technician

Pharmacy technicians support the pharmacist in the delivery of pharmacy services. Pharmacy technicians are not listed as authorised persons in *The Act* and *The Regulations*. All activities performed by a pharmacy technician must be under the supervision of a registered pharmacist. Pharmacy technicians can assist the pharmacist to prepare, dispense and supply medicines suited to their level of competence, training, and experience at a point in time[14]. Tasks and responsibilities of pharmacy technicians are outlined in *Standard of Practice in Dispensing and Distribution for Pharmacy Services*[15] published by Advanced Pharmacy Australia and are applicable in this framework for handling S4D, S8 and S9. Additional activities assigned to pharmacy technicians must be in accordance with the Pharmacy Board of Australia guidelines and Advanced Pharmacy Australia standards of practice guidelines[14,15,16,17].

Scope of medicines applicable to this framework

The Framework applies to medicines that are:

- Schedule 9
- Schedule 8
- Drugs of Dependence as defined and listed in Schedule 11 of *The Act* for the state of Victoria
- Schedule 4 Drugs of Dependence (S4D)
- Medicines Subject to Misuse (MSM) which may be S2, S3 or S4 medicines that require additional controls similar or equal to S4D medicines[6].
    - The *Assessment tool for medicines subject to misuse (MSM) that may require additional controls* (see appendix 1) has been developed to assist health service perform a local risk assessment of medicines subject to misuse. The resultant agreed decisions regarding how to manage these medicines (i.e. S4D or S8), the relevant recommendations in this framework will apply.

Table 1 lists examples of medicines with the potential for harm or unsafe use within scope of the framework. This is not an exhaustive list, however, provides a guide of common S9, S8, S4D, MSM. Consult legislative instruments for more detailed information.

Table 1. Medicines with potential for harm or unsafe use[18]

Schedule	Medicine class	Medicines
S9	Prohibited Substances	● Cannabis ● Dimetamfetamine ● Heroin ● Methylenedioxymethamphetamine (MDMA, commonly known as Ecstasy, when not in Schedule 8) ● Psilocybin (when not included in Schedule 8) ● Synthetic cannabinomimetics ● Tetrahydrocannabinols (when not in Schedule 8) ● Clinical trial medicines classified as S9
S8	Controlled Drugs	Benzodiazepines (except when included in Schedule 4) ● Alprazolam ● Flunitrazepam Opioids

		● Buprenorphine ● Codeine ● Fentanyl ● Hydromorphone ● Methadone ● Morphine ● Oxycodone ● Pethidine ● Remifentanil ● Tapentadol Stimulatnts ● Dexamphetamine ● Lisdexamfetamine ● Methylphenidate Other ● Nabiximols (botanical extract of Cannabis sativa as defined in The Poison Standard 2024) Cannabis (when not in Schedule 9) ● Cocaine ● Ketamine ● Methylenedioxymethamphetamine (MDMA) ● Psilocybin ● Tetrahydrocannabinols (when extracted from cannabis for human use as defined in The Poison Standard 2024) ● Clinical trial medicines classified as S8
S4D/ S11	Drugs of Dependence	Benzodiazepines (except when included in Schedule 8) ● Bromazepam ● Clobazam ● Clonazepam ● Diazepam ● Lorazepam ● Midazolam ● Nitrazepam ● Oxazepam ● Temazepam Sedating medicines ● Chloral hydrate ● Phenobarbitone (phenobarbital) Stimulants ● Phentermine ● Pseudoephedrine containing preparations Steroids

		● Anabolic steroidal agents Other ● Cannabidiol (as defined in The Poison Standard 2024) ● Clinical trial medicines classified as a medicine with potential of drug dependence
MSM[#]		Analgesic ● Cannabidiol (as specified in *The Poison Standard Schedule 3*)[18] ● Codeine containing preparations (e.g. paracetamol with codeine preparations where codeine is ≥ 15mg) ● Gabapentin ● Pregabalin ● Tramadol Sedating medicines ● Zopiclone ● Zolpidem Antipsychotic ● Quetiapine Anaesthetic medicines ● Methoxyflurane ● Propofol ● Thiopentone
Unknown/ illicit substances		Examples include ● Amphetamine, including crystal methamphetamine (ICE) ● Illicitly used prescription medicines and their analogues ● Lysergic acid diethylamide (LSD) ● Unidentified substance

[#]It is recommended health services determine a list of MSM using a risk assessment approach, refer to Appendix 1: Assessment tool for medicines subject to misuse (MSM) that may require additional controls

Deviations from the recommendations in the framework

The Framework provides recommendations based on the minimum legislative requirements as defined in Victorian legislation and what is considered best practice across health services. Due to a myriad of circumstances, deviations from these recommendations may occur. It is recommended under these circumstances the health services, in consultation with relevant key stakeholders:

1. Document the deviations against the recommendations in this framework **AND**
2. Conduct a risk assessment of the deviation **AND**
3. Describe how the deviations will affect any identified risks and operational workflows **AND**
4. Where an alternate approach is considered, define the purpose **AND**

5. Obtain endorsement from the Standard 4 Medication Safety Committee and other stakeholder committee/groups as required.

1. Storage and Security

This section covers the following topics:

- **Storage facilities** - recommendations on types of storage facilities including portable storage units (e.g. anaesthetic and resus trolleys)
- **Security systems** – recommendations on how to store medicines securely including keys, combination code access, swipe card access, biometric authentication and closed-circuit television (CCTV)
- **Pharmacy department access** - recommendations on maintaining secure access to the department by pharmacists and pharmacy technicians (in the presence of a registered pharmacist)
- **Storage of patient own medicines** - recommendations for storing patient own medicines and dispensed medicines for discharge or outpatients

Storage and security requirements for S9, S8 and S4D medicines are covered in Victorian legislation and must be adhered to at all times:

- *The Act* Part XI- Regulations, 129 Regulations
- *The Regulations* Division 2 – Storage Regulations (73) (74) (75) (76)

The Framework provides additional best practice guidance on storage and security for S4D and MSM. While managing and maintaining access to storage facilities is the responsibility of clinical area managers, security departments can provide support.

1.1 Storage facilities

1.1.1 Storage requirements for S9, S8, S4D and MSM

Store S9, S8, S4D and MSM in storage facilities with the required specifications as outlined in *The Act* and *The Regulation*[4,8]:

- General Security Requirements – Schedule 4 poisons, Regulation 73(1)(2)(3)
- Storage of Schedule 8 and 9 poisons and drugs of dependence, Regulation 74(1)(2)(3)

Additional guidance on secure storage requirements for S4D and MSM to mitigate potential diversion, theft or loss is not currently specified in *The Act* and *The Regulations*. Where space does not permit, S4D as defined in Schedule 11 of *The Act*[8] can be stored in the same storage facility as S9 and S8 medicines. Consider the risks associated with this practice, including accessing highly restricted medicines more frequently than clinically necessary[8].

Recommendations for storage of S9, S8, S4D and MSM to reduce diversion, theft or loss

- Store S9 and S8 medicines separately to S4D and MSM in accordance with legislative requirements
- Store S9 and S8 medicines in a secure storage facility in accordance with *Regulation 74(1)(2)(3)*

- Store S4D and MSM in a secure storage facility in accordance with *Regulation 73(1)(2)(3).* This may include:
    a. Open shelf or unlocked cupboard in a secure area, or
    b. Locked cupboard installed in such a way it cannot be easily removed, or
    c. A safe of equal compliance as described in *Regulation 74(2)*

- Separate storage of S9, S8, S4D and MSM from other scheduled, non-scheduled medicines and non-medicine items such as keys, swipe access cards, money or other personal items

- Refrigerated medicines to be stored in a medicine fridge that can be secured to prevent unauthorised access
    a. Where secure refrigerated storage is not available, consider the stability and expiry of medicines at room temperature and whether short term storage in an unrefrigerated safe is appropriate

- Locate storage facility in a secure storage area (e.g. medicine room, theatre/procedure room, pharmacy department) or in a secure clinical location* to restrict access to medicines to authorised persons.

**Where ADC are being used please refer to the Victorian Framework for the Safe Implementation of Automated Dispensing Cabinets for guidance on ADC placements*

1.1.2 Automated dispensing cabinets as secure storage facilities for S9, S8, S4D and MSM

Automated dispensing cabinets (ADC) are considered an electronic lockable storage facility. ADC generally have in-built features that offer:

- A variety of medicine storage options, such as drawers, shelves and bins to accommodate various medicines.
- Enhanced security features that prevent unauthorised access to medicines such as biometric authentication and tamper evident locks.[4,19]

Regulation 74(3)(b) states electronic storage equipment must provide at least equivalent security requirements as outlined for storage facilities of S9 and S8 medicines[4].

Refer to the *Victorian Framework for the Safe Implementation of Automated Dispensing Cabinets* for additional information.

1.1.3. Storage and security measures for S4D and MSM stored in portable storage units

Portable storage units include equipment or apparatus that can be easily removed. These units are usually accessed during time critical periods to facilitate patient care.

Examples of portable storage units:

- Trolley (anaesthetics and emergency)
- Emergency bags
- Tackle boxes for kits for emergency use (e.g. stroke kits)

Under a valid health service permit, some medicines may be stored in portable storage units. Note that Schedule 8 and Schedule 9 medicines cannot be stored in portable storage units.

Recommendations for security measures for portable storage units storing S4D and MSM

- **Secure the unit with either**
  - Tamper evident security tag with individualised serial number
  - Key lock
  - Pin code combination (e.g. pin code pad on the trolley or code lock).
    - Codes to be changed every 6 months or sooner if code breach identified.
  - Tamper proof seals

- **Store securely**
  - Store emergency bags or tackle box kits within the storage facility (e.g. medication room) separate from other medicines stored in the facility
  - Stow trolleys in a designated area accessible only by authorised persons

- **Ensure direct supervision by an authorised person(s) when in use**

- **Perform and record security checks by authorised person(s).** May include:
  - Physical inspection of portable unit to ensure it is secured when not in use
  - Integrity of the security modality (e.g. tamper evident security tag is secured or tamper proof seal is not broken)
  - Regular checks where the frequency is determined by completing risk assessment Suggestions include:
    - At least once per day
    - At each time the portable storage unit is access
    - At the same time as expiry date checking of medicines stored in the unit

- **Review medicines regularly for appropriateness**
  - Medication Safety Committee (or equivalent) in consultation with other key stakeholders' review and endorses medicines stored in portable storage units

1.2 Security systems for storage facilities

Systems to control access to storage facilities vary depending on the facility. A multifaceted approach is recommended to securely store S9, S8 and S4D and MSM medicines to mitigate risks of diversions, theft and loss.

Security systems for storage facilities:

- Keys
- Code combination
- Swipe card access
- Biometric authentication
- Close Circuit Television (CCTV) is an additional security system that may be used in combination with other security systems in all areas storing S9, S8, S4D medicines

1.2.1 Keys

Systems to control access and security of the keys are required.

Recommendations for handling keys

- **Keys should not be able to be easily copied**
  - Director of Pharmacy (or delegate) or poison permit holder may authorise procurement of keys
- **Store keys securely and separately from medicines.** Examples include:
  - Key safe (accessible by a key or code combination) with similar level of security to the S8 safe accessible only by authorised person(s)[20]
  - ADC in an individual compartment separate to other scheduled medicines
  - A copy of the key to remain in pharmacy department at all times
  - ADC security override keys to be kept in the pharmacy department and retrieved by authorised person(s) when ADC is down
- **Only authorised persons to have access to keys *(refer to Table 2)***
  - Where storage facilities are located in a pharmacy department registered by Victorian Pharmacy Authority, access is restricted to pharmacists only
- **Maintain a record of access to keys**
  - Document unique ID key number and authorised person(s) who accessed the keys. Details may include date and time key was accessed and returned
- **Ensure keys are in the possession of an authorised person at all times when in use**
  - Return keys to the secured location when not in use

Table 2. Access to keys that unlock storage facilities

Storage facility	Registered pharmacist	Intern Pharmacist	Pharmacy Technician	Registered nurse	Medication-endorsed enrolled nurse	Registered midwife	Registered nurse practitioner	Registered medical practitioner
S9 and S8	✓	✓ *	X	✓	✓	✓	✓	✓
S4D and MSM	✓	✓ *	✓ *	✓	✓	✓	✓	✓

**Under the supervision of an authorised person, usually a pharmacist, as defined in the Victorian legislation[4,8]*

1.2.2 Code combination

Systems to control knowledge and communication of code combinations are required.

Recommendations for code combinations

- **Managed by clinical area managers**

- **Communicated verbally to authorised persons who require access to medicine within scope of practice**
    - Ensure codes are not written and/or visible to unauthorised persons to ensure security of the code. For example:
        - Not published in procedures
        - Not communicated via email or other written means
        - Not displayed

- **Changed every 6 months**
    - Codes can be changed earlier in the event of suspected or known inappropriate access

- **Maintain a record of past and current code combinations and store in a secure manner**
    - Example: stored in locked electronic file or location only accessible by clinical area managers

1.2.3 Swipe Card Access

Card reader devices can be installed and configured to unlock storage facilities. Cards that may be configured to unlock storage facilities may include:

- Identification cards of authorised persons
    - Configure access to scheduled medicines based on employment designation and scope of practice (e.g. registered nurse versus pharmacy technician)
- Blank cards (also referred to as *loan cards*)
    - To be issued to bank or casual staff, who are authorised persons to access medicines during their rostered shift
    - Clinical area managers are responsible for the appropriate allocation of loan access cards

Swipe card access:

- Reduces the burden for code combination and key management
- Enables real-time monitoring of access to scheduled medicines
- Generate a log of access on centralised database. Data may be used for auditing and incident management purposes.

Recommendations for swipe card access

- **Centrally managed by clinical area manager in collaboration with security and human resource departments**
    - Clinical area managers inform security department of authorised person designation and level of access required to storage facilities and storage areas.
    - Configure access that is within scope of practice of authorised person
    - Strongly recommend additional measures are in place to ensure security personnel only enable authorised staff access to scheduled medicines within their scope of practice.

- **In possession of an authorised person at all times**
    - Ensure there is no sharing of swipe cards between staff

  - Ensure swipe cards are not left unsupervised (e.g. on benches, in office areas or patient areas)
  - Store loan access cards securely

- **Card readers are configured with dual card access to unlock the S9, S8 and S4D safes/ locked cupboards**
  - Wherever possible, two cards are required to contact the card reader to unlock the facility. For example:
    - Two authorised persons each swipe their card against the card reader to unlock the facility and access medicines
    - Where single card access is configured, health services are advised to
      - Assess practice and identify potential risk
      - Limit single card access to high acuity areas where single authorised person may practice or timely access to medicines are required, for example, resuscitation rooms or rural and remote areas where two authorised persons may not always be available.
- **Maintain a record for loan cards**
  - Document unique card number and authorised person(s) issued the card, date and time card was accessed and returned

- **Business continuity plan during swipe system failure**
  - Override access measures are implemented. For example:
    - Access points (e.g. medication rooms doors and/or safes) to be fitted with BiLock key access. These keys are to be kept with pharmacy department and/or after- hours site manager
    - Swipe override access key to medication rooms and/or safes issued to clinical area managers from pharmacy

1.2.4 Biometric Authentication

Biometric authentication provides a robust system to prevent unauthorised access to medicines and is the preferred method to access storage facilities. Fingerprint scan is an example of biometric authentication. Biometric authentication is usually the preferred method of accessing ADCs.

Recommendations to manage biometric authentication

- **Clinical area manager configures access for authorised persons**
  - Align access with the designation and scope of practice of the authorised person(s)

- **Access to include biometric authentication in combination with one other authentication method (where possible)**
  - For example, biometric data AND manual entry of username and/or password
  - Access information must not be disclosed to any other persons

- **Securely store biometric data**

- Consult vendors to ensure stored data can resist cyberattack and unauthorised access

1.2.5 Closed-Circuit Television (CCTV) System

The Victorian Pharmacy Authority (VPA) and Advanced Pharmacy Australia (AdPha) Standard of Practice in Dispensing and Distribution for Pharmacy Services, recommend CCTV monitoring in pharmacy dispensaries[15,20]

In addition, health services should aim to install CCTV monitoring in areas where S9, S8, S4D and MSM are stored outside of pharmacy dispensaries (e.g. in clinical areas and medication rooms). Health services should ensure policies are in place to govern routine maintenance and review of CCTV system infrastructure as required.

CCTV monitoring systems:

- Enable real-time monitoring of activities near scheduled medicines
- Record video footage that may be used for auditing and incident management purposes

Recommendations for CCTV systems:

- **Install CCTV in areas where medicines are stored and accessed by authorised person(s)**
  - At a minimum, within pharmacy dispensaries
  - Where possible, in all storage areas (e.g. medication rooms) and all clinical areas where storage facilities are located (e.g. ADC unit located in a clinical area outside the medication room)
- **Record footage 24 hours 7 days per week**
  - Connectivity breaches are to be escalated to the clinical area manager and vendor to be investigated
- **Link CCTV to security department or external security company[18] to enable tamper-proof remote viewing**
- **Maintenance of CCTV is performed regularly**
  - Check to ensure infrastructure is fit for purpose

1.3. Security measures to access pharmacy departments storing S9, S8, S4D and MSM medicines

Victorian Legislative instruments[4,8,20] outline the security measures required to access pharmacy departments. Only registered pharmacists are authorised to control access to the pharmacy department. In the presence of a registered pharmacist, intern pharmacists, pharmacy technicians, and pharmacy students may access the pharmacy department.

Recommendations to manage access to pharmacy department(s)

- **Maintain a record of registered pharmacists who have access to the department**
  - Responsibility of the Director of Pharmacy (or delegate)

- **Implement systems to identify person(s) entering and exiting the department(s) including after hours.** For example:
  - Card access to the department
    - The Director of Pharmacy (or delegate) liaises with the security department to configure card access based on staff designation and scope of practice
    - A record is maintained that ideally, date and time stamps access
  - Key access to the department
    - The Director of Pharmacy (or delegate) maintains a record of keys issued to the pharmacists. Details may include:
      - Unique key ID number
      - Name of registered pharmacist
      - Date and time key issued and returned
  - Alarm code access to the department
    - The Director of Pharmacy (or delegate) together with registered pharmacist programs a unique alarm code assigned to the pharmacist to disable alarm in the pharmacy department(s)
    - Pharmacist must not share their code with other pharmacy staff

1.4 Storage of S9, S8, S4D and MSM medicines dispensed to a patient

For patient's own medicines, refer to *7. Managing Patient Own Medicines (POMs) section.*

1.4.1 Inpatient supply and dispensed discharged medicines

Inpatient dispensed medicines:

- Supplied from pharmacy department(s) for use during inpatient stay at the health service
- Medicines may be individually dispensed to the patient or distributed to the clinical area upon receipt of a prescribed order or requisition request
- Nurse administers these medicines to the patient
- Medicines are not given to the patient at discharge
- Medicines are stored in a secure locked storage facility within the clinical area

Discharge dispensed medicines:

- Supplied from pharmacy department(s) for a patient to continue administration after discharge from the health service
- Medicines are supplied to the patient in accordance with legislative requirements*, Part 3 – Prescriptions (16 -17A)(20)(21)(24)* of *The Regulations* and best practice guidelines *Pharmacy Board of Australia Guidelines for Dispensing Medicines, March 2023*
- Medicines are provided to the patient at the point of discharge. The medicines are then in the patient's possession and can remain with the patient

Recommendations to store dispensed inpatient or discharge S9, S8, S4D and MSM medicines *in pharmacy* prior to delivery to the clinical area and/or patient

- **During pharmacy operating hours:**

- **Store medicines in the dispensary, under supervision of the pharmacist**

- **Assemble medicines securely**
  - Example: medicines stored in sealed brown paper bags, in designated baskets for collection by an authorised person(s)

- **<u>At close of pharmacy business and after pharmacy operating hours:</u>**
  - **Store uncollected medicines in a tamper evident manner**
    - For example, tamper evident bag that is sealed

  - **Store medicines separate from regular stock in the storage facility**
    - Store medicines in the storage facility suitable for the schedule of the medicine (e.g. S8 safe for S8 medicines, locked cupboard for S4D medicines)
    - Store medicines separately from regular stock kept in the storage facility to minimise selection error (e.g. store on a separate shelf)[5, 8, 18, 20]

  - **Record transaction of medicines in a register** (see transaction section 2)

Securely store dispensed discharge medicines where there is an expected minimum time delay of greater than 60 minutes between the patient receiving discharge medicines from the pharmacist and when they physically leave the health service. This is to ensure medicines are not diverted, lost or stolen.

Recommendations for secure storage of dispensed discharge S9, S8, S4D, MSM medicines in *<u>clinical area</u>*

- **Obtain patient consent to retrieve and securely store medicines**
  - Discharged medicines are now in the patient possession and are their medicines. Document consent in patient medical record

- **Store medicines in a tamper evident manner.** Examples include:
  - Tamper evident bag that is sealed and labelled with patient identification
  - Tamper proof seal applied on the medicine
  - Proprietary pack is already tamper proof

- **Store medicines separate from imprest medicines within the storage facility**
  - Store medicines in the storage facility suitable for the schedule of the medicine (e.g. S8 safe for S8 medicines, locked cupboard for S4D medicines)
  - Store medicines separately from regular stock kept in the storage facility to minimise selection error (e.g. store on a separate shelf)[5, 8, 18, 20]

- **Record transaction of medicines in a register** (see transaction section 2)

<u>1.4.2 Outpatient dispensed medicines</u>

Outpatients dispensed medicines are usually stored in the pharmacy department until the patient or their carer can collect medicines from the pharmacist.

Consider secure storage arrangements of outpatient dispensed medicines when expected minimum time delay between the patient requesting and collecting medicines is greater than 60 minutes. This is to ensure medicines are not diverted, lost or stolen.

Recommendations for storing outpatient dispensed S9, S8, S4D and MSM medicines

- **<u>During pharmacy operating hours:</u>**
  - **Store medicines in the dispensary, under supervision of the pharmacist**
  - **Assemble medicines securely**
    - Example: medicines stored in sealed brown paper bags, in designated baskets for collection by an authorised person(s).
- **<u>At close of pharmacy business and after pharmacy operating hours:</u>**
  - **Store uncollected medicines in a tamper evident manner**
    - For example, tamper evident bag that is sealed
  - **Store medicines separate from regular stock in the storage facility**
    - Store medicines in the storage facility suitable for the schedule of the medicine (e.g. S8 safe for S8 medicines, locked cupboard for S4D medicines)
    - Store medicines separately from regular stock kept in the storage facility to minimise selection error (e.g. store on a separate shelf)[5, 8, 18, 20]
  - **Record transaction of medicines in a register** (see transaction section 2)

1.5 Pre-packs for S9, S8, S4D and MSM medicines

Pre-packs are referred to in the Framework as a small quantity, a total of 6 divided doses or less of a S8, S4D and MSM intended for emergency use. While Regulation (7) of *The Regulations* allows for a small quantity of S8 medicines to be stored outside of a compliant storage facility (e.g. S8 safe), it is required these medicines are stored in a lockable storage facility.

Implementation of pre-packs may be useful for the following circumstances:

- For health services that do not have an on-site pharmacy service available 24 hours 7 days per week
- For patient's who lives in a rural or remote area where access to a community pharmacy is not practicable, the patient would suffer hardship to access medicines that may compromise patient safety

Recommendations for pre-packs

- **Complete a local risk assessment**
  - This may include consultation with multiple stakeholders to assess the clinical need for pre-packs, risks to the organisation, staff and patients
- **Endorsement from Medication Safety Committee and other key stakeholders**
- **Develop a governance procedure for use of pre-packs.** This may include:
  - Indications for use, applicable clinical areas and requirements for storage, transactions and record requirements
  - Obtaining prescriptions for access to pre-packs is recommended, enables SafeScript transaction record to be made

- **Maintain a record to monitor use.** For example:
    - A register to record pre-pack quantities, patient details who were issued a pack

2. Transactions and Records

This section covers the following topics:

2.1 Records - includes types and persons authorised to maintain records, the role of the intern pharmacist and pharmacy technician.

2.2 Transactions - includes different types of transactions, persons authorised to document transactions across the clinical and operational pharmacy services continuum

2.1 Records

Examples of a ***record*** include:

- Registers (paper based or electronic) to record the receipt, supply and administration of medicines. Refer to Appendix 2 for recommended format of a paper-based register.
    - Examples of a paper-based register may include (but not limited to):
        - S4D register
        - S8 Controlled Medicine register
        - Patient own S8 and S4D register
        - Transfer register
        - Register to record the distribution of paper-based registers
- Distribution slip (for supply)
- Requisition slip (for supply)
- Delivery docket (for supply)
- Dispensing record (for supply)

2.1.1 Authorised persons to maintain records

Refer to *The Act Section 32 Record Keeping in Relation to Sale or Supply of Drugs of Addiction* and *The Regulations Part 13 Records* for authorised persons required to keep records of transactions for S9, S8, S4D medicines. Transactions involving MSM may be subject to the same legislative requirements for recording transactions as S9, S8, S4D[4,8]

One authorised person is required to keep records of transactions for S9, S8, S4D and MSM[4]. Authorised person(s) include[4]:

- Registered medical practitioner
- Registered nurse practitioner
- Registered midwife
- Registered nurse
- Registered pharmacist

Regulation 108 of *The Regulations* requires an authorised person as soon as practicable after completing a transaction to document particulars required for the transaction. Where an emergency exists, a record must be documented within 24 hours of the transaction. In addition, Regulation 109 of *The Regulations* outlines requirements for S8 and S9 transactions.

2.1.2 Types of records

- Bound paper-based register book with consecutive numbered pages
- Electronic registers (e.g. HS8)
- Prescription duplicates
- Invoices from wholesalers
- Dispensing and distribution records

For S9 and S8 a separate record is required to the dispensing record (e.g. S8 register to record transactions). For S4D and MSM, the dispensing record is sufficient to constitute a record although, it is best practice across health service to also maintain a separate record of transactions.

Recommendations to recording transactions for S4D and MSM

- **Record transaction in the same manner as required for S9 and S8.** For example:
  - In a separate register (e.g. paper based or electronic)
  - Details of the transactions as specified in Regulation 108 of *The Regulations*
    - Name of patient / suppliers
    - Medicine name, form, strength and quantity of the medicine
    - Balance
    - Name of authorised person completing transaction

2.1.3 Storing records

Authorised persons are responsible for the storage of records. Access codes of authorised persons to electronic records, are not to be shared amongst staff[4]. Store records in accordance with Regulation 109 of *The Regulations.* Where records are managed by the pharmacy department, additional measures may be implemented to systemise storage of records.

Recommendations for managing records

- **Maintain a master record of all records in use**
  - This may include a separate register to document:
    - Register number
    - Location for use
    - Distribution date
    - Returned date
    - Archived location

- **Store in a secure manner**. For example:
  - Archived boxes storing paper-based registers in pharmacy department or other secure location accessible only by authorised staff
  - A separate cloud server with restricted access to authorised persons for electronic register data
  - Accessible by biometric authentication. For example, access records on ADC unit

2.2 Transactions

Examples of transactions to be documented in a record include:

- Receipt of medicines from a supplier
- Medicines dispensed for inpatient use, discharge or outpatient
- Medicines distributed/supplied from pharmacy to clinical areas
- Disposal and destruction (including partial discards)

2.2.1 Authorised persons to document transactions

Recommendations for documenting transactions are summarised in:

- **Transactions excluding disposal and destruction:**
  - ***Table 3. Authorised persons to document transactions of S9, S8, S4D and MSM in the clinical setting: Administration of medicines***
  - ***Table 4. Authorised persons to document transactions of S9, S8, S4D and MSM in the clinical setting: Stock management***
    - Includes receipt and delivery of medicines
  - ***Table 5. Authorised persons to document transactions of S9, S8, S4D and MSM in pharmacy departments for supply of medicines***

Regulation 107 of *The Regulation* states only one authorised person (e.g. the primary person) is required to document a transaction in the record. The exception to this rule is for destruction of S9 and S8 medicines as outlined in Regulation 114 and 115 of *The Regulations*. To maintain consistency in practice, it is common place across most health services in Victoria to have two people involved in *all* transactions involving S9, S8, S4D and MSM.

The primary person documenting the transaction of:

- S9 or S8 must be an authorised person
- S4D or MSM may be an authorised person (including intern pharmacist) or pharmacy technician

The term witness means a second person observed and verified the transaction documented by the primary person to be true and accurate and annotates the record with their name and signature.

Persons who can be a witness may include:

- An authorised person (including intern pharmacist) as outlined in *The Act* and *The Regulations*
- Pharmacy technician
- Medication-endorsed enrolled nurse

2.2.2 Pharmacy technicians documenting S4D and MSM medicines transactions

There is a growing movement amongst health services in Victoria to expand the role of pharmacy technicians to expand scope of dispensing practices[14,21]. Examples include technician lead documentation of S4D and MSM transactions in the appropriate record. Transactions documented by pharmacy technicians are to be performed under the supervision of a registered pharmacist. The registered pharmacist is responsible for keeping, maintaining and ensuring the integrity of the record.

Recommendations for health services to implement two pharmacy technicians for documenting transactions of S4D and MSM in records include[14,21]

- **Approved governance systems**
  - Process to train or credential technicians to accurately document transactions
  - Monitor the accuracy of documented transactions
  - Monitor risks and errors that may arise and implement corrective actions

- **Pharmacist to pharmacy technician ratios should ensure appropriate supervision of pharmacy technicians**

Table 3. Authorised persons to document transactions of S9, S8, S4D and MSM in the *clinical setting: Administration of medicines*

	Witness							
Primary person	**Registered pharmacist§**	**Intern Pharmacist+**	**Pharmacy Technician**	**Medication-endorsed enrolled nurse**	**Registered Nurse**	**Registered Midwife**	**Registered Nurse Practitioner**	**Registered Medical Practitioner**
Registered pharmacist§	X	X	X	✓	✓	✓	✓	✓
Intern Pharmacist+	X	X	X	✓	✓	✓	✓	✓
Pharmacy Technician	X	X	X	X	X	X	X	X
Medication-endorsed enrolled nurse	✓	✓	X	✓	✓	✓	✓	✓
Registered Nurse	✓	✓	X	✓	✓	✓	✓	✓
Registered Midwife	✓	✓	X	✓	✓	✓	✓	✓
Registered Nurse Practitioner	✓	✓	X	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	X	✓	✓	✓	✓	✓

§Pharmacist are not usually involved in administration of medicines, however, where another clinician is unavailable, a pharmacist can be a witness for transactions

+ Intern pharmacists must be supervised by a registered pharmacist

Table 4. Authorised persons to document transactions of S9, S8, S4D and MSM in the *clinical setting: Stock management*

	Witness							
Primary person	**Registered pharmacist**	**Intern Pharmacist[+]**	**Pharmacy Technician[#]**	**Medication-endorsed enrolled nurse**	**Registered Nurse**	**Registered Midwife**	**Registered Nurse Practitioner**	**Registered Medical Practitioner**
Registered pharmacist	✓	✓ +	✓	✓	✓	✓	✓	✓
Intern Pharmacist[+]	✓	✓ *	✓	✓	✓	✓	✓	✓
Pharmacy Technician[#]	✓	✓	✓	✓	✓	✓	✓	✓
Medication-endorsed enrolled nurse	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse	✓	✓	✓	✓	✓	✓	✓	✓
Registered Midwife	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse Practitioner	✓	✓	✓	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	✓	✓	✓	✓	✓	✓

[+] *Intern pharmacists must be supervised by a registered pharmacist*

[*] *Although intern pharmacists are considered to be an authorised person (registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession), it is uncommon practice to have two intern pharmacists involved in documenting transactions of medicines.*

 # Excludes S9 and S8 transactions. Pharmacy technicians are not authorised persons to maintain a record for S9 and S8. Two pharmacy technicians can be involved in recording transactions for S4D and MSM, the true and accurate documentation in the record is the responsibility of the registered pharmacist who is supervising pharmacy technician practice.

Table 5. Authorised persons to document transactions of S9, S8, S4D and MSM in the *pharmacy departments for supply of medicines*

	Witness		
Primary person	**Registered pharmacist**	**Intern Pharmacist[+]**	**Pharmacy Technician[#]**
Registered pharmacist	Not required		
Intern Pharmacist[+]	✓	✓ *	✓
Pharmacy Technician[§#]	✓	✓	✓

[+] *Intern pharmacists must be supervised by a registered pharmacist*

[*] *Although intern pharmacists are considered to be an authorised person (registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession), it is uncommon practice to have two intern pharmacists involved in documenting transactions of medicines.*

 # Excludes S9 and S8 transactions. Pharmacy technicians are not authorised persons to maintain a record for S9 and S8. Two pharmacy technicians can be involved in recording transactions for S4D and MSM, the true and accurate documentation in the record is the responsibility of the registered pharmacist who is supervising pharmacy technician practice.

§Pharmacy technician cannot lawfully supply a scheduled medicine to a patient without a pharmacist; however, a pharmacy technician can assist a pharmacist in supplying medicines.

2.2.3 Transactions of supplied and labelled medicines for inpatient use

Patients admitted to a health service may require S9, S8, S4D and MSM dispensed and supplied, for example:

- Labelled for individual patient
- Distribution to the clinical area imprest

Transactions of supplied medicines are to be documented in the appropriate record (*refer to section 2.1 Records*).

Recommendations for details of a transaction

- Generic medicine name
- Dose form, strength
- Date and time
- Clinical area location or patient details (e.g. patient name and unique identifier number)
- Quantity
- Balance
- Name and signature of authorised person(s)
- Distribution number, dispensing record number

2.2.4 Transactions for delivered or collected medicines for inpatient use

Delivery or collection of medicines from the pharmacy department to clinical areas for inpatient use should be recorded to:

- Ensure medicines are not diverted, stolen or lost during transit
- For auditing and incident management purposes

2.2.4.1 Delivery of medicines from pharmacy department to clinical areas

Regulation 7(1) of *The* Regulations outlines authorised persons to have in their possession scheduled medicines for specific purposes who can facilitate the delivery of medicines from the pharmacy department to clinical areas.

Recommendation for *preparing medicines* for *delivery* from pharmacy department to clinical areas

- **Sealed in a tamper evident manner**
  - To ensure medicines are not tampered with after the dispensing process has been completed by a pharmacist
  - Example: tamper proof bag or sealed satchel

- **Record medicines packed inside of the delivery parcel**
  - Example of record
    - Distribution slip
    - Delivery docket
    - Dispensing record
  - Details of the record may include:

- Date, time
- Generic medicine name
- Strength and dose form
- Quantity
- Location of clinical area or patient details (e.g. patient name and hospital unique identifier number)
- Name and signature of pharmacy staff who assembled the medicines
- Security seal number
- Prescriber details (where appropriate)
    - Not a legal requirement to document in the dispensing software for medicines intended for inpatient use. If there is capacity to do so and prescriber details are known, it is recommended to document

Recommendations for *documenting transactions* in records for *delivered* medicines from pharmacy department to clinical area

- **Document medicines for delivery from the pharmacy department**
    - Pharmacy staff member makes a record of the delivery parcel. Details may include:
        - Date, time
        - Delivery parcel identifier (e.g. security seal number)
        - Location for delivery
        - Name and signature of pharmacy staff member

- **Authorised person is to accept delivery of medicines**
    - Authorised person reconciles medicine received against the record in delivery parcel

- **Authorised person requests a witness**
    - Witness reconciles the delivery record to ensure no tampering during transit
    - If correct, the witness annotates the name and signature on the delivery record
    - The delivery slip record is to be returned to the pharmacy department

- **Two authorised persons* document transactions in the appropriate record in the clinical area** (e.g. Schedule 8 Controlled Medicines register). Particulars may include:
    - Patient details (name and UR) or location “from pharmacy”
    - Date and time
    - Medicine particulars: generic name, dose form and strength
    - Quantity
    - Balance
    - Name and signature of two authorised persons, or one authorised person where a sole practitioner is only available

- **Return delivery record to pharmacy department**
    - Keep the physical copy of the record in a secure location in clinical area for collection by pharmacist or pharmacy technician and/or send to the pharmacy electronically (e.g. email/fax). Secure location may include:

- Within medicine storage facility (e.g. medication room), or
- Another agreed upon location

**Single authorised person can maintain the record if they are sole practitioner or the health service has implemented a credentialing system to endorse single persons check and record transactions*

2.2.4.2 Collecting medicines from pharmacy department for inpatient use

Authorised persons may attend the pharmacy department to collect medicines for inpatients use.

Recommendations for documenting transactions in records for *collected* medicines from pharmacy departments

- **Authorised person reconciles medicines collected against the record**
  - Example of record
    - Distribution slip
    - Delivery docket
    - Dispensing record
  - Annotate name and signature on the record

- **Keep a copy of the record in pharmacy department (original or copy):**
  - Retain in pharmacy for record keeping and as evidence that medicines were collected **and/or**
  - Authorised person brings the record (original or copy) with the medicines to the clinical area. The record is used as evidence to show the medicine was not tampered with during transit.

- **On arrival at the clinical area, the authorised person requests a witness**
  - Witness reconciles the delivery record to ensure no tampering during transit
  - If correct, the witness annotates the name and signature on the delivery record

- **Two authorised persons* document transactions in the appropriate record in the clinical area** (e.g. Schedule 8 Controlled Medicines register). Particulars may include:
  - Patient details (name and UR) or location "from pharmacy"
  - Date and time
  - Medicine particulars: generic name, dose form and strength
  - Quantity
  - Balance
  - Name and signature of two authorised persons, or one authorised person where a sole practitioner is only available

- **Return record to pharmacy department**
  - Keep the physical copy of the record in a secure location in clinical area for collection by pharmacist or pharmacy technician and/or send to the pharmacy electronically (e.g. email/fax). Secure location may include:
    - Within medicine storage facility (e.g. medication room), or
    - Another agreed upon location

- **Single authorised person can maintain the record if they are sole practitioner or the health service has implemented a credentialing system to endorse single persons check and record transactions*

2.2.5 Transactions for outpatient and discharge medicines

2.2.5.1 Transactions for medicines stored in the storage facility awaiting patient collection

This section applies when:

- Patient does not collect outpatient medicines on the same day medicines dispensed
- Patient does not leave the health service immediately with an expected minimum time delay of greater than 60 minutes after discharge medicines are given by the pharmacist

In either scenario above, medicines are to be stored in a secured storage facility and a transaction made in a record.

Recommendations for transactions for *uncollected* outpatient or discharge medicines

- **Document transaction in appropriate record**
  - Details may include:
    - Date, time
    - Patient details (name and unique hospital identifier number)
    - Either:
      - Security seal number (e.g. tamper evident bag number)
        - Record medicine name, strength, dose form and quantity on tamper evident bag or secure satchel
      - Medicine name, strength, dose form and quantity (if not using tamper evident storage solution)
    - Name and signature of authorised persons

2.2.6 Transactions for pre-packs medicine

This section applies when:

- Pre-packs are issued to a patient
- Pre-packs are used to facilitate emergency care to a patient

In either scenario, a transaction should be made in a record.

Recommendations for transactions for pre-pack medicines

- **Document transactions in appropriate records**
  - Details may include:
    - Date and time
    - Patient details (name and unique hospital identifier number)
    - Quantity of packs removed from storage facility
    - Balance remaining
    - Name and signature of authorised persons performing the transaction

- Wherever possible, two authorised persons to record transaction

2.2.7 Transactions for medicines received from suppliers for pharmacy stock, direct to clinical area delivery systems and clinical area imprest

Receipt of delivered medicines usually involves a multistep process including:

- Unpack and reconcile delivered stock against delivery invoice
- Document received stock into the appropriate register
- Document received stock into pharmacy dispensing software
- Perform balance check
    - A minimum of two reference points to complete a balance check; dispensing software balance, physical balance and register balance
- Sign invoices/ records
- Returned signed invoices to the wholesaler
- Keep record of invoices in pharmacy

Recommendations for transactions involving receipt of delivery of medicines are outlined in

- ***Table 6. Persons involved in receipt of delivered S9, S8, S4D and MSM for pharmacy stock***
- ***Table 7. Persons involved in receipt of S9, S8, S4D and MSM for clinical area delivery system and imprest items***

Table 6: Persons involved in receipt of delivered S9, S8, S4D and MSM for pharmacy stock

	Unpack and reconcile delivered stock against delivery invoice	Document received stock into the appropriate register	Document received stock into pharmacy dispensing software	Perform balance check	Sign invoices/ records	Returned signed invoices to the wholesaler	Keep record of invoices in pharmacy
Registered pharmacist	✓	✓	✓	✓	✓	✓	✓
Intern Pharmacist[+]	✓	✓	✓	✓	✓	✓	✓
Pharmacy Technician[±∞]	✓	✓	✓	✓	✓	✓	✓

[+] *Intern pharmacists must be supervised by a registered pharmacist*

±Pharmacy technicians must be supervised by a registered pharmacist

∞Pharmacy technicians cannot be primary person to maintain record of balance transactions for S9 and S8, cannot sign records for S9 and S8 and are not authorised persons to keep a record of S9 and S8.

Table 7. Persons involved in receipt of S9, S8, S4D and MSM for clinical area delivery system and imprest items

	Unpack and reconcile delivered stock against delivery invoice	Document received stock into the appropriate register	Perform balance check	Sign invoices/ records	Returned signed invoices to the wholesaler	Keep record of invoices in pharmacy
Registered pharmacist	✓	✓	✓	✓	✓	✓
Intern Pharmacist[+]	✓	✓	✓	✓	✓	✓
Pharmacy Technician[±∞]	✓	✓	✓	✓	✓	✓
Medication-endorsed enrolled nurse	✓	✓	✓	✓	X	X
Registered Nurse	✓	✓	✓	✓	X	X
Registered Midwife	✓	✓	✓	✓	X	X
Registered Nurse Practitioner	✓	✓	✓	✓	X	X
Registered Medical Practitioner	✓	✓	✓	✓	X	X

[+] *Intern pharmacists must be supervised by a registered pharmacist*

±Pharmacy technicians must be supervised by a registered pharmacist

∞Pharmacy technicians cannot be primary person to maintain record of balance transactions for S9 and S8, cannot sign records for S9 and S8 and are not authorised persons to keep a record of S9 and S8.

2.2.8 Transactions for transferred medicines

Medicines may need to be transferred between clinical areas, campuses of a health service or between health services. Authorised persons are to be involved throughout the transfer process and a record of these transactions maintained. Transfer medicines in a secure tamper evident manner to minimise diversion, theft or loss of medicines.

A transfer record:

- Provides a traceable and auditable record of medicines transferred between locations across the health service
- Reduces potential diversion, theft or loss of medicines

Transfer records may include (but not limited to):

- Separate bound paper-based transfer register for each clinical area
    - Reduces risk of clinical area registers being misplaced. Maintains integrity of records of other transactions documented in the clinical area registers
- Paper-based transfer record form
- Paper-based clinical area register (e.g. S8 Controlled Drugs Register)
- Electronic registers (e.g. HS8)

Recommendations for documenting transactions in the transfer record

- Details may include:
    - Date, time
    - Generic medicine name
    - Dose form, strength
    - Quantity transferred
    - Supply location
    - Received location
    - Balance
    - Name and signature of authorised persons

Transactions of medicines between hospitals at time of patient transfer may be difficult to implement and monitor. Alternatively, where medicines are required to be transferred between health services for a patient, dispense and supply medicines from a hospital prescription. Dispensed medicines to be assembled in a tamper evident manner (e.g. sealed brown paper bag, tamper evident bag) and given to the patient.

2.2.9 Single nurse transactions

Single nurse transactions for administered medicines is an evolving practice across health services. This process excludes the need for a witness to document transactions of prepared medicines for administration. Medicines approved for single nurse transactions are to be determined by the health service following a risk assessment.

Single nurse transactions:

- Streamlines the documentation process of transactions at point of administration, enabling timely access of medicines for patients
- Extends the scope of practice of registered nurses

Recommendations for single nurse transactions in health services

- **Completed a risk assessment**
    - This may include assessment of
        - Infrastructure and processes in place to support practice
        - Risk factors to staff, patient and health service
        - Gaps in service that can be addressed with single nurse transactions
        - Audit history of risks associated with transactions and/or record keeping and/or administration incidents that warrant a minimum two persons check
        - Applicable S8, S4D and MSM
        - Clinical areas suitable for single nurse transactions
        - Nursing expertise required

- **Seek endorsement from key stakeholders**
    - For example, Medication Safety Committee, Nursing Leadership Committees

- **Implement a credentialing and learning package**
    - To ensure registered nurses are able to practice in a consistent manner with minimal risk

Where possible, it is strongly recommended to have a witness for all transactions documented in the record.

2.2.10 Balance check transactions in clinical areas and pharmacy departments

Regulation 109 (1b) of *The Regulations* states a true and accurate balance of each S9 and S8 medicine remaining in the person's possession after each transaction is required[4,8].
The Act and *The Regulations* at time of writing do not enforce a true and accurate balance to be maintained for transactions involving S4D and MSM, however, it is considered best practice to do so.

Health services are strongly encouraged to implement balance check transactions for S4D and MSM to the same requirements outlined in Regulation 109 (1b) for S9 and S8

Recommendations on when to complete a balance check

Clinical areas

- **After each transaction for accessed medicines**
    - ADCs
        - Blind counts at the time of each transaction[2]
        - Regular cycle counts can be completed weekly for all accessed medicines[2]

    - Safes/locked cupboard
        - Physical count of medicine accessed at the time of transaction[4]

- **At change of nursing shift in all area's operation 24 hours 7 days per week**
  - For all medicines stored in safes/locked cupboard only

- **At the start and end of nursing shift in areas non-operational 24 hours 7 days per week**
  - For all medicines stored in safes/locked cupboard only

- **In addition, at end and start of new bottle of liquid**
  - To account for overage or loss due to measure

- **Non-accessed medicines on a regular basis (e.g. weekly)**
  - ADCs
    - R*egular cycle count* for all medicines[2]

Pharmacy departments

- **After each transaction for accessed medicines**
  - ADCs
    - *Blind count* after each transaction[2]
  - Electronic registers
    - *Blind count* after each dispensing
  - Safes/locked cupboard
    - Physical count of medicine accessed at the time of transaction[4]

- **For all stock kept in the storage facility**
  - ADCs, safes, locked cupboards
    - Once per week complete regular cycle count and physical stock count. Longer time period for balance check, for example, completed quarterly may be acceptable depending on local risk assessment

Recommendations for balance check transactions

- **Where able, two authorised persons perform the balance check, particularly in clinical areas where access to medicines occurs frequently by many staff**
  - Clinical areas
    - Usually a registered nurse or registered midwife with another registered nurse, registered midwife, medication-endorsed enrolled nurse. A registered pharmacist, nurse practitioner and medical practitioner may also be involved
  - Pharmacy department
    - Usually a single pharmacist documents balance check transaction
    - Pharmacy technicians, intern pharmacists may perform balance check transactions for S4D and MSM medicines. The registered pharmacist is responsible for the accuracy of the record.

- **Inspect packaging of medicines to ensure tamper evident seals are in tact**
  - Check for any damaged products, remove damaged products from storage facility and document as discard in record

- **Count physical stock and reconcile against secondary source of information**
  - Secondary sources of information may include:
    - Documented balance in the record (e.g. S8 Controlled Drugs Register)
    - Balance recorded in the dispensing software

- **Document balance check in the record.** This includes:
  - Date and time
  - Current balance
  - Authorised person's name and signature

2.1.10.1 Carrying balances forward in paper-based registers

Balances of medicines are carried forward to the next consecutive page of the bound paper-based registered. Two authorised persons involved in transcribing balances between pages are to reconcile the balance is true and accurate, document name and signature against the balance transfer in the record.

3. Destruction

This section covers the following topics:

3.1 Authorised persons to perform destruction
3.2 Partial destruction of medicines and records required
3.3 Records required for destruction
3.4 Storage of pharmaceutical waste bins

Destruction of S9, S8 and S4D medicines must be rendered non-recoverable and non-identifiable prior to being disposed of in a pharmaceutical waste bin[4,6,20]. For example, placed in a purpose made medicine disposal kit containing a chemical neutralising agent[7]. Destruction of S9 and S8 medicines requires two authorised persons (see Table 8) as stated in Regulation 115 of *The Regulations*. The exception to this rule is outlined in Regulation 115(4)(6) where destruction of S9 and S8 medicines in a partially used ampoule, or in unused portions of tablets or lozenges, one single authorised person (including any single nurse) can carry out the destruction without a witness[4]. At the time of writing, *The Act* and *The Regulations* do not outline a destruction process for S4D however, it would be considered best practice, where possible, to implement the same destruction requirements as for S9 and S8 to S4D and MSM.

All pharmaceutical waste is to be destroyed by incineration, generally performed by a waste management company[5]. Refer to the *Victorian Framework for handling and disposal of Pharmaceutical Waste* for more information.

3.1 Authorised persons to perform destruction

Destructions that occur on the health service premises must be performed by two authorised persons[4,20,22]. Table 8 summarises authorised persons to perform destruction and Table 9 summarises persons who can document destruction transactions. Registered nurse and a registered

midwife are not authorised to destroy S9 and S8 medicines but may act as a witness to destruction of S9 and S8 medicines in the presence of another authorised person.

Table 8. Authorised persons to perform destruction

	S9 and S8							
	Witness							
Primary person	**Registered pharmacist**	**Intern Pharmacist+**	**Pharmacy Technician**	**Medication-endorsed enrolled nurse^**	**Registered Nurse**	**Registered Midwife**	**Registered Nurse Practitioner**	**Registered Medical Practitioner**
Registered pharmacist	✓	✓	X	✓	✓	✓	✓	✓
Intern Pharmacist+	✓	✓ ~	X	✓	✓	✓	✓	✓
Pharmacy Technician	X	X	X	X	X	X	X	X
Medication-endorsed enrolled nurse*	X	X	X	X	X	X	X	X
Registered Nurse*	X	X	X	X	X	X	X	X
Registered Midwife*	X	X	X	X	X	X	X	X
Registered Nurse Practitioner	✓	✓	X	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	X	✓	✓	✓	✓	✓
	S4D and MSM							
Registered pharmacist	✓	✓	✓	✓	✓	✓	✓	✓

Intern Pharmacist[+]	✓	✓ ~	✓	✓	✓	✓	✓	✓
Pharmacy Technician	✓	✓	✓	✓	✓	✓	✓	✓
Medication-endorsed enrolled nurse^	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse	✓	✓	✓	✓	✓	✓	✓	✓
Registered Midwife	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse Practitioner	✓	✓	✓	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	✓	✓	✓	✓	✓	✓

[+] *Intern pharmacists must be supervised by a registered pharmacist*

^Medication-endorsed enrolled nurse has a different scope of practice to registered nurse. Medication-endorsed enrolled nurses may not be authorised to record transactions of S9, S8, S4D and MSM

~ Although intern pharmacists are considered to be an authorised person, it is not commonplace to have two intern pharmacists involved destruction of S9, S8, S4D and MSM

**Registered nurse (including medication-endorsed enrolled nurse) and registered midwife are not authorised primary person to destroy S9 and S8 medicines but may act as a witness*

Table 9. Authorised persons to document destruction transactions

	S9 and S8 medicines							
	Witness							
Primary person	**Registered pharmacist**	**Intern Pharmacist+**	**Pharmacy Technician**	**Medication-endorsed enrolled nurse**	**Registered Nurse**	**Registered Midwife**	**Registered Nurse Practitioner**	**Registered Medical Practitioner**
Registered pharmacist	✓	✓	X	✓	✓	✓	✓	✓
Intern Pharmacist+	✓	X ~	X	✓	✓	✓	✓	✓
Pharmacy Technician	X	X	X	X	X	X	X	X
Medication-endorsed enrolled nurse*	X	X	X	X	X	X	X	X
Registered Nurse*	X	X	X	X	X	X	X	X
Registered Midwife*	X	X	X	X	X	X	X	X
Registered Nurse Practitioner	✓	✓	X	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	X	✓	✓	✓	✓	✓
	S4D and MSM							
Registered pharmacist	✓	✓	✓	✓	✓	✓	✓	✓
Intern Pharmacist+	✓	✓ ~	✓	✓	✓	✓	✓	✓

Pharmacy Technician	✓	✓	✓ #	✓	✓	✓	✓	✓
Medication-endorsed enrolled nurse*	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse*	✓	✓	✓	✓	✓	✓	✓	✓
Registered Midwife*	✓	✓	✓	✓	✓	✓	✓	✓
Registered Nurse Practitioner	✓	✓	✓	✓	✓	✓	✓	✓
Registered Medical Practitioner	✓	✓	✓	✓	✓	✓	✓	✓

[+] *Intern pharmacists must be supervised by a registered pharmacist*

^Medication-endorsed enrolled nurse has a different scope of practice to registered nurse. Medication-endorsed enrolled nurses may not be authorised to record transactions of S9, S8, S4D and MSM

~ Although intern pharmacists are considered to be an authorised person, it is not commonplace to have two intern pharmacists involved in disposal and destruction of S9 and S8 medicines

#Two pharmacy technicians can be involved in recording transactions for S4D and MSM, the true and accurate documentation in the record is the responsibility of the registered pharmacist who is supervising pharmacy technician practice.

**Registered nurse (including medication-endorsed enrolled nurse) and registered midwife are not authorised primary person to destroy S9 and S8 medicines but may act as a witness*

3.2 Partial destruction of medicines

Regulation 115 (4)(6) of *The Regulations* states a single person can perform a destruction of a partially used S9 or S8 ampoule, vial or unused portion of tablets or lozenges[4,7]. A witness is not required for these destruction and transactions, however, where possible it is best practice to have a witness. Destruction transactions typically take place either at time of medicine preparation or at patient bedside. Authorised persons to perform partial destructions are outlined in Table 10 below.

Table 10. Authorised persons to perform partial destruction and document transaction

	S9 and S8	
Primary person	**Authorised to perform partial destructions**	**Witness where possible**
Registered pharmacist	✓	Best practice to have a witness who is also either a: • Registered pharmacist • intern pharmacist+ • Medication-endorse enrolled nurse • Registered nurse • Registered midwife • Registered medical practitioner
Intern pharmacist+	✓	
Pharmacy Technician	X	
Medication-endorsed enrolled nurse	✓	
Registered Nurse	✓	
Registered Midwife	✓	
Registered Nurse Practitioner	✓	
Registered Medical Practitioner	✓	
	S4D and MSM	
Registered pharmacist	✓	Best practice to have a witness who is also either a: • Registered pharmacist • intern pharmacist • Pharmacy technician# • Medication-endorse enrolled nurse • Registered nurse • Registered midwife • Registered medical practitioner
Intern pharmacist	✓	
Pharmacy Technician#	✓	
Medication-endorsed enrolled nurse	✓	
Registered Nurse	✓	
Registered Midwife	✓	
Registered Nurse practitioner	✓	
Registered Medical Practitioner	✓	

+ *Intern pharmacists must be supervised by a registered pharmacist*

#Pharmacy technician must always have a witness when destroying and documenting destruction transactions. Pharmacy technician must be supervised by a registered pharmacist.

3.3 Records required for destruction and partial destruction

Destruction (whole or partial) of S9, S8, S4D and MSM must be documented in a legally compliant record (also known as a *primary record*) as stated in Regulation 115 of *The Regulations.*

Examples of a record for whole and partial discard include:

- Bound paper-based register (e.g. S8 Controlled Drugs register)
    - Template for paper-based destruction record is provided in **Appendix 2.**
- Electronic registers (e.g. HS8)

Additional examples of records for partial discard include:

- Paper form (e.g. intravenous infusion form with additives)
    - Paper forms do not meet the requirements of a primary record to document destruction transactions, as they are not bound and can easily be misplaced. Therefore, in addition to the use of paper forms, the authorised person is required to document the transaction in the primary record (e.g. S8 Controlled Drugs register).
- Compliant electronic medicine management record for the patient (refer to section 3.3.1 electronic records for partial destruction transactions of infusion medicines)

Details of destruction transaction required in the record are stated in Regulation 115 of *The Regulations* and are required to be completed at the time of destruction by authorised person and witness. This includes:

- Medicine name
- Medicine form (e.g. tablets, liquids, powder)
- Medicine strength
- Transaction date and time
- Quantity destroyed
- Place of destruction
- Method of destruction
- Name of witness

To support the legislative requirements for recording destruction transactions further recommendations are made.

Recommendations for documenting destruction transactions in addition to requirements outlined in Regulation 115 of *The Regulations*

- **Ideally, against the original transaction in the record at the time medicine is prepared, administered or dispensed**
- **As a separate entry in the record**
    - This is required if the destruction is occurring in a separate location to where the initial transaction was made, including partial discards

3.3.1 Electronic records for partial destruction transactions of *infusion medicines*

Electronic medicine management systems, such as an Electronic Medical Record (EMR) may be used to record transactions for partial discard of *infusion medicines (e.g. epidurals containing opioids)*.

The EMR may sufficiently satisfy as a primary record, provided the EMR recording software enables the health service to comply with the provisions of *The Act* and *The Regulations* as outlined in Table 17.

Recommendations for using EMR as a primary record for documenting partial discard or disposal of infusion medicines

- It is advisable health services seek confirmation, from prospective software suppliers, that the software will enable the health practitioner to comply with the legislation and that following the provided operating instructions will ensure compliance with the legislation
- A summary of the recording requirements of electronic records as defined in *Regulations 108 and 109* of *The Regulations is summarised in Table 10*

Table 11. Regulatory requirements for the electronic recording software for documenting partial discards and disposals in EMR

Regulation	Requirements to meet
Regulation 109(4) *Requires that S9 and S8 records must be able to be readily sorted by poison and readily retrievable and produced on demand to an authorised officer.*	To achieve this outcome, the electronic recording software must be auditable and retrieve the required information / required elements.
Regulation 109(6) *Requires that S9 and S8 records are kept in a manner that ensures they cannot be altered, obliterated, deleted or removed without detection*	Only very specialised electronic systems have provisions in place to make it completely impossible for someone to make changes without any detection afterwards. Transactions on the report generated by electronic system that has been revised/altered/deleted **must** give clear indication that it has been altered, detailing the alteration itself within the record.
Regulation 109(7) *Requires that a person keeping records take all reasonable steps to ensure the person's personal access code for making an electronic transaction record for S9 and S8 medicines or is not known or used by another person*	The electronic recording software should have capacity for personal access codes and users must ensure codes are kept private to ensure that any record bearing the name of an authorised person was made by that person and not made fraudulently by someone else.
Regulation 108 and 115(4) *Outlines the details to be contained in records*	Electronic recording software should have the capacity to capture the following details: ● The details of the medicine, including: ○ Name of the medicine ○ Form of the medicine (e.g.: tablets, liquid, powder etc)

	○ Strength of the medicine ● Date of the transaction ● Quantity of the medicine involved ● The method of destruction ● The place of destruction ● The names of the persons carrying out the destruction; and ● The names of relevant witness(es)

3.4 Storage of pharmaceutical waste bins

The Environment Protection Authority (EPA)'s Clinical and Related Waste – Operational Guidance regulates the storage, transport, treatment and disposal of pharmaceutical waste in Victoria. Pharmaceutical waste bins which have additional security measures, including brackets or locks, are preferred to ensure the waste is secured in clinical areas and pharmacy departments prior to being removed for disposal[7].

Recommendations to storing pharmaceutical waste bins

- Stored in a secure location accessible only by authorised person(s) when in use[4,8] (e.g. medication room, pharmacy department)
- Bins ready for disposal in clinical areas and pharmacy departments are to be removed and replaced immediately, where possible.
  - If unable, store in a secure location only accessible to authorised persons (e.g. medication room, locked cage at the supply loading dock of the hospital)
- Bins are transported by authorised personnel for incineration

4. Transport

This section covers the following topics:

4.1 Secure storage solutions when transporting medicines

4.1 Secure storage solutions when transporting medicines

Medicines are to be secured in a concealed, tamper evident manner prior to transport to minimise the potential for diversion, theft or loss[4]. For inter-hospital transfers or transfer amongst regional campuses, attention the sealed package to authorised persons.

Examples of secure, concealed transport solutions include:

- Tamper evident bag (TEB)
- Zip lock opaque bag with security seal
- Enclosed satchel with a security seal
- Enclosed box with tamper evident seal
- Lockable tin containers
- Temperature controlled container with tamper proof seals

Authorised persons to transport medicines are summarised in Regulation 7 of *The Regulations.*

5.Measuring liquids and acceptable loss tolerance

This section covers the following topics:

5.1 Balance checks for liquid medicines
5.2 Acceptable volume discrepancy
5.3 Investigation of unacceptable volume discrepancies

Loss due to measure is commonplace for oral liquid medicines. To minimise loss, commercially available oral liquid formulations without unit dose packaging are to be fitted with either:

- EnFit® adapter cap and EnFit compatible oral syringe used to decant oral liquid **OR**
- An ISO 80369-1 compliant small-bore connector system[23]

5.1 Balance checks for liquid formulations

At time of writing, there is a lack of consensus guidance or practice on how to perform a balance check for liquid medicines. Methods of measure are varied and include either weighing bottles of medicine, using an approximation chart to visually estimate remaining volume or visual estimation of remaining volume of liquid. Health services are to complete a local risk assessment of current practice in clinical areas and pharmacy departments and optimise method used to balance check liquid medicines. Refer to *2.2.9 Balance checks transactions.*

Recommendations for balance check of liquid formulations

- **Performed by two authorised persons**
- **Use a method informed by local risk assessment**
  - E.g. visually inspect the bottle, mark the bottles outstanding volume, weight of bottles.
- **Complete at the start and end of a new bottle**
  - Physically measure the remaining liquid in existing bottle before opening the new bottle. The combined total of liquid is the new balance

5.2 Acceptable volume discrepancy

Volume discrepancies can result from incorrect calculation, missed entries in the record, wrong medicine selected, or a result of misappropriation or diversion of medicines. Volume discrepancies between the recorded balance and physical balance are to be investigated to account for the loss. At the time of writing, there is there is a lack of consensus guidance or practice on what is acceptable volume discrepancy for liquid medicines. Across most health services in Victoria, where the volume discrepancy between the recorded balance and physical balance is more than 5% of the total volume of the propriety container, the discrepancy needs to be investigated as it is less likely due to negligible loss or loss due to measure. Although, volume discrepancies less than 5% should also be investigated to identify the source of discrepancy. Acceptable volume discrepancy threshold and approach to management should be informed by completing a local risk assessment and endorsed by the heath service Medication Safety Committee.

The Medicines and Poisons Regulation Western Australia provide other methods to identify volume discrepancies. These include volume loss per dose or when the volume difference between the physical balance and recorded balance is more than 10mL[24].

Recommendations for *acceptable* volume discrepancy

- **Less than or equal to 5% of the total volume of the propriety container**
  - May not be suitable for small volume liquids (e.g. less than 100mL). In these circumstances a higher threshold above 5% may be used, for example in paediatric and neonatal areas. Consider the acceptable 'per dose' loss described below
- **The total amount lost per dose is less than 0.2 mL/dose measured**[24]
- **Total volume difference between the physical balance and the recorded balance is not significant (for example, not more than 10 mL)**[24]

5.3 Investigation of unacceptable volume discrepancy

A volume discrepancy that exceeds the determined threshold by the health service, would trigger an investigation to identify the loss. *Refer to 8.3.1 Investigating Balance Discrepancies.*

6. Managing Patient Own medicines (POMs)

This section covers the following topics:

6.1 Patient own medicines during admission to the health service
6.2 Dispensed discharge medicines to patient's in clinical areas– particularly when patients do not immediately leave the health service
6.3 Illicit or unknown substances in patient's possession
6.4 Patient's own medicinal cannabis

6.1 Patient own medicines during admission to the health service

Patients may have in their possession their own S9, S8, S4D and MSM. Management of POMS requires consideration of potential risks of misadministration, diversion, theft or loss. Health services are to have policies and procedures in place to govern handling, security, storage and documentation of managing POMs

Recommendations to managing patient own medicines during admission to health service

- **Obtain patient consent to retrieve medicines**
  - Document consent in patient medical record
  - If patient declines to handover POMs:
    - Assessment of risk versus benefits of not retrieving medicines to be considered by the treating clinician including risk of harm to patient and patients treated under the Mental Health and Wellbeing Act 2022. Seek guidance from other stakeholders including legal team, senior clinicians and senior pharmacist
- **Store in a tamper evident manner to reduce risk of loss**

- Example: tamper-evident bag, sealed satchel with unique identifying label
  - Record date, contents within the bag
- Exception may apply if the medicine is prescribed for treatment during hospital admission (e.g. medicinal cannabis, high-cost medicine, clinical trial medicine)

- **Store securely in appropriate storage facility within pharmacy department or clinical area**
  - On a separate shelf within the lockable storage facility (e.g. S8 safe) to reduce risk of selection errors
  - Document storage location in the patient medical record
  - If storage of POMs is not feasible:
    - Patients can maintain possession of their medicines unless there is an identified risk of doing so, for example, a patient enters with a medication overdose in possession of their own controlled substance

- **Record transaction of medicines in the appropriate record**
  - *Refer to section 2. Transactions and Records*

6.2 Dispensed discharged medicines to patient's in clinical areas

Refer to section 1.4.1 for storage and security of dispensed discharge medicines. A time delay of greater than 60 minutes from the time the pharmacist has provided discharge medicines to the patient increases the risk of medicine being lost, stolen, diverted or administered incorrectly and therefore require to be stored securely. Health services are to have policies and procedures in place to govern handling, security, storage and documentation of managing discharge dispensed medicines.

Recommendations to manage discharge medicines when patient remains in clinical area for greater than 60 minutes

- **Obtain patient consent to retrieve medicines**
  - Document consent in patient medical record
  - If patient declines to handover POMs:
    - Assessment of risk versus benefits of not retrieving medicines to be considered by the treating clinician including risk of harm to patient and patients treated under the Mental Health and Wellbeing Act 2022. Seek guidance from other stakeholders including legal team, senior clinicians and senior pharmacist

- **Store in a tamper evident manner to reduce risk of loss**
  - Example: tamper-evident bag, sealed satchel with unique identifying label
    - Record date, contents within the bag

- **Store securely in appropriate storage facility within pharmacy department or clinical area**
  - On a separate shelf within the lockable storage facility (e.g. S8 safe) to reduce risk of selection errors

- If storage of POMs is not feasible:
  - Patients can maintain possession of their medicines unless there is an identified risk of doing so, for example, a patient enters with a medication overdose in possession of their own controlled substance

- **Document location of medicines in patient medical record and inform primary nurse of location**
- **Record transaction of medicines in the appropriate record**
  - *Refer to section 2. Transactions and Records*

6.3 Illicit or unknown substances in patient's possession

These substances can include but are not limited to:

1. Illicit substances
2. Unknown substances
3. Scheduled medicines as specified in The Poisons Standard (The SUSMP)
4. Unscheduled medicines

Health services are to have policies and procedures in place to govern handling, security, storage and documentation of managing patient's own illicit or unknown substances.

Recommendations for managing patient's own illicit or unknown substances

- **Obtain patient consent to retrieve and destroy substances**
  - If the patient refuses to hand over the substance, escalation to Director of Pharmacy and other relevant stakeholders (e.g. legal team, senior clinicians) are required for further discussion of risks and a management plan implemented

- **Store in a tamper evident manner to reduce risk of loss, diversion and theft**
  - Example: tamper-evident bag, sealed satchel with unique identifying label
    - Record date, contents within the bag

- **Store securely in appropriate storage facility within pharmacy department or clinical area (e.g. S8 safe) until destruction can be performed by authorised person**

- **Document location of substances in patient medical record and inform primary nurse of location**
  - In the appropriate record and patient medical record

- **Assess if escalation to notify other stakeholders is required**
  - Senior medical staff, legal department, pharmacist (or Director of Pharmacy) to discuss the requirement for destruction and reporting to Victoria Police while balancing patient safety and risks including risk of harm to patient, staff and patients treated under the Mental Health and Wellbeing Act 2022

- **Authorised person to perform and record destruction of substances**
  - *Refer to section 2. Transactions and Records*

6.4 Patient's own medicinal cannabis

There is a growing number of medicinal cannabis products available in Australia. Cannabidiol (CBD) and tetrahydrocannabinol (THC) are the two main active substances within medicinal cannabis products. The Poisons Standard (the SUSMP 2024) classifies medicinal cannabis products as either S3, S4 or S8 medicines based on the proportion of CBD and THC. THC as a S8. Pure CBD preparations containing two percent or less of any other cannabinoids (including THC) are classified as S4[13]. The Therapeutic Goods Administration approved medicinal cannabis products are listed on the Australian Register of Therapeutic Goods (ARTG)[25]. At the time of writing, medical and nurse practitioners in Victoria can prescribe medicinal cannabis for any patient with any condition if clinically appropriate to do so. For S8 medicinal cannabis products, prescribers are required to check SafeScript each time before prescribing.

Health services are to have policies and procedures in place to govern prescribing, administration, dispensing, security, storage and documentation of managing patient's own medicinal cannabis.

Recommendations for patient's own medicinal cannabis

- **At a minimum, store medicinal cannabis products in accordance with the product schedule and storage requirements outlined in *The Act, The Regulations* and *The Poisons Standard***
  - *However, it is strongly recommended to handle medicinal cannabis products to the same manner as S8 medicines* to provide a consistent approach across the health service and provide additional controls to reduce potential risk of loss, theft and diversion

7. Real Time Prescription Monitoring

In Victoria, SafeScript is an electronic real-time monitored medicine platform that records the prescribing and dispensing of high risk monitored medicines. SafeScript is a clinical tool used by prescribers and pharmacists to support safe, appropriate and judicious use of monitored medicines. SafeScript collects data from prescribing and dispensing software via a prescription exchange service. The data transmission occurs when a prescription is issued or dispensed. Prescribed and supplied medicines to patients other than from a prescription (e.g. for inpatient supply from a charted order) will not be transmitted via the prescription exchange service. Consequently, no data will be collected in SafeScript. For these reasons, other sources of information will be required to support clinical decision making at time of prescribing and dispensing a monitored medicine.

From April 2020, it became mandatory for hospital pharmacists to check SafeScript prior to dispensing a monitored medicine on prescription[11,12]. Regulations 132F, 132G and 132H of *The Regulations* outline exceptions for authorised prescribers and pharmacists to check SafeScript before or at the time of prescribing and dispensing a monitored medicine. While exceptions apply, it is

considered best practice for authorised prescribers and pharmacists to check SafeScript to assist with clinical decision making at time of prescribing and dispensing a monitored medicine for admitted patients at the health service.

Recommendations for the use of SafeScript in health services

- **Integrate into hospital systems**
  - In-built into dispensing software
    - Alert function is enabled to prompt dispensing pharmacist to check SafeScript at the time of dispensing a monitored medicine
  - In-built into electronic prescribing platforms
    - Alerts prescribers to check SafeScript at time of prescription generation of a monitored medicine
  - In-built into electronic medicine management systems to access SafeScript
    - For example, access link embedded into the banner bar of EMR
- **Encourage use to support clinical decision making**
  - Access SafeScript when:
    - Clinician performs a best possible medication history
    - Prescriber chart/ prescribes a monitored medicine
    - Pharmacist dispenses a monitored medicine
    - Pharmacist completes a pharmaceutical review of a monitored medicine
- **Document SafeScript review in the patient medical record**
  - Details may include:
    - Date SafeScript was accessed
    - Details of the actions in SafeScript
    - Alert status and colour displayed on patient profile in SafeScript
    - Any comments by the treating clinician/pharmacist for patient management

8. Incident management

This section covers the following topics:

8.1 Notification to The Secretary at the Department of Health and Victoria Police
8.2 Guidance on completing an incident review

Standard 4 Medication Safety requires health services to use established risk management systems to identify, monitor and review risks.

Internal incident management systems (e.g. Riskman) are to be used to record clinical and operational incidents involving S9, S8, S4D and MSM. In addition, and where appropriate, incidents are to be reported to the clinician's professional indemnity provider. Incidents may include a wide range of scenarios including prescribing, administration and dispensing events.

Reportable incidents may include, but are not limited to:

- Wrong patients, dose, route, formulation, concentration, rate, time, storage and handling of medicines
- Clinically significant change in patient care as a result of error
- Unresolved balance discrepancies of medicines
- Damaged or broken medicines (e.g. broken glass ampoule)
- Security compromise to storage facilities (e.g. lost swipe cards or keys accessing locked storage facilities)

8.1 Notification to The Secretary at the Department of Health and Victoria Police

Table 12 below outlines instances where notification to the secretary and Victoria police are required. Notification to The Secretary and/or Victoria Police is to be made as soon as practicable.

Table 12. Notification to Secretary and Victoria Police

	The Secretary at Department of Health	Victoria Police
Regulation 152 Medicine or controlled substance is lost or stolen[4]	✓	✓
Regulation 112 If balance discrepancy remains unresolved after conducting a thorough investigation[4]	✓	X
Regulation 113 Loss, destruction or theft of records of S4, S8 and S9 medicines has occurred[4]	✓	X

8.2 Conducting an incident review

Due to the high-risk nature of these medicines and the clinical and operational workflows required to maintain secure and safe practices, incidents are to be reviewed and an investigation commenced as soon as possible, ideally within five business days. Recurring trends or themes of incidents, may benefit from an in-depth investigation and a report to the Medication Safety Committee (or equivalent).

Recommendations for conducting an incident review

- **Completed by at least two authorised persons**
  - Example: Medication Safety Pharmacist and clinical area manager
- **Multifaceted approach** using four key steps to identify root cause and possible corrective actions (*refer to Table 13*)[15]
  - *Identification:* What is the incident?
  - *Assessment:* Review the incident and identify potential cause
  - *Intervention/prevention:* Identify corrective actions

- *Review:* Audit and monitor changes to practice

8.2.1 Investigating balance discrepancies

An investigation is commenced as soon as possible to:

- Identify the source of discrepancy
- Report the incident (refer to table 12 above)
- Reconcile the record to reflect the true and accurate balance

Table 13. Multifaceted approach to conduct incident review

Steps	Process	Example
1. Identification	Identify if a reportable incident has occurred Initiate investigation as soon as possible[4,20] and log incident (e.g. via Riskman). Notify clinical area manager	Balance discrepancy is identified
2. Assessment	Review the incident and identify potential cause Clinical area manager to investigate with the support of another person (e.g. ward pharmacist, Medication Safety pharmacist)	Clinical area manager to investigate the discrepancy by checking: • Calculations and documentation in the register (to rule out calculation error) • Review the records (National Standard Medication Chart (NSMC)), electronic medical record, administration record, registers (paper-based, electronic and ADC records) to determine if dose administered but not signed out of register • Review the records (NSMC, electronic medical record, administration record, registers) to determine if the dose was refused by patient /not administered and not signed as discarded in register • Review the records (NSMC, electronic medical record, administration record, registers) to determine if wrong strength, quantity, formulation or medicine signed out of register compared to that prescribed ○ Review access reports to storage facilities with swipe card access.

		○ Consider review of CCTV footage if available. ● Check surrounding area to determine if medicine has fallen out of secured storage facility (e.g. safe, locked cupboard) ● Interview authorised persons who completed the transactions and/or performed last balance check related to discrepancy ● Escalate if balance discrepancy remains unresolved
3. Intervention	Identify corrective actions and if escalation to other stakeholders are required Report incident findings	Unresolved balance discrepancies are escalated to either: ● A pharmacist and/or ● Director of Pharmacy (or their delegate) or Director of Nursing (or their delegate) and/or ● Poisons Permit Holder (or their delegate) to report to the Secretary at the Department of Health (e.g. completion of Medicine and Poison Regulation online form and Victoria Police. Documentation: ● Poisons Permit Holder (or delegate) to include report number and Victoria Police Constable name in the incident report logged on the incident management system (e.g. Victorian Health Incident Management Systems (VHIMS)) ● Actual quantity of medicine as a new entry in the register and document reason for correction e.g. *"discrepancy 1x tablet unaccounted for, notified DOP"* Staff management: ● If staff members are suspected of theft, contact internal human resources and legal departments for advice.
4. Review	Audit and monitor changes to practice	• Identify areas for improvement to mitigate risks

		• Audit and review current processes to assess suitability and effectiveness • Audit and monitor changes in practice and report to the Medication Safety Committee and other key stakeholder groups

9. Auditing and Reporting

Standard 4 Medication Safety requires health services to implement quality improvement strategies for medication management. Routine audit and reporting on safety, financial, legislative, operational and clinical risks associated with systems and process for storage, security, transactions, records and transport of medicines are recommended.

Table 14 summarises the recommended audits to monitor risks. Ideally, the persons conducting the audits are not the same staff operating within the area to eliminate bias.

Table 14. Recommended audits for quality improvement and risk assessment

Audits	Frequency*	Points of measure	Who performs the audit?	Where is it reported?
Storage and Security				
Medication room walk-around	Annual	• Are medicines stored in appropriate locations (e.g. medication room, ADC)? • Are medicines stored in a secure manner (e.g. locked medicine room, locked cupboard/safe, ADC)? • Method of access to secured storage area (swipe, keys, codes etc) • Where keys are used, how are they stored (e.g. key lock safe, NIC)? • Where keys are used, is a key register used? • Where keys are used and locked in a key-lock safe, how often is pin code changed? • Are the medicine fridges secured? • Are medicines stored in the appropriate locked storage facility? • Accuracy of transaction records in register, including reconciling MAR/NSMC orders versus register documentation. Includes alerts in electronic registers. • Prescription pad/paper storage • Emergency trolley security • Stock expiry checks • Presence of EnFit syringes and caps for liquid medicines • Correct paper-based registers are used, correct access to electronic register • Correct safe in use / locked cupboard in use • Camera control/ CCTV installed • Only authorised persons have access to medication storage areas and locked storage facilities • Security processes to ensure permitted staff swipe card access to the medication rooms and storage facilities	Poisons permit holder (or delegate) Pharmacist (including intern pharmacist under supervision of a pharmacist) in collaboration with nurse manager or another authorised person	• Medication Safety Committee (or another committee where applicable) • Nursing leadership committee • Head of Unit meetings (where applicable)
Medication storage and security audit • **Including bedside storage of medicine** • **Including imprest review audit (including S8)**	Biannual			
Transaction records				
Register documentation	Biannual	All particulars of the record in registers are documented correctly in accordance with procedures and legislative requirements: • Destruction records • Balance checks • Details include: • Patient identifiers, clinical area location • Date, time • Current balance • Signatures of authorised persons	Pharmacists (including intern pharmacist under supervision of a pharmacist) Nurse manager where pharmacist is not available onsite	• Medication Safety Committee (or another committee where applicable) • Nursing leadership

		• Destruction and disposal documentation • Liquid measurements documented correctly at new bottle opens • Discrepancies • Overwriting of entries and whether errors have been corrected with annotations		committee (where applicable) • Pharmacy meetings • Head of Unit meetings (where applicable)
Aggregate review of schedule 9, schedule 8, schedule 4D and MSM medicines	Annual	• % discrepancies resolved • % discrepancies investigated per procedure requirements • Thematic analysis including medicine schedule, formulation and discrepancy issues	• Pharmacists (including intern pharmacist under supervision of a pharmacist) • Nurse manager where pharmacist is not available onsite	
ADC discrepancy reports: • **Regular Cycle Counts**	Weekly to monthly	• Weekly count reconciles physical stock against record for accessed medicines • Monthly count reconciles physical stock against record for all medicines	• Pharmacist • Registered nurse	
Transport and delivery of medicines				
Records of medicine transaction of transported medicines	Annual (or more frequently where applicable)	Review transaction records for particulars including: • Medicines delivered to intended location (clinical area delivery systems and pharmacy dispensing) • Return deliveries of medications to pharmacy from clinical carea • Requisition and delivery slips are signed by authorised persons • Time of delivery documented	• Pharmacists (including intern pharmacist under supervision of a pharmacist) • Nurse manager where pharmacist is not available onsite	• Medication Safety Committee (or another committee where applicable) • Nurse leadership committee (where applicable) • Pharmacy meetings (where applicable) • Head of Unit meeting

**Audits can be performed at a different frequency based on local risk factors, trends and workforce availability.*

Appendices

Appendix 1: Assessment tool for Medicines Subject to Misuse (MSM) that may require additional controls

PART A: ASSESSMENT TO IDENTIFY A MEDICINE THAT MAY REQUIRE ADDITIONAL LOCAL CONTROLS		
Questions	**Assessment**	**Commentary**
Does the medicine have a high-risk potential for misuse?	☐ Very unlikely ☐ Unlikely ☐ Likely ☐ Very likely	*Risk can be identified from community and professional publications, professional committees or groups, discussion forums*
Is the misuse potential a known risk in our health service?	☐ Very unlikely ☐ Unlikely ☐ Likely ☐ Very likely	*Risk potential for misuse may be informed from local incident reporting trends, themes with reported risks across select areas of practice, raised as a safety-first concern at committee*
Is the medicine also a *monitored medicine* as defined by Department of Health Medicine and poison legislation?	☐ Yes ☐ No	*A list of monitored medicines can be found at Medicines Monitored in SafeScript*
What is the misuse potential of the medicine?	Comment:	*Reflect upon current areas the medicine is used, clinical and operational workflows that may contribute to the risk of misuse. Reflect upon local incident trends and emerging themes that may contribute to the misuse potential of the medicine.*
Are there existing systems to monitor and detect potential misuse already in place?	☐ Implemented ☐ Partially implemented (go to Part B) ☐ Considered but not yet implemented (go to Part B) ☐ Not considered or implemented (go to Part B)	*Reflect upon current workflows, auditing and monitoring processes, do these capture the risk identified for this medicine. Are there improvements to current workflows, audits required to capture and monitor the risk associated with misuse potential?*
Is there infrastructure in place to securely store this medicine as an MSM?	☐ Implemented ☐ Partially implemented (go to Part B) ☐ Considered but not yet implemented (go to Part B) ☐ Not considered or implemented (go to Part B)	*Secure storage conditions as recommended in this framework need to be considered when introducing additional controls on the medicine. Refer to Storage and Security*
What clinical and operational risks will be addressed or mitigated if the medicine was to have additional controls introduced?	Comment	*Risks may include but not limited to diversion, theft, harm to patient and staff, loss of medicines, inappropriate prescribing, administration and dispensing.*

Has the decision to introduce additional controls of the medicine to those of a Schedule 4D or Schedule 8 medicine requirements been discussed and or endorsed by a multi-disciplinary stakeholders group/committee?	☐ Yes (go to Part B) ☐ No	*Where potential for misuse of a medicine has been identified, this risk should be raised as a safety first at a local multidisciplinary committee and/or Medication Safety Committee for discussion.* *Implement a process for clinicians to submit Part A: Assessment to identify a medicine that may require additional local controls form to multidisciplinary review panel to reach consensus to introduce additional control on the medicine.* *Examples of multidisciplinary stakeholder group may include:* ● *Medication Safety Committee* ● *Risk and Quality Improvement Committee* ● *Divisional Clinical Governance Committee* ● *Drugs and Therapeutics Committee* ● *Nursing Leadership Committee* ● *Head of Units Committee*
PART B) GAP ANALYSIS TOOL TO ASSESS ADDITIONAL CONTROLS ON A MEDICINE		
Criteria	**Assessment**	**Commentary**
Governance and Stakeholder Consultation		
Have key stakeholder groups which will be affected by the additional controls imposed on the medicine had their concerns documented and addressed?	☐ Addressed ☐ Partially addressed ☐ Considered but not yet addressed ☐ Not considered or addressed	*Feedback and recommendations proposed by the stakeholder group should inform part of the actions to strategy to add additional controls to the medicine*
Are there policies/ procedures/ protocols in place which outlines how to handle, store and document the use of the medicine with additional controls to that of a Schedule 4D or Schedule 8 medicine?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Health services should have policies/procedures/protocols in place that outline the governance of Schedule 8 and Schedule 4D medicines, which can be updated to include medicines subject to misuse.*
Storage and Security		

Is the immediate storage facility (e.g. safe/cupboard/ADC), stored in a secure manner only easily accessible by authorised persons?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Secure manner includes* *1. Mounted to a wall OR* *2. Located in a medicine room OR* *3. Located in a clinical area only accessible by authorised persons e.g. Biometric ID, swipe access, pin code or key access*
Are there security systems in place to monitor the use of medicine?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Examples of security systems include:* *1. CCTV* *2. Transactions records (paper or electronic)* *3. Automated dispensing systems*
Are there process and system in place to procure, handle, dispense, transport the medicine in a secure manner that minimises risk of diversion, misuse or theft?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Refer to Transaction and Transport sections of The Framework for recommendations*
Are there processes and systems in place to record transactions of the medicine to monitor usage patterns and potential theft, diversion or misuse?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Examples of records include* *1. Electronic records (e.g. electronic registers, electronic medical records)* 1. *Paper-based bound registers* *2. Dispensing reports* *3. EMR reports* *Monitoring may include audits and reports, refer to Auditing and Reporting section of The Framework for recommendations*
Are there processes and systems in place to facilitate the destruction and discard of the medicine?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Refer to the Destructions and Disposal section of The Framework for recommendations*
Clinical impact		
Will the impact to patient and staff safety be significantly affected if the medicine was to have additional controls introduced?	☐ Very unlikely ☐ Unlikely ☐ Likely ☐ Very likely	*Examples where safety is affected may include* ● *Delay to patient care* ● *Medicine not readily accessible in acute clinical scenarios* *Benefits may include:*

		• *Reduce risk of harm, diversion of medicines*
Risk Management		
Are there processes and systems in place to record and investigate clinical and operational workflows of the medicine under additional controls?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Health services should have a procedure which outlines how to identify, report and investigate medication related risks and incidents. Incident reporting systems (e.g. VHIMS) should be used to communicate the risks and used as part of clinical governance strategies. Refer to the Incident Management section of The Framework for recommendations*
Is there an audit and monitoring structure in place, to monitor improvements and risks of the medicine under additional controls?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Refer to the Auditing and reporting section of The Framework for recommendations*
Are there governance structures in place to escalate and discuss improvements and/or risks of the medicine under additional controls?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Examples of a governance structures may include Medication Safety Committee, Nursing Leadership Committee, pharmacy committees, Head of Units committee.*
Education		
Is there educational material available to equip authorised persons with the knowledge and practical skills necessary for the safe, secure and responsible handling of the medicine under additional controls?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Educational material may include reason why for introducing additional controls, how this affects current practice, what system or process has been introduced, how to operate within the system and process, how to escalate for assistance where needed.*
Is there a record of authorised persons completing education and training?	☐ Implemented ☐ Partially implemented ☐ Considered but not yet implemented ☐ Not considered or implemented	*Evidence of staff attendance for education can be used to support the introduction of additional controls and assist in identifying select groups that may require more support.*

Appendix 2: Recommended paper-based register template to record transactions (including destruction)

Note: template is not to scale and will need to be adapted for size of register used

Name of register: ________________________________

Ward/ Department: ______________________________

Year: ____

Reviewer(s):
Sign: __________________
Date: _________________

						Print medicine name, strength and dose form																C = crushed D = denatured E = expelled and absorbed F = fold and cut (patches)		
Date	Time	Balance carried forward from page________															Sign & print name of person accepting delivery or administering/checking this medicine				Notes/ Comments	Discard quantity	Method of disposal (e.g. C)	Print name of person discarding and witness
		Patient name to whom administered or name of supplier	UR Number / invoice number	In	Out												Signature of person	Print name	Signature of person	Print name				
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All destruction of medicines occurs on the premises of the [insert health service name here]

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