Guide to developing a Substance management plan for medicines:

Medicines and Poisons Act 2019 and Medicines and Poisons (Medicines) Regulation 2021

September 2021

Queensland Government

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Disclaimer:

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Transition arrangements for Substance management plans (SMP)
Section 280 of the *Medicines and Poisons Act 2019* (**MPA**) provides that a responsible person is not required to make an SMP until 1 year after the commencement i.e. 27 September 2022.

Introduction

Purpose

This guide has been designed to assist a responsible person at a regulated place to prepare a Substance Management Plan (**SMP**), in keeping with the requirements set out in the Departmental Standard: Substance management plans for medicines (the Standard).

The Standard was developed in accordance with the *Medicines and Poisons Act 2019* (**MPA**) and the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**). It outlines the elements, outcomes and minimum requirements that are to be addressed by an entity in an SMP. An SMP is a tool to assist entities identify and manage known and foreseeable risks specific to how they deal with regulated substances.

The Standard covers all dealings that apply to medicines: manufacture, buy (give a purchase order), possess, supply (including sell, dispense, and give a treatment dose), prescribe or make a standing order, administer, and dispose of waste.

This guide contains all the dealings to be addressed in an SMP, providing examples of material that can be evidenced as demonstrating compliance with the Standard, and other information that may assist in the development of an SMP.

Regulated places and dealings

Schedule 17 of the MPMR specifies the list of regulated places that require an SMP and the person responsible for making the SMP for the type of place.

As indicated in the Standard, not all dealings will apply to the regulated place. The table in Appendix 1 outlines the dealings that the regulated place could *usually* be expected to undertake.

To ensure compliance with the Standard, all regulated places must meet the general requirements outlined in section 1 of the Standard as well as the requirements for each dealing performed at the place.

Using this guide

The examples provided throughout this guide are suggestions for compliance. They are not exhaustive, and not mandated; providing flexibility for regulated places to choose the most appropriate strategies to achieve the required outcome relevant to their individual environment.

Further information

- Departmental Standard: Substance management plans for medicines
- Factsheet: Substance Management Plans for medicines

Guide to preparing an SMP for medicines

Risk identification and assessment

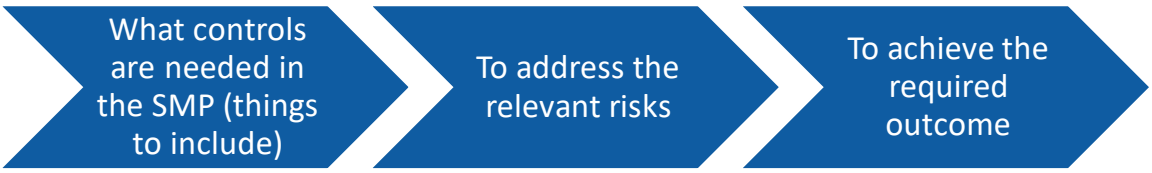
Before preparing an SMP, it is recommended that entities identify the risks associated with medicines handling, storage, use and distribution at or for the place, including the risk that:

- medicines are diverted, stolen or tampered with or otherwise lost
- medicines are not fit for purpose because, for example, they have not been stored within the manufacturers recommended temperature range or have another quality issue
- medicines are improperly or inappropriately used
- staff do not have the necessary competencies or supervision to perform an activity with a medicine
- there is non-compliance with legislation or codes of practice.

Entities should assess each risk for each applicable regulated activity to determine the likelihood of the risk occurring and the consequences. By conducting risk identification and assessment prior to preparing an SMP, entities will be better placed to develop and put in place effective controls to mitigate these risks.

Considerations

An SMP is a tool for entities to establish appropriate governance and oversight to manage known and foreseeable risks. When preparing and reviewing an SMP; entities should think about what needs to be included to manage the relevant risks in order to achieve the outcome required for an SMP.



To be effective, a responsible person for, or in relation to, a place should consider and state in their SMP the following for each of the requirements in the SMP Standard:

- Who, at the place, may carry out the activity (e.g. purchase medicines) for the entity
- In what circumstances, and under what conditions, the person may carry out that activity
- The type and quantities of medicines that may be dealt with
- Whether carrying out the activity can be delegated, and if so, by whom, to whom and how.

Level of detail

An SMP is required for various types of regulated places, from schools and childcare to pharmacies to public hospitals, all of which have medicines for different purposes. As such the range of regulated activities carried out, the nature and size of the risks, and subsequent controls required to mitigate these risks, are expected to differ significantly. In preparing an SMP for a regulated place (a local SMP), a responsible person should consider several factors that will influence the level of detail necessary for the local SMP to achieve the required outcomes and manage the risks. These include:

- The volume of medicines stored and used at the regulated place
- The type of medicines stored and used at the regulated place
- The nature and size of the regulated place (e.g. the number of buildings or separate locations that are covered by the plan, whether members of the public have access to the place)
- The number of persons who will have access to medicines at the regulated place and the skills and experience of persons who will be using medicines
- The type of dealings to be undertaken at the regulated place and the frequency of activities.

Where less detail is needed for a requirement in the Standard, a statement of how the risks will be managed may be sufficient; where more detail is needed for a requirement, entities should consider whether documentation (e.g. policy or procedure) should be prepared. If references are made to external documents, an SMP should state the relevant pages in those documents that address the requirement (in the Standard).

Existing policies and procedures

It is possible to utilise existing policies, standard operating procedures, instruction manuals, or other relevant documentation if they meet the requirements of the Standard. It is expected that many regulated places will have existing policies and procedures from accreditation or quality assurance activities that can be utilised and referenced as part of preparing an SMP. Existing policies and procedures being considered as evidence of compliance should be reviewed and amended if required. This will address any gaps identified and ensure the minimum requirements of the Standard are met.

Content of an SMP

The following sections in this guide refer to the dealings covered by the Standard. The key tasks, strategies, and use of resources provided in this guide are not mandatory. Entities can choose improvement strategies that are specific to their local context. These strategies should be meaningful, useful and relevant to the entity's governance, structure, workforce and consumers.

Section 1 – General

1.1 An SMP is easy to understand when, where, how and to whom it applies.

Outcomes required	Relevant information and examples of compliance
1.1.1 The SMP must state: • the day the SMP commences • the locations of the places where the SMP applies • the dealings and regulated substances (medicines) to which the SMP applies • the persons (staff) to whom the SMP applies	• A regulated place has a 12-month transition period from the commencement date of the MPMR to make an SMP. • If an entity has multiple locations where dealings are undertaken, then an SMP will be required for each location. - If a regulated place moves location, the SMP is required to be updated. • An SMP addresses all the applicable dealings that the regulated place undertakes (see **Appendix 1**). - A list of the Schedule of medicines (e.g. Schedule 4 and Schedule 8 medicines) held at a regulated place is sufficient; there is no requirement to individually list the medicines in the SMP. • An existing human resources or accreditation document that articulates the governance structure, delegations and reporting lines can be used as a list of persons (staff) to whom the SMP applies. - This needs to be updated when position descriptions and/or roles and responsibilities change. - The positions undertaking applicable roles specified in the MPMR including manufacturing supervisor, a medicines store establisher and manager, S8 safe establisher and manger, and system manager and system administrator for electronic prescription management systems need to be identified.
1.1.2 The SMP must be written in such a way that is easily understood by all relevant staff.	• The SMP should be documented clearly and concisely and written in plain English.

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Outcomes required	Relevant information and examples of compliance
1.1.3 The SMP must be made available to all staff when it is made, including when materially revised.	• Examples of documentation that demonstrates how a responsible person has made staff aware of the SMP could include one or more of the following: - written correspondence to staff regarding the SMP (e.g. letter, email or newsletter) - minutes and attendance records from meetings where the SMP was discussed - intranet page about the SMP - staff employment contracts that articulate relevant roles and responsibilities that are signed by staff members - sign-off sheets confirming staff are aware of the SMP and their responsibilities (this may form part of the entity's induction/orientation process).
1.1.4 The SMP must be a controlled document, specifying the version history, date of review(s), the name(s) of the person who completed any review and the reason/s for the review(s).	• The SMP should include the required details such as the document's version history, document location, review strategy, reason for review, and responsible person for the reviewed plan.

1.2 Known and foreseeable risks are identified and addressed.

Outcomes required	Relevant information and examples of compliance
1.2.1 In the preparation (and review) of the SMP the following risks must be considered and addressed for each regulated activity in the SMP: • diversion/theft or other loss • fraud and tampering • expiry, cold chain breach, or other substance quality issue • improper or inappropriate use • public, patient, or environmental harm • staff having insufficient training, qualifications or experience to perform an activity • non-compliance with legislation or codes of practice.	• The SMP should consider the applicable risks of the entity and can refer to risk assessments (risk matrix) undertaken to determine: - the severity of the risk - whether any existing control measures are effective - what action you should take to control the risk, and - how urgently the action needs to be taken. • Internal procedures to be followed should consider how risks are reported, recorded, and reviewed.

1.3 An SMP is reviewed as frequently as necessary to maintain currency and effectiveness.

Outcomes required	Relevant information and examples of compliance
1.3.1 The SMP must reference or describe the processes /procedures for the conducting a review of the SMP in the event a review incident occurs. Note: Review must occur when any of the following review incidents occur: • There is a substantial change to the internal or external operations related to the dealings at, or in connection with, the place • A non-compliant audit outcome results in new risks being identified or recommendations to modify how known and foreseeable risks related to dealings with medicines are managed • A systemic issue is identified as a result of: a) failure of risk-management systems for dealings in the SMP contributing to a critical or major incident, or b) a recurrence of undesirable incidents related to dealings with medicines, or c) a pattern of non-compliance with legislation, codes of practice or other requirements, including an SMP, across a substantial number of staff.	• The SMP should consider applicable legislative obligations, Standards, Codes, policies and procedures. These should be reviewed and updated following a substantial incident, non-compliant audit outcome, or if systemic issues have been identified. • Information about what is a reportable incident and distributing the information to staff should be considered (e.g. sharing of learnings or changes in processes, etc.). • Reasonable timeframes for a review should be considered (e.g. a non-compliant audit outcome is investigated within two business days to determine what action is required, if any). • Examples of documentation that demonstrates risk processes/ procedures in the event of an incident should consider but are not limited to: - Quality improvement process (mapping steps in sequential order) - Root Cause Analysis Procedure (clinical incident management) - Severity Assessment Code Procedure (clinical incident management) - Incident investigation (evidence collecting and analysis process) - Terms of reference for a review committee - RiskMan (incident management system) - Audit process, strategy, and frequency - Incident report and monitoring plan - Incident register/log (including outcome/closure records) • Documented strategies utilised should consider but are not limited to a risk analysis report considering the following details: - the nature of the incident - when the incident occurred - who was involved in the incident - the actions taken to rectify the incident - if the incident was reported to another agency e.g. to the Police or Public Health Unit - the person(s) responsible for investigating, reporting and recording the incident (investigations may be referred to an external agency, with the responsible person at the regulated place determining the level of investigation and escalation required, depending on the review incident severity - actions taken to mitigate future review incidents - timeframes for reporting, investigating, resolving, monitoring and evaluating.

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Outcomes required		Relevant information and examples of compliance
1.3.2	The SMP must describe or reference how a routine review of the SMP will be undertaken at least every 5 years to ensure that all known and foreseeable risks have been identified and appropriate controls are in place to mitigate those risks.	• The SMP should describe the proposed routine review process (required at least every five years unless an incident has triggered a review sooner). • A change in the responsible person and staff with significant responsibilities (e.g. roles specified in the MPMR) will trigger a review of the SMP as this would usually be identified as a risk and must be recorded in the SMP. • Examples of documentation that evidences appropriate controls may include but are not limited to: - a schedule of regular internal audits and/or quality assurance processes to reduce the likelihood of incidents occurring. - report analysis undertaken to identify trends, minimise potential risks and promote proactive medicine safety. - examples of strategies used to encourage staff to report incidents. - policy and/or procedure of steps immediately taken to ensure the safety of staff, clients/customers and the public to prevent recurrence of the incident. - a report on the effectiveness of the strategies implemented post-incident (reviewed three months post-incident and/or after rectification action has been taken). That if further concerns are identified as a result of a post-incident review, outlining the rectification action taken to address the concerns.

Section 2 – Manufacture

2.1 Medicines manufactured are fit for purpose

Outcomes required		Relevant information and examples of compliance
1.1.5	The SMP must describe or reference how quality assurance is maintained throughout the manufacturing and/or compounding process to ensure the medicine is fit for purpose and free from contamination.	• The SMP should consider referring to the manufacturing quality assurance framework required for a manufacturing licence if applicable. • The SMP should consider referring to policy or procedures for the compounding process that aligns with the *Departmental Standard: Compounding* • The SMP should document the quality control strategy including: - quality control testing of batches with sampling and frequency in line with industry standards - quality control testing for compounded medicines in line with the Pharmacy Board of Australia's *Guidelines on compounding of medicines*. - how testing services are accessed for quality control for batch manufactured or compounded medicines • The SMP should consider a documented procedure and identifying the person responsible for releasing finished products for supply
2.1.2	The SMP must describe or reference how steps in the manufacturing process are only carried out by authorised personnel with the appropriate qualification/training/ experience.	• The SMP should consider the following documents as evidence: - Induction procedure and/or checklist that can evidence the employee can apply relevant processes, policies and procedures related to medicines. - Mandatory training plans including frequency of training, and records with staff signatures and dates of completion. - Position descriptions including role responsibilities, relevant authorities, reporting lines, essential qualifications. - Copies of employment contracts (including probation periods). - Evidence of any self-assessment against Professional Practice Standards checklist, Code of Conduct, other mandatory training with completion timeframes included. - Staff rostering and skill mix policy/procedures

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Outcomes required		Relevant information and examples of compliance
2.1.3	The SMP must describe or reference how continuous and adequate supervision of the manufacturing and/or compounding process is maintained and recorded.	• The SMP should consider the following documents as evidence: - The manufacturing operations management policy and processes - The manufacturing operations system used to manage processes - The manufacturing supervisors' names recorded on the manufacturing licence. - A logbook or timesheet detailing the manufacturing supervisor/s working hours (considered acceptable evidence of continuous supervision). - A policy or agreement outlining supervision requirements and responsibilities between supervisor and trainee/student/employee. - Staff roster process that considers skills mix and resourcing levels.
2.1.4	The SMP must describe or reference how adequate record-keeping is maintained to allow a clear audit trail and prevent tampering.	• The SMP should consider its record keeping policies and procedures (paper and/or electronic) including a procedure for planned data backup schedules and data recovery plan, including: (a) How records are stored so they cannot be tampered with and are readily retrievable. - *For handwritten records*, they are stored in a way that ensures damage or destruction is minimised (e.g. stored in plastic storage containers to reduce the effects of moisture, rodents; or in a fireproof containers). - *For electronic records*, a password is required to access the database (i.e. to restrict access to Schedule 8 medicine records). This includes recording which staff have access to passwords. (b) Stipulating the retention period for medicine records that is in accordance with legislative requirements. (c) A disposal schedule that articulates the minimum amount of time specific types of records are kept and the person/s responsible for their disposal (Note: Disposal of public sector records must be in accordance with the *Public Records Act 2002).* • The SMP should consider standard operating procedures that align with the documentation and record keeping requirements in the *Departmental Standard: Compounding* • Procedures to ensure that confidential records are disposed of appropriately (i.e. shredded or sent for destruction).

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Outcomes required		Relevant information and examples of compliance
2.1.5	The SMP must describe or reference how the traceability of raw materials, unfinished and finished products will be sufficient to handle complaints, recalls and returns	• The SMP should consider standard operating procedures that align with the raw materials storage requirements in the *Departmental Standard: Compounding* • As the following are relevant to good manufacturing practice (GMP), credentialing and/or accreditation documentation should be considered that shows compliance with these: - Good Manufacturing Practice for Medicines (Therapeutic Goods Administration) - Relevant Standards Australia/Standards New Zealand (AS/NZS) or International Organisation for Standardization (ISO) Standards - Pharmaceutical Inspection Convention (PIC/S) *Guide to good practices for the preparation of medicinal products in healthcare establishments.* - Pharmacy Board of Australia: Guidelines on compounding medicines • The SMP should consider documented quality improvement processes like: - policies, procedures and/or guidelines that address product recall, damaged goods, and matters of complaint. - documented report/s on the outcome of quality improvement reviews.
2.1.6	The SMP must describe or reference how processing, packing and labelling, including repacking and relabelling meet the applicable Standards	• The SMP should consider referencing compliance with Therapeutic Goods Administration (TGA) Standards for medicine labelling and TGA Code of Practice for tamper evident packaging as applicable. • The SMP should consider the steps undertaken to produce or prepare the medicine for supply that includes, for example, details of packing, repacking, labelling and handling of medicines that: - ensures the integrity of products (e.g. from damage due to moisture) - prevent or detect manufacturing errors - the use of containers that are child resistant - medicines are labelled appropriately (e.g. medication generic name, strength, batch and expiry).

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Outcomes required		Relevant information and examples of compliance
2.1.7	The SMP must describe or reference how plant and equipment, buildings and facilities are maintained to meet requirements for sanitation and calibration	• The SMP should consider standard operating procedures that align with the place and equipment requirements of the *Departmental Standard: Compounding* • The SMP should consider the policies and/or procedures of the maintenance and testing of equipment including documented evidence of: - the type of maintenance and testing undertaken (e.g. calibration) - the persons responsible for maintaining and testing equipment (e.g. staff or an external organisation) - the frequency of maintenance and equipment testing, and in the event of equipment failure, the backup processes in place to continue manufacturing.
2.1.8	The SMP must describe or reference how materials, machinery, storage facilities, packaging and finished products are maintained to minimise contamination.	• The SMP should consider the policies and procedures to prevent contamination including: - storage and quarantine of goods at different stages of manufacture - cleaning and decontamination of equipment and facilities between uses - cold chain is maintained for all refrigerated medicines and monitoring logs kept - refrigerated medicines are stored in a refrigerator only used to store medicine (i.e. no food). - backup procedures for emergency situations or system failures (e.g. power failure or temperatures outside of recommended range). - regular maintenance and testing of equipment is undertaken. - storage of medicines at the temperature required for optimum stability of the product.

2.2 Access to the manufacturing area and storage areas for raw materials and finished products is controlled to prevent theft and tampering.

Outcomes required		Relevant information and examples of compliance
2.2.1	The SMP must describe or reference how only authorised personnel are granted access to the manufacturing area	• The SMP should consider policies and procedures to ensure only authorised personnel are granted access to the manufacturing area
2.2.2	The SMP must describe or reference how medicines, both finished products and raw materials, are stored and handled in a secure manner	• The SMP should consider: - the secure places or receptacles for medicines at different stages of manufacture - procedures to ensure tampering is readily detected and for record keeping and reconciliation of the amount of medicine for each manufacturing step.

2.3 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
2.3.1	The SMP must describe or reference how suspicious activity in and around the premises is detected and reported to the Queensland Police Service and/or relevant government authorities	• The SMP should consider the following as documentary evidence: - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. - That reports of loss, theft or suspicious activity are assessed/reviewed as soon as practicable (registered practitioners have mandatory reporting requirements).
2.3.2	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to manufacturing, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	• The SMP should consider the policy and procedure in the event of a manufacturing breach or failure. Consider listing potential failures in the manufacturing process and how each would be addressed and analysed: - Design - System/processes - Contamination - Packaging - Storage - Improper handling • Following a review incident, a record of the version history of the SMP is updated and all changes communicated to staff: - When updated, it is appropriate to provide staff with only the updated sections of the SMP rather than the whole document. • A recorded document confirming staff are aware of any changes made to the SMP (e.g. a sign-off sheet confirming staff have read and understood the changes).

Section 3 – Buy

3.1 Purchase orders for medicines are made by appropriate persons or their delegates.

Outcomes required		Relevant information and examples of compliance
3.1.1	The SMP must describe or reference how only authorised personnel, with the appropriate position at the entity, can make or access and submit a purchase order for stock of medicine before or at the time of supply.	• The SMP should consider referencing the delegations in line with the schedules in the MPMR • The SMP should consider the internal system used to allow purchasing/procurement of inventory, access and work instructions for purchasing. For example, iPharmacy system of Queensland Health • The SMP should consider documenting the following: - Identifying and recording staff authorised to place a purchase order - Delegations and reporting lines for placing purchase orders - Identifying preferred suppliers and procedures for using alternate suppliers • The SMP should consider outlining the process for placing a purchase order, including: - measures to ensure purchase orders are compliant before placing an order - a list of licensed wholesalers from whom medicines are bought - identifying the databases used to place a purchase order (this may include several wholesale databases if more than one wholesaler is used to buy medicines) - the frequency with which purchase orders are placed (e.g. weekly or as required). - security mechanisms used to minimise possible fraudulent purchase orders (e.g. use of electronic purchase orders, database passwords are only known by authorised persons). Note: If the medicine order is placed by a delegate (e.g. pharmacy employee or Queensland Ambulance Service (QAS) Commissioner's delegate, the responsibility remains with the authorised person to ensure the orders are complete and received in full.
3.1.2	The SMP must describe or reference how delegations may be exercised, by whom and to what extent	

3.2 The stock received is secure and fit for purpose.

Outcomes required		Relevant information and examples of compliance
3.2.1	The SMP must describe or reference how goods received are recorded, secured and stored to maintain medicine quality/integrity.	• The SMP should consider procedures for the receipt of medicines ordered including the following: - Acknowledgment of delivery and reconciliation of the goods received against the expected delivery - Checks of stock integrity including any evidence of tampering or cold chain breaches and related follow up actions e.g. Action taken if a cold chain breach occurs (a breach is when the temperature is outside of recommended conditions at any time during transit). - Recording and reporting of anomalies in the amount of stock received against invoices with the delivery including any notification requirements in the MPMR - Measures for ensuring the security and integrity of the medicine order once received e.g. ensuring Schedule 8 medicines are immediately stored in an S8 safe or that cold chain items are refrigerated within appropriate timeframes in accordance with manufacturers' recommendations - If the order is received by a delegate, expected supervision and procedures to access the S8 safe for Schedule 8 medicines and security arrangements for other medicines at risk of diversion/theft - . Identifying their transport companies or carriers that comply with the requirements in Schedule 15, Part 1 of the Medicines Regulation.
3.2.2	The SMP must describe or reference how any damaged, unsuitable or expired medicines are identified, quarantined and returned, destroyed or disposed of in a manner that is safe and secure.	• The SMP should consider the following documentation as evidence: - Internal audit schedule to ensure quality/integrity of medicine is maintained - Recording and reporting procedures for compromised medicines - Procedure for quarantining and returning compromised medicine stock - Procedure for destroying or disposing of compromised medicine stock

3.3 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
3.3.1	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to buying stock, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	• The SMP should consider the following documentation as evidence: - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. - That reports of loss, theft or suspicious activity are assessed/reviewed as soon as practicable (registered practitioners have mandatory reporting requirements).

Section 4 – Possess

4.1 Medicines are only accessible and possessed by appropriate persons.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 4.1.1 only appropriate persons, with respect to character and understanding of regulatory requirements, are employed, contracted or engaged by the entity to possess medicines 4.1.2 access to medicines is restricted to those appropriate persons with a need to access the medicine in order to minimise opportunities for diversion, theft and inappropriate use 4.1.3 adequate supervision is provided for persons who can only possess medicines temporarily, under direct supervision or at the direction of an authorised person.	• The SMP should consider recording/documenting who can possess medicines as per the MPMR schedules • The SMP should consider a policy/procedure for medicine management that includes: - defining supervision and how it is undertaken - outlining endorsements/authority - alignment with the National Safety and Quality Health Service (NSQHS) Medication Safety Standard - measures in place to ensure timely access to medicines in an emergency • The SMP should consider the following information: - Evidence of current qualifications – for example, registration (e.g. registration certificate or listing on AHPRA health practitioner register), first aid certificates, vaccination competency for pharmacists who provide this service. - Evidence of any self-assessment against Professional Practice Standards checklist, Code of Conduct, other mandatory training with completion timeframes included. - Induction procedure and/or checklist that can evidence the employee can apply relevant processes, policies and procedures related to medicines. - Mandatory training plans including frequency of training, and records with staff signatures and dates of completion. - Position descriptions including role responsibilities, relevant authorities, reporting lines, essential qualifications. - Copies of employment contracts (including probation periods). - Policy and procedures for employing staff and engaging contractors including pre-employment screening for criminal history and discipline checks. - Staff have access and/or can source internal policies, procedures, guidelines, or manuals to assist and provide support to perform duties (documented or online). - Staff have access and/or can source external Standards, Codes, legislative requirements to assist and provide support to perform duties (documented or online). - A policy or agreement which supports placement of trainees or students (as applicable) outlining their qualifications, registration details, scope of practice, experience, and skills. - A policy or agreement outlining supervision requirements and responsibilities between supervisor and trainee/student/employee. - Strategies to track and monitor who is in possession of a medicine at any given time (e.g. *Schools* - possession of medicine when on excursion, camps, during lunch duties).

4.1 table continues next page

Outcomes required	Relevant information and examples of compliance
As per outcomes 4.1.1 to 4.1.3 detailed on page 20	• A persons authorisation should consider demonstrating the level of security and training proportionate to the schedule of the medicine has been considered when moving or distributing stock within a place (e.g. moving nitrous cannister from delivery point to hospital ward and level of training required of porters moving the nitrous oxide). • Documentation should consider demonstrating chain of custody (e.g. signing an acknowledgement form of receipt) and traceability of stock is accounted for.

4.2 Medicines are stored in secure and appropriate storage.

Outcomes required		Relevant information and examples of compliance
4.2.1	The SMP must describe or reference how medicine stock is stored and handled in a secure, stable and safe manner considering the recommended storage conditions and separating and quarantining substances where necessary.	• The SMP should consider a policy/procedure that aligns with storage systems for medicines in accordance with the MPMR • Documentation should consider demonstrating the level of security is proportionate to the schedule of the medicine and storage is in accordance with the *Departmental Standard: Storage of Schedule 8 medicines.* • The SMP should consider a policy/procedure/process demonstrating how access and security of the regulated place and medicine storage areas identifying types of access (e.g. key holder, security swipe access, PIN code).
4.2.2	The SMP must describe or reference how any medicines that are expired, damaged or otherwise unsuitable for use are identified, separated and removed from use.	• The SMP should consider a policy or procedure for managing expired, damaged, or unsuitable medicines.

4.3 Recording and keeping of information enables traceability of medicines.

Outcomes required		Relevant information and examples of compliance
4.3.1	The SMP must describe or reference how the movement of medicines, both internal and external, is tracked and recorded, including the receipt, transfer, distribution, division, dilution, disposal or loss of medicine.	• The SMP should consider a system or documentation that can evidence: - Recording and keeping of information for medicines is in accordance with the MPA and the MPMR. - The movement of medicines is tracked and recorded as per legislative requirements (includes the receipt, transfer, distribution, compounding, disposal and loss of medicines). - The traceability of medicines, enabling reconciliation and the identification of loss, theft or diversion, and shows recalls and returns. - How raw materials and products are traced and managed (for manufacturing and compounding).
4.3.2	The SMP must describe or reference how reconciliation of medicines registers with stocks of medicines on hand will occur.	• The SMP should consider a policy/procedure that includes: - The schedule for regular reconciliation of medicines registers with stocks of medicines on hand including triggers for additional reconciliation - Who is assigned the task to complete the required reconciliation
4.3.3	The SMP must describe or reference how records are to be kept so as to be retrievable, secure and tampering prevented.	• The SMP should consider its record keeping policies and procedures (paper and/or electronic) including a procedure for planned data backup schedules and data recovery plan, may include: - how records are stored so they cannot be tampered with and are readily retrievable. - accessibility management to both paper and electronic records *For paper records*, they are stored in a way that ensures damage or destruction is minimised (e.g. stored in plastic storage containers to reduce the effects of moisture, rodents; or in a fireproof containers). *For electronic records*, a password is required to access the database (i.e. to restrict access to Schedule 8 medicine records). This includes recording which staff have access to passwords. - Stipulating the retention period for medicine records that is in accordance with legislative requirements. - A disposal schedule that articulates the minimum amount of time specific types of records are kept and the person/s responsible for their disposal (Note: Disposal of public sector records must be in accordance with the *Public Records Act 2002).* - Procedures to ensure that confidential records are disposed of appropriately (i.e. shredded or sent for destruction).

4.4 There is compliance with relevant Departmental Standards.

Outcomes required		Relevant information and examples of compliance
4.4.1	The SMP must describe or reference how access and security measures for storage of S8s are compliant with the Departmental Standard - Secure storage of Schedule 8 medicines	• The SMP should consider a policy/procedure that describes the level of security required for the storage of S8 medicines aligning with the *Departmental Standard: Secure storage of S8 medicines*, including: - Storage requirements - Physical location of the lockable medicine store - Who and how access is obtained to the medicine store (as well as prevented) - Steps taken in the event of missing, damaged, or tampered medicines

4.5 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
4.5.1	With respect to the quantity, schedule and illicit value of medicines possessed, the SMP must describe or reference how suspicious activity in and around each storage location is detected and reported both internally and externally.	• The SMP should consider the following documentation as evidence: - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Queensland Police Service, as soon as practicable, but no later than the next business day. - That reports of loss, theft or suspicious activity are assessed/reviewed as soon as practicable (registered practitioners have mandatory reporting requirements).
4.5.2	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to possession, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	• The SMP should consider the following documentation as evidence: - The SMP should refer to the incident policy and procedure in the event of a breach or failure. • Following a review incident, a record of the version history of the SMP is updated and all changes communicated to staff: - When updated, it is appropriate to provide staff with only the updated sections of the SMP rather than the whole document. • A recorded document confirming staff are aware of any changes made to the SMP (e.g. a sign-off sheet confirming staff have read and understood the changes).

Section 5 – Supply (of stock)

5.1 Medicines are only supplied by appropriate persons.

Outcomes required		Relevant information and examples of compliance
5.1.1	The SMP must describe or reference how persons supplying medicine have the necessary qualifications and experience to maintain the quality, safety and security of medicines.	• The SMP should consider the following documentation as evidence: - A policy/procedure that outlines and authorises who can supply medicine stock - Position descriptions of staff who supply medicines outlining the qualifications/experience and responsibilities required to maintain the quality, safety, and security of medicines. - Referencing persons authorised to supply in accordance with the schedules in the MPMR
5.1.2	The SMP must describe or reference how persons supplying medicine are authorised to do so and adequate supervision of the supply is provided if applicable.	• The SMP should consider the following documentation as evidence: - The relevant licence can be produced and confirms its currency and approval for the supply of medicine. - A compliant purchase order is raised before the medicine is supplied - Supervision policy and procedures outline the roles and responsibilities for the supply process.

5.2 Medicines are only supplied to persons authorised to buy.

Outcomes required		Relevant information and examples of compliance
The SMP must describe or reference how:		• The SMP should consider the following documentation as evidence: - A list of persons authorised to buy and the entity they represent - A list of location addresses where medicines are supplied to - Validation protocol ensuring medicines are only supplied to authorised persons - Copy of licence held by the entity confirming authorisation.
5.2.1	the authority of the person or entity directing or requesting the supply will be validated	
5.2.2	medicines will only be supplied to persons authorised to buy or their nominated representative/delegate.	

5.3 Medicines are delivered in a safe, secure and timely manner.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 5.3.1 medicines being transported will be protected from damage or deterioration from weather, light, heat etc., including at points of transfer and delivery; 5.3.2 the integrity of the cold chain is maintained so supply of medicine is not compromised; 5.3.3 medicines being transported will be secured and tracked, to prevent unauthorised access and minimise the opportunity for theft or diversion.	• The SMP should consider the following documentation as evidence: - Procedures for ensuring medicines are packed securely for delivery, to minimise damage, exposure, and prevent tampering - Policies and procedures for transportation conditions to maintain the quality of the medicines during transfer and delivery - Policies and procedures that align with the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8. - Cold chain management procedures - Cold chain self-audit tool (frequency and monitoring reports) - Vaccine management procedures - Security and tracking arrangement procedures for carriers including surveillance and detection systems including process for signing over the medicines to the transport company and obtaining a signature on delivery of the medicines - Security measures policy

5.4 Carriers engaged to deliver medicines are capable and reliable.

Outcomes required	Relevant information and examples of compliance
5.4.1 The SMP must describe or reference how a carrier engaged to deliver medicines will be assessed as capable to meet their obligations, including those in this Standard	• The SMP should consider policies and procedures that align with the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8 including practices on: - Transport - Cold chain • The SMP should consider processes for assessment and identification of preferred transport companies or carriers who comply with the requirements in Schedule 15, Part 1 of the MPMR • The SMP should consider documenting processes for carriers to explain missing medicines that occur between pickup and drop off.
5.4.2 The SMP must describe or reference how the performance of a carrier engaged to deliver medicines will be monitored and reviewed.	• The SMP should consider the governing body review processes for carrier performance via an annual audit schedule.

5.5 Recording and keeping of information enables traceability of medicines.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 5.5.1 the movement of medicines (internal and external) is tracked and recorded; including the receipt, transfer, distribution, division, disposal or loss of medicine; 5.5.2 records are to be kept secure and tampering prevented; 5.5.3 the checks and balances that are in place to ensure the right medicines are supplied to the right person; 5.5.4 traceability of medicines is sufficient to handle complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion.	• The SMP should consider the following documentation as evidence: - A register of standard operating procedure documents for the movement of medicines - Procedure for the management of records including responsible persons, retention periods, storage facilities, management of electronic records including access and protecting data integrity - Systems that are in place to manage documentation - Policy documents indicating supply of medicines to the authorised persons in accordance with the schedules in the MPMR.

5.6 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
5.6.1	The SMP must describe or reference how suspicious activity in and around the premises is detected and reported to the Queensland Police Service and/or relevant government authorities	• The SMP should consider the following documentation as evidence: - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Queensland Police Service, as soon as practicable, but no later than the next business day.
5.6.2	The SMP must describe or reference how incidents including breaches or failures to achieve the outcomes required with respect to supply of stock, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	• The SMP should consider the following documentation as evidence: - The SMP should refer to the incident policy and procedure in the event of a breach or failure. • Following a review incident, a record of the version history of the SMP is updated and all changes communicated to staff: - When updated, it is appropriate to provide staff with only the updated sections of the SMP rather than the whole document. • A recorded document confirming staff are aware of any changes made to the SMP (e.g. a sign-off sheet confirming staff have read and understood the changes).

Section 6 – Supply (for a person or animal)

6.1 Medicines are dispensed, given as a treatment dose or otherwise supplied for a person or animal by appropriate persons

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 6.1.1 medicines are only supplied by authorised persons with the appropriate qualifications/training/ experience. 6.1.2 adequate supervision of supply is provided where necessary 6.1.3 If medicines are supplied at the place under an extended practice authority, then the SMP must also describe or reference how: 6.1.3.1 persons engaged or credentialled to supply a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies; 6.1.3.2 the process to grant a credentialled scope of practice allowing a health professional to supply a medicine in accordance with a health management protocol meets the requirements of the current Health Service Directive: Credentialing and defining the scope of clinical practice or the current Australian Commission on Safety	• The SMP should consider the following documentation as evidence: - Employee records confirming qualifications and checks by employer for those who are involved in medicine management - Registration confirmation via AHPRA and endorsements - Credentialing and scope of clinical practice processes to ensure that only authorised persons of the workforce can supply medicines - Documented scope of clinical practice recorded and available as required by a relevant extended practice authority - Governance structures for medicine management that can describe delegations, roles and responsibilities - Supervision policy and procedure for medicine management - Annual training and competency assessments ensuring development and maintenance for qualified personnel who can supply medicine - Procedures for making and approving health management protocols or guidelines for the supply of medicines, and maintaining their currency - Access to clinical protocols or standing orders that authorise supply.

	and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice (where applicable for an extended practice authority);	
6.1.3.3	the process to make and approve a health management protocol and to ensure health management protocols in use are current.	

6.2 Medicines supplied for a person or animal are appropriately labelled.

Outcomes required	Relevant information and examples of compliance
6.2.1 The SMP must describe or reference how persons supplying medicines procure and apply the appropriate labels ensuring the relative requirements are met.	• The SMP should consider the following as evidence: - The labelling system used that procures and applies the labelling requirements of the Poison Standard (*Therapeutic Goods Act 1989*) - Labelling policy that meet other legislative requirements - Dispensing procedure that ensures compliant labelling requirements - Procedure for the labelling of S3 medicines

6.3 Records are kept of medicines dispensed, given as a treatment dose or otherwise supplied for a person or animal.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 6.3.1 records of medicines supplied for persons/animals are maintained to minimise the risk of diversion, overdose, or other negative outcomes; 6.3.2 traceability of medicines is sufficient to handle complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion.	• The SMP should consider the following documentation as evidence: - Policy/procedure of documentation requirements for the recording of medicines - A register of standard operating procedure documents for the movement of medicines - Procedure for the management of records including responsible persons, retention periods, storage facilities, management of electronic records including access and protecting data integrity - Description of systems that are in place to manage documentation (electronic or hard/paper copy)

6.4 There is compliance with relevant Departmental Standards.

Outcomes required		Relevant information and examples of compliance
6.4.1	The SMP must describe or reference how records of pseudoephedrine sold are kept in compliance with the Departmental Standard: Pseudoephedrine recording	• The SMP should consider the mandatory requirements for the record keeping system used for the purpose of pseudoephedrine sales in a: - Policy and/or procedure - Description of the system used by the pharmacist - Standard operating procedure to be followed by employees
6.4.2	The SMP must describe or reference how monitored medicines are supplied in compliance with the Departmental Standard: Monitored Medicines	• The SMP should consider a policy/procedure outlining the recording or documentation requirements that complies with the *Departmental Standard: Monitored Medicines.*
6.4.3	The SMP must describe or reference how electronic prescription management systems meet the conformance and management requirements in compliance with the Departmental Standard: Requirements for an electronic prescription management system.	• The SMP should consider a policy or procedure for the management and administration of electronic prescription management system used for dispensing and how it aligns with the *Departmental Standard: Requirements for an electronic prescription management system.*

6.5 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
6.5.1	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to dispensing, giving a treatment dose or other supply of medicines for a person or animal, will be identified in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	• The SMP should consider the following documentation as evidence: - Policy/procedures for incident management systems - Processes and practices that minimise the occurrence of medicine-related incidents and the potential harm from medicines. - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting incidents, loss, theft or suspicious activity such as presentation of prescriptions suspected to be fraudulent. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. • That reports of an incident, loss, theft or suspicious activity are reviewed and analysed as soon as practicable (Please note: health practitioners have notification requirements to the Health Ombudsman, defined in the Health Practitioner Regulation National Law Queensland, if they suspect another health practitioner or student may have issues impacting their health, conduct or performance). • Following a review incident, a record of the version history of the SMP is updated and all changes communicated to staff: - When updated, it is appropriate to provide staff with only the updated sections of the SMP rather than the whole document. • A recorded document confirming staff are aware of any changes made to the SMP (e.g. a sign-off sheet confirming staff have read and understood the changes).

Section 7 – Prescribe or make a standing order

7.1 Only appropriate persons can prescribe or make a standing order for medicines.

Outcomes required		Relevant information and examples of compliance
7.1.1	The SMP must describe or reference how persons engaged or credentialled to prescribe a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies	• The SMP should consider the following information: - A list of all staff who are authorised to prescribe or make a standing order - Evidence of current qualifications – for example, registration (e.g. registration certificate or listing on AHPRA health practitioner register) - Evidence of any self-assessment against Professional Practice Standards checklist, Code of Conduct, other mandatory training with completion timeframes included. - Induction procedure and/or checklist that can evidence the employee can apply relevant processes, policies and procedures related to medicines. - Mandatory training plans including frequency of training, and records with staff signatures and dates of completion. - Position descriptions including role responsibilities, relevant authorities, reporting lines, essential qualifications. - Copies of employment contracts (including probation periods). - Policy and procedures for employing staff and engaging contractors including pre-employment screening for criminal history and discipline checks. - Staff have access and/or can source internal policies, procedures, guidelines, or manuals to assist and provide support to perform duties (documented or online). - Staff have access and/or can source external Standards, Codes, legislative requirements to assist and provide support to perform duties (documented or online). - A policy or agreement which supports placement of trainees or students (as applicable) outlining their qualifications, registration details, scope of practice, experience, and skills. - A policy or agreement outlining supervision requirements and responsibilities between supervisor and trainee/student/employee.

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Outcomes required		Relevant information and examples of compliance
7.1.2	The SMP must describe or reference how access by unauthorised persons to stationery, computers, devices, software etc. used for making a prescription is prevented	• The SMP should consider the following information in a policy or procedure: - Identifying who is authorised to access prescription stationery. - The steps taken to restrict access to prescription stationery or paper prescriptions generated using a computer (e.g. stationery is kept in a locked drawer). - Physical security measures - How monitoring that only authorised persons have access to prescription stationery occurs. - Outlining how computer access is restricted to only allow authorised person(s) to generate prescriptions (e.g. password restricted access, ensuring generic passwords are not used to access computers). - Identifying the timeframe for reporting lost/stolen prescription stationery or unauthorised access to computer-generated prescriptions to appropriate authorities. - Outlining the process for notifying the Queensland Police Service or other relevant authorities if there is a reasonable belief that prescription stationery or computer-generated prescriptions have been lost, stolen or misused.

7.2 Standing orders and prescriptions remain appropriate.

Outcomes required		Relevant information and examples of compliance
7.2.1	The SMP must describe or reference how standing orders and longer-term prescriptions will be reviewed to ensure they remain appropriate for the circumstances and context and deliver improved health outcomes.	• The SMP should consider the following documentation as evidence: - Hospital unit specific standing orders and clinical protocols - Longer term prescriptions policy - Minutes of meetings by the interdisciplinary committee responsible for approving standing orders that record decisions and reviews. - Review strategy for standing orders and prescriptions including frequency or review and audits of compliance with standing orders - Communication strategy for any updates and or changes to standing orders or prescriptions

7.3 There is compliance with relevant Departmental Standards.

Outcomes required		Relevant information and examples of compliance
7.3.1	The SMP must describe or reference how monitored medicines are prescribed in compliance with the Departmental Standard: Monitored Medicines.	• The SMP should consider the following as evidence: - A policy in place to ensure prescribers have access to, and are aware of their obligations under the *Departmental Standard: Monitored Medicines* - A procedure that outlines the requirements for prescribers in compliance with the *Departmental Standard: Monitored Medicines*
7.3.2	The SMP must describe or reference how electronic prescriptions are generated, signed, sent, stored, amended, cancelled etc. in compliance with the Departmental Standard: Requirements for an electronic prescription management system.	• If an electronic medication management system is in use, there is documentation that confirms the system in use conforms with the *Departmental Standard: Requirements for an electronic prescription management system.*
7.3.3	Electronic prescription management systems meet the minimum system requirements and are appropriately managed with clear policies/procedures for administration, operation, technical maintenance, audit etc. in compliance with the Departmental Standard: Requirements for an electronic prescription management	• The SMP should consider a policy or procedure for the management of electronic prescription management system used and how it aligns with the *Departmental Standard: Requirements for an electronic prescription management system.* • The SMP should include strategies to ensure these policies and procedures are complied with by the system administrators and users of the system.

7.4 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
7.4.1	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to prescribing medicines, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence	• The SMP should consider the following documentation as evidence: - Processes or practices that align with the NSQHS Medication Safety Standard - Medicine management guidelines - Policy/procedures for incident management systems - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. - That reports of an incident, loss, theft or suspicious activity are reviewed and analysed as soon as practicable (registered practitioners have mandatory reporting requirements).

Section 8 – Administer

8.1 Medicines are only administered by persons who are competent and authorised to administer medicines in the circumstances.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 8.1.1 medicines are only administered by authorised persons with the appropriate qualifications, training and experience; 8.1.2 adequate supervision of administration is provided where necessary; 8.1.3 If medicines are administered at the place under an extended practice authority, then the SMP must also describe or reference how: 8.1.3.1 persons engaged or credentialled to administer a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies; 8.1.3.2 the process to grant a credentialled scope of practice allowing a health professional to administer a medicine in accordance with a health management protocol meets the requirements of the current Health Service Directive: Credentialing and defining the scope of clinical practice or the current Australian	• The SMP should consider the following information: - Evidence of current staff qualifications – for example, registration (e.g. registration certificate or listing on AHPRA health practitioner register) - Evidence to support staff registration without conditions or undertakings for administration of medicine - Evidence of any self-assessment against Professional Practice Standards checklist, Code of Conduct, other mandatory training programs with completion timeframes included. - A policy or agreement which supports placement of trainees or students (as applicable) outlining their qualifications, registration details, scope of practice, experience, skills, and duration of placement. - A policy or agreement outlining supervision requirements and responsibilities between supervisor and trainee/student/employee including when and how supervision will be carried out. - Credentialing and scope of clinical practice processes to ensure that only authorised persons of the workforce can administer medicines - Documented scope of clinical practice recorded and available as required by a relevant extended practice authority - Procedures for making and approving health management protocols or guidelines for the administration of medicines, and maintaining their currency - Access to clinical protocols or standing orders that authorise administration. - Induction procedure and/or checklist that can evidence the employee can apply relevant processes, policies and procedures related to medicines. - Mandatory training plans including frequency of training, and records with staff signatures and dates of completion. - Position descriptions including role responsibilities, relevant authorities, reporting lines, essential qualifications. - Copies of employment contracts (including probation periods). - Policy and procedures for employing staff and engaging contractors including pre-employment screening for criminal history and discipline checks. - Access pathway for staff to source internal policies, procedures, guidelines, or manuals to assist and provide support to perform duties (documented or online).

	Commission on Safety and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice (where applicable for an extended practice authority);	- Intranet access and/or can source external Standards, Codes, legislative requirements to assist and provide support to perform duties (documented or online). - Training and competency levels are appropriate for all persons administering medicines (e.g. Enrolled Nurses). - Ethics approvals from relevant committees has been given for medicines administered in clinical trials or to animals.
8.1.3.3	the process to make and approve a health management protocol and to ensure health management protocols in use are current.	

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8.2 Records are kept of medicines administered.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 8.2.1 records of medicines administered are maintained to minimise the risk of diversion, overdose, or other negative outcomes; 8.2.2 records of medicines administered can assist with the management of complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion; 8.2.3 records are secure and cannot be tampered with.	• The SMP should consider documentary evidence including but not limited to: - Policy/procedure of documentation requirements for the recording of medicines - NSQHS Standards and accompanying guidelines for medication safety and record keeping - Policy/procedures for medicine complaints, recalls and returns including reconciliation strategies - A register of standard operating procedure documents for the movement of medicines - Procedure for the management of records including responsible persons, retention periods, storage facilities, management of electronic records including access and protecting data integrity - Description of systems that are in place to manage documentation

8.3 Incident, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required	Relevant information and examples of compliance
8.3.1 The SMP must describe or reference how incidents, including breaches or failures to	• The SMP should consider the following documentation as evidence: - Processes or practices that align with the NSQHS Medication Safety Standard

	achieve the outcomes required with respect to administering medicines, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.	- Medicine management guidelines - Policy/procedures for incident management systems - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. - Procedures for the loss or theft of diversion-risk medicines: these are required to be reported to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. - That reports of an incident, loss, theft or suspicious activity are reviewed and analysed as soon as practicable (registered practitioners have mandatory reporting requirements).

Section 9 – Dispose

9.1 Medicine waste is disposed of appropriately by appropriate persons.

Outcomes required	Relevant information and examples of compliance
The SMP must describe or reference how: 9.1.1 S8 diversion-risk medicine waste is only disposed of by an authorised person and that adequate supervision/witnessing of the disposal is provided for as required; 9.1.2 S8 diversion-risk medicine waste is to be destroyed so that it is rendered unusable, unrecognisable and unfit for human or animal use and incapable of growth or germination; 9.1.3 diversion-risk medicine waste is to be disposed of so that access by an unauthorised person is prevented; 9.1.4 medicine waste is to be disposed of in a way that does not endanger a person, animal or the environment.	• The SMP should consider the following documentation as evidence: - If medicine waste will be sent away for destruction, to whom it will be sent. This may be, for example, a pharmacy that is willing to accept the medicine waste or an approved waste management contractor. - If S8 medicine waste will be destroyed on site, procedures for the destruction, including who is authorised to destroy the waste and to witness the destruction. - For S8 medicine waste, procedures for documenting the disposal (transfer of custody) or destruction of the waste.

9.2 Disposal of S8 diversion-risk medicine waste is recorded.

Outcomes required		Relevant information and examples of compliance
9.2.1	The SMP must describe or reference how disposed S8 diversion-risk medicine waste is recorded including the location, method of destruction, timing, personnel and any other relevant details.	• Procedures for maintaining S8 medicine records should consider including: - the method of destruction and timing - security measures to unauthorised access and tampering - the person responsible for making entries in the Schedule 8 medicine register (e.g. the pharmacist who dispenses the medicine) - the frequency of S8 stock checks - the person/s responsible for completing stock checks - the location of where records are kept (e.g. electronic or paper based) - the location of the S8 medicine register if the medicine is to be carried in a bag or vehicle - how corrections to the S8 medicine register are made and verified.
9.2.2	The SMP must describe or reference how records are to be kept secure and are unable to be tampered with.	• The SMP should consider its record keeping policies and procedures (paper and/or electronic) including a procedure for planned data backup schedules and data recovery plan, may include: - How records are stored so they cannot be tampered with and are readily retrievable. *For handwritten records*, they are stored in a way that ensures damage or destruction is minimised (e.g. stored in plastic storage containers to reduce the effects of moisture, rodents; or in a fireproof containers). *For electronic records*, a password is required to access the database (i.e. to restrict access to Schedule 8 medicine records). This includes recording which staff have access to passwords. - Stipulating the retention period for medicine records that is in accordance with legislative requirements. - A disposal schedule that articulates the minimum amount of time specific types of records are kept and the person/s responsible for their disposal (Note: Disposal of public sector records must be in accordance with the *Public Records Act 2002).* - Procedures to ensure that confidential records are disposed of appropriately (i.e. shredded or sent for destruction).

9.3 Incidents, including potential incidents, are deterred, identified and reported in a timely manner.

Outcomes required		Relevant information and examples of compliance
9.3.1	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to disposal of medicines waste, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence	• The SMP should consider the following documentation as evidence: - The process for completing regular internal audits for diversion-risk medicines (includes the persons responsible for conducting the audit and audit frequency). - How staff are made aware of the internal process for reporting incidents, loss, theft or suspicious activity. - How suspicious activity is defined and how staff are encouraged to report such behaviour/actions. - What steps are taken if an unauthorised person gains custody or control of a medicine. • The SMP should consider procedures for the loss or theft of diversion-risk medicines including: - reporting to the appropriate authorities, such as the Department of Health and Queensland Police Service, as soon as practicable, but no later than the next business day. - reports of loss, theft or suspicious activity are assessed/reviewed as soon as practicable (registered practitioners have mandatory reporting requirements).

Appendix 1

Regulated Place (As listed in Schedule 17 of the Medicines Regulation)	Functions and dealings likely* to be undertaken at the regulated place
A place where a medicine is manufactured under a manufacturing licence.	Manufacture Buy Possess Supply Dispose
A place where a medicine is supplied by wholesale, other than a community pharmacy or specified pharmacy	Buy Possess Supply Dispose
Substance authority holder	Buy Possess Administer Supply Dispose
An isolated site under a general approval (acute health conditions at isolated sites)	Buy Possess Administer Supply
An authorised site under a general approval (emergency first aid)	Buy Possess Administer
An authorised location under a general approval (emergency management of animals)	Buy Possess Administer
Aged care facility	Buy Possess Administer Prescribe Dispose
Ambulance station (Queensland Ambulance Service)	Buy Possess Administer (under Extended Practice Authority) Supply (under Extended Practice Authority) Dispose
Childcare facility	Buy Possess Administer

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Regulated Place (As listed in Schedule 17 of the Medicines Regulation)	Functions and dealings likely* to be undertaken at the regulated place
Community pharmacy	Manufacture (Compounding) Buy Possess Supply Administer Dispose
Specified pharmacy	Manufacture (Compounding) Buy Possess Supply Administer Dispose
Detention centre	Buy Possess Administer Dispose
Prison	Buy Possess Administer Supply Dispose
Private health facility	Buy Possess Administer Prescribe Dispose
Public sector hospital under the *Hospital and Health Boards Act 2011*	Manufacture (Compounding) Buy Possess Administer Prescribe (Nurse Practitioner, Medical Practitioner, etc.) Supply Dispose
Schools (State and non-state)	Buy Possess Administer

*The responsible person at each regulated place should assess the range of dealings undertaken in accordance with the Standard.