



Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy

1. Purpose

The purpose of the *Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy* (Policy) is to set out the obligations of Health Service Providers to identify and investigate discrepancies of Schedule 8 (S8) and Schedule 4 Restricted (S4R) medicines. It outlines the mandatory requirements, and the minimum consistent procedure to be followed, for reporting of instances where a medicine discrepancy cannot be resolved and may be considered a loss or the result of theft.

This Policy should be read in conjunction with:

- *MP 0125/19 Notifiable and Reportable Conduct Policy*; and
- *MP 0127/20 Discipline Policy*.

This Policy is a mandatory requirement under the *Public Health Policy Framework* pursuant to section 26(2)(l) of the *Health Services Act 2016*.

This Policy supersedes *OD 0377/12 - Reporting of medicines discrepancies in public hospitals and licensed private facilities which provide services to public patients in Western Australia*.

2. Applicability

This Policy is applicable to all staff of Health Service Providers, who are required to handle scheduled medicines.

3. Policy requirements

The *Medicines and Poisons Regulations 2016* require a record of S8 medicines to be kept in an approved register. S4R medicines also require additional controls to prevent misuse and abuse, including keeping of a register of transactions as outlined under *OD 0528/14 - Storage and recording of Restricted Schedule 4 (S4R) medicines*.

Wherever an inventory balance of S4R or S8 medicines is kept, there is potential for discrepancies to occur. These may result from various causes, including administrative and clinical errors, at an operational level. Discrepancies may also be the result of failure to follow policy, as well as deliberate diversion or theft.

All authorised health practitioners are required under the *Medicines and Poisons Regulations 2016* to report the loss or theft of a S4R or S8 medicine to the Chief Executive Officer (CEO) of the Department of Health. Health Service Providers also have obligations under the *Corruption, Crime and Misconduct Act 2003* to notify suspected misconduct to the Corruption and Crime Commission and / or the Public Sector Commission.

Staff members of Health Service Providers are routinely required to handle S4R and S8 medicines, to provide care to patients, as part of their lawful practice as health practitioners within their professional scope of practice. Medicine must be used in accordance with the *Medicines and Poisons Act 2014* and *Medicines and Poisons Regulations 2016*. Any use of medicine outside lawful practice will breach legislation and serious penalties may apply.

Using a medicine for personal reasons, where not part of the lawful treatment of a patient under the care of the Health Service Provider, regardless of circumstances or intended purpose, is both theft and serious misconduct that may result in disciplinary action. Other legislation and penalties for unethical conduct or practising while impaired (due to drug use) may also apply, such as Health Practitioner National Law.

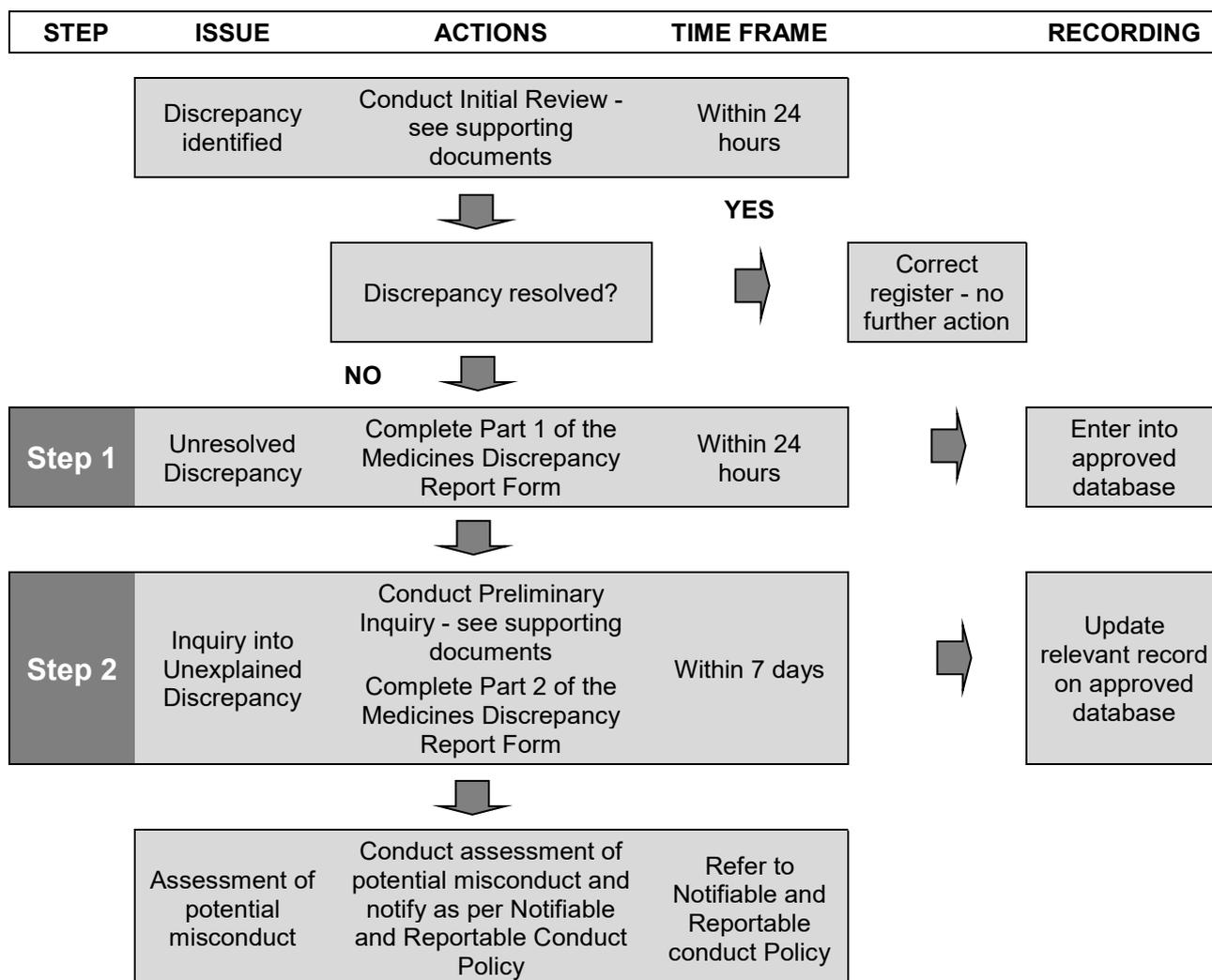
3.1 Policies and systems

Health Service Providers are required to maintain policies and systems to support the identification of discrepancies, and the investigation and documentation of medicines loss or theft, consistent with this Policy.

- 3.1.1 Any staff member required to handle a S4R or S8 medicine, or to make entries in a transaction register, is required to act immediately upon identifying a discrepancy in accordance with the procedure outlined in this policy.
- 3.1.2 The procedure outlined in Section 3.2 is also applicable to the unexplained loss or suspicion of unauthorised use or theft of a Schedule 2, 3 or 4 medicine.
- 3.1.3 The suspected theft of a medicine, by any staff member, or member of the public, requires immediate response and escalation. The *MP 0125/19 Notifiable and Reportable Conduct Policy* and the *MP 0127/20 Discipline Policy* must be followed / applied.

3.2 Discrepancy Procedure

The procedure to be followed in response to a discrepancy is illustrated in the diagram below.



3.3 Discrepancy Identified – Initial Review

An Initial Review is to be performed locally by staff identifying a discrepancy. The Initial Review is to identify potential causes – refer to *Guidelines for dealing with a S4R or S8 Medicines Discrepancy*. The review must commence immediately and be completed within 24 hours. Where a specific cause is evident and the discrepancy is resolved, corrective action is to be taken, as appropriate.

3.4 Step 1 – Unresolved Medicines Discrepancy

3.4.2 If the discrepancy is not resolved through the Initial Review, all possible causes, including potential misconduct must be considered and the loss investigated further – refer to *Guidelines for dealing with a S4R or S8 Medicines Discrepancy (Part 1 – Performing an Initial Review)*.

3.4.3 Part 1 of the Medicines Discrepancy Report Form is to be completed and forwarded within 24 hours, to the System Manager and coordinating area of the Health Service Provider.

3.5 Step 2 – Preliminary inquiry into circumstances of an Unexplained Medicines Discrepancy

- 3.5.2 A Preliminary Inquiry is to be conducted to determine possible and most probable cause – refer to *Guidelines for dealing with a S4R or S8 Medicines Discrepancy (Part 2 – Performing a Preliminary Inquiry)*.
- 3.5.3 The Health Service Provider is to appoint an appropriate officer, independent of the Initial Review, to conduct the inquiry.
- 3.5.4 The Preliminary Inquiry should be commenced immediately and concluded within 7 days of Part 1 of the Medicines Discrepancy Report Form being submitted.
- 3.5.5 Part 2 of the Medicines Discrepancy Report Form is to be completed and forwarded to the System Manager and coordinating area of the Health Service Provider.

3.6 Assessment of information relating to the circumstances of Medicine Discrepancy

- 3.6.2 The Health Service Provider is to appoint an officer to assess any potential misconduct identified through the Preliminary Inquiry.
- 3.6.3 Assessment of misconduct is to be conducted in accordance with the *Corruption, Crime and Misconduct Act 2003*, and where required, notification is to be made in accordance with *MP 0125/19 Notifiable and Reportable Conduct Policy*.
- 3.6.4 Assessment of misconduct should consider if further action is necessary, and referral as required, including where:
 - 3.6.4.1 Health Service Provider systems and policies were not followed;
 - 3.6.4.2 Quality or other system failures are present; or
 - 3.6.4.3 Disciplinary or other responses are warranted - consider in conjunction with *MP 0127/20 Discipline Policy*.

3.7 Where exceptional operational circumstances exist, the steps should be completed as soon as reasonably practicable, and reasons for any delays clearly documented.

3.8 Information from Medicines Discrepancy Report Forms is to be entered into the Case Management System (CMS) database maintained by the System Manager.

- 3.8.2 The Health Service Provider is to appoint officers responsible for accessing the database for the purposes of monitoring and compliance.
- 3.8.3 Officers will be assigned secure access to the CMS database by the System Manager.
- 3.8.4 Upon entry to the approved database, *Medicines and Poisons Act 2014* and *Medicines and Poisons Regulations 2016* reporting requirements are completed.

4. Compliance monitoring

The Health Service Provider is responsible for implementation of this Policy and ensuring compliance. Health Service Provider monitoring of compliance may include:

- conducting compliance audits on reported discrepancies and S4R / S8 records;

- reporting on the CMS database use and data; and
- trend analysis of the CMS database information.

The System Manager may choose to monitor this Policy by undertaking activities including:

- reviews of discrepancy reports received from Health Service Provider;
- reporting on system-wide patterns, trends and issues; and
- benchmarking between different Health Service Providers.

Further monitoring and compliance may be taken by the System Manager, acting as the regulator for Medicines and Poisons Legislation, in relation to individual discrepancies, where indicated for potential regulatory breaches.

5. Related documents

The following documents are mandatory pursuant to this Policy:

- [Medicines Discrepancy Report Form](#)

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- [Guidelines for dealing with a S4R or S8 Medicines Discrepancy](#)

7. Definitions

The following definition(s) are relevant to this Policy.

Term	Definition
Approved Database	Case Management System database maintained by the System Manager
Authorised Health Practitioner	Person authorised under the <i>Medicines and Poisons Act 2014</i> and <i>Medicines and Poisons Regulations 2016</i> to obtain, possess, administer, use, dispense or prescribe a medicine
Discrepancy	Mismatch between the physical stock on hand and the expected stock as indicated in the respective medicines register
Loss	Where the discrepancy cannot be resolved, regardless of the cause.
Misconduct	As relates to a medicine: taking, giving, selling, theft or use that is not related to the legitimate treatment of a patient of the Health Service Provider, or any other unlawful use of a medicine, may include a breach of policy relating to medication.
Initial Review	Preliminary actions to identify the possible cause of a discrepancy
Preliminary Inquiry	Subsequent actions to identify the probable cause of a

	loss
Case Management System database	Whole of health database maintained by the System Manager for recording of data on medicines losses.

8. Policy contact

Enquiries relating to this Policy may be directed to:

Title: Medicines and Poisons Regulation Branch

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Email: MPRB@health.wa.gov.au

9. Document control

Version	Published date	Effective from	Review date	Effective to	Amendment(s)
MP 0103/19	22 February 2019	22 February 2019	22 February 2022	9 January 2020	Original version
MP 0103/19 v.1.1	9 January 2020	9 January 2020	22 February 2022	15 December 2020	Minor amendment detail set out below.
<p><i>Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy</i></p> <ul style="list-style-type: none"> Minor amendment to the Policy and Supporting information <i>Guidelines for dealing with a S4R or S8 Medicines Discrepancy</i> to update references to superseded policies <i>MP 0029/16 Notifying Misconduct Policy</i> and <i>MP 0040/16 Discipline Policy</i> and replaced with <i>MP 0125/19 Notifiable and Reportable Conduct Policy</i> and <i>MP 0127/20 Discipline Policy</i>. <p>Hyperlink updated to Related document <i>Medicines Discrepancy Report Form</i>.</p>					
MP 0103/19 v.1.2	15 December 2020	15 December 2020	22 February 2022	Current	Minor amendment to Medicines Discrepancy Report Form.

10. Approval

Approval by	Dr David Russell-Weisz, Director General, Department of Health
Approval date	14 February 2019

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