Queensland Health Departmental Standard

Pseudoephedrine recording – version 1

27 September 2021

Queensland Government

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Published by the State of Queensland (Queensland Health), September 2021

For more information contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Queensland Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au

Disclaimer:

Version control

Version	Replaces version	Date approved	Commencement date
1	NA	12 August 2021	27 September 2021

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Preface

The *Medicines and Poisons Act 2019* (the Act) establishes a contemporary framework for the regulation of medicines, poisons, pesticides and other prohibited substances in Queensland. This framework will impact a broad range of persons.

This framework includes three regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021;
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021; and
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

The Act authorises the Chief Executive of Queensland Health to make departmental standards in relation to matters regulated under the Act (section 233, Part 4, Chapter 7 of the Act).

A departmental standard outlines the mandatory expectations and specific requirements needed to ensure regulatory compliance with the Act and Regulations.

This Standard (Pseudoephedrine recording standard) has been made by the Director-General, Queensland Health in accordance with section 233 of the Act.

Object

Pseudoephedrine is used therapeutically for the relief of sinus and nasal congestion associated with conditions such as sinusitis and the common cold. In recent decades, however, pseudoephedrine has become sought after for non-therapeutic purposes, including for the manufacture of illicit drugs.

In order to minimise the risk of pseudoephedrine being diverted for illicit use, the Medicines and Poisons (Medicines) Regulation 2021 (Medicines Regulation) requires a pharmacist who sells pseudoephedrine to make a record of the sale in a way that complies with this standard. A record made in accordance with this standard will be available in an online, real-time electronic form, and will assist pharmacists to make an informed decision on the appropriateness of a proposed sale. The record may also be accessed, under certain circumstances, by the Queensland Police Service and Queensland Health.

Scope

This standard applies to pharmacists in Queensland who make a record of the sale of pseudoephedrine (section 162 of Medicines Regulation) and includes sales on prescription. The requirement to make a record of the sale applies in addition to other requirements in the Medicines Regulation that apply when selling Schedule 3 medicines, including the requirement to establish a therapeutic need for the medicine, to attach a label to the medicine and to give instructions about the appropriate way to use the medicine.

The mandatory requirements for the record keeping systems to be used by pharmacists in accordance with this Standard are set out in Section 1 (System integrity, security and capability) and Section 2 (System report output) below.

Section 1 -System integrity, security and capability

1. The system must be capable of uniquely identifying the purchaser otherwise than by the unique reference number of photo identification.
2. The system must record and can display a minimum of two (2) years of the purchaser's transaction history.
3. The system must be able to integrate with a common data store for display and reporting on an aggregate of pseudoephedrine sales records across all Queensland pharmacies.
4. The system must be accessible only by Username and Password.
5. The system must provide an Administrator function which allows a nominated user to create, edit and disable Username/Password credentials and assign those credentials to individual system users.
6. All transactions must be stored unaltered in the electronic system for a minimum of two (2) years. Archived records must remain available in the electronic system for a minimum of two (2) years for audit purposes.
7. The system must be secure and tamper-proof, protected by accepted IT industry standards and security practices.
8. The system must be capable of being integrated with a central back-up and recovery system such that all data would be restored in full up to the time of system failure.
9. The pharmacist's name must be included in each record of supply.

Section 2 -System report output

1. The system must be able to produce transaction records in real time, and industry standard format (e.g. CSV format) as may be requested by a Queensland police officer or an authorised officer under the Act.
2. The record of transactions must be capable of being reproduced on paper on demand by a Queensland police officer or an authorised officer under the Act.
3. The electronic system must be capable of producing reports of transactions displayed on-screen, in print, and as an electronic file output able to be forwarded by email.
4. The system reports for a period (date to date) must include:

- A list of all transactions;
- The pharmacist's name by whom the pseudoephedrine was supplied;
- The name and address of the purchaser of the pseudoephedrine;
- The name and strength and quantity of pseudoephedrine supplied; and
- The unique reference number of a photo identification, if recorded.