

ELECTRONIC FORM TO RECORD PSEUDOEPHEDRINE SALES

The *Poisons and Therapeutic Goods Regulation 2008* (the Regulation) requires that a pharmacist in a community pharmacy in NSW who supplies pseudoephedrine to a person without a prescription must, at the time of the supply, record the details of the sale in an electronic form approved by the Secretary, NSW Health, in accordance with clause 24(1A) of the Regulation.

The Secretary may consider an application for approval of an electronic form to record pseudoephedrine sales that meets the system criteria below. Applications from software vendors should be addressed to:

The Chief Pharmacist
Pharmaceutical Services
Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Mail Bag 961
NORTH SYDNEY NSW 2059

Email: pharmserv@doh.health.nsw.gov.au

The following information describes the system capability criteria and provides guidance on the governance to support the use of the electronic form.

CRITERIA FOR ELECTRONIC FORM TO RECORD PSEUDOEPHEDRINE SALES

Purpose of the system

The purpose of the system is to record the sale and purchase details of pseudoephedrine in a state-wide system that is accessible by all pharmacists, to help reduce diversion of pseudoephedrine from community pharmacies into illicit drug manufacture.

The system:

- allows community pharmacists to record identification of purchasers of Schedule 3 pseudoephedrine-containing products,
- is a web based real-time recording system that provides connectivity for rapid and secure information-sharing between NSW pharmacies,
- enhances pharmacists' ability to distinguish between suspicious requests which may suggest illegitimate use against legitimate therapeutic need for the product,
- holds records that may be accessed, under certain circumstances, by NSW Police, and by the NSW Ministry of Health, as required by NSW law.

1. System Integrity, Security and Capability

1.1. The system must record the following details of pseudoephedrine supply transactions in accordance with clause 24 of the Regulation (**APPENDIX A**):

- a. a unique reference number for the supply;
- b. the name of the pharmacist by whom the pseudoephedrine is supplied;
- c. the name and address of the person to whom the pseudoephedrine is supplied;
- d. the name, strength (if not readily apparent) and quantity of the pseudoephedrine product supplied;
- e. the date on which it is supplied;
- f. identifying information of the purchaser by the unique reference number of photo identification of the person to whom the pseudoephedrine is supplied and the type of that identification.

1.2. The system must be capable of uniquely identifying the person supplied otherwise than by the unique reference number of photo identification.

1.3. The system must record and be capable of displaying a minimum of two years of the purchaser's transaction history.

1.4. The system must be capable of integrating with a common data store for display and reporting on an aggregate of pseudoephedrine sales records across all NSW pharmacies.

1.5. The system must be accessible only via Username and Password.

1.6. 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.

1.7. All transactions must be stored unaltered in the electronic system for a minimum of two years. Archived records must remain available in the electronic system for a minimum of two years for audit purposes.

1.8. The system must be secure and tamper-proof, protected by accepted IT industry standards and security practices.

1.9. 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.

1.10. The pharmacist's name shall be included to each record of supply.

2. System Report Output

2.1. 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 NSW police officer or an authorised officer under the *Poisons and Therapeutic Goods Act 1966* (the Act).

2.2. The record of transactions must be capable of being reproduced on paper on demand by a NSW police officer or an authorised officer under the Act.

2.3. 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.

2.4. The system reports for a period (date to date) shall include:

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

3. Guidance on Governance, Accountability and Administration of the System

3.1. The pharmacist is deemed to have performed any action recorded against their name unless proven otherwise.

3.2. The pharmacist (or on their request the system administrator) must make all transaction records available on request, in certain circumstances, to a NSW police officer or an authorised officer under the Act.

3.3. The pharmacist must ensure each record of transaction includes ALL the details required to be kept in accordance with clause 24 of the Regulation.

3.4. Disclosure of transactions in the electronic form shall only occur in accordance with the *Health Record Information Privacy Act 2002*.

3.5. Following any system downtime, all records that were not previously stored in the system must be captured into the system with minimum delay.

For further information or clarification of this document, contact the Duty Pharmaceutical Officer, Pharmaceutical Services, during office hours on (02) 9391 9944.

This document has been produced by:

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Appendix A – Relevant clause from the Poisons and Therapeutic Goods Regulation 2008

Poisons and Therapeutic Goods Regulation 2008



Part 2 Poisons (S1, S2, S3, S5, S6, S7)

Division 5 Records of supply

Clause 24 Supply of certain Schedule 2 or 3 substances to be recorded

(1) A pharmacist who supplies pseudoephedrine on prescription must record details of the supply in accordance with clause 55 as if pseudoephedrine were a restricted substance.

Maximum penalty: 20 penalty units or imprisonment for 3 months, or both.

(1A) A pharmacist who supplies pseudoephedrine to a person without a prescription must, at the time of the supply, record the following details in an electronic form approved by the Secretary:

- (a) a unique reference number for the supply,
- (b) the name of the person by whom the pseudoephedrine is supplied,
- (c) the name and address of the person to whom the pseudoephedrine is supplied,
- (d) the name, strength (if not readily apparent) and quantity of the pseudoephedrine supplied and the date on which it is supplied,
- (e) if the pharmacist does not know the identity of the person to whom the pseudoephedrine is supplied, the unique reference number of a photo identification of the person and the type of that identification.

Maximum penalty: 20 penalty units or imprisonment for 3 months, or both.

(2) Subclauses (1) and (1A) apply to pseudoephedrine only in so far as it is a Schedule 3 substance.

(2A) The operator of a residential care facility in which medication charts are used must ensure that an employee of the facility makes a record in the medication chart of a

resident of the facility of the administration of any Schedule 2 or 3 substance to the resident.

Maximum penalty: 10 penalty units.

(3) The Secretary may, by order in writing, exempt any person or any class of persons from the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

(5) In this clause:

photo identification means any of the following types of identification held by the person being supplied:

(a) an Australian driver licence that displays a photograph of the person, or

(b) a passport, or

(c) a NSW Photo Card issued under the Photo Card Act 2005, or

(d) a card issued under a law of the Commonwealth or another State or Territory for the purpose of proving the person's age which contains a photograph of the person in whose name the card is issued. Secretary means the Secretary of the Ministry of Health.